

**Introducing multifactorial quality improvement
into the medicine supply services
of Australian pharmacies and aged care facilities**

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ERRATA

p 40 line 15 In the sentence beginning “These two...” replace the word “publically” with “publicly”

ADDENDUM

p x line 20 Replace “An evidence-based,” with “A”

p 3 line 14 Insert an additional reference at the end of “common” in the sentence beginning “In older...”

Reference: Kaur S, Roberts JA, Roberts MS. Evaluation of medication-related problems in medication reviews: a comparative perspective. *The Annals of pharmacotherapy* 2012; **46** (7-8): 972-982.

p 7 line 13 Before “PCAs are...” insert “A RN may delegate medicine administration to a PCA if they believe the PCA is appropriately qualified or the task is within their scope of practice.⁵¹ The RN is accountable for their decision to delegate medicine administration and the PCA is also accountable for their actions.⁵¹”

p 27 line 8 Replace the sentence “These studies...” with “These studies can be described as quantitative, where observations are quantified in terms of numeric frequencies,¹⁰⁰ or qualitative.”

p 28 line 25 Before “In contrast...” insert “It may also take more time for the respondent to answer the question, potentially impacting on the quality of the response and the response rate.”

p 39 line 20 Replace the sentence “To identify...” with “To identify a statistically significant, arbitrarily determined, halving of the DAA incident rate from 3% of audited DAAs (identified from previous research)¹³ to 1.5%, 3,068 DAAs would need to be audited pre- and post-intervention.”

p 39 line 22 Before the sentence “This sample...” insert “The sample size was calculated using the difference in proportion method.”

p 95 line 27 Replace “an evidence-based,” with “a”

p 132 line 16 Replace “an evidence-based” with “a stakeholder-derived”

p 140 line 25 After the word “phases” insert “(Figure 7.1)”

p 144 line 10 Delete “evidence-based,”

ADDENDUM - continued

p 142 At the end of Section 7.1 insert diagram below

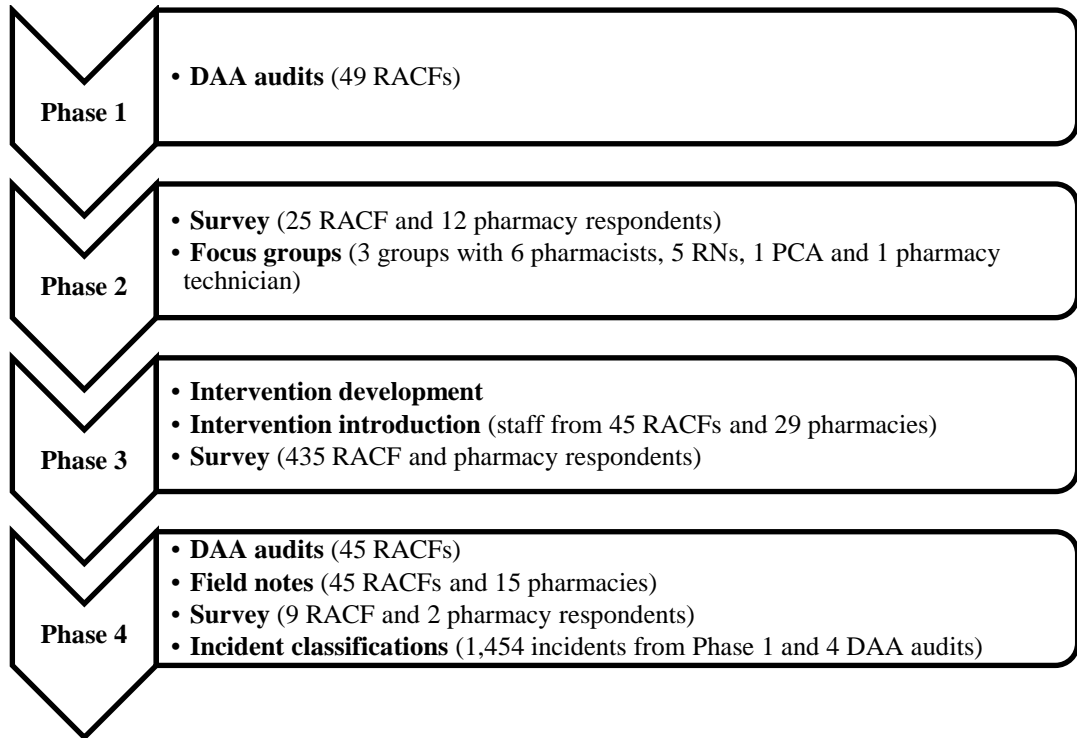


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List of Abbreviations

ABS	Australian Bureau of Statistics
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
ANF	Australian Nursing Federation
CD-ROM	Compact Disc-Read Only Memory
CMUS	Centre for Medicine Use and Safety
DAA	Dose Administration Aid
GDP	Gross Domestic Product
MAC	Medication Advisory Committee
MIMS	Monthly Index of Medical Specialties
MRP	Medicine-Related Problem
MUHREC	Monash University Human Research Ethics Committee
NVivo	QSR NUD*IST Vivo
PCA	Personal Care Assistant
PhD	Doctor of Philosophy
PIM	Potentially Inappropriate Medicine
PSA	Pharmaceutical Society of Australia
QI	Quality Improvement
RACF	Residential Aged Care Facility
RN	Registered Nurse
SHPA	The Society of Hospital Pharmacists of Australia
SPSS	Statistical Package for the Social Sciences
tds	three times daily

Abstract

Australian community pharmacies frequently supply dose administration aids (DAAs) to residential aged care facilities (RACFs) to assist with medicine administration. These medicine organisers are packed manually or via automation, either onsite at the pharmacy or offsite by a DAA packing company. In all cases, medicines are removed from their original containers and packed into the DAA according to the medicine record of the RACF resident. Limited available literature indicates that the process of packing medicines into DAAs can be inaccurate or unsuitable, leading to DAA incidents. Targeted evidence-based interventions have not been developed, introduced and assessed to address these incidents. To improve the overall quality of medicine supply from community pharmacies to RACFs and specifically address these DAA incidents, a large-scale Australian study was needed to identify how widespread this problem is and propose strategies to address it. The overall aim of the study presented in this thesis was to evaluate how accurately and suitably medicines were packed into DAAs supplied by Victorian community pharmacies for RACF medicine administration. This study also aimed to develop, introduce and evaluate an evidence-based intervention, designed to reduce the occurrence of DAA incidents and improve the overall DAA medicine supply service. The study was conducted over four phases.

Phase 1 of this study identified the types of DAA incidents and how frequently they occurred in Victorian DAAs. Cross-sectional DAA audits were conducted at 49 RACFs that were supplied DAAs from 40 community pharmacies in Victoria. A DAA incident included discrepancies between DAAs and medicine records, unsuitable medicine packing according to pharmaceutical guidelines, and medicines that were damaged, inappropriately altered or incorrectly divided. Of the 3,959 DAAs audited for 1,757 residents, 684 incidents involving 457 DAAs were identified (11.5% incident rate). The top five DAA incident types were unsuitable packing according to pharmaceutical guidelines (50.1% of all incidents identified), added medicine (9.8%), incorrect medicine quantity packed (5.4%), omitted medicine (5.3%) and damaged medicine (5.1%). This study phase confirmed the occurrence of DAA incidents, at a higher rate than previous research, and highlighted the need for an intervention to improve RACF standard of care.

Phase 2 of this study identified health professionals' perceptions regarding the types and frequencies of DAA incidents in their workplaces, as well as factors contributing to these incidents and strategies to reduce their occurrence. A questionnaire was sent by email or

facsimile to one contact from all 49 RACFs and 14 of their affiliated community pharmacies (recruited pharmacies). Three focus groups were also conducted with six pharmacists, five nurses, a personal care assistant and a pharmacy technician, who were employees of the workplaces involved in Phase 1. Questionnaires were returned from 25 RACFs (51.0% response rate) and 12 pharmacies (85.7%). On average, RACF respondents perceived DAA incidents to occur more frequently (daily or weekly) than pharmacy respondents, who mostly perceived DAA incidents to occur monthly. The DAA incident types noted by respondents were similar to those identified in Phase 1. Four themes contributing to DAA incidents emerged from the focus groups, with strategies to reduce their occurrence aligned to these themes: medicine handling, communication, knowledge and awareness, and attitude. Constructive feedback was generated regarding researcher-suggested intervention strategies, including educational strategies, DAA guidelines and protocols, a pharmacist conducting additional DAA checks at the RACF, a stamp or bookmark to be used with medicine records, a communication logbook and sticker, and a medicine identification sheet. Of these, focus group participants did not universally identify one strategy that would improve the DAA medicine supply service and both advantages and disadvantages were outlined for each. It was also highlighted that the development and implementation of a multifactorial intervention would be more favourable than a single strategy, as it may increase the chance that at least one component may be useful for a specific workplace.

An evidence-based, stakeholder-derived intervention was then developed, introduced and initially evaluated in **Phase 3**. The researcher-suggested intervention strategies from the second phase were refined using input from the research team and feedback from pharmacy and nursing organisations and focus group participants. The final intervention included a 30 minute education session and a 12 component toolkit, titled 'Be alert and work together for medicine safety - DAA incident awareness toolkit.' The toolkit included a guideline outlining what medicines should not be packed into DAAs, a research article concerning sodium valproate instability within DAAs, posters, bookmarks and stickers for the medicine record, a compact disk-read only memory (CD-ROM) with a presentation, a handout with the CD-ROM presentation slides, a question, answer and reflection handout, template certificates, a medicine identification sheet, a DAA incident policy and procedure, and DAA guidelines for the RACF or pharmacy workplace. The intervention was piloted in one RACF and one community pharmacy. It was later introduced to staff from 45 RACFs and 29 pharmacies that were involved in Phase 1. A questionnaire identified initial perceptions of the potential usefulness and effectiveness of the intervention. Four-hundred and thirty-five questionnaires were returned (85.0% response rate). Respondents believed the toolkit had the potential to reduce the occurrence of DAA incidents 'very' (49.6% of those who

responded to this question) or ‘extremely’ well (20.5%), and felt that the education session was ‘very’ (46.6%) or ‘extremely’ (38.0%) useful.

The intervention was evaluated both qualitatively and quantitatively in **Phase 4**. At least three months after the intervention was introduced at participating workplaces, the DAA audits were repeated at the 45 RACFs that were introduced to the intervention, to quantitatively assess whether the DAA incident rate identified in Phase 1 had decreased. Field notes also recorded which toolkit components were implemented. A questionnaire was sent by email or facsimile to one contact at each of the 45 RACFs and the 14 recruited community pharmacies to evaluate the perceived usefulness and effectiveness of the toolkit after it was implemented. Lastly, all of the DAA incidents identified in the Phase 1 and 4 DAA audits were classified according to their risk of causing an adverse event if they were transferred to the RACF resident. Of 2,389 DAAs audited from 39 pharmacies for 983 residents, 770 incidents involving 502 DAAs were identified (21.0% incident rate) in Phase 4.

There was a significant increase in the DAA incident rate post-intervention compared to pre-intervention ($p<0.001$). Statistically significant increases occurred in the proportion of DAAs experiencing specific DAA incident types post-intervention, including added medicine, inaccurate medicine division, incorrect time interval and ‘other’ incidents ($p<0.001$). However, statistically significant decreases were seen in the frequency of specific incident types when compared to the total number of incidents identified, including unsuitable medicine packing according to pharmaceutical guidelines ($p<0.001$), incorrect medicine quantity ($p<0.001$), omitted medicine ($p<0.001$), incorrect medicine strength ($p<0.05$), incorrect tablet division ($p<0.05$) and incorrect medicine form ($p<0.05$). The poster was the most commonly implemented toolkit component and the survey identified generally positive feedback from health professionals regarding the toolkit. The majority of incidents identified post-intervention were also of a lower risk category, compared to those identified pre-intervention. This final phase identified that an intervention more specifically designed for the RACF or community pharmacy workplace and targeting specific DAA incident types, may be more successful at reducing the occurrence of DAA incidents and improving the DAA medicine supply service.

Statement of originality

The work presented in this thesis is, to the best of my knowledge and belief, original except as acknowledged in the text. Full acknowledgement has been made where work of others have been cited or used. This thesis has not been submitted in part or in whole for the award of any other degree or diploma in any university or other institution.

Julia Fiona-Maree Gilmartin

September 2013

Communications arising from this thesis

Publications

Gilmartin JFM, Hussainy SY, Marriott JL. Medicines in Australian nursing homes: A cross-sectional observational study of the accuracy and suitability of re-packing medicines into pharmacy-supplied dose administration aids. *Research in social & administrative pharmacy: RSAP* 2013: (**Epub ahead of print**). DOI: 10.1016/j.sapharm.2013.01.002.

Gilmartin JFM, Marriott JL, Hussainy SY. Towards improving dose administration aid supply: a quality improvement intervention aimed at reducing dispensing errors. *International journal of clinical pharmacy* 2013: (**published online**). DOI: 10.1007/s11096-013-9839-z.

Gilmartin JFM, Hussainy SY, Marriott JL. Exploring factors that contribute to dose administration aid incidents and identifying quality improvement strategies: The views of pharmacy and nursing staff. *The International journal of pharmacy practice* 2013: (**submitted**).

Gilmartin JFM, Marriott JL, Hussainy SY. Medicines in Australian nursing homes: the impact of quality improvement designed to reduce the occurrence of dose administration aid incidents (**in preparation** for submission to *Research in social & administrative pharmacy: RSAP*).

Conference presentations - oral

Gilmartin JFM, Hussainy SY, Marriott JL. *Quality improvement for safe aged care dose administration aid use*. Australian Association of Gerontology 45th National Conference, Brisbane, Queensland, November 2012.

Gilmartin JFM, Hussainy SY, Marriott JL. *Dose administration aids for older Australians - is quality improvement necessary? The perspectives of stakeholders*. Australian Nursing Federation (Victorian Branch) and National Enrolled Nurse Association Professional Issues in Practice Conference: The Future is Now, Melbourne, Victoria, September 2012.

Gilmartin JFM, Hussainy SY, Marriott JL. *How to Improve Dose Administration Aids for Aged Care Facilities*. 17th International Social Pharmacy Workshop, Phuket, Thailand, July 2012.

Gilmartin JFM, Hussainy SY, Marriott JL. *A review of dose administration aids: Improving medicine management*. Australasian Pharmaceutical Science Association Conference, Adelaide, South Australia, December 2011 (awarded Outstanding oral presentation in Pharmacy Practice).

Conference presentations - poster

Gilmartin JFM, Hussainy SY, Marriott JL. *Could community pharmacy medicine supply to aged care facilities benefit from quality improvement? Stakeholder perspectives and the resulting initiative*. International Pharmaceutical Federation World Centennial Congress of Pharmacy and Pharmaceutical Sciences, Amsterdam, The Netherlands, October 2012.

Gilmartin JFM, Hussainy SY, Marriott JL. *Dose administration aids for older Australians - a survey of stakeholder perspectives on accuracy*. 17th International Social Pharmacy Workshop, Phuket, Thailand, July 2012.

Gilmartin JFM, Hussainy SY, Marriott JL. *Dose administration aids for older Australians - is quality improvement necessary? The perspectives of stakeholders*. National Medicines Symposium, Sydney, New South Wales, May 2012 (winner of the National Medicinewise Award 'Education for health professionals to build quality use of medicines skills').

Gilmartin JFM, Hussainy SY, Marriott JL. *A review of dose administration aids: Improving medicine management*. Pharmacy Australia Congress, Melbourne, Victoria, October 2011.

This thesis is dedicated to my parents, Jane and John, and my partner Rees.

You have given me the most wonderful life imaginable.

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1 Introduction and literature review

In Australia, dose administration aids (DAAs) are often used to facilitate medicine adherence and simplify the process of medicine administration in residential aged care facilities (RACFs). DAAs organise medicines according to the day of the week and time of the day in which they need to be taken and commonly take the form of blister packs and sachets in Australian RACFs. DAAs may be packed manually or via automation and may be prepared by the patient, a carer, pharmacy staff, or a DAA packing company. Medicines are removed from their original containers and arranged in the DAA according to the patient's medication regimen, as stipulated by their prescriber.

DAA medicine packing occurs commonly in many Australian community pharmacies, as Australian RACFs often use pharmacy-supplied DAAs. However, literature evaluating how accurately medicines are supplied by community pharmacies predominantly focuses on dispensed medicines stored within their original containers. Error rates and types of errors associated with this form of dispensing, contributing factors and strategies to reduce their occurrence have been explored.¹⁻⁹ In contrast, literature evaluating medicines dispensed from their original containers and placed into DAAs is relatively limited.¹⁰⁻¹³

To continually meet outcomes of safety, quality, and efficacy, as desired by health professionals and medicine consumers alike and in line with Australia's National Medicines Policy,¹⁴ DAA medicine supply services would benefit from regular evaluation and quality improvement (QI). This is also important as DAAs are a topical issue in Australia and have been the subject of recent media attention.^{15, 16} These devices are becoming increasingly relied on by medicine consumers and staff in RACFs, to ensure medicines are taken or administered accurately, increasing the popularity of news stories concerning their use.

This chapter provides an overview of Australia's ageing population and RACF environment, an outline of DAA use in RACFs, and a review of the existing literature evaluating this medicine supply service. Gaps in the available literature are highlighted and community pharmacy dispensing error studies are also reviewed. These discussions provide the basis for the study presented in this thesis. The chapter concludes with the aims and outline of this study.

1.1 Australia's ageing population

1.1.1 Australia's projected age distribution and economic impact

Although there is no defined age threshold at which one becomes an 'older' person, those aged over 65 years old, or Aboriginal and Torres Strait Islanders aged over 50, are often referred to as aged, older or elderly.¹⁷

Due to sustained low levels of fertility and increasing life expectancy at birth, Australia's population is ageing.¹⁸ The Australian Bureau of Statistics (ABS) has projected that the median age of Australia's population will increase from 36.8 years in 2007, to 45.2 years in 2056.¹⁸ Over the same time period, the proportion of those aged 65 years and over is projected to increase from 13% to 25%, and the proportion of those aged 85 years and over is projected to more than quadruple, from 1.6% to 7.3%.¹⁸

Australia's ageing population is expected to cause an increase in Australian Government spending.¹⁹ Ageing and health pressures are expected to increase total spending from 22.4% of Gross Domestic Product (GDP) in 2015-2016, to 27.1% in 2049-2050.¹⁹ Slower economic growth associated with ageing, increased demand for age-related services and payments, technological advances in health, and demand for higher quality health services, are all expected to cause financial pressure.¹⁹

Along with general population growth, ageing is expected to contribute around 40% of the projected increase in Government health spending over the next forty years.¹⁹ Health spending is projected to increase from 4.0% of GDP in 2009-2010, to 7.1% in 2049-2050.¹⁹ Over the same time period, health spending on those aged over 65 years old is expected to increase around seven-fold and on those aged over 85 years, around twelve-fold.¹⁹ Over the next 40 years, from 2009-2010 to 2049-2050, aged care spending is also projected to increase from 0.8% to 1.8% of GDP.¹⁹

1.1.2 Medicine use in older Australians

It has been shown that medicine use increases with age.²⁰ A 1995 ABS survey found that the proportion of Australians using medicines increased from 42% of those less than 15 years old, to 86% of those aged 65 years and over.²⁰ Of those who used medicines and were aged between 45 and 64 years old, 41% used only one medicine and 40% used two or three.²⁰ Of those aged 85 years or older, 17% used one medicine, 45% used two or three and 38% used four or more.²⁰

A 2012 Australian survey of conventional and complementary medicine use among individuals aged 50 years and over, found that the mean number of medicines per participant was 4.6.²¹ In the 24 hours preceding survey completion, 87.1% of respondents took one or more medicines, 43.3% took five or more, and 10.7% used 10 or more medicines.²¹

Studies conducted in Australian RACFs have shown high medicine usage amongst older residents.^{12, 22, 23} Snowden *et al.* identified that residents of RACFs in Sydney were prescribed a mean number of 6.8 medicines each.²² Eighty one point eight per cent of residents were prescribed four or more medicines and 71.3% were prescribed five or more.²² Similarly, residents from an Adelaide-based study by Crotty *et al.* took a mean of approximately six medicines,²³ and in a Victorian study by Hussainy *et al.*, an average of 8.9 regular medicines was prescribed per resident.¹²

1.1.3 Medicine-related problems in older Australians

In older individuals, medicine-related problems (MRPs) are common and often preventable, and can include inappropriate medicine prescribing, adverse medicine effects and drug interactions.²⁴ This population is at increased risk of MRPs²⁵ due to:²⁴

- age-related physiological changes;
- multiple chronic co-morbidities;
- large medicine consumption;
- physical disabilities that may prevent accurate medicine use; and
- complex care arrangements that may involve multiple prescribers changing medication regimens without inter-professional consultation.

Australian literature has identified that this population is particularly vulnerable to medicine-related hospitalisations.²⁶⁻²⁹ Roughead's examination of hospital morbidity data concluded that adverse drug reactions (ADRs) occurred predominantly in those aged over 55 years old.²⁷ Similarly, Burgess *et al.* identified that in 2002, the rate of hospital stays related to ADRs increased with age, from 7.7 per 1,000 person years at 60-69 years old, to 34.3 per 1,000 person years at 80 years old and over.²⁸

Chan *et al.* identified that adverse drug events (ADE) are a common preventable cause of unplanned hospitalisations in older people, with 30.4% of emergency admissions potentially due to an ADE from medicine noncompliance, omission or cessation.²⁹ Additionally, a medical record review of 100 individuals aged 65 years and over and admitted to an

Australian public teaching hospital, identified 54 patients with potentially inappropriate medicines (PIMs).³⁰ A total of 92 PIMs were identified using the Screening Tool of Older Person's Prescriptions.³⁰ It was found that the most commonly identified PIM could adversely affect individuals prone to falls.³⁰

RACF residents are potentially at greater risk of experiencing MRPs than other individuals.³¹ Factors that may contribute to this increased risk have been proposed:

- residents are more likely to receive more medicines³² than the rest of the population;³³
- medicine management systems may be complex and involve multiple health professionals;³¹
- medicines may be dispensed from multiple sites;³¹ and
- multiple medicine packaging systems may be used.³¹

In an Australian study by Elliott *et al.*, it was identified that 75 medicine doses for 18.3% of 202 RACF residents were missed or significantly delayed in the 24 hours after discharge from hospital.³⁴ Of these medicine administration errors, 65.3% were classified as high or moderate risk.³⁴ After examining medicine dispensing data, Dolton *et al.* identified potentially harmful medicine interactions for 6.1% of 3,876 RACF residents.³⁵ Interactions commonly involved high-risk medicines or those with narrow therapeutic windows, such as warfarin, amiodarone, verapamil, lithium and methotrexate.³⁵ Finally, Hilmer and Gnjdic highlighted the potentially inappropriate use of psychotropic medicines amongst RACF residents.³⁶ It was reported that there is limited data supporting the efficacy of these medicines in this population and there is growing evidence of risks associated with their use, including falls, pneumonia, hospitalisations and mortality.³⁶

1.2 Residential aged care in Australia

1.2.1 Definition and funding of Australian residential aged care

The Australian Aged Care Act 1997 defines residential care as:³⁷

“personal care or nursing care...provided to a person in a residential facility in which the person is also provided with accommodation that includes: (i) appropriate staffing to meet the nursing and personal care needs of the person; and (ii) meals and cleaning services; and (iii) furnishings, furniture and equipment for the provision of that care and accommodation...”

Australian RACFs, previously referred to as nursing homes or hostels,³⁸ accommodate individuals who are unable to live at home due to the effects of ageing, illness or disability.³⁹

In Australia, these residents may be provided with care that is classified as high or low.³⁹ High level care involves 24 hour nursing care, and the provision of meals, laundry, cleaning and personal care, while low level care provides assistance for individuals to live independently within the RACF.³⁹ Residents may permanently reside in RACFs, or may be provided with short-term or respite care.

Australian residential aged care services are delivered by the Australian Government and private, or not-for-profit, providers.³⁸ The Australian Government financially supports the cost of care and accommodation for eligible individuals to live in RACFs.³⁹ To receive Government funding, Australian RACFs are assessed against accreditation standards concerning:³⁹

- management systems;
- staffing and organisational development;
- health and personal care;
- resident lifestyle; and
- physical environment and safe systems.

These facilities can be accredited for up to three years, with ongoing monitoring conducted by the Aged Care Standards and Accreditation Agency.³⁹

In 2011, there were 2,750 Australian facilities providing Government-funded residential aged care.³⁸ Sixty-one per cent of facilities were located in major cities, 25% in inner regional areas, 12% in outer regional areas, and 2% in remote or very remote areas.³⁸

1.2.2 Australian residential aged care resident demographics

According to a 2006 report by The Royal Australian College of General Practitioners, approximately 6% of Australians aged over 65 years old, and 30% aged over 85, live in Australian RACFs.⁴⁰ Over the last 10 years, the number of residents in RACFs has increased due to the ageing population and the increase in residential places.³⁸ From 1999 to 2011, the number of permanent residents increased by 24.6%, from 132,420 to 165,032.³⁸ As at 2011, 70% of these residents were female and 77% were aged 80 years old and over.³⁸ Older residents also make up a larger proportion of the permanent resident population, with those aged 85 years and over increasing from 48.8% to 56.9%, from 1999 to 2011.³⁸

Australia's RACF residents are frail and often have complex needs.⁴¹ Of 154 residents in a South Australian study by Crotty *et al.*, between 63% and 74% had a diagnosis of dementia and between 28% and 31% had depression.²³ Similarly, a report by the Australian Institute of Health and Welfare highlighted that, of the 164,116 permanent residents who were assessed for their level of care in 2011, 78% were reported to have a mental illness and more than half (52%) had a diagnosis of dementia.³⁸ Common medical conditions of residents listed in this report included:³⁸

- circulatory system diseases (24.4% of listed conditions), such as heart disease, cardiovascular disease and hypertension;
- musculoskeletal and connective tissue disorders (17.9%), such as osteoarthritis, rheumatoid arthritis and osteoporosis; and
- endocrine, nutritional and other metabolic disorders (8.4%), such as diabetes.

1.2.3 Australian residential aged care staff

The Australian RACF workforce comprises nurses, personal care assistants (PCAs) and support staff involved in cleaning, laundry and catering.⁴² Medical practitioners and allied health professionals also provide health care services to RACF residents.⁴²

In Australia, nurses are required to have a post-school qualification⁴³ and may be classified as a registered nurse (RN - Division 1 nurse) or an enrolled nurse (Division 2).⁴⁴ Enrolled nurses provide nursing care under the direction and supervision of RNs.⁴⁴ Although PCAs are not required to have a post-school qualification to work in RACFs, a 2007 Australian workforce survey found that 64.6% of PCA respondents had a Certificate III in aged care, which is normally awarded upon completion of a training course that is not at university level.⁴³ Only 23.7% reported that they did not have any post-school qualifications.⁴³

PCAs make up the largest occupational group in RACFs.⁴⁰ From 2003 to 2007, the RACF workforce shifted towards greater use of PCAs compared to RNs, suggesting that more direct resident care is being provided by the former.⁴³ Over the same time period, the proportion of RNs fell from 21.0% to 16.8%, while the proportion of PCAs rose from 58.5% to 63.6% of the workforce.⁴³ This shift may reflect the lower wages associated with employing PCAs, who are less qualified than RNs.

1.2.4 Medicine administration in Australian residential aged care

Professional standards, legislations and regulations (national, state and territory) govern health professional medicine administration roles, responsibilities and practice in Australian

RACFs.⁴⁵ Professional and Government bodies also have policies and procedures to assist with medicine administration to RACF residents and other older individuals.^{40, 46-55}

Due to a high prevalence of disease and co-morbidity, Australian RACF residents are significant consumers of medicines and are dependent on staff to administer them.⁴⁰ Nurses are commonly responsible for medicine administration in RACFs.⁴⁵ Enrolled nurses may administer medicines if they have the appropriate qualification and have not been restricted from this practice, while RNs are qualified and legally allowed to administer medicines in Australia.⁴⁵ Permission to administer medicines is covered by the Health Practitioner Regulation National Law Act 2009 and relevant state or territory legislation and regulation.⁴⁵ Nurses are professionally regulated through the Nurses and Midwives Board of Australia and are accountable to professional standards.⁴⁵

PCAs may also administer medicines, in accordance with state or territory legislation, regulation and RACF policy and procedures.⁴⁵ PCAs are not bound by standards set by a licensing authority, though they may have training in medicine management.⁴⁵

In Australia, the process of administering medicines in RACFs is guided by the resident's medicine record. This record is held at the RACF and outlines the medication regimen of the resident, as stipulated by the prescriber. It is common practice for the prescriber to visit the RACF, to review residents and their medicine records. Any medication regimen changes must be communicated to the pharmacy so that their copy of the medicine record is updated and the DAA is accurately prepared. If new medicines are ordered, the prescriber must also send a medicine prescription to the pharmacy, to facilitate medicine dispensing.

Dose administration aids (DAAs) are frequently used to administer medicines in Australian RACFs^{13, 45} and are usually supplied by community pharmacies.

1.3 Dose administration aids

1.3.1 Definition and types of dose administration aids

The Australian Government Department of Health and Ageing defines DAAs as:⁴⁵

“...devices or packaging systems such as blister packs, bubble packs or sachets for organising doses of medicines according to the time of administration.”

Solid, orally administered medicines are removed from their original containers and placed into the DAA according to the day of the week and time of the day in which they must be

taken, as stipulated by medicine records. Packed medicines may include prescription, non-prescription, and complementary and alternative medicines.⁴⁵

DAA's may be referred to as daily dose reminders, monitored dosage systems,⁵⁶ medicine organisers,^{57, 58} and multi-compartment medicine compliance devices.⁵⁹ They may be classified as unit dose, where one single medicine type is packed within a DAA compartment, or multi dose, where different medicine types are packed within a compartment.⁴⁵ In Australian RACFs, blister packs and sachets are commonly used DAA types. Figure 1.1 includes a photograph of a blister pack⁶⁰ and a sachet DAA.⁶¹



Figure 1.1 From left to right: a blister pack and a sachet DAA

Blister packs consist of a piece of bubble plastic with 28 clear blister wells in seven rows of four, where each day of the week may be separated into breakfast, lunch, dinner and bedtime.⁶² The bubble plastic is attached to a piece of labelled cardboard or foil⁶² that is pierced to access the medicine within.⁶³

Sachet DAAs comprise a continuous roll of labelled plastic sachet squares.⁶² Each square corresponds to a specific day of the week and to a specific dosing interval. Medicines are liberated by tearing each sachet square open.

1.3.2 Advantages and disadvantages of dose administration aids

Medicines are becoming more commonly packed into DAAs for older people.⁶⁴ These devices may be portable and disposable,⁶² tamper-evident,⁶² and may include useful printed medicine information.⁶² Advantages specifically related to sachets include, single sachets may be removed for enhanced portability, medicines may be crushed and administered

directly from the sachet, and medicines can be easily identified through the clear sachet packaging.⁶²

Disadvantages associated with DAAs include:

- errors in DAA preparation and delivery;⁴⁵
- inflexibility towards medicine ordering and supply, following medication regimens changes;^{45, 62}
- interruptions to medicine supply when residents move across care settings;⁴⁵
- the cost to residents and the RACF;⁴⁵
- liquids cannot be packed;⁶²
- medicines that are taken irregularly, or ‘when required’, are not usually packed;⁶²
- small medicines may be overlooked;⁶²
- maximum filling capacities exist;⁶² and
- medicine identification can be difficult if the DAA is full.⁶²

Additionally, DAAs have the potential to deskill RNs¹³ and may be associated with safety concerns related to fewer medication regimen changes and increases in the number of medicines used, including potentially harmful medicines.⁶⁵ Specific limitations of sachets include fewer pharmacies provide sachet DAAs compared to blister packs,⁶² adjacent sachets may be inadvertently torn from sachet rolls,⁶² and the sachet roll must be unwound to enable thorough checking.⁶² In contrast, blister packs do not allow medicines to be crushed within them⁶² and it may not be possible to separate individual blisters for enhanced portability.⁶²

1.3.3 Stability of packed medicines

There is limited information regarding medicine stability once packed into a DAA.⁶⁶ It has been suggested that short term stability data concerning medicines removed from their original containers should be available or manufacturers could indicate which medicines should not be packed into DAAs.⁶⁶ Australian professional body guidelines have provided some indication of medicines that may be unsuitable for DAA packing.⁶⁷ To protect medicine integrity, it has also been recommended that medicines should not be kept within DAAs for more than eight weeks and DAAs should be stored in a cool dry place.⁵⁶

Due to specific medicine storage and stability requirements some medicines may not be suitable for DAAs,^{13, 45, 56, 67, 68} such as those that:⁶⁷

- pose occupational health and safety risks and require special handling, such as cytotoxics and teratogens;
- are sensitive to DAA heat sealing, such as soft gel capsules;
- are moisture sensitive, such as effervescent or dispersible tablets and wafers;
- are light or air sensitive;
- are of a large size; and
- may interact with the DAA packaging material.

Church and Smith have compiled information concerning medicine stabilities when packed into DAAs, based on information received from medicine manufacturers.⁶⁸ Out of 392 investigated medicines, none had undergone stability testing while in a DAA.⁶⁸ However, it was still recommended that a number of medicines should not be packed into DAAs due to stability concerns, such as sodium valproate and certain nifedipine and aspirin products.⁶⁸

Both positive and negative findings have been identified in the published literature concerning the stability of specific medicines, when they are packed into DAAs. Donyai's study of DAA-packed atenolol identified changes in tablet appearance without any change in tablet dissolution,⁶⁹ while another study showed increased disintegration time and decreased dissolution time at accelerated conditions of temperature and humidity, compared to atenolol stored in its original container.⁷⁰

Physical and chemical stability of clozapine was maintained when packed into a DAA in the study by Perks *et al.*⁷¹ Conversely, Bowen *et al.* identified that the resulting discolouration of frusemide was unacceptable when packed into a DAA⁷² and an examination of prochlorperazine by Glass *et al.* concluded that medicine quality had been compromised due to discolouration and the potential for photodegradants to cause adverse effects.⁷³

Llewelyn *et al.* identified that unacceptable weight variation and dissolution profile changes occurred when sodium valproate was packed into a DAA.⁷⁴ It was recognised that bioavailability changes could occur, there could be clinical non-equivalence with tablets that had not been packed into DAAs, and breakthrough seizures could result.⁷⁴ Llewelyn *et al.* cautioned against packing sodium valproate into DAAs due to potential exposure to uncontrolled conditions of temperature and humidity.⁷⁴ Glass *et al.*'s literature review also concluded that caution should be exercised when packing sodium valproate and atenolol into DAAs.⁷⁰

1.3.4 Dose administration aid use in residential aged care

DAAs may assist in the process of RACF medicine management.^{45, 75} They may support and increase the convenience of medicine administration, provide an audit trail for dispensed and administered medicines,⁴⁵ reduce medicine administration errors,⁷⁶ reduce the time associated with medicine administration,^{13, 75} and ease the burden of medicine ordering and medicine prescription management.¹³

Scott *et al.*'s comparison of RACF medicine administration from original medicine containers or sachets found that RACF staff were satisfied with the sachets.⁷⁵ Staff perceived that they were a safer method of medicine administration, they involved less container handling and time for medicine management procedures, and staff could more easily focus on medicine administration when interruptions occurred.⁷⁵

Enrolled nurses or RNs may administer medicines from DAAs.⁴⁵ According to state or territory legislation and regulation, and RACF policies and procedures, PCAs may also be authorised to undertake this practice.⁴⁵

1.3.5 Preparation of dose administration aids

In Australia, DAAs may be prepared onsite at the community pharmacy or offsite by a DAA packing company. Blister packs may be prepared both manually or via automation, while sachets are only prepared via automation.

Community pharmacists prepare DAAs in accordance with professional guidelines and standards, and relevant state or territory legislation.⁴⁵ Dispensary assistants, pharmacy students, internship pharmacists and pharmacy technicians may assist with DAA preparation by placing medicines into the DAA, preparing and attaching labels, keeping records, and undertaking other non-judgemental tasks.⁶⁷ However, the Pharmacy Board of Australia considers that the supplying pharmacist carries ultimate responsibility for all aspects of DAA supply even if DAAs are prepared by a DAA packing company using automated processes.⁷⁷ As a result, the completed DAA must still be checked by a pharmacist prior to supply.⁶⁷

Various Australian professional bodies and Government agencies have developed resources to assist with DAA preparation.^{67, 77-79} The Pharmaceutical Society of Australia (PSA) has outlined guidelines and standards that cover:⁶⁷

- the DAA preparation area;

- staff responsibilities;
- staff training;
- policies and procedures;
- DAA packing, labelling and sealing;
- record keeping; and
- quality assurance.

The PSA has also outlined criteria to guide DAA preparation and suggested systems to minimise packing errors, indicating that the pharmacist should:⁶⁷

- prepare DAAs;
- ensure support staff are trained in DAA preparation;
- check the DAA contents and packing records for all DAAs prepared or supervised;
- produce and maintain a current medicine profile for packing and signing;
- ensure medicines can be tracked to their original container via an audit trail;
- use a quality assurance system to monitor, record and review discrepancies in the DAA packing process; and
- maintain a log of all DAAs packed.

1.4 Evaluation of dose administration aid preparation

1.4.1 Literature evaluating packing accuracy

The Australian Commission on Safety and Quality in Health Care has devised a list of preferred terms and definitions describing medicine-related occurrences. Error is defined as:⁸⁰

“...failure in the (drug) treatment process that leads to, or has the potential to lead to, harm to the patient and includes an act of omission or commission.”

An incident is defined as:⁸⁰

“An event or circumstance which could have, or did lead to unintended and/or unnecessary harm to a person, and/or a complaint, loss or damage.”

Currently available literature^{10-13, 81} evaluating how accurately DAAs are prepared, does not often evaluate whether medicines are suitably packed. That is, the suitability of packing potentially unstable medicines into DAAs is often overlooked, as opposed to whether medicine packing accurately correlates with medicine records. A comprehensive evaluation

of DAA medicine packing should consider both of these issues. As a result, the term ‘DAA incident’ is used in this thesis, as opposed to ‘DAA error’, as it was felt to encompass both medicine packing errors and instances of unsuitable medicine packing.

There is limited published literature concerning DAAs, apart from studies relating to medicine adherence.^{56-59, 63, 82-88} Despite the common use of DAAs in Australian RACFs and how frequently they are prepared by many Australian community pharmacies, the DAA medicine supply service has not been extensively evaluated for accuracy. Only five studies have been identified examining how accurately medicines are packed into these devices.^{10-13,}

⁸¹ Of these five studies, four included DAAs prepared by pharmacy staff,¹⁰⁻¹³ and one study, conducted by Levings *et al.*, included DAAs prepared by a number of different individuals.⁸¹

Levings *et al.* identified DAA-related events from incident reporting forms used in all South Australian and some Victorian public hospitals, and by a nursing service in South Australia.⁸¹ Fifty per cent of incidents (26/52) were considered to be instances of inaccurate DAA packing and responsible individuals included nursing staff (80.8% of errors), pharmacy staff (11.5%), the patient (3.8%), and unknown individuals (3.8%).⁸¹ Incidents included overdose or wrong medicine (50%), omission (25%), and underdose or unspecified wrong dose (25%).⁸¹ Contributing factors included:⁸¹

- failure to follow medicine protocols or check DAAs;
- documentation problems;
- poor communication; and
- distractions or being busy.

Levings *et al.* suggested that staff education should emphasise the importance of meticulous care and medicine checking by adhering to strict protocols.⁸¹ Additionally, the danger associated with these incidents was highlighted, in terms of their potential to cause harm on multiple occasions, when DAAs are prepared for one week at a time.⁸¹

The remaining four studies examined DAAs prepared solely by pharmacy staff for RACFs.¹⁰⁻¹³ The single German¹¹ and three Australian studies^{10, 12, 13} are outlined in Table 1.1. DAA incident rates ranged from 3.1% to 10.8% of DAAs audited.¹⁰⁻¹³ The most common incident types in each study included missing medicine,^{10, 11, 13} generic medicine brand substitution occurring without it being noted,¹³ ‘other’ incident,¹⁰ unauthorised/inappropriate alteration of medicine (such as incorrect halving or removal of medicine from foil packaging) or incorrect time of administration,¹² and incorrectly halved medicine.¹¹

Table 1.1 Literature evaluating DAA medicine packing and incident rate findings

Author (year), sample size, setting	Method of DAA auditing	DAA incident rate
Roberts <i>et al.</i> (2004), included 25 RACFs from six out of eight Australian states and territories, supplied by an unclear number of pharmacies. ¹³	Pharmacy and nursing students compared blister packs, sachets and plastic pill organisers to resident medicine records. DAA incidents were described as a mismatch between the record and the medicines administered from the DAA that could be attributed to the pharmacy.	672 dose/resident combinations of medicine record and DAA observations occurred. An incident rate of 3.1% of DAAs was identified.
Carruthers <i>et al.</i> (2008), included 42 RACFs in New South Wales, supplied by 12 pharmacies. ¹⁰	Blister packs were compared to resident medicine records by RNs. Incidents were described as a discrepancy between the record and the DAA.	6,972 DAAs for 2,480 residents were audited. 297 incidents were identified, corresponding to an incident rate of 4.3% of DAAs .
Gerber <i>et al.</i> (2008), included 3 RACFs in Germany, where pharmacy staff prepared the DAAs at the RACFs. ¹¹	A pharmacist compared pill organisers to resident medicine records. Incidents were categorised as incorrect time of administration, incorrect or extra dose, incorrect halving of tablets, and incorrect, missing or damaged medicines.	8,798 DAAs for 196 residents were audited. 645 incidents were identified, corresponding to an incident rate of 7.3% of DAAs .
Hussainy <i>et al.</i> (2012), included two RACFs in Victoria, supplied by one pharmacy. ¹²	A pharmacy student compared blister packs to resident medicine records. Incidents were described as a discrepancy between the record and the DAA.	166 DAAs for 91 residents were audited. 18 incidents were identified in 18 DAAs, corresponding to an incident rate of 10.8% of DAAs .

1.4.2 Limitations of the literature evaluating packing accuracy

The different DAA incident rates identified across the four studies that evaluated DAAs packed for RACFs by pharmacy staff, may be explained by their varying methodologies. The higher incident rates seen in two studies (7.3%¹¹ and 10.8%¹²) may be attributed to the pharmacist researcher's attention to medicine detail,¹¹ classification of incidents other than medicine record and DAA discrepancies, such as removing medicines from foil packaging,¹² or examining DAAs at fewer than five RACFs (a non-representative sample).^{11, 12} The two studies with relatively lower incident rates (3.1%¹³ and 4.3%¹⁰) audited DAAs in a larger sample of RACFs and did not use pharmacist researchers.^{10, 13} The study by Roberts *et al.* involved 25 RACFs and pharmacy and nursing students,¹³ while Carruthers *et al.* involved 42 RACFs and RNs.¹⁰ Additionally, the lower incident rate reported by Roberts *et al.* only included incidents attributed to the pharmacy, while the other studies provided an all-encompassing finding.

In three of the studies,^{10, 11, 13} DAA incident rates do not appear to be calculated accurately and may provide an overestimation. The incident rates are presented as a proportion of DAAs affected by incidents, and should therefore reflect the total number of DAAs that were affected by incidents compared to the total number of DAAs audited. However, only one of the four studies appears to have calculated the incident rate in this way.¹² Two of the studies^{10, 11} considered the total number of incidents identified compared to the total number of DAAs audited, which does not account for the occurrence of multiple incidents within a single DAA. The remaining study¹³ did not provide a clear indication of how the incident rate was calculated, but appeared to consider the total number of incidents compared to the total number of medicines audited.

In the four reviewed studies,¹⁰⁻¹³ limitations were identified in the study methodologies, potentially affecting the generalisability, validity, reliability and clinical applicability of findings.

Small samples¹¹⁻¹³ of non-randomly selected RACFs^{12, 13} from limited geographical areas and with small numbers of affiliated pharmacies¹⁰ reduce variability in DAA packing environments that influence DAA accuracy, and thus the generalisability of findings. The types of DAA incidents and incident rates identified, may reflect the unique environments of the study samples. The cost and time associated with quality improvement (QI) is therefore hard to justify in clinical settings that differ from those of the studies.

Whether incident verification occurred can potentially influence the validity of findings. Incidents with the potential to be misinterpreted could benefit from verification with a member of the usual health care team at the RACF to minimise overestimation of DAA inaccuracy. Overestimation could occur where discrepancies between DAAs and medicine records are due to transcription errors. Only two studies clearly involved RACF staff for incident verification.^{10, 11}

To enable repetition of these studies and to compare findings, clear incident definitions must be provided, as may be seen in studies evaluating pharmacy dispensing accuracy.^{89, 90} Though all four of the studies considered discrepancies between the DAA and the medicine record as an incident, only one study clearly defined what would constitute an incident,¹¹ while the remaining three studies provided vague definitions.^{10, 12, 13}

To comprehensively evaluate the accuracy of medicines packed within DAAs for RACF residents, unsuitable medicine packing should be considered in the incident definition,^{89, 90} including:

- poorly divided or damaged medicines;
- packing medicines that have the potential to become unstable when removed from their original containers; and
- hygiene and safety issues related to DAA preparation, such as inadvertently packing pieces of foil or hair.

Only one study included some of these considerations in their definition of what constituted a DAA incident.¹¹

With the advent of novel DAA packing technology, a comparison between manual and automated DAA preparation methods would be useful to inform decisions and direct QI efforts. Automation may be perceived to be more accurate, as there is less chance of human error. Additionally, medicine dispensing studies in the community and hospital setting have shown greater accuracy and reduced errors with automated processes.^{91, 92} Only one study clearly audited sachets in addition to blister packs, but a direct comparison between the two DAA types did not occur.¹³

Finally, it is useful to classify DAA incidents according to clinical significance such as potential MRPs that may result if the incident was not rectified prior to administration. By determining the severity of identified incidents, informed resource allocation can occur and can guide QI intervention development. Classification in this way occurred in only one

study, where 66.7% of identified incidents were deemed to be significant or have potential to cause harm.¹²

1.4.3 Factors contributing to, and strategies to address, packing incidents

There were a number of common factors contributing to the occurrence of DAA incidents amongst the studies, involving prescribers and RACF or pharmacy staff, as identified by the authors. Inadequate communication may contribute to DAA incidents, especially between members of the health care team.^{10, 12, 13} Medicine records may not be updated, may be updated inaccurately¹² or may be difficult to decipher.^{10, 11, 13} DAA preparation can contribute to incidents through packing stages, the staff involved and packing protocols.^{10, 11, 13} Medicines may be damaged upon handling,¹¹ staff may experience concentration lapses or fatigue,^{11, 13} or packing may occur too far in advance, preventing recent medication regimen changes being actioned.¹⁰ Finally, inadequate auditing processes at pharmacies and RACFs can contribute to systematic errors.¹²

All studies outlined author-suggested recommendations to increase the accuracy of DAAs or presented characteristics of RACFs and DAA supply environments that resulted in lower comparative incident rates. A number of common suggestions among the studies involved prescribers and staff at RACFs and pharmacies. Aspects of interprofessional communication, quality control processes, education and technology were targeted.

Improved and more streamlined communication and collaboration between members of the regular (prescriber/pharmacist/RACF staff) and occasional (hospital) health care team^{10, 13} regarding the resident and their medicines can ensure that the prescriber's intentions are clear and DAAs are prepared accurately. Quality control processes, involving guidelines and standard operating procedures, should be developed or improved for DAA supply,¹⁰⁻¹³ in collaboration with all members of the health care team.^{12, 13} RACFs and pharmacies should be involved collaboratively in audits, as well as participating in residential medication management reviews with prescribers.¹⁰ DAA preparation staff could benefit from education regarding the consequences and significance of medicine altering^{11, 12} and the worthwhile nature of DAAs.¹⁰ Medicine records should undergo regular auditing, updating and archiving of older versions,¹² as well as a legislative shift that would recognise them as legal medicine prescriptions.¹⁰ Both medicine records and medicine prescriptions may benefit from terminology standardisation and the use of generic names for medicines.¹⁰ Electronic charting, ordering and dispensing can be useful, as well as electronic signatures,¹⁰

although this may lead to a different set of errors.⁹³ Prescribers can be educated on the disadvantages of prescribing higher strength medicines that require division.¹¹ Additionally, using a smaller number of prescribers per RACF may also reduce errors.¹⁰

1.4.4 Quality improvement directed towards packing incidents

There is a paucity of published research describing evidence-based recommendations to improve how accurately and suitably medicines are packed into DAAs. Published literature specifically developing, implementing, evaluating and drawing conclusions from interventions targeting DAA incidents, has not been identified.

Roberts *et al.* made recommendations to improve the general RACF DAA medicine supply service.¹³ It was recommended that pharmacists should be appropriately remunerated for supplying DAAs and standard operating procedures should be developed to optimise service efficiency and effectiveness.¹³

It was also suggested that DAA best practice guidelines should be developed, to:¹³

- address the professional responsibilities of pharmacy and RACF staff;
- ensure RACF staff are adequately trained in DAA use;
- ensure pharmacy and RACF staff, residents and prescribers are communicating at an adequate frequency and with appropriate quality;
- address packing medicines that are irregularly administered, or taken ‘when required’;
- address RACF staff medicine knowledge;
- address standard operating procedures that concern medicine administration from DAAs over original medicine containers; and
- ensure efficient DAA supply to RACFs.

A later report by Roberts *et al.* outlined general best practice models for supplying DAAs to RACFs and recommended that:⁹⁴

- DAA services should reflect best practice and should incorporate quality assurance measures;
- pharmacy organisations should develop best practice implementation plans for RACF DAA services;
- RACF accreditation models should include best practice DAA services;
- pharmacies should be appropriately funded for DAA supply;

- pharmacy and Government organisations should develop DAA preparation guidelines that cover staff training and competencies, and staff should be educated on these guidelines;
- strategies to define DAA medicine stability should be implemented;
- there should be effective collaboration between the prescriber, pharmacist, RACF staff, resident, carer and the Government;
- medicine records should be recognised as medicine prescriptions; and
- there should be further stakeholder consultation to determine future direction of best practice models, as well as plans for continuing development and implementation.

1.5 Evaluation of community pharmacy medicine dispensing

1.5.1 Literature evaluating dispensing accuracy

A dispensing error has been previously defined in the literature as:³

“...any unintended deviation from an interpretable written prescription or medication order. Both content and labelling errors are included. Any unintended deviation from professional or regulatory references, or guidelines affecting dispensing procedures, is also considered a dispensing error.”

In Australia, packing medicines into DAAs may be considered a form of medicine dispensing,¹³ as it involves the supply of medicines by a pharmacist, from a community pharmacy to a medicine consumer. The main difference between dispensing medicines in their original containers and in a DAA, is the form in which medicines are supplied. Therefore, literature that examines the accuracy of community pharmacy medicine dispensing of original medicine containers can provide insight into the factors that may contribute to, and strategies to reduce the occurrence of, DAA incidents. This holds true despite the location in which DAAs are prepared, whether it be onsite at the pharmacy or offsite by a DAA packing company, as both cases still involve the community pharmacist checking the DAA before final supply to the RACF.

There is comparatively more research examining community pharmacy dispensing accuracy involving original medicine containers¹⁻⁹ compared to literature that evaluates how accurately and suitably medicines are packed into DAAs.¹⁰⁻¹³ Studies have evaluated the frequency at which community pharmacy dispensing errors occur (Table 1.2) and have suggested potential contributing factors and strategies to reduce their occurrence.¹⁻⁹

Dispensing error rates arising from the community pharmacy setting vary across studies and have been presented in different ways.

Table 1.2 Community pharmacy dispensing error rates

Author (year)	Dispensing error rate	Percentage
Flynn <i>et al.</i> (2009) ⁵	22 errors from 100 dispensed items	22.0
Franklin <i>et al.</i> (2007) ³	49 errors from 2,859 dispensed items	1.7
Flynn <i>et al.</i> (2002) ⁹	91 errors from 5,784 medicine prescriptions	1.6
Allen <i>et al.</i> (2003) ¹	39 errors from 51,357 dispensed items	0.1
Teagarden <i>et al.</i> (2005) ²	16 errors from 21,252 dispensed items	0.1
Knudsen <i>et al.</i> (2007) ⁶	1 error per 10,000 medicine prescriptions	<0.1
Ashcroft <i>et al.</i> (2005) ⁴	3.99 errors per 10,000 dispensed items	<0.1
Norden-Hagg <i>et al.</i> (2010) ⁹⁵	19.41 errors per 100,000 dispensed items	<0.1

Dispensing error rates have also been presented as 28 errors from 145 reports of actual errors and near misses,⁸ and 677 dispensing errors among 968 reported errors (69.9%).⁷ Common types of dispensing errors included incorrect medicine instructions,^{2, 3, 5, 96} incorrect medicine or medicine form,^{4, 96} incorrect quantity,^{4, 5} incorrect strength,^{4, 96} too many or too few dose units,³ and incorrect patient name.³

Limitations associated with these studies include difficulty comparing dispensing error rates due to differences in study design, error definitions, and error rate calculations.^{96, 97} Additionally, in studies that describe dispensing errors along with near misses, prescribing errors, transcription errors or administration errors, it is difficult to identify those findings specifically relating to dispensing errors.

1.5.2 Factors contributing to, and strategies to address, dispensing accuracy

There is limited published research examining the factors that contribute to pharmacy dispensing errors.⁹⁷ Factors that have been identified as possibly contributing to community pharmacy dispensing errors or circumstances that may have led to errors include:

- misreading the medicine prescription;⁴
- similar medicine containers;⁴
- selecting the next medicine on the shelf;⁴

- a busier than normal work environment;⁴
- fewer staff than usual;⁴
- phone interruptions;⁴
- worker distraction;⁵ and
- computer software limitations preventing instructions from fitting on the medicine label.⁵

Research that examined both dispensing errors and near misses suggested additional contributing factors including:

- tight medicine packing on shelves;⁹
- the absence of containers to store individual patient medicines;⁹
- high ambient noise levels, other than radio or television noises;⁹
- inadequate lighting;⁹
- manual medicine checking without the use of bar-code technology;⁹ and
- the process of entering medicine prescriptions into the pharmacy computer system.²

Studies have also examined health professional perceptions of factors that contribute to community pharmacy dispensing errors or strategies that may reduce their occurrence.^{89, 98,}

⁹⁹ Identified contributing factors that have not already been mentioned included pharmacy design,⁹⁹ drive-through pick-up windows,⁹⁹ carelessness,⁹⁸ heavy workloads,⁹⁸ illegible medicine prescriptions or handwriting,⁹⁸ talkative customers,⁹⁸ and conversations with customers.⁹⁸

Strategies to reduce the occurrence of dispensing errors and factors that may lead to reduced error rates included:

- barcoding medicines;⁴
- different medicine containers;⁹⁸
- electronic prescribing, to prevent labelling errors;⁵
- incorporating automation into the mechanical aspects of dispensing.²
- authentication at the point of dispensing using the patient medicine record or the electronically transferred medicine prescription;³
- conducting independent checks of dispensed medicines⁴ and comparing the final medicine label to the original medicine prescription;⁵
- documenting errors⁶ and analysing contributing factors;⁸⁹
- discussing the error with pharmacy staff;^{89, 98}
- changing work routines based on the error;⁹⁸

- carefulness and concentration;⁹⁸ and
- working with sufficient personnel in undisturbed work environments.⁹⁸

Though studies have implemented strategies to reduce the occurrence of dispensing errors, few studies have measured their impact and most were specific to local settings.² One study that implemented and evaluated strategies to reduce community pharmacy dispensing errors, focused on errors of incorrect medicine strength.⁹⁵ Norden-Hagg *et al.* evaluated the impact of a barrier integrated into computerised medicine prescription data entry that required staff to verify any medicine strength entered into the computer system.⁹⁵ It was found that the intervention decreased the number of error reports and led to a statistically significant change in slope from slight increase to decrease, of reported numbers of errors ($p=0.0035$).⁹⁵ The intervention was also associated with a significant decrease ($p<0.0001$) in the number of reports of wrong strength, and in the slope of reporting figures.⁹⁵

1.6 Summary, aims and outline of the study

Medicines have the potential to improve the quality of life of an individual by preventing disease, alleviating manifestations of a current illness, or even cure. The use of medicines in older RACF residents plays a central role in their health management as they are a subset of the population who are commonly unwell and have multiple comorbidities. It is essential that medicines are supplied accurately and suitably to this frail, vulnerable population, as these individuals often do not manage their own medicines and rely on others to meet their health care needs. Though innovative DAA medicine supply systems are commonly used in Australian RACFs, there is limited research ensuring that they continue to meet the expected high standards of health professionals and medicine consumers alike. Additionally, as the proportion of PCAs in RACFs increases, it is important that they are supported in their workplace roles with accurate medicine supply services. This chapter highlights the gaps in the literature evaluating the DAA medicine supply service and developing and implementing interventions designed to improve it.

Despite studies showing that there is the potential for relatively high rates of DAA medicine packing incidents to occur, limited large scale research in an Australian context has been conducted to investigate how accurately and suitably medicines are packed into DAAs according to the prescriber's intentions. Research is needed to identify how widespread DAA incidents are and to validate previous research, with larger randomised samples over a wide geographic area, using clear DAA incident definitions, and accurate incident rate calculations.

Additionally, the limited literature evaluating DAA medicine packing has not comprehensively and systematically consulted health professionals concerning the factors contributing to DAA incidents or strategies to reduce their occurrence. Given the occurrence of DAA incidents,¹⁰⁻¹³ regular evaluation of this medicine supply service is required, followed by interventions for RACFs and community pharmacies, to reduce these DAA incident rates.

Therefore, the hypotheses of this study were:

- incidents of inaccurate or unsuitable medicine packing occur within DAAs supplied by Victorian community pharmacies for RACF medicine administration; and
- the DAA incident rate can be reduced with an intervention.

The overall aims of this study were threefold:

- to evaluate how accurately and suitably medicines are packed into blister pack and sachet DAAs, prepared manually or via automation, and supplied by Victorian community pharmacies to RACFs;
- to identify health professional perceptions of the factors that contribute to DAA incidents and strategies to reduce their occurrence; and
- to develop, introduce and evaluate an intervention designed to reduce the occurrence of DAA incidents and improve the DAA medicine supply service.

The main study outcomes included identifying:

- the overall DAA incident rate, defined as the proportion of DAAs that have at least one incident compared to the total number of DAAs audited (primary outcome);
- the proportion of DAAs affected by a specific DAA incident type (secondary outcome); and
- the frequency of specific DAA incident types as a proportion of the total number of DAA incidents identified (secondary outcome).

This thesis is structured as follows:

Chapter 2: the research methodology underpinning the study.

Chapter 3: evaluation of how accurately and suitably medicines are packed into DAAs supplied by Victorian community pharmacies (Phase 1).

Chapter 4: investigation of factors contributing to DAA incidents, and potential strategies to reduce their occurrence and improve the DAA medicine supply service (Phase 2).

Chapter 5: design, development, introduction and initial evaluation of the intervention (Phase 3).

Chapter 6: final evaluation of the intervention (Phase 4).

Chapter 7: a summary of the study and its findings and suggestions for further research in this area.

2 Research methodology

2.1 Summary

This study involved four phases (Figure 2.1). **Phase 1** evaluated how accurately and suitably medicines were removed from their original containers and packed into dose administration aids (DAAs). A cross-sectional audit of DAAs supplied by Victorian community pharmacies to a large sample of residential aged care facilities (RACFs) occurred. Instances of inaccurately or unsuitably packed medicines, otherwise known as DAA incidents, were identified. In **Phase 2** a survey and focus groups were used to identify health professional perceptions of the factors contributing to DAA incidents and to explore strategies to reduce their occurrence.

In **Phase 3**, the findings from Phase 1 and 2 were used to develop an intervention, designed to reduce the occurrence of DAA incidents and improve the DAA medicine supply service. The intervention comprised an education session and toolkit. In this thesis, the term ‘intervention’ refers to both the education session and the toolkit. Alternatively, each component may be referred to separately. After it was piloted, the intervention was introduced to the RACFs from Phase 1 and their affiliated community pharmacies, and was initially evaluated via a survey.

The intervention was further evaluated in **Phase 4**, at least three months after the intervention was introduced, by repeating the Phase 1 DAA audits, recording field notes and conducting a second survey. All of the DAA incidents identified in Phase 1 and 4 were classified according to their potential risk of causing an adverse event, if they were transferred to the RACF resident.

All phases of this study were approved by the Monash University Human Research Ethics Committee (MUHREC) (Appendix 1). Additional ethics approval pertaining to specific RACFs was obtained from the Barwon Health research office (Appendix 2) and both the Ballarat Health Services and St John of God Healthcare Human Research Ethics Committee (Appendix 3).

This chapter describes the research methodology of this study and the quantitative and qualitative research methods used.

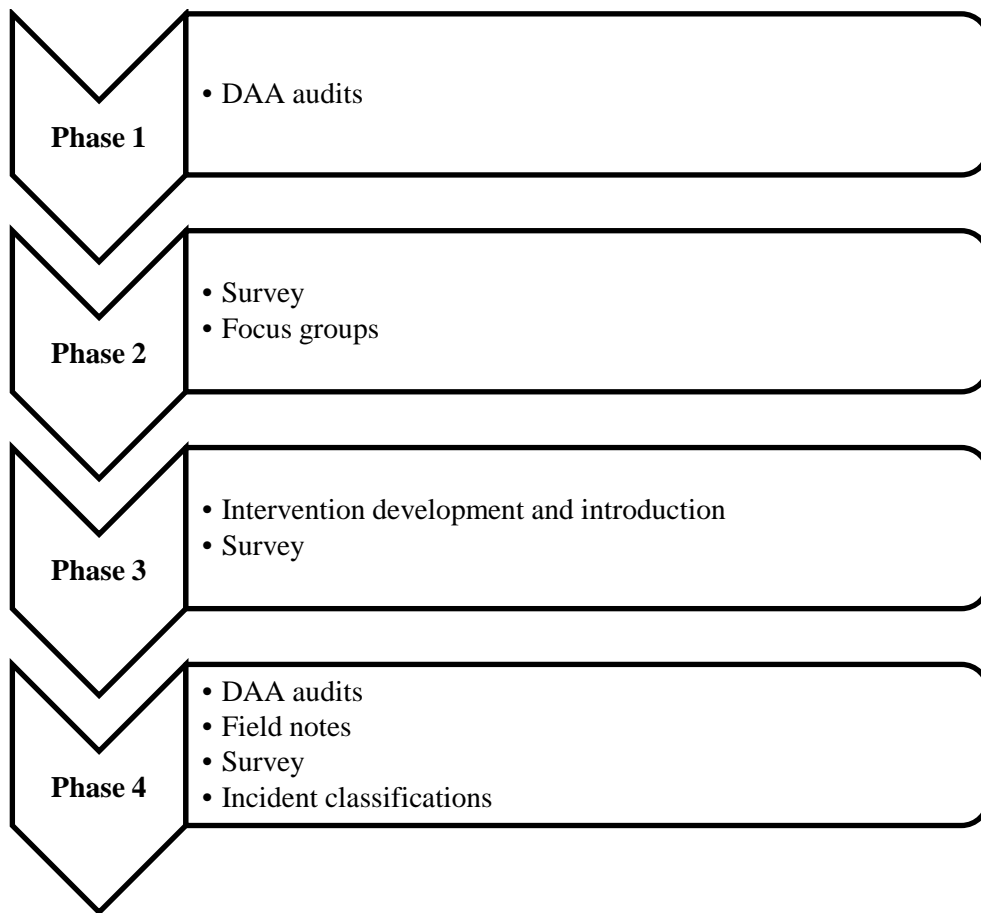


Figure 2.1 The four phases of this study

2.2 Quantitative methodology

Quantitative research involves testing a hypothesis, investigating frequencies of events and quantifying relationships between variables.¹⁰⁰ Pre-determined and standardised frameworks¹⁰⁰ are used to record data in a numeric form in preparation for statistical analysis.¹⁰¹ Quantitative findings can be reproduced and generalised outside the study settings.¹⁰⁰ The quantitative methods used in this study included nonparticipant observations, surveys, intervention development, incident classifications, and a before-and-after study design.

2.2.1 Nonparticipant observations

The Phase 1 (Chapter 3, Section 3.2.1) and 4 (Chapter 6, Section 6.2.1) DAA audits and Phase 4 field notes (Chapter 6, Section 6.2.2) are forms of nonparticipant observation.

Observation allows the researcher to document behaviours, activities and events, and to count and characterise them, while investigating associations between variables.¹⁰⁰ Though observational studies may be labour intensive and relatively expensive,¹⁰² findings can have higher reliability and validity as the researcher is in control of the completeness and quality of data collection, rather than relying on potentially inaccurate self-reports.¹⁰⁰ Observation has been frequently used to detect medicine errors in the literature and there is evidence supporting its validity, efficiency and accuracy.¹⁰³

Nonparticipant observations occur as an outside observer.¹⁰⁰ These studies are usually described as quantitative, where observations are quantified in terms of numeric frequencies.¹⁰⁰ In contrast, participant observation involves participating as a member of the community under observation.¹⁰⁰ This is regarded as a qualitative technique as the context of observations, including the constraints, difficulties or facilitative aspects of environments, can be observed.¹⁰⁰

In Phase 1 (Chapter 3, Section 3.2.1), the DAAs supplied by 40 Victorian community pharmacies to 49 metropolitan, rural and regional RACFs were audited to determine how accurately and suitably medicines were packed. Accuracy was determined by comparing the medicine contents in the DAA with the current medicine record of the RACF resident. Suitability was assessed using pharmaceutical guidelines⁶⁷ and professional pharmaceutical judgement. A DAA incident was defined as a discrepancy between the DAA and the medicine record, medicines that should not be packed according to pharmaceutical guidelines, and medicines that are damaged, inappropriately altered and incorrectly divided.

The Phase 1 DAA auditing method was repeated in Phase 4 (Chapter 6, Section 6.2.1.3), at the 45 RACFs introduced to the intervention (Chapter 5, Section 5.3.2.1). These audits occurred at least three months after the intervention was introduced at participating workplaces. A comparison of the total DAA incident rate and individual rates of specific DAA incident types, pre- and post-intervention, was used to quantitatively assess how well the intervention reduced the occurrence of DAA incidents (Chapter 6, Section 6.3.1.4).

Other research methods that were considered but not used to identify DAA incidents were interviews or examining pre-existing DAA incident reports at RACFs and pharmacies. Interviews may not have elicited complete and accurate DAA incident rate information, as the nature of a query regarding DAA incidents can be sensitive and may have prevented full disclosure. Responses may also have been subject to recall bias, would have only elicited information regarding perceived and not actual incident rates, and would only have included those incidents recognised by staff. Analysing pre-existing DAA incident reports may have

limited the accuracy, reliability and completeness of findings as this method would have relied on data collected by individuals other than the pharmacist-led research team.

Around the time of the Phase 4 DAA audits a record was made of the toolkit components that were implemented (Chapter 6, Section 6.2.2) in the RACFs and pharmacies that were provided with a toolkit (Chapter 5, Section 5.2.2.3). These field notes provided additional insight into the usefulness of the toolkit.

2.2.2 Surveys

Questionnaires were used in Phase 2 (Chapter 4, Section 4.2.1) to identify health professionals' perceptions regarding DAA incidents, and in Phase 3 (Chapter 5, Section 5.2.3) and 4 (Chapter 6, Section 6.2.4) to evaluate the initial and subsequent perceptions of the intervention effectiveness and usefulness.

As a survey instrument, questionnaires are effective for collecting descriptive and statistical information regarding the characteristics, opinions and activities of a large population, quickly and economically.¹⁰⁴ This research method identifies event frequencies, describes associations between variables and enables populations to be quantified by predetermined and standardised characteristics.¹⁰⁰ The incidence of missing data and non-responders can be reduced via repeat mailings, reminder letters, telephone calls, careful timing of contacts, incentives, avoiding holiday periods, and attention to the covering letter content and questionnaire presentation.¹⁰⁰

Questionnaires may be delivered by post, hand, via the internet or telephone and may be self-completed or researcher-administered. Anonymous, self-completed questionnaires do not provide the opportunity for follow-up or clarification, or to gather more details on responses.¹⁰⁰ Open-ended questions allow respondents to provide more complete answers and may highlight issues not previously considered,¹⁰⁵ however, analysis is more time-consuming. In contrast, closed questions are easier to complete, code and analyse, but the validity of findings may be influenced¹⁰⁴ as the respondents are limited to certain alternative responses.¹⁰⁵

The Phase 2 (Chapter 4, Section 4.2.1.3) email- or facsimile-delivered questionnaire was predominantly open-ended as it was exploratory in nature and wished to identify all potential responses. Electronically delivered questionnaires were an efficient means to access respondents and for them to complete and submit information. The questionnaire was sent to one contact from each of the 49 RACFs and from a sample (14) of the pharmacies involved in Phase 1 (Chapter 3, Section 3.3.1.1). Respondents were asked to outline the

types and frequencies of incidents that occur in DAAs supplied to RACFs, as well as factors contributing to them and strategies to reduce their occurrence.

The Phase 3 (Chapter 5, Section 5.2.3.3) hand-written and Phase 4 (Chapter 6, Section 6.2.4.3) email- or facsimile-delivered questionnaires included open-ended questions, questions that were a combination of open-ended and closed (mixed questions), and questions associated with a five-point Likert scale. The personally delivered hard copy questionnaire in Phase 3 allowed individuals who were introduced to the intervention to complete the questionnaire without delay. The Phase 4 questionnaire was sent to one contact from each of the 45 RACFs and from a sample (14) of the pharmacies where the intervention was introduced (Chapter 5, Section 5.3.2.1). Respondents commented on the potential or actual usefulness and effectiveness of the intervention at reducing the occurrence of DAA incidents and improving the DAA medicine supply service. The Phase 3 survey concerned the entire intervention, while the Phase 4 survey only evaluated the toolkit. Additionally, Phase 3 questionnaire respondents were asked for their perceptions regarding the intervention before it was implemented, while the Phase 4 questionnaire was sent at least three months after the intervention was introduced at participating workplaces.

Interviews were not used in place of the Phase 2, 3 or 4 surveys, as this would have limited the number of respondents.

2.2.3 Intervention development

A number of different approaches can be used to implement change and improve clinical practice in health care settings,¹⁰⁶ such as the RACF or pharmacy workplace. Approaches may be educational, epidemiological, behavioural, organisational or coercive.¹⁰⁷ Approaches may also target social interaction or incorporate a marketing aspect.¹⁰⁷ The intervention developed in this study was largely educational.¹⁰⁷ Change was driven by targeting an individual's internal motivation to improve, which was encouraged through a learning environment.¹⁰⁷ As the research team were not employed by the study sites, it would have been difficult to implement change using other approaches that may require significant influence in study settings.

Though reading educational material or attending education sessions may have a limited effect on professional behaviours, education is recognised as a necessary first step in implementing interventions.¹⁰⁶ Education may be more effective if it is small-scale, interactive, has an appropriate group composition, incorporates needs assessment before the activity and is combined with other interventions.¹⁰⁶ The education session that formed part

of the intervention in this study, was usually conducted with relatively small groups of staff from a single workplace, involved time for questions, was informed from earlier study phases and was combined with a toolkit. Theories about changing professional and organisational performance have also been outlined in the literature.¹⁰⁶ Those based on attitudes, such as the Theory of Planned Behaviour, formed the basis of the intervention in this study.¹⁰⁸ This theory explains that change is encouraged by convincing professionals about the importance of an issue and showing them that they can address it.¹⁰⁶ The education session highlighted the importance of reducing the occurrence of DAA incidents and improving the DAA medicine supply service, while the toolkit provided health professionals with the necessary resources to facilitate change in their workplace.

2.2.4 Incident classifications

The process of classifying DAA incidents identified in Phase 1 (Chapter 3, Section 3.3.1.3) and 4 (Chapter 6, Section 6.3.1.2) is a quantitative research method.

The Doctor of Philosophy (PhD) candidate classified all of the DAA incidents for consistency, using the Phase 1 and 4 DAA audit forms and the risk-classification system for geriatric ambulatory care medicine-related problems (MRPs).¹⁰⁹ This tool was adapted from The Society of Hospital Pharmacists of Australia (SHPA) risk classification system.¹⁰⁹ The risk associated with a particular DAA incident, from almost certain to rare, was determined after assigning a numerical rating to the *severity* and *likelihood* of the most probable adverse event that could occur if the incident was transferred to the RACF resident. A comparison of the risk categories assigned to DAA incidents identified pre- and post-intervention was used to further evaluate the intervention (Chapter 6, Section 6.3.3.1).

An expert panel of health professionals with RACF medicine management experience was considered for the incident classifications but was not used. It was not feasible to involve individuals external to the study, considering the large number of DAA incidents identified in Phase 1 (Chapter 3, Section 3.3.1.3) and 4 (Chapter 6, Section 6.3.1.2) and the time-consuming nature of classifications. Also, incident classifications involving only a small sample of DAA incidents would not accurately represent the entire sample.

2.2.5 Before-and-after study design

This study followed the principles of a before-and-after study design.

Before-and-after studies can evaluate service initiatives by comparing data collected on variables expected to be impacted by the intervention, before and after the intervention.¹⁰⁰ Without a control group it can be difficult to attribute any change in the data to the intervention under evaluation, as opposed to other confounding factors.¹⁰⁰ A control group was not used in this study as it was not feasible to obtain the required RACF sample size.

The overall and individual DAA incident rates identified from the Phase 4 DAA audits (Chapter 6, Section 6.3.1.2) were compared to those identified in Phase 1 (Chapter 3, Section 3.3.1.3), to quantitatively assess whether the intervention reduced the occurrence of DAA incidents and to compare the risk associated with incidents identified pre- and post-intervention.

2.3 Qualitative methodology

Qualitative research is often exploratory in nature¹⁰⁰ and enables issues to be studied in-depth and in-detail.¹⁰² It involves the generation of hypotheses¹⁰⁰ and the exploration of understandings, meanings and interpretations that individuals attribute to their world.¹⁰¹ Qualitative research tools are not standardised to enable comparisons or generalisations of findings.¹⁰⁰ The data collected are context-specific and should be interpreted and described considering the circumstances from which they were derived.¹⁰⁰ The qualitative methods used in this study included focus groups.

2.3.1 Focus groups

The Phase 2 focus groups (Chapter 4, Section 4.2.2) expanded on the Phase 2 survey findings (Chapter 4, Section 4.3.1). They also sought feedback regarding researcher-suggested intervention strategies that were the precursor to the intervention (Chapter 5, Section 5.3.1.1).

Focus groups are a group interview technique that provide insight into a wide range of attitudes, perceptions and opinions¹¹⁰ in relation to a topic of interest.¹⁰⁰ Interaction among participants generates a wider range of ideas than would occur from individual interviews¹⁰⁰ and responses can be modified after listening to others.¹⁰² Discussions are led by a moderator with open-ended questions from a discussion guide and an observer can record participant dynamics.¹⁰⁴ The moderator must be appropriately skilled to ensure all participants are able to contribute and to guide discussions without influencing them.¹⁰² Despite fewer questions being asked¹⁰² compared to other research methods, greater depth of understanding can be elicited from participants. It is an efficient method to obtain the

views of many people in a short period of time¹⁰² compared to individual interviews, which were considered to explore DAA incident perceptions for Phase 2 (Chapter 4) but were not used.

Homogenous groups, as opposed to heterogeneous, share background characteristics or common experiences.¹⁰⁰ While in-depth insight into the perspectives of this group may be generated, findings may be limited in terms of generalisability.¹⁰⁰ Discussion may be encouraged when participants are unknown to each other by creating a supportive and anonymous environment.¹⁰⁴ The total number of focus groups relates to the desire to represent the population under study and to ensure all relevant issues are identified without the emergence of new ideas.¹⁰⁰ Additionally, the group size is chosen to ensure all participants may contribute¹⁰⁰ while allowing a diverse range of views to be identified;¹¹⁰ between five to seven participants are preferred.¹⁰⁰

Three focus groups were conducted in Phase 2 (Chapter 4, Section 4.3.2.1). The pharmacist and registered nurse (RN) focus groups were homogenous. Due to participant availability, the personal care assistant (PCA) and pharmacy technician group was heterogeneous. All participants worked with DAAs used in RACFs and were employed at the RACFs or community pharmacies involved in Phase 1 (Chapter 3, Section 3.3.1.1). Most participants were not known to one another. For up to two hours, the six pharmacists, five RNs, one PCA and one pharmacy technician discussed the factors that contributed to DAA incidents, strategies to reduce their occurrence and evaluated researcher-suggested intervention strategies.¹¹¹ Feedback from the focus groups led to the development of the intervention in Phase 3 (Chapter 5, Section 5.3.1.1).

2.4 Sampling

Sampling is the process by which units of analysis are selected for research purposes.¹⁰¹

In quantitative research, **probability samples** are usually selected.^{100, 101} These samples include individuals from the population who have an equal chance of being selected,¹¹² thus generating a random sample. For probability samples, sample sizes can be calculated via statistical procedures and findings can be generalised to the population¹⁰⁰ with a degree of confidence in the accuracy of results.¹⁰¹ Types of probability sampling include simple random, systematic, cluster or stratified.¹⁰⁰ Systematic sampling involves sampling individuals from the population, in a systematic or sequential manner.¹¹³ Cluster sampling divides the population into clusters and then randomly selects clusters and individuals from those clusters.¹⁰⁰ Multistage sampling occurs in stages, where the population is divided into

different levels that can be arranged in a hierarchy and sampled one after the other.¹¹⁴ Stratified sampling ensures certain subgroups or strata in the population are included at an appropriate level within the sample and randomly selects individuals from each of those strata,¹⁰¹ so that the sample reflects the population subgroups.¹¹⁵

A combination of clustered, multistage and stratified sampling was used to select most *metropolitan* RACFs for the Phase 1 DAA audits (Chapter 3, Section 3.2.1.2). The population of Australian Government accredited RACFs was divided into clusters relating to one of four Victorian regions, regions were then further broken down into Victorian federal electorates, which were broken down into RACF-containing suburbs. Multistage sampling occurred when an RACF was randomly selected from a randomly chosen suburb, corresponding to a particular electorate, located in a specific Victorian region. Stratified sampling was used to increase the likelihood that all electorates were represented by the RACF sample involved in Phase 1 and that a specific proportion of RACFs were selected from each Victorian region.

In qualitative research, **nonprobability sampling** is used.¹⁰¹ In these samples there is no way of estimating the probability of each individual being included or any assurance that each individual has a chance of being included in the final sample.¹¹⁶ Nonprobability samples include convenience, purposive, snowball, quota and self-selected.¹⁰¹ Though findings may be relevant to the wider population,¹⁰⁰ this form of sampling does not allow generalisation as the sample representativeness is unknown.¹⁰¹ Convenience samples include the most readily accessible or willing participants,^{100, 101} while purposive sampling selects individuals in a systematic or purposive way based on what is known about the target population and the study purpose.¹⁰¹ Those who share characteristics relevant to the study may be chosen in purposive sampling.¹⁰⁰ Snowball sampling selects individuals from difficult-to-access groups by asking participants to suggest other prospective individuals.¹⁰¹ Quota sampling ensures specific proportions of individuals are represented in the sample and self-selected sampling occurs when individuals volunteer for study involvement.¹⁰⁰ It is neither appropriate to calculate sample sizes mathematically nor apply probability statistics in qualitative research.¹⁰⁰ Sample sizes are usually small due to the detailed and intensive research involved¹⁰⁰ and can depend on the research question, budget, time limits, other resources and saturation of findings.¹⁰¹

Convenience and purposive sampling was used to select *rural* and *regional* RACFs for Phase 1 (Chapter 3, Section 3.2.1.2). This form of sampling ensured that rural and regional RACFs were a feasible travelling distance from Melbourne, Victoria and were of a

sufficient size for auditing a large number of DAAs. RACFs using sachet DAAs were purposively sampled as sachets are not as commonly used as blister packs.

Convenience and purposive sampling was also used to select the contacts for the Phase 2 survey (Chapter 4, Section 4.2.1.2) and Phase 2 focus groups (Chapter 4, Section 4.2.2.2). Employees of the RACFs and community pharmacies involved in Phase 1 (Chapter 3, Section 3.3.1.1) were selected as these individuals shared characteristics relevant to the research and could inform the intervention development (Chapter 5, Section 5.2.1). The Phase 2 focus group participants were also selected by snowball sampling, where participants passed study information onto other potentially interested individuals.

Convenience and purposive sampling was used to identify participants for all remaining study phases as generalisation was not as important as gathering information-rich data to evaluate the intervention.

As the intervention was developed using the Phase 1 (Chapter 3, Section 3.3) and 2 (Chapter 4, Section 4.3) findings, it was introduced to the RACFs involved in Phase 1 and their affiliated community pharmacies, to ensure the best chance of success. The Phase 3 (Chapter 5, Section 5.2.3.2) and 4 surveys (Chapter 6, Section 6.2.4.2) were sent to those individuals who had been introduced to the intervention (Chapter 5, Section 5.3.2.1), that is, employees of the Phase 1 (Chapter 3, Section 3.3.1.1) RACFs and pharmacies. The PhD candidate conducted the Phase 4 incident classifications (Chapter 6, Section 6.2.3.2) as she had the required skills, level of education and work experience required for this task. Lastly, the Phase 4 DAA audits (Chapter 6, Section 6.2.1.2) and field notes (Chapter 6, Section 6.2.2.2) involved those workplaces that had been introduced to the intervention.

2.5 Validity

Validity refers to the extent to which findings accurately represent the phenomena they report to represent.^{100, 104}

Validity in **quantitative** research depends on the ability of the research instrument to measure what it is supposed to measure¹⁰² and its ability to collect accurate data relevant to the study objectives.¹⁰⁰ This can be influenced by the ability and willingness of participants to provide the requested information.¹⁰⁰ Quantitative research methods should pose questions that are relevant to the study area and allow participants to answer accurately and reliably.¹⁰⁰ The types of validity that can be applied to quantitative research methods include face, criterion, content and construct.¹⁰⁵ Face validity is assigned if the test superficially appears to test what it is supposed to.¹⁰⁵ It is the first examination of survey instrument

validity and aims to identify questions that may be misinterpreted, ambiguous, inaccurately reflect the variable of interest, or that participants may be unable or reluctant to answer.¹⁰⁰ Criterion validity ensures the instrument or questions correlate with other measures of the same variable, and content validity is assigned if the instrument gathers data on all the relevant issues under study.¹⁰⁰ Finally, construct validity indicates that the findings support the theory behind the research and that the constructs under investigation are actually being measured to the exclusion of others.¹⁰⁵

The quantitative DAA audit form used in Phase 1 (Chapter 3, Section 3.2.1.4), the Phase 4 process for recording field notes (Chapter 6, Section 6.2.2.3), and the Phase 2 (Chapter 4, Section 4.2.1.3), 3 (Chapter 5, Section 5.2.3.3) and 4 (Chapter 6, Section 6.2.4.3) surveys were assessed for face and content validity by individuals within or outside the research team and/or through piloting or testing. The Phase 4 (Chapter 6, Section 6.2.1.3) DAA audit form was further validated after it had been used in Phase 1, while the risk classification system used in Phase 4 had previously been assessed for face validity.¹⁰⁹

Validity in **qualitative** research depends on the ability of instruments to produce findings that are a true reflection of the participant's views.¹⁰⁰ The validity, meaningfulness and insights generated from qualitative inquiry have more to do with the information richness of the cases selected and the methodological skill and competence of the researcher than with sample size.¹⁰² Additionally, findings may possess inherent validity as the direction and content of qualitative enquiry, such as interviews, may be guided by participant responses.¹⁰⁰ Open-ended questions allow participants to raise issues they believe are important to the study area, which the researcher can explore in greater detail.¹⁰⁰ The types of validity that can be applied to qualitative research methods include argumentative, communicative and cumulative.¹⁰⁰ Argumentative validity, uses findings to argue a contradictory viewpoint, communicative validity returns to the field to verify findings with additional collected data, and cumulative validity shows that findings are consistent with existing knowledge on the subject.¹⁰⁰

Communicative validity was assessed by comparing the Phase 2 focus group findings (Chapter 4, Section 4.3.2) with the results from the Phase 2 survey (Chapter 4, Section 4.3.1) and the Phase 1 DAA audits (Chapter 3, Section 3.3.1). The focus group question guide was also assessed for face and content validity by the research team.

2.6 Reliability

Reliability refers to the reproducibility of measurements.^{100, 104}

In **quantitative** research, reliability refers to the extent to which findings are reproducible or internally consistent.¹⁰⁰ Reliability depends on participants being able and willing to provide the requested information.¹⁰⁰ Poor reliability may be due to ambiguous questions, variation in interviewer questioning style, or the inability of participants to provide accurate information.¹⁰⁰

Reliability of this study was assessed through pilot work, testing and evaluation of the Phase 1 DAA audit form (Chapter 3, Section 3.2.1.4) and the Phase 2 (Chapter 4, Section 4.2.1.3), 3 (Chapter 5, Section 5.2.3.3) and 4 (Chapter 6, Section 6.2.4.3) surveys, by individuals within and outside the research team. The Phase 4 DAA audit form (Chapter 6, Section 6.2.1.3) was assessed via the Phase 1 DAA audits, while the Phase 4 incident classifications (Chapter 6, Section 6.2.3.2) were conducted by the same researcher.

The reliability of **qualitative** data depends on the methodological skill, sensitivity and integrity of the researcher,¹⁰² however, reliability in qualitative findings is not a major consideration as the findings are context specific.¹⁰⁰ The researcher must understand the underlying contexts and reasons for differences and consistent interpretations or responses are not necessary.¹⁰⁰

Research consistency and reliability in the Phase 2 focus groups was ensured by using the same individual to moderate each group and by following a focus group question guide (Chapter 4, Section 4.2.2.3).

2.7 Generalisability

Generalisability, or external validity, refers to the extent to which findings can be applied to individuals beyond the sample.¹⁰⁰ It is determined by sampling procedures, sample sizes and response rates.¹⁰⁰

Where possible, generalisability for the **quantitative** research methods used in this study was increased by using probability sampling procedures and large sample sizes based on statistical power calculations.¹⁰⁰ Sample size calculations are based on the likelihood of there being any differences between the groups under study and the likelihood of them being detected.¹⁰⁰ In Phase 1 (Chapter 3, Section 3.2.1.2), a range of RACFs from across Victoria were chosen to identify a baseline DAA incident rate. Additionally, the Phase 4 incident classifications (Chapter 6, Section 6.2.3.2) involved all of the DAA incidents identified from the Phase 1 (Chapter 3, Section 3.3.1.3) and 4 (Chapter 6, Section 6.3.1.2) DAA audits.

Generalisability to the wider population was not sought in the Phase 2 (Chapter 4, Section 4.2.1), 3 (Chapter 5, Section 5.2.3) and 4 (Chapter 6, Section 6.2.4) surveys. These phases sought the views of individuals from the Phase 1 workplaces (Chapter 3, Section 3.3.1.1) to inform the intervention and to gather information from individuals who had been introduced to it. Additionally, the field notes recorded in Phase 4 (Chapter 6, Section 6.3.2.1) sought information regarding the toolkit, in workplaces where it had been introduced.

Qualitative research aims to explore and explain phenomena rather than test the extent to which characteristics apply to a large population, however, findings may have relevance and applicability to those outside the sample.¹⁰⁰

Generalisability to the wider population was not sought for the Phase 2 focus groups (Chapter 4, Section 4.2.2). These discussions were only interested in the views of individuals from the Phase 1 (Chapter 3, Section 3.3.1.1) workplaces, to increase the likelihood of producing a successful intervention in Phase 3 (Chapter 5, Section 5.3.1.1).

2.8 Analysis

Quantitative data from the Phase 1 (Chapter 3, Section 3.3.1) and 4 DAA audits (Chapter 6, Section 6.3.1), Phase 2 (Chapter 4, Section 4.3.1), 3 (Chapter 5, Section 5.3.3) and 4 surveys (Chapter 6, Section 6.3.4), and Phase 4 incident classifications (Chapter 6, Section 6.3.3.1) were managed using Microsoft Excel 2010® (Microsoft Corporation, Redmond, WA, USA) and Statistical Package for the Social Sciences (SPSS) Version 19® (SPSS, Inc., Chicago, IL, USA).

Quantitative analysis involved calculating descriptive summary statistics such as the measures of central tendency, including the mean and median.^{100, 101} The difference in the overall proportion of DAAs that contained incidents and the difference between the rates of individual DAA incident types, pre- and post-intervention (Chapter 6, Section 6.3.1.4), as well as the difference between risk categories assigned to incidents identified pre- and post-intervention (Chapter 6, Section 6.3.3.1), were examined with the Pearson's Chi-squared test. Statistical significance was assessed by using a 5% or less probability that findings occurred by chance ($p \leq 0.05$).¹⁰¹

Qualitative data from the Phase 2 focus groups (Chapter 4, Section 4.3.2) were managed with QSR NUD*IST Vivo 9 (NVivo) (QSR International [Americas] Inc., Cambridge, MA, USA QSR).¹⁰¹ Thematic analysis was used to identify themes or central ideas from the data, which were organised via coding.¹⁰¹ Qualitative data from the Phase 2 (Chapter 4, Section 4.3.1), 3 (Chapter 5, Section 5.3.3) and 4 surveys (Chapter 6, Section 6.3.4), the Phase 2

focus groups (Chapter 4, Section 4.3.2) and the Phase 4 field notes (Chapter 6, Section 6.3.2.1) were also managed with Microsoft Excel 2010® (Microsoft Corporation, Redmond, WA, USA) and Microsoft Word 2010® (Microsoft Corporation, Redmond, WA, USA).

2.9 Conclusion

This chapter has outlined the study methodology that identified the baseline DAA incident rate, of medicines that are packed into DAAs inaccurately or unsuitably, and that are supplied by Victorian community pharmacies to RACFs. The study methodology used to identify health professionals' perceptions of the factors contributing to these DAA incidents and strategies to reduce their occurrence has also been outlined. Additionally, the methodology involved in the development, introduction and evaluation of an intervention designed to reduce the occurrence of DAA incidents and improve the DAA medicine supply service has been described. The following chapters provide details of the study methods and their findings.

3 Phase 1 - Identification of dose administration aid incidents

3.1 Summary

Limited studies have evaluated how accurately and suitably medicines are packed into dose administration aids (DAAs) that are supplied by pharmacy staff for residential aged care facilities (RACFs).¹⁰⁻¹³ Varying rates of inaccurate or unsuitable medicine packing have been identified, ranging from 3.1% to 10.8% of DAAs audited.¹⁰⁻¹³ Before any intervention targeting these DAA incidents could be developed, a larger, more comprehensive Victorian study investigating the types and frequencies of these incidents, was needed. This chapter describes the cross-sectional DAA audits (Chapter 2, Section 2.2.1) used for this purpose.

3.2 Method

3.2.1 *Dose administration aid audits*

3.2.1.1 Audit aim

To identify the types and frequencies of DAA incidents that occur in blister pack and sachet DAAs, supplied by Victorian community pharmacies to RACFs.

3.2.1.2 Selecting participants for the audits

To increase the generalisability (Chapter 2, Section 2.7) of findings, a large sample of DAAs was needed from a large cross-section of RACFs and community pharmacies, across Victoria.

To identify a statistically significant halving of the DAA incident rate from 3% of audited DAAs (identified from previous research)¹³ to 1.5%, it was determined that 3,068 DAAs would need to be audited pre- and post-intervention. This sample size would allow a comparison to occur between DAAs prepared manually and via automation (1,534 DAAs per method of preparation), with 80% power to detect a difference and with $p \leq 0.05$. After conferring with the researcher involved in a previous Victorian DAA audit pilot study,¹² it was predicted that if 60 DAAs were audited at each RACF, approximately 52 RACFs would need to be recruited. It was estimated that half of these RACFs would use blister packs and half would use sachets.

To ensure the RACF sample included facilities from across Victoria, the Victorian federal electorates¹¹⁷ were used as a sampling frame (Appendix 4). The Australian Electoral Commission website¹¹⁷ was used to identify all 37 Victorian federal electorates and the suburbs and towns within each electorate. As the geographical boundaries of each electorate are determined by the number of voting individuals residing within them, they evenly divide the state of Victoria. Additionally, the electoral boundaries are clearly identifiable and RACFs can be easily located within them.

A second Australian Government online database was used to identify all Government accredited (Chapter 1, Section 1.2.1) Victorian RACFs.¹¹⁸ This database was filtered to include RACFs that provided at least one high care resident placement (Chapter 1, Section 1.2.1) and were thus more likely to use DAAs to manage the complex medication regimens of their residents. This database was also used to ensure the sampling list of suburbs and towns located within the 37 electorates only included those with at least one accredited RACF.

These two online resources were publically available and likely to include complete and accurate information.

The electorates were further classified according to the Victorian region in which they were located: outer metropolitan, inner metropolitan, rural and regional. The list of electorates, suburbs and towns, and the RACFs located within them were alphabetised and numbered in ascending order. Using the Microsoft Excel 2010® (Microsoft Corporation, Redmond, WA, USA) random number generator, from each electorate a suburb or town and RACF was sampled without replacement. Once each electorate was sampled at least once; RACFs were then sampled from randomly selected electorates without replacement. The number of RACFs to be sampled from each region was related to the proportion of electorates it possessed (Table 3.1).

Table 3.1 RACFs to be sampled from each Victorian region, n (%).

Victorian region	Victorian federal electorates n=37	RACFs to be sampled n=52
Outer metropolitan	16 (43.2)	22
Inner metropolitan	9 (24.3)	13
Rural	8 (21.6)	11
Regional	4 (10.8)	6
Column total of percentages does not equal exactly 100% due to rounding		

Most RACFs from inner and outer metropolitan regions of Victoria were selected by multistage, cluster sampling, stratified by Victorian region and electorate (Chapter 2, Section 2.4). RACFs from rural and regional electorates were purposively and conveniently sampled (Chapter 2, Section 2.4).

Community pharmacies were selected by their affiliation with the recruited RACF. As the DAA audits were only conducted at the RACFs, it was necessary to sample RACFs first. This sampling process did not guarantee the inclusion of a large number of pharmacies from across Victoria, as it was possible that single pharmacies could provide DAAs to multiple RACFs.

DAA packing companies were not selected for study involvement as the community pharmacist was considered to be the final responsible supplier of the DAA⁷⁷ and any intervention developed would only be informed by, and designed for, RACFs and community pharmacies (Chapter 5, Section 5.2.1.2).

3.2.1.3 Recruiting participants for the audits

Recruitment occurred between November 2010 and May 2011. RACFs were contacted by telephone, email, facsimile or post to determine if DAAs were used in medicine administration, if there was interest in study involvement, and to send study information. A letter of invitation (Appendix 5), explanatory statement (Appendix 6), consent form (Appendix 7) and permission letter (Appendix 8) was sent to the primary contact person at interested RACFs. An RACF was recruited once a permission letter and consent form was signed and received. RACFs were contacted multiple times until a decision was reached regarding study involvement or until the period of recruitment was complete.

After their affiliated RACF had been recruited, community pharmacies were contacted regarding study involvement, or study information was sent to them via their affiliated RACF. If interested, a letter of invitation (Appendix 9), explanatory statement (Appendix 10), consent form (Appendix 11) and permission letter (Appendix 8) was sent via email, facsimile or post to the primary contact person at the pharmacy. A pharmacy was recruited once a permission letter and consent form was signed and received. As the DAA audits only occurred at the RACF, it was not necessary to recruit pharmacies for the DAA audits; however, their participation was required for later study phases.

3.2.1.4 Developing and testing the auditing protocol

The DAA auditing protocol and the DAA audit form were initially modelled on those used in a previous Victorian DAA audit pilot study.¹² The PhD candidate and one of two research assistants, tested the protocol and DAA audit form using ten sample DAAs prepared by two practising pharmacists who were not involved in the study. Following this testing period, the PhD candidate and both research assistants were trained to conduct the DAA audits in a consistent manner and the audit form was refined to improve its ease of use and the clarity and usefulness of recorded information. The protocol and DAA audit form (Appendix 12) underwent minor modifications after the first few RACFs were audited. Minor changes included removing information fields that were not useful, such as those relating to resident allergies and medicine administration instructions, and including more space to record details of medicines that were regularly packed into DAAs. These documents were assessed for face and content validity by two academic pharmacists from the research team (Chapter 2, Section 2.5).

3.2.1.5 Conducting the audits

Between January and June 2011, the PhD candidate alone, or with one or both of the research assistants, audited the DAAs at each recruited RACF. All researchers were practising pharmacists. The DAA audits were not planned to occur during the month of December as the increased community pharmacy workload common for this time of year could have artificially increased the DAA incident rate.

The DAA audits occurred when the newly prepared DAAs first arrived at the RACF, after being checked and delivered by pharmacy staff, and before they were used for medicine administration. It was considered acceptable that the DAAs were often audited prior to RACF in-house DAA checking as they were considered to be ready for use, once they had left the pharmacy. Either an RACF staff member or the PhD candidate liaised with the

pharmacy to ensure that the DAA delivery time would allow auditing to occur over the course of a full day and during normal working hours. In most cases, arrangements were made for the DAAs to be delivered to the RACF earlier than usual or for the DAAs to be collected from the pharmacy. Though pharmacy staff may have been aware of the study, they could not anticipate which DAAs would be audited. Approximately eight hours over a single day were spent at each RACF, on any day of the week. At only one RACF, the DAAs were audited over two days, because of their large sachet volume that could help meet the required sachet sample size (Section 3.2.1.2).

Upon arriving at the RACF, the researchers were orientated to the workplace and the DAA audit location, and given access to the most current resident medicine records and newly prepared DAAs.

As prescribers often update medication regimens while visiting residents at the RACF (Chapter 1, Section 1.2.4), the RACF medicine records, rather than the DAA label or pharmacy medicine record, were considered to be the most current reflection of their intentions. DAA auditing therefore involved comparing all the DAAs that corresponded to one week's supply of a resident's regularly packed oral medicines, against the RACF medicine record.

Medicine records were randomly selected from those available and their corresponding DAAs were audited. In some cases, medicine records were not selected randomly if the researchers wished to audit DAAs from each of the different pharmacies that supplied medicines to a single RACF. Handwritten copies or photocopies of the medicine record were sometimes used when RACF staff were in possession of originals. Restrictions were not placed on the number of DAAs that could be audited at each RACF and all DAAs had the potential to be included in the sample without regard to the level of resident care (high, low or respite, Chapter 1, Section 1.2.1), to ensure a large number of DAAs were audited. Medicines could be packed into weekly or monthly blister packs or sachets and could be classified as unit or multi dose (Chapter 1, Section 1.3.1).

A DAA incident was described as an inaccurately or unsuitably packed medicine (Chapter 2, Section 2.2.1). Incidents included discrepancies between DAAs and medicine records, medicines that should not be packed according to pharmaceutical guidelines, and medicines that were damaged, inappropriately altered or incorrectly divided.

Online or electronic references used to assist with medicine identification and to identify medicine storage requirements included the electronic Monthly Index of Medical Specialties® (eMIMS),¹¹⁹ Consumer Medicine Information, and internet search databases

such as Google. Additionally, the Pharmaceutical Society of Australia's (PSA) list of medicines not to pack into DAAs was used.⁶⁷ Medicine pictures printed on DAAs were not relied on for medicine identification, as they often did not correspond with the medicine brand packed in the DAA.

The researchers conferred with each other to verify incidents in some cases where professional pharmaceutical judgment was required. Medicine record and DAA discrepancies were also verified with RACF medicine administration staff, including nurses and personal care assistants (PCAs) (Chapter 1, Section 1.2.3). To assist with verifications, the staff and researchers often referred to older or additional, resident specific medicine records and medicine notes. Although it may have been more accurate to verify incidents with pharmacy staff, this was not practical and it was considered sufficient to consult the RACF staff who were directly involved in medicine administration.

Incident verification ensured that discrepancies between the DAA and the medicine record were not transcription errors. Transcription errors can occur when the prescriber transcribes a new medicine record from an older version. In these cases, the DAA may accurately reflect the prescriber's true intentions, but this may not be reflected in the inaccurately transcribed medicine record. A transcription error was not considered a DAA incident for the purposes of this study.

A DAA incident was recorded if it was an incident according to the definition used and the researcher was able to identify the medicine, if they felt that it was an incident according to their professional pharmaceutical judgement, if the discrepancy was verified as an incident by RACF staff, and if RACF staff were not able to explain the discrepancy. In some cases photographs of incidents were taken.

To allow for follow-up and rectification if necessary, RACF and pharmacy staff were notified of incidents verbally and in writing. While efforts were made to ensure that DAA incidents did not reach the RACF resident, it must be acknowledged that not all incidents recorded in this study were considered to be incidents by RACF staff, such as inaccurately halved tablets.

3.2.1.6 Analysing the audit data

The data were entered into Microsoft Excel 2010® (Microsoft Corporation, Redmond, WA, USA), where medicines were coded according to the internationally recognised World Health Organisation Anatomical Therapeutic Chemical Classification System.¹²⁰

Seventeen predetermined DAA incident types were used to describe each identified incident (Table 3.2). Although a single medicine was commonly involved in a single incident, it could potentially be involved in more than one type of DAA incident if, for example, a medicine was considered unsuitable to be packed into a DAA and it also had major damage. Two DAA incident types were then recorded.

Incidents were counted by medicine identification (i.e. if three different medicines were missing from a DAA, then three incidents were counted) and by dose interval (i.e. if the same incident type occurred in the breakfast and the lunch time interval, then two incidents were counted, but if the same incident type occurred for a single medicine in a single time interval over multiple days, then only one incident was counted).

Descriptive statistics were calculated using SPSS Version 19® (SPSS, Inc., Chicago, IL, USA). The primary study outcome was the overall DAA incident rate, defined as the proportion of DAAs that had at least one incident compared to the total number of DAAs audited (Chapter 1, Section 1.6). The secondary outcomes included the proportion of DAAs that were affected by a specific incident type, and the frequency of specific incident types compared to the total number of incidents identified (Chapter 1, Section 1.6).

Table 3.2 The 17 predetermined DAA incident types

DAA incident type	Example
Addition	<ul style="list-style-type: none">• A medicine has been packed but it is not on the medicine record• A ceased medicine has been packed• An irregularly administered medicine taken ‘when required’ has been packed for regular administration• Packed medicine pieces do not appear to belong
Unauthorised brand substitution	<ul style="list-style-type: none">• A specific brand is noted on the medicine record with a request that it should not be changed, but a different brand is packed.
Damage	<ul style="list-style-type: none">• There is significant damage to a medicine or a medicine appears to have degraded• There is minor damage to a medicine with an enteric or controlled release coating that could affect its release• A medicine appears to be contaminated, with the exclusion of potential manufacturing faults.
Incorrect day	<ul style="list-style-type: none">• A medicine is packed to be given on a day that does not correlate with the medicine record
Inappropriate division	<ul style="list-style-type: none">• A controlled release medicine is divided
Inaccurate division	<ul style="list-style-type: none">• A medicine is not accurately divided and may be a slight deviation from its specification on the medicine record
Incorrect division	<ul style="list-style-type: none">• A medicine should have been halved but it is quartered• A medicine is divided and it shouldn’t have been• Medicine division is a significant deviation from its specification on the medicine record
Incorrect form	<ul style="list-style-type: none">• A capsule is packed instead of a tablet

Table 3.2 continued

DAA incident type	Example
Incorrect formulation	<ul style="list-style-type: none"> • A medicine is packed as a conventional release formulation instead of a controlled release formulation
Incorrect frequency of administration	<ul style="list-style-type: none"> • A medicine is packed on alternate days instead of daily • A medicine is packed once daily instead of twice daily
Omission	<ul style="list-style-type: none"> • A medicine is included on the medicine record but it is not packed
‘Other’	<ul style="list-style-type: none"> • Fluff, foil, paper, hair, moisture or other foreign object is included with packed medicines. • The DAA is overfilled and medicine identification is impossible without opening the DAA
Incorrect quantity	<ul style="list-style-type: none"> • Two tablets of the same medicine are packed, instead of one.
Unsuitable packing	<ul style="list-style-type: none"> • A packed medicine should not be included in a DAA according to pharmaceutical guidelines • A medicine is packed even though its product information cautions its removal from the original medicine container due to specific instability concerns, including nifedipine, hexamine hippurate, telmisartan, dispersible levodopa/benserazide, chewable phenytoin, sodium valproate, soluble aspirin, and both dissolvable potassium and lansoprazole. • A packed medicine is protected in its original foil packaging but the foil is not sealed
Incorrect strength	<ul style="list-style-type: none"> • The strength of a packed medicine does not correlate with the medicine record
Incorrect time	<ul style="list-style-type: none"> • An antibiotic or medicine for Parkinson’s disease is not packed at the exact time stipulated by the medicine record
Incorrect time interval	<ul style="list-style-type: none"> • A medicine, other than an antibiotic or medicine for Parkinson’s disease, is packed at a time that differs by more than two hours from the medicine record.

3.3 Results

3.3.1 Dose administration aid audits

3.3.1.1 Recruiting participants for the audits

Forty-nine *RACFs* were recruited from a total of 130 contacts, resulting in a 37.7% recruitment rate.

A number of difficulties were encountered when recruiting *RACFs*, including:

- contacting *RACF* staff;
- obtaining permission for *RACF* involvement from multiple individuals, or staff who were not located onsite at the *RACF*;
- requests for additional ethical approval pertaining to specific *RACFs*, which had the potential to significantly delay data collection; and
- *RACFs* that did not use DAAs (n=8).

Reasons for declining to participate included:

- the DAAs were already audited;
- other workplace issues were of a higher priority, such as upcoming Australian Government accreditation deadlines (Chapter 1, Section 1.2.1);
- the timing was not appropriate or other research was currently under way; and
- participation was perceived to be time-consuming, staff were busy, and staff changes were occurring.

Fourteen community *pharmacies* were recruited out of a total of 40 pharmacies (35.0%) that supplied the audited DAAs. These recruited pharmacies supplied DAAs to 22 of the 49 *RACFs* (44.9%) in the sample.

A difficulty associated with pharmacy recruitment was that *RACFs* often had to pass recruitment information onto the pharmacy. Reasons for declining to participate included busy staff and a lack of interest or time.

3.3.1.2 Characteristics of the audit sample

RACFs located in outer metropolitan Melbourne comprised 51.0% (25) of the sample, while 24.5% (12) of *RACFs* were from inner metropolitan, 14.3% (7) were from rural Victoria

and 10.2% (5) were from regional Victoria. In terms of Victorian federal electorate coverage, 81.3% (13/16) of outer metropolitan electorates were represented by a RACF, 88.9% (8/9) of inner metropolitan, 87.5% (7/8) of rural and 100% (4/4) of regional electorates were represented.

A total of 3,959 DAAs were audited, supplied by 40 pharmacies for 1,757 residents, from the 49 Victorian RACFs. Of the DAAs audited, 73.8% (2,920) were blister packs and 26.2% (1,039) were sachets.

Blister packs alone were audited in 69.4% (34) of RACFs, sachets alone were audited in 22.4% (11) of RACFs and both DAA types were audited in 8.2% (4) of RACFs. In this sample, the blister packs were prepared manually and the sachets were prepared via automation. As the majority of RACFs predominantly accommodated residents with high care needs, the audited DAAs are more likely to have been administered by staff than self-administered by residents.

The average resident whose DAAs were audited was female (67.7% of all residents audited), 85 years old (range: 31-106 years), took seven regularly packed medicines (range: 1-19), and had an average of two DAAs in total (range: 1-15), or an average of three blister packs or one sachet DAA (range: 1-15 and 1-4 respectively).

3.3.1.3 Overall incident rates

Six hundred and eighty-four incidents, involving 457 DAAs were identified, resulting in an overall DAA incident rate of 11.5% (457/3,959). Incidents were identified in DAAs belonging to 23.7% (416) of all residents audited. A major contributing factor to the incident rate was the frequent occurrence of unsuitable medicine packing, such as hygroscopic sodium valproate, which is not recommended for removal from its original container.^{67, 74}

The overall incident rate is reduced to 6.5% (256/3,959) of DAAs, if the 201 DAAs affected **only** by incidents of unsuitable packing are removed from the sample. As more than one incident type may occur in a single DAA, the number of DAAs experiencing unsuitable packing, among other incident types, is greater (227) than the number of DAAs **only** experiencing the incident type of unsuitable packing (201) (Table 3.3). The DAA incident rate of 6.5% can be compared with studies^{10, 11, 13} that have only audited DAAs for their accuracy and not the suitability of medicine packing.

Table 3.3 outlines the 17 predetermined DAA incident types and their frequency of occurrence. The findings are presented as a proportion of the total number of DAAs affected

by a specific incident type, and as a proportion of the total number of DAA incidents identified. This allows interventions to be evaluated for their impact on either finding, for example, if the overall DAA incident rate remained unchanged post-intervention, there is still the potential that specific DAA incident types may have occurred less frequently. Additionally, as one DAA may experience multiple incidents, it is important to examine the change in frequency of specific incident types rather than solely the change in the proportion of DAAs affected.

The most common incidents included unsuitable packing (50.1% of all incidents), addition (9.8%), incorrect quantity (5.4%), omission (5.3%), and damage (5.1%).

The incident types can also be collapsed into five main categories:

- 50.1% of all incidents were classified as unsuitable packing;
- 17.8% were classified as incorrect or missing medicines, including incorrect formulation and form, addition or unauthorised brand substitution;
- 15.3% were classified as incorrect dose, including incorrect quantity, strength and frequency of administration, inaccurate and incorrect division, and inappropriate division;
- 6.7% were classified as incorrect dose schedules, including incorrect time, time interval or day; and
- 10.1% were classified as 'other' incidents, including damage.

Table 3.3 Frequency of incident types and the proportion of DAAs affected, n (%).

DAA incident type	DAAs affected by a specific incident type compared to the total number of DAAs audited n=3,959	Frequency of a specific incident type compared to the total number of incidents identified n=684	DAA where incident occurred more frequently B = blister pack S = sachet
Unsuitable packing	227 (5.7)	343 (50.1)	B
Addition	52 (1.3)	67 (9.8)	S
Incorrect quantity	28 (0.7)	37 (5.4)	B
Omission	25 (0.6)	36 (5.3)	B
Damage	35 (0.9)	35 (5.1)	S
‘Other’	31 (0.8)	34 (5.0)	B
Inaccurate division	26 (0.7)	28 (4.1)	B
Incorrect strength	23 (0.6)	23 (3.4)	B
Incorrect time interval	19 (0.5)	22 (3.2)	B
Incorrect time	18 (0.5)	21 (3.1)	B
Incorrect formulation	12 (0.3)	13 (1.9)	B
Incorrect division	12 (0.3)	12 (1.8)	S
Incorrect form	4 (0.1)	5 (0.7)	B
Incorrect frequency of administration	3 (0.1)	4 (0.6)	S
Incorrect day	2 (0.1)	3 (0.4)	S
Unauthorised brand substitution	1 (<0.1)	1 (0.1)	B
Inappropriate division	0 (0)	0 (0)	n/a
The first column above does not equal the total number of DAAs with an incident (n=457 DAAs), as multiple incident types often occurred within a single DAA.			

Incidents were detected in 10.5% (306/2,920) of blister packs and 14.5% (151/1,039) of sachets audited. In many cases, residents were supplied with long sachet rolls comprising more than 28 sachet squares and greater than four dosing intervals. These long sachet rolls could not be considered equivalent to one blister pack DAA, comprising seven rows of four dosing intervals (Chapter 1, Section 1.3.1). To determine how many sachet squares comprised 'one sachet DAA', equivalent to one blister pack, the majority of sachet rolls were theoretically divided. One sachet DAA usually comprised four dosing intervals of seven sachets each. This enabled meaningful comparisons of overall incident rates between sachets and blister packs.

The majority of incidents were not isolated, but were repeated within a specific time interval an average of nine times. This was possible as a specific incident type could have occurred on multiple days within a time interval, though only one incident was counted (Section 3.2.1.6).

Of the 684 incidents identified, 434 incidents involved blister packs and 250 involved sachets. The frequency of incidents was greater in DAAs prepared via automation, sachets in this sample, than those prepared manually (blister packs).

Figure 3.1 includes photographs of specific DAA incident types.

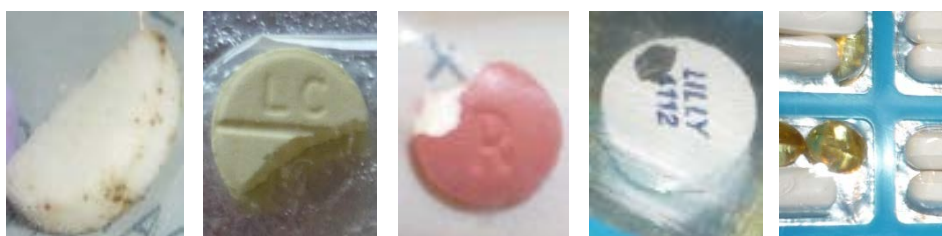


Figure 3.1 From left to right: pictures of a mottled sodium valproate tablet, inaccurate division, damage, 'other' incident (foil on tablet) and omission (of a long white tablet).

3.3.1.4 Incident rates by location and medicine class

Forty-nine RACFs participated in the DAA audit where between 17 and 287 DAAs were audited. All RACFs had at least one DAA with an incident, with an incident rate ranging from 1.6% up to 40.0% of all DAAs audited at that RACF. A major contributing factor for the RACF with the highest incident rate was the frequent packing of unsuitable medicines into DAAs, such as hygroscopic sodium valproate, and the large proportion of residents audited who were taking this medicine.

A range of 1-750 DAAs were audited from the 40 pharmacies that supplied the 49 RACFs. No incidents occurred in three pharmacies and in the other 37 pharmacies, incident rates ranged from 1.6% to 38.2% of all DAAs audited from that pharmacy. It was not identified whether the DAAs were prepared onsite at the pharmacy or offsite by a DAA packing company, as this information could inadvertently identify DAA packing companies involved in incidents.

Of the DAAs audited from regional Victoria, 15.9% (55/345) had an incident, followed by 12.0% (46/382) from rural Victoria, 11.0% (247/2,237) from outer metropolitan Melbourne and 11.0% (109/995) from inner metropolitan Melbourne.

Of the 616 incidents where a medicine class was noted, Table 3.4 outlines those involved. Medicine classes may not have been recorded when 'other' incidents occurred, for example, when foil pieces were inadvertently packed into the DAA or when small tablet pieces were inadvertently added to the DAA (an incident of addition). The three medicine classes most commonly involved in incidents (nervous system, cardiovascular system and alimentary tract and metabolism) may reflect the fact that these were also the three most commonly packed medicine classes. Sodium valproate, telmisartan and levodopa/benserazide were the top three medicines involved in incidents.

Table 3.4 Medicine classes involved in DAA incidents, n (%).

Medicine class	Frequency n= 616 incidents
Nervous system	335 (54.4)
Cardiovascular system	112 (18.2)
Alimentary tract and metabolism	87 (14.1)
Antiinfectives for systemic use	38 (6.2)
Blood and blood forming organs	27 (4.4)
Systemic hormonal preparations (excluding sex hormones and insulins)	9 (1.5)
Musculo-skeletal system	7 (1.1)
Respiratory system	1 (0.2)
Column total of percentages does not equal exactly 100% due to rounding	

3.4 Discussion

Previous research examining how accurately and suitably medicines are packed into DAAs supplied by pharmacy staff for use in RACFs is limited to only four studies.¹⁰⁻¹³ The overall DAA incident rate (11.5%) found in this study was higher than previously reported,¹⁰⁻¹³ but is similar to the Victorian DAA audit pilot study that preceded this research.¹²

Past studies have identified incident rates of 3.1%,¹³ 4.3%,¹⁰ 7.3%¹¹ and 10.8%¹² of DAAs audited. Three of these studies appear to have reported an overestimated incident rate as they may not have considered the occurrence of multiple incidents within a single DAA (Chapter 1, Section 1.4.2).^{10, 11, 13} Their incident rates are reported as the proportion of DAAs affected by incidents, however, they appear to have compared the total number of incidents identified (as opposed to the total number of DAAs affected by incidents) to the total number of DAAs audited. A comparison of DAA incident rates between this study and past studies, other than the preceding Victorian DAA audit pilot study,¹² is of limited value due to the imprecise or unclear calculations of previous research.

The higher incident rate in this study phase could be explained by the increased medicine expertise and attention to medicine detail of the pharmacist researchers compared to previous studies that used students^{12, 13} or nurses¹⁰ as DAA auditors. Additionally, this study included the incident of unsuitable packing according to pharmaceutical guidelines, which only appeared to be considered in one previous study.¹² However, when this incident type is removed, the overall incident rate (6.5%) is still higher than two of the previous studies.^{10, 13} Incident recording could have been influenced by the method of incident verification. Although efforts were made to report incidents to the pharmacists who supplied the DAA, the incidents were not verified with them and RACF staff were not always certain if DAA and medicine record discrepancies were actual incidents or transcription errors.

Compared to previous research, a number of the most commonly identified DAA incident types were shared, including medicines that may have stability concerns upon packing (unsuitable packing)¹² and missing medicines.^{10, 11, 13} Future interventions should target these commonly occurring incident types.

The most common medicine class involved in incidents (nervous system) may be explained by the fact that these medicines were the second most commonly packed. Additionally, this medicine class included sodium valproate that was considered unsuitable to be packed into a DAA due to poor stability, and this medicine was often prescribed for the residents audited in this study. Medicines for the nervous system are frequently used in older populations.³⁶

Compared to two previous studies that presented incident rates in relation to commonly affected medicine classes, incidents occurred commonly in nervous system medicines,¹² and analgesics, also considered a nervous system medicine.¹⁰

The rate of incidents varied widely across the RACFs and pharmacies. As only five RACFs and a smaller relative number of DAAs were audited from regional Victoria, this may partly explain the higher incident rate in this area. This limitation makes the generalisability of findings to regional areas difficult and the inclusion of more RACFs from regional areas could be considered in future research. Additionally, the very small number of DAAs audited from three pharmacies may explain why they did not have any incidents attributed to them. Alternatively, if these pharmacies only prepared a small number of DAAs, pharmacy staff may potentially have had more time to concentrate and therefore detect any incidents that may occur, before supplying the DAAs to the RACF.

The high occurrence of unsuitable packing could be explained by the DAA-preparing pharmacist's lack of knowledge regarding certain medicine storage requirements and the perceived need to pack all medicines into DAAs. Although there is limited research concerning the stability of medicines when packed into DAAs, by using a combination of the available published literature, pharmaceutical product information, professional pharmacy organisation guidelines and pharmaceutical knowledge, medicines that are unsuitable for DAAs can be identified and avoided (Chapter 1, Section 1.3.3). Although Australian guidelines are available to assist pharmacy staff with preparing DAAs for RACFs,^{53, 54, 67, 78} the high incidence of unsuitable packing (50.1% of all incidents identified) indicates that this topic needs further clarification in the guidelines and wider dissemination. Information is readily available concerning the unsuitability of packing sodium valproate and it should be used by pharmacy staff to discuss alternative supply arrangements with RACFs.^{67, 68, 70, 74}

A recent Australian study cautioned against packing hygroscopic sodium valproate into DAAs, which was the medicine found to be most commonly involved in the DAA incident of unsuitable packing.⁷⁴ Llewelyn *et al.* found that sodium valproate 100 mg immediate-release tablets packed into a heat-sealed DAA and stored at room temperature (25°C) exhibited weight gain and dissolution profile variation.⁷⁴ It was stated that potential changes in bioavailability could cause breakthrough seizures due to clinical non-equivalence with non-packed tablets.⁷⁴ This incident could be avoided by keeping medicines with stability concerns in their original containers for nurses to administer or consulting the prescriber about prescribing comparatively more stable medicine formulations. Additionally, medicines could be packed into DAAs with their original foil or plastic protection intact,

however, care must be taken when administering these medicines, to ensure that medicine packaging is not swallowed.¹²¹ RACF staff may be reluctant to administer medicines from their original containers if they employ PCAs in their workplace. As described in Chapter 1 (Section 1.2.3), the majority of the Australian aged care workforce comprises PCAs, who may assist in the care of RACF residents, but are not required to undertake the extensive medicine training that is required of nurses.⁴³ However, these strategies have the potential to be feasible and successful if pharmacy and RACF staff discuss the best strategy to suit their local setting and are provided with targeted education concerning medicine and DAA handling.

The occurrence of any DAA incident indicates that medicine management systems are not working optimally and would benefit from further evaluation. There is the potential that workplace factors leading to potentially low risk incidents can also lead to high risk incidents if a different medicine was involved. Identified incidents had the potential to be transferred to the RACF resident had they not first been identified by the researchers.

When PCAs participate in Australian medicine administration, they are not required to identify medicines before administration⁵⁴ and this may increase the potential for DAA incidents, such as those involving incorrect medicines, to be transferred to the resident. If it is perceived that DAAs supplied by the pharmacy are accurate because of pharmacist involvement, there is also the potential for RACF staff to dismiss in-house DAA checking procedures as unnecessary. Further investigation of RACF staff perceptions concerning DAA accuracy is detailed in the next chapter (Chapter 4, Section 4.2.1.1). Additionally, to determine the clinical importance of identified incidents, it would be useful to classify the severity and likelihood of any potential medicine-related problem (MRP) that could occur if the incident was transferred to the resident. Classification of clinical significance concerning the DAA incidents identified in this study is described in Chapter 6 (Section 6.2.3).

Though automated DAA packing processes may be perceived to be more accurate than manual methods, the sachets prepared via automation in this study were found to have a higher incident rate (14.5%) than the manually prepared blister packs (10.5%). Further research is needed to identify reasons for this difference. In this study, the sachets were compared with medicine records held at the RACF to identify an incident rate, as opposed to the pharmacy medicine records that may have been used to prepare the sachets, though, in practice, each record should be a replica of the other. Despite that fact that this study was statistically powered to compare incident rates between DAAs prepared manually and via automation (Section 3.2.1.2), this comparison did not occur as it was later deemed to be outside the scope of this study. It was not the intention of this study to identify a more

accurate method of DAA preparation, but to highlight and address deficiencies in both blister packs and sachets (Chapter 1, Section 1.6).

While conducting the DAA audits, the researchers identified a number of factors that could potentially contribute to DAA incidents, including inadequate:

- DAA checking by RACF staff, after pharmacy delivery;
- transfer of resident medicine information between RACF and pharmacy staff;
- prescriber communication to RACF and pharmacy staff concerning medication regimen changes; and
- DAA checking by pharmacy staff.

As these factors could arise from the RACF, the pharmacy and the prescriber, the multidisciplinary nature of DAA medicine supply services means that future interventions should be designed to target all health professionals involved in the aged care team.

A number of limitations associated with the DAA audits were identified, including:

- difficulty identifying some medicines and determining medicine storage conditions, especially if tablets were quartered or their photograph could not be found using available resources;
- difficulty verifying incidents if RACF staff were not familiar with resident medication regimens or were unwilling to assist the researchers;
- disruptions caused by RACF staff using medicine records for medicine administration;
- delays caused by pharmacists from the supplying pharmacy checking newly delivered DAAs, at the RACF; and
- difficulties interpreting medicine record information if multiple records existed, if non-standard medicine records were used, or if omissions, ambiguities or inaccuracies were present.

3.5 Conclusion

In this study, the rate at which medicines are inaccurately or unsuitably packed into DAAs and supplied by community pharmacies for RACFs was found to be higher than previous research, possibly reflecting the large sample size of this study. These findings indicate that regular evaluation of the DAA medicine supply service is required, as there is the potential for RACF residents to receive inaccurate or unsuitably packed medicines. There is also the potential for residents to experience adverse health consequences if these incidents are not

identified and rectified. Further research is needed to identify RACF and community pharmacy staff perceptions of DAA incident types and frequencies to compare them with observed findings, and to explore in greater depth perceived causes of DAA incidents. This is described in the next chapter. Additionally, health professionals must be consulted on how the DAA medicine supply service could be improved, to inform the development of interventions designed to increase the accuracy and suitability of DAA medicine packing.

4 Phase 2 - Factors contributing to, and strategies to address, incidents

4.1 Summary

It was essential to investigate factors contributing to, and strategies to reduce the occurrence of, the dose administration aid (DAA) incidents identified in Phase 1 of this study (Chapter 3, Section 3.3.1.3), prior to developing an intervention targeted at this medicine supply service. Previous studies that have evaluated the accuracy and suitability of DAA medicine packing, have neither rigorously nor systematically examined health professionals' perceptions of DAA incidents.¹⁰⁻¹³ Described in this chapter are the Phase 2 quantitative surveys (Chapter 2, Section 2.2.2) and qualitative focus groups (Chapter 2, Section 2.3.1) used to explore these issues.

4.2 Methods

4.2.1 Survey

4.2.1.1 Survey aim

To identify health professionals' perceptions of the types and frequencies of DAA incidents that occur in their workplace, as well as factors contributing to these incidents and strategies to reduce their occurrence.

4.2.1.2 Selecting participants for the survey

The survey was sent to one staff contact at each of the 49 residential aged care facilities (RACFs) and 14 community pharmacies that had been recruited in Phase 1 (Chapter 3, Section 3.3.1.1). These individuals were selected using purposive and convenience sampling methods (Chapter 2, Section 2.4), as their perceptions of workplace DAA incident types and frequencies could validate the Phase 1 findings. Useful insight could also be gained into the type of intervention that was to be developed for their workplaces (Chapter 5, Section 5.3.1.1). The survey only sought preliminary data from one person at each participating workplace, as focus groups (Section 4.2.2) were later used to discuss the contributing factors and strategies to reduce DAA incident occurrence in more detail. It was not necessary to

individually recruit these staff contacts, as their affiliated workplace was recruited into the study and was deemed to be the study participant.

4.2.1.3 Developing and testing the survey

Survey questions were derived from an understanding of the DAA medicine supply service that was informed from the literature (Chapter 1, Section 1.3) and from the PhD candidate's personal experience as a pharmacist. Workplace-specific questionnaires were developed to target RACF- and pharmacy-specific environments. Questionnaire face and content validity (Chapter 2, Section 2.5) was assessed by two academic pharmacists from the research team. The pharmacy questionnaire was also assessed by a practising pharmacist who was not involved in the study.

The first version of the *RACF* questionnaire comprised two landscape-orientated pages. It included 18 open-ended questions, one closed question and two mixed questions. After testing this version with staff contacts from three out of the 49 RACFs, the questionnaire structure and order of questions was modified. The second version of the questionnaire was presented on one portrait-orientated page and included 17 open-ended questions, one closed question and two mixed questions. This version was sent to staff contacts at 44 of the RACFs. The three RACF contacts who tested the first version of the questionnaire were only sent the second version as a reminder. Both versions were very similar despite structural changes.

In order to elicit more definitive answers, one question was modified in the third and final version of the *RACF* questionnaire. As some of the respondents provided vague answers when asked how often DAA incidents occurred, it was suggested that responses in the answer field could take the form of 'per week, per month or per year'. This questionnaire was sent to staff contacts at the remaining two out of the 49 RACFs and was also used as a reminder questionnaire for seven RACFs.

The final *RACF* questionnaire (Appendix 13) asked respondents about the types and frequencies of DAA incidents that occurred in their workplace, as well as contributing factors and strategies to reduce their occurrence. Questions also sought information about the DAA medicine supply service, medicine records and communication amongst the aged care team.

The *pharmacy* questionnaire included 31 open-ended questions, five closed questions and four mixed questions on landscape-orientated pages (Appendix 14). Questions were similar to those in the *RACF*-specific questionnaire; however, additional questions elicited

information concerning the demographic details of the pharmacy and the processes of DAA incident handling, DAA packing and DAA checking. Staff from the 14 recruited pharmacies had not interacted with the research team as extensively as staff from the 49 RACFs; therefore, more information about these workplaces was sought via a longer questionnaire.

4.2.1.4 Conducting the survey

After the Phase 1 DAA audits were conducted at an RACF (Chapter 3, Section 3.2.1.5), the questionnaire was sent via email or facsimile to one staff contact at the RACF. The affiliated pharmacy was also sent the questionnaire if it was one of the 14 recruited pharmacies (Section 4.2.1.2). The RACF contact was often the individual who had organised the Phase 1 DAA audits to occur at their workplace, while the pharmacy questionnaire was sent to the pharmacist who was involved in DAA supply. The completed questionnaires were returned via email, facsimile or post.

To prevent over-contacting the RACFs, only one reminder with an attached questionnaire was sent, approximately one month after the initial contact. The pharmacy questionnaires were sent with two reminders, two and five weeks after the initial contact, and one telephone reminder after a total of six weeks. There was less risk of over-contacting the pharmacies as their staff had limited prior engagement with the researchers.

4.2.1.5 Analysing the survey data

The data were managed with Microsoft Excel 2010® (Microsoft Corporation, Redmond, WA, USA) and Microsoft Word 2010® (Microsoft Corporation, Redmond, WA, USA).

4.2.2 *Focus Groups*

4.2.2.1 Focus group aim

To discuss health professionals' perceptions of the factors contributing to DAA incidents and strategies to reduce their occurrence, in greater depth, and to evaluate researcher-suggested intervention strategies.

4.2.2.2 Selecting and recruiting participants for the focus groups

Staff who worked at the RACFs and pharmacies that were involved in the Phase 1 DAA audits (Chapter 3, Section 3.3.1.1) were selected for the focus groups via purposive and convenience sampling (Chapter 2, Section 2.4). These individuals were chosen as it was

expected that they could discuss the factors contributing to the DAA incidents identified in their workplaces (Chapter 3, Section 3.3.1.4) and could provide useful insight into the type of intervention that was to be developed (Chapter 5, Section 5.3.1.1). The focus group findings could also validate and contribute to the survey findings (Section 4.3.1).

Participants were sampled to capture the views of health professionals from a variety of the Phase 1 RACF and community pharmacy workplaces and to include individuals who were involved in different aspects of the DAA medicine supply service, including nurses, pharmacists, personal care assistants (PCAs) and pharmacy technicians. Snowball sampling (Chapter 2, Section 2.4) was also used when nurse and pharmacist participants were asked to pass study information onto their PCA and pharmacy technician colleagues.

Letters of invitation (Appendix 15), explanatory statements (Appendix 16) and consent forms (Appendix 17) were left at the RACFs and pharmacies in communal meeting places or with specific individuals for themselves or to pass onto others. Individuals were also contacted via telephone and email regarding their potential involvement and were asked to advertise the focus groups using emailed posters (Appendix 18).

Prescribers and staff who worked at DAA packing companies were not selected for focus group participation as it was unlikely that they could contribute meaningfully to discussions. This is because prescribers have minimal interaction with DAAs and the intervention was not designed for DAA packing companies (Chapter 5, Section 5.2.1.1).

4.2.2.3 Developing and piloting the focus group questions and process

A structured question guide was developed to facilitate focus group discussions and was assessed for face and content validity by two academic pharmacists from the research team (Chapter 2, Section 2.5). The focus group questions were piloted with six postgraduate students from the Centre for Medicine Use and Safety (CMUS), Monash University, and their feedback was used to refine the moderating technique.

The focus group questions included:

- What are the factors that contribute to DAA incidents?
- Which DAA incident types should be targeted with an intervention designed to reduce their occurrence?
- What strategies have been implemented or should be implemented to reduce the occurrence of DAA incidents, to increase how accurately and suitably medicines are packed into DAAs, and to improve the DAA medicine supply service?

Participants were also asked to evaluate researcher-suggested intervention strategies (Table 4.1). The PhD candidate developed these strategies after considering the Phase 1 DAA audit findings (Chapter 3, Section 3.3.1.3), the Phase 1 RACF and community pharmacy workplace environments, the survey responses (Section 4.3.1), and after discussions with the research team and the Phase 1 research assistants. Participants were asked to suggest how the strategies could be improved, discuss their potential usefulness and effectiveness, and outline their advantages and disadvantages. Barriers and facilitators to implementing interventions in the RACF and pharmacy workplace were also discussed.

Table 4.1 Researcher-suggested intervention strategies

Intervention strategy	Aim of the strategy
<i>Education sessions, posters, pamphlets or lanyards for the RACF or pharmacy. Additionally, a compact disc-read only memory (CD-ROM) presentation strategy was developed after the first two focus groups and was presented to the third focus group.</i>	To increase awareness of DAA incidents and strategies to reduce their occurrence, to remind staff to check DAAs, and to encourage communication of medicine information between RACF and pharmacy staff.
New or revised <i>guidelines and protocols</i> for the RACF or pharmacy	To guide staff who are involved in the DAA medicine supply service
<i>A pharmacist conducting additional DAA checks at the RACF, using the RACF medicine records.</i>	To ensure that DAAs are prepared according to the original RACF medicine records as well as the pharmacy medicine records
<i>A stamp or bookmark for the RACF medicine record</i>	To highlight that a medication regimen change had recently occurred and to encourage RACF staff to communicate this information to pharmacy staff
<i>A communication logbook and accompanying sticker for both the RACF and the pharmacy</i>	To describe recent medication regimen changes and the resulting actions taken by pharmacy staff
<i>A medicine identification sheet for RACFs</i>	To facilitate the process of checking DAAs and DAA incident recording

4.2.2.4 Conducting the focus groups

Before attending a focus group, participants received an email outlining the focus group aim and discussion topics, and were provided with a summary of the Phase 1 DAA audit findings (Chapter 3, Section 3.3.1.3).

The focus groups were held in November and December 2011 and March 2012 from approximately 6.30pm until 8.30pm at CMUS, Monash University, Parkville campus. The central location, day and time were chosen for the convenience of participant work schedules.

The PhD candidate moderated all three focus groups and a research assistant recorded key observations and seating arrangements. The focus groups were assisted with a Microsoft PowerPoint 2010® presentation (Microsoft Corporation, Redmond, WA, USA) and discussions were audio-recorded.

Upon arrival, participants were welcomed, the PhD candidate and research assistant were introduced, the purpose of the focus group was explained, and the reasons for recruiting the participants were outlined. The ground rules, an overview of the focus group structure and the discussion topics were then described.

The importance of the study was explained, as well as how the focus group discussions would contribute to the overall findings, and an overview of the Phase 1 DAA audit results (Chapter 3, Section 3.3.1.3) was provided. The structured question guide was then used to facilitate discussions. During the focus group, participants were presented with brief factual descriptions of the DAA incident types identified from Phase 1 and were referred to these incidents when discussion topics were introduced.

The focus groups concluded with a summary and opportunity for further comments. Participants were thanked for their participation and remunerated for their time and travel.

4.2.2.5 Analysing the focus group data

At the end of each focus group, the PhD candidate and research assistant briefly discussed participant responses. The focus groups were transcribed verbatim and coded with the assistance of NVivo 9 (QSR International [Americas] Inc., Cambridge, MA, USA) and Microsoft Word 2010® (Microsoft Corporation, Redmond, WA, USA), using a thematic approach (Chapter 2, Section 2.8).¹²² This involved familiarisation with the raw data, identifying key themes and indexing the data to those themes.¹²² The data were rearranged

and associations between themes were identified.¹²² The findings were repeatedly checked against the raw data and the emerging themes were discussed amongst the research team.

4.3 Results

4.3.1 Survey

4.3.1.1 Characteristics of survey participants

Completed questionnaires were received from 51.0% (25/49) of the RACFs and 85.7% (12/14) of the recruited community pharmacies. Qualifications or workplace roles of RACF respondents included director or deputy director of nursing, clinical care coordinator, manager (e.g. facility manager, care service manager, manager of integrated services), registered nurse (RN), clinical educator, quality assurance staff member, and deputy director of care. Twenty-eight per cent (7) of respondents worked at RACFs located in inner metropolitan Melbourne, 48.0% (12) from outer metropolitan Melbourne, 16.0% (4) from rural and 8.0% (2) from regional Victoria.

Workplace roles of pharmacy respondents included proprietor, owner, partner, and manager (e.g. professional services manager). The respondents worked in pharmacies that supplied DAAs to 34.7% (17/49) of the RACF sample from Phase 1 (Chapter 3, Section 3.3.1.1). Three of the pharmacy respondents worked in three separate pharmacies that supplied DAAs to the same RACF. Workplaces that used, or prepared, blister packs and sachets were both represented in the sample.

Only data relating to the types and frequencies of DAA incidents and perceptions of the contributing factors and strategies to reduce their occurrence are reported in this chapter.

4.3.1.2 Types and frequencies of incidents

RACF and pharmacy respondents listed a wide range of DAA incidents that were commonly seen. Some responses were not descriptive enough to enable comparison with the 17 DAA incident types identified in this study (Chapter 3, Section 3.2.1.6); however, 51 responses from the RACF surveys and 33 pharmacy responses did correlate (Table 4.2).

Of those responses where a specific frequency was noted, the most frequently RACF respondents saw DAA incidents was daily or weekly (41.2% of responses, 7), monthly (35.3%, 6) or yearly (23.5%, 4). Pharmacy respondents saw these DAA incidents monthly (58.3%, 7), yearly (25.0%, 3) or weekly (16.7%, 2).

Table 4.2 Common DAA incident types identified by survey respondents, n (%).

DAA incident type	Frequency of RACF responses n= 51 responses	Frequency of pharmacy responses n= 33 responses
Incidents related to medicine quantity or added medicines	13 (25.5)	10 (30.3)
Medicine omission	12 (23.5)	10 (30.3)
Time-related incidents	10 (19.6)	3 (9.1)
Incorrect medicine dose	10 (19.6)	1 (3.0)
Incorrect medicine	4 (7.8)	2 (6.1)
Damage	1 (2.0)	1 (3.0)
Incorrect medicine formulation	1 (2.0)	-
Issues related to dose schedule (e.g. incorrect alternating doses)	-	2 (6.1)
Incidents related to DAA compartments (e.g. medicines in the incorrect compartment)	-	2 (6.1)
‘Other’ incidents (e.g. inadvertently packing foil with medicines)	-	1 (3.0)
Incorrect tablet halving	-	1 (3.0)

4.3.1.3 Factors contributing to incidents

Respondents identified a range of circumstances associated with DAA packing and checking processes at the **pharmacy** that may contribute to DAA incidents. It was noted that incidents are likely to occur if staff are interrupted or distracted, are insufficiently trained, or work long hours completing monotonous tasks. Staff may rush or deviate from guidance systems and may incorrectly select medicines or deliberately change brands. Medicines may ‘jump’ between DAA compartments and DAAs may be inaccurately sealed. It may be difficult to check multiple medicines packed together or to check medicines without the assistance of reference pictures, and DAAs may be checked inaccurately, or not at all. It was also noted that pharmacy staff may inaccurately interpret medicine information. Medicine records may be incorrect or out-of-date and facsimile printing may be unclear. Finally, automated DAA packing processes may inadvertently pack extra tablets into the DAA.

Factors attributed to the **RACF** included inaccurate or absent DAA checking, failing to notice medication regimen changes, and inaccurately completing medicine records. Respondents outlined that RACF staff may not notify the pharmacy of medication regimen changes or they may communicate medicine information in an untimely or inaccurate manner.

Staff related factors that were attributed to both the pharmacy and RACF included new, busy or stressed staff, as well as staff changes and non-regular staff.

Respondents outlined that the **prescriber** may contribute to DAA incidents by providing incomplete, inaccurate, illegible, unclear or non-standard medicine information. Prescribers may prescribe multiple medicines and change medication regimens frequently, after hours, or at the last minute.

It was noted that human error and a lack of more organised and structured communication between the prescriber, RACF and pharmacy staff may also contribute to DAA incidents.

4.3.1.4 Strategies to reduce the occurrence of incidents

Respondents noted that DAA incident occurrence could be reduced by targeting DAA packing and checking at the **pharmacy**. It was suggested that staff should be trained, should follow DAA preparation systems, and could be rotated to prepare DAAs for different RACFs. Packing could occur away from the dispensary to minimise distractions, and telephone calls can be screened and talking discouraged. It was noted that one medicine should be packed per DAA compartment, resident photographs could be included on the DAA, and medicines should correlate with information printed on the DAA label. The process of DAA checking could be a rotating task and could involve different individuals, as well as occurring out-of-hours when there are fewer interruptions. All aspects of packed medicines should be checked accurately, DAAs should be signed once checked, and DAAs should be checked multiple times. Respondents also outlined that pharmacy staff should be notified of DAA incidents and incidents should be monitored. Current medicine records should also be requested from the RACF, to allow pharmacy records to be updated for medication regimen changes and to ensure they correlate. Other pharmacy related strategies included providing regular staff breaks, ensuring workloads are sufficiently resourced with the necessary time and staff needed, and receiving remuneration for DAA supply.

It was suggested that nurses could be involved in DAA checking at **RACFs**, and reference should be made to both medicine records and the DAA label. Checking should occur both after DAAs have been delivered by the pharmacy and before medicines are administered to

residents. It was recommended that RACF staff communicate medicine information regularly and accurately, and they should notify the pharmacy of DAA incidents and medication regimen changes in a timely manner. Communication could occur by both telephone and facsimile, and information could be transmitted to those who actually prepare DAAs. Staff at RACFs should be informed of medication regimen changes at handover meetings and multidisciplinary medication advisory committee (MAC) meetings could be used as a forum to discuss DAA incidents and prescriber-related issues. Medicine information could also be handled more effectively by recording incidents, removing outdated documentation, and using electronic medicine management systems, such as computerised medicine records. Other strategies related to the RACF included using nurses to administer medicines, rather than PCAs, reviewing the workforce, providing regular medicine education for staff, and receiving DAAs from only a small number of pharmacies.

Finally, respondents suggested that **prescriber** handwriting could improve, medicine prescriptions could be typed, and information should not be omitted from medicine records.

4.3.2 Focus Groups

4.3.2.1 Characteristics of focus group participants

Three focus groups were conducted with six pharmacists (three female and three male), one pharmacy technician (female), five RNs (all female) and one PCA (female). All participants worked in a RACF or community pharmacy that was involved in Phase 1 (Chapter 3, Section 3.3.1.1), and worked with blister packs or sachets for RACF medicine administration (Table 4.3).

The pharmacist and nurse focus groups were homogenous while the third group was conducted with the PCA and pharmacy technician. The homogenous groups were designed to create a comfortable discussion environment amongst similar participants (Chapter 2, Section 2.3.1). The heterogeneous group was chosen as only one PCA and one pharmacy technician were recruited. The majority of participants did not know one another, except for two nurses who worked at the same RACF.

Table 4.3 Focus group participant characteristics, n (%).

Profession	Workplace role	Employment location	DAA currently using		Average years working with blister packs or sachets	Average years with qualifications
			Blister packs alone	Blister packs and sachets		
Nurse	Supervisor, deputy director of nursing/clinical educator, clinical coordinator and team leader.	RACFs located in outer metropolitan Melbourne (2 RACFs), inner metropolitan Melbourne (1) and regional Victoria (2).	4 (80.0)	1 (20.0)	8.2	19.0
Pharmacist	Assistant pharmacist, owner/partner, professional services manager, proprietor and chief pharmacist.	Community pharmacies that serviced 13 RACFs. These RACFs were located in inner metropolitan Melbourne (6), outer metropolitan Melbourne (6) and rural Victoria (1).	3 (50.0)	3 (50.0)	12.0	22.2
PCA and pharmacy technician	Medicine administration (PCA) and aged care operations manager	The pharmacy technician worked at a pharmacy that serviced three RACFs located in inner (1) and outer metropolitan Melbourne (2), while the PCA worked in a rurally located RACF.	1 (50.0 PCA)	1 (50.0 pharmacy technician)	5.5	6.0

4.3.2.2 Factors contributing to incidents and strategies to reduce their occurrence

Factors that contributed to DAA incidents were aligned to four main themes, including medicine handling, communication, knowledge and awareness, and attitude. Suggested strategies to reduce the occurrence of DAA incidents were aligned to those same four themes. Factors and strategies were identified both from what participants said and how they responded to the discussion topics.

Contributing factors related to medicine handling

Participants identified that DAA incidents may occur when medicines are packed into DAAs or as a result of inadequate DAA checking, either at the pharmacy or at the RACF. It was suggested that pharmacy financial pressures may also impact on DAA preparation and contribute to incidents occurring.

DAAs may be prepared inaccurately and may not reflect recent medication regimen changes if changes are assumed to be unintentional, if medicine records are not updated, if DAA preparation at the pharmacy becomes routine, and if pre-prepared DAAs are not amended. Manual aspects of DAA packing may contribute to incidents, as well as human error, conversations or interruptions, deviating from systems, and time constraints.

“We had a sort of problem...where someone got so used to packing [DAAs for] their nursing home [that] they didn't pick up the [medication regimen] changes because they were just so used to, ‘that person has one [medicine] three times a day’, and so...if they'd start to make errors [DAA incidents] in their packing, then we were rotating them to a different facility [RACF] to pack, because they'd just gotten too used to it.” Pharmacist 1

“...where the [DAA] packers don't follow the system, that's when all the errors come, you lay out all these systems, but as soon as they deviate from the system, they eventually make a mistake.” Pharmacist 4

Factors that may contribute to specific DAA incident types are outlined in Table 4.4.

Table 4.4 Factors contributing to specific DAA incident types

DAA incident type	Suggested contributing factor
Damage	Heat sealing or overfilling DAA compartments
Inaccurate division	Dividing small tablet quantities or deviating from score lines
Incorrect form or unauthorised brand substitution	Changing medicine brands in response to stock shortages or failing to check resident brand preferences
Incorrect medicine administration times	Inflexible computer software and failing to consider the preferences of RACF staff
Incorrect quantity	Small tablets falling into DAA compartments
Omission	Medicine prescriptions are not supplied to the pharmacy
‘Other’	Foil adhering to medicines or foil shedding from DAA packaging and original medicine containers
Unsuitable packing	Pharmacists or RACF staff requesting that certain medicines are packed into the DAA to facilitate medicine administration

DAA incidents may be later identified if DAAs are inadequately checked by pharmacy staff. Checking may be difficult if multiple medicines are packed within single DAA compartments, when large DAA quantities require checking, and if medicines lack distinguishing features or medicine brands are changed. DAAs may not be checked at all, or they may be checked inaccurately if medicine records are not referred to.

“...it's just very difficult to check one container [DAA] with multiple medications.”

Pharmacist 4

“I think it depends on the volume you've got packing...tomorrow, we've got four [pharmacy] technicians packing [DAAs] all day, you couldn't be going around checking everything they're doing.” Pharmacist 3

“...I've got a couple of pharmacists who just don't really check [DAAs].”

Pharmacist 4

Pharmacy participants pointed out that financial pressures could contribute to DAA incidents occurring. Profitability could be reduced by Government initiatives to increase the transparency of medicine prices, inadequate remuneration for DAA supply, and prescribers failing to supply medicine prescriptions to the pharmacy.

“...more training costs money, more [medicine] checking costs money...as much as it really needs to be a hundred per cent right all the time, they don’t want to put more people on [staff at the pharmacy].” Pharmacy technician

“...we’ve lost [a RACF] because the guy said ‘oh I run lots of nursing homes...and I don’t get charged anything [for DAA supply], I get them all for nothing’...and I said, ‘you’ve got to be kidding, my service is worth something...you’ll get a delivery service, you’ll get an after hours service, you can call out a pharmacist [to visit the RACF] any time...if you want that sort of service you have to pay for it’.” Pharmacist 6

“...there’s a massive loss of money for us through...not getting [medicine] prescriptions.” Pharmacist 1

DAA incidents may also arise when DAAs are checked inadequately at the RACF or if checking is difficult. It was noted that information on the DAA label may not correlate with packed medicines, medicine photographs may be absent, medicine records may not be referred to, DAAs may not be checked at all, and PCAs may not identify medicines prior to administration. Time constraints may hinder checking processes, as well as large workloads, limited staff, or the presence of new staff. Incidents may also be attributed to the lack of formal DAA incident policies at RACFs.

“There is an issue I have noticed on occasion, where [RACF] staff don’t sign off their medication charts [medicine records] until after they’ve done their [medicine administration] round. And also, I was watching somebody one day and she doesn’t read her medication charts first, she trusts the blister pack, she trusts the sachets, and that’s a huge issue and [it] needs to be rammed home in education...you’re obviously going to miss things, you’re obviously not going to be aware of things...I see that as a huge problem.” Nurse 1

“I know the sachets wouldn’t [be checked by RACF staff after they have been delivered from the pharmacy], it would be such a pain to have to open the [storage] box and do it, and I know they’re just put away. [It was suggested that] the RN who is putting away the sachets had to undo all the rolls [and check them], but...there was only one RN within the facility [RACF], it’s about 100 beds, and it was a physical impossibility.” Nurse 1

Strategies related to medicine handling

Participants suggested that DAA packing and checking at the pharmacy and RACF could be targeted with strategies to reduce the occurrence of DAA incidents.

To ensure DAAs reflect updated medicine records, medication regimen changes should be attended to immediately and specific staff could be designated to this task. DAAs should only be prepared a few days in advance and if they are pre-prepared, they should be easily located to facilitate amendments following medication regimen changes. Staff could be rotated to prepare DAAs for different RACFs and they should follow systems designed to facilitate DAA preparation. Medicine record information should be closely followed and resident medicine preferences should be updated on computer software. Strategies to reduce the occurrence of specific DAA incident types are outlined in Table 4.5.

Table 4.5 Strategies to reduce the occurrence of specific DAA incident types

DAA incident type	Suggested strategy
Addition	Remove tablet chips from DAAs
Damage	Place heat sensitive capsules on the bottom of DAA compartments, away from heat sealing apparatus, and do not pack damaged medicines.
Inaccurate medicine division	Pack the correct medicine dose or divide tablets along scorelines
‘Other’	Limit the number of medicines packed into each DAA compartment, spread medicines across multiple DAAs to prevent overfilling, and ensure food is not present during DAA preparation.
Unsuitable packing	Pack medicines into the DAA while still protected by their original and intact foil packaging, change certain medicines to liquid form so that they cannot be packed and refuse to pack potentially unstable medicines. <i>“...we don't pack anything that's in the [DAA]...guidelines, and we have a Div 1 [RN] on the floor [at the RACF] and they have to give out all the non-packed stuff [medicines in their original containers]...” Pharmacist 6</i>

Participants also suggested that pharmacy staff could increase how accurately and comprehensively they check DAAs. All staff should be involved in DAA checking, technological assistance could be sought, and time restrictions can be used to prevent fatigue. Staff should be alert for medicine discrepancies in DAAs and to RACFs where DAA incidents are more likely to occur, and DAAs should be signed for after they have been checked. DAAs should be checked against the medicine record, after medication regimen changes have occurred, before and after the DAA is sealed, and before delivery. Packed medicines should also correlate with both the DAA label and the medicine record.

“...I think they [staff packing DAAs] have to look at the [medicine] bottle...when they pick it up, and it would be nice [if they]...actually pick up [that] that’s a different colour or a different sized tablet, or it’s a different strength to what they packed [in the DAA] last time.” Pharmacist 6

“...we have an error policy...everybody’s got to sign their [DAAs]...if they start making too many errors [DAA incidents] then they have to go and do something else or they have to recheck their packs [DAAs] twice...and if they get really bad, they go out and clean a few shelves and they go off packing [DAAs].” Pharmacist 6

“...we go to the facility [RACF] every single week [to check DAAs with RACF medicine records], so then if anything’s wrong, it’s minimised to a week, which is not cost effective at all, especially when you have really slack pharmacists.” Pharmacist 1

Participants suggested that DAA checking could be assisted with coloured pictures and medicine information on the DAA label, packing one medicine per DAA compartment, ensuring consistent medicine brands are used, and using incident policies to monitor DAA checking.

Suggestions to address pharmacy financial pressures included adequately remunerating pharmacies for DAA supply, paying minimum staff wages, and packing less expensive generic medicine brands into DAAs. Additionally, medicine supply could be facilitated by recognising medicine records as legal medicine prescriptions.

“If they just make drug charts [medicine records, medicine] prescriptions, that would be very nice.” Pharmacist 1

It was suggested that RACF staff should check DAAs carefully and comprehensively, both upon delivery and prior to administration, and all staff should be involved. It was noted that staff should be wary of and query medicine irregularities and DAAs should be checked in

conjunction with the medicine record, DAA label and medicine identification sheets. The necessary time and numbers of staff should be allocated to DAA checking and it should be stipulated as a staff duty.

“...you’re looking at checking medications aren’t you, before you give them, and you’re counting and...check also that they are the familiar drug...take an interest in what’s in there [in the DAA]...if they normally have, say, two Panadol Osteos® [white tablet] and a Caltrate® [white tablet] and today they’ve suddenly got a bright purple pill, look and be interested and be aware.” Nurse 1

“...be aware that other people make errors just as we do, therefore, you need to be part of the team and part of the [DAA] checking process.” Nurse 1

“...you need multiple people checking [DAAs]. So there’s the original pack and the original pharmacist and then maybe the RNs and then maybe the staff giving it. Everybody just needs to be vigilant.” Nurse 1

Contributing factors related to communication

DAA incidents may arise from ineffective communication of medicine information between prescribers and staff at RACFs, pharmacies and hospitals.

RACF staff may not effectively communicate medicine information if they do not notify pharmacy staff of DAA incidents or medication regimen changes at all, or communication is not timely. Staff may experience difficulty communicating via telephone, especially if their English is inadequate, and they may be unable to operate facsimiles or machines may be of poor quality. It was indicated that communication may be hindered if pharmacy staff infrequently communicate face-to-face with the RACF.

“...with our pharmacist, whenever I phone him [about a DAA incident], he’ll say ‘use [the medicines] from Sunday and I’ll send you a new [DAA] pack’, so sometimes I don’t bother [notifying the pharmacist], I just correct it if I can.” Nurse 4

“Once a month I check them all [DAAs with medicine records at the RACF], the amount of mistakes [DAA incidents] we pick up is incredible, just charts [medicine records] that aren’t faxed [from the RACF to the pharmacy].” Pharmacist 5

“...some of them [PCAs] probably would not acknowledge the error [DAA incident], they [would] leave it for two [or] three days and come and tell you ‘this tablet is missing’...” Pharmacist 2

“Yeah, they all are [foreign trained RACF staff] and half the time you’re speaking to them on the phone and you’re not understanding what they’re saying anyway.”

Pharmacist 3

Medicine information may be ineffectively communicated between RACF staff when workplace shift changes occur, if prescriber instructions are not recorded in the medicine record, if records are annotated inaccurately, and when medication regimen changes are not checked following prescriber review. Medicine information may not be communicated after RACF residents return from a hospital visit, leading to discrepancies between medicine records at the pharmacy and RACF.

“[DAA incidents can occur] When they come home...from hospital, and nobody’s told anybody that something’s [a medicine] been ceased or been added [to the medication regimen]...” Pharmacist 6

Participants discussed how prescribers may not notify RACF or pharmacy staff when changing medication regimens and they may be difficult to contact for follow-up or to clarify information. Written communication may be unclear, illegible, incomplete or inaccurate, and unusual dose schedules may be requested. Pharmacy participants noted that medicine prescriptions are often not supplied in a timely manner, contributing both to communication problems and financial pressures.

“...you try to ring a doctor and he’s got a patient in with him and they say ‘oh ring back at lunchtime’...I’ve got to the point now where I type a huge intervention history note up, fax it through, and say, please sign off on it or call the pharmacy, because you just can’t get through to them [prescribers].” Pharmacist 3

“...and sometimes the charts [medicine records] are difficult to read and...some doctors, their one and a halves and their halves look really similar and they’re hard to figure out...” Pharmacist 1

“...sometimes you’ll get a drug chart [medicine record] and it won’t have any [specific] times written on it, it’ll just say...‘tds’ [three times a day] or ‘nocte’ [night]...if it doesn’t have times on it we just go by what the pharmacist says is the best time to give it.” Pharmacy technician

Strategies related to communication

Participants outlined strategies to improve how medicine information is communicated between prescribers and staff at RACFs, pharmacies and hospitals.

RACF staff should communicate medicine information accurately and comprehensively. Medication regimen changes and newly transcribed medicine records should be communicated to the pharmacy and followed-up with a complete copy of the medicine record. Transmitted information should be followed-up to ensure it is received, standard of English should be adequate, and instances of communication could be recorded and stored for future referral. Medicine records at the RACF and the pharmacy should be accurate and correlate.

“...when drugs are ceased, if you don't fax [the] pharmacy and let them know that the drugs have been ceased, they will continue packing it [in the DAA].” Nurse 4

“...I think it's important that we fax the chart [medicine record] to the pharmacy and make sure that it's been faxed, so that they've got the message...” Nurse 3

RACF and pharmacy staff should be made aware of DAA incidents promptly and reminded of the importance of incident reporting. Incidents could also be discussed at medication advisory committee (MAC) meetings and evaluated over time.

Pharmacy staff could regularly communicate and collaborate with RACF staff to ensure that the DAA medicine supply service operates optimally. They could attend MAC meetings, use online methods of communication, and should force RACF staff to communicate medicine information. Pharmacy staff could also notify RACFs of new medicines or brands that are packed in the DAA and could annotate medicine records with alternative brand names.

“...we insist that we get every page of the drug chart [medicine record] faxed, and today I had...drugs one to nine...faxed, two different pages for the same resident. [I] rang them [the RACF] and said 'I'm still missing some', there was another one [page] in between, [it] just hadn't [been] faxed...” Pharmacist 3

Communication regarding DAA incidents could be improved at the pharmacy by notifying staff involved in incidents, recording their names, and asking them to rectify the incident.

“...if someone was continually making errors [DAA incidents] the pharmacist would say... 'you're putting the pills in back to front'...I guess our pharmacists are really good, any errors that they find in the [DAAs]...they'll actually, particularly with new people, go and explain [to] them 'this is what you've done', and that's part of the reason [why] they give them back to the [DAA] packers to fix, so they're fixing their own mistakes...” Pharmacy technician

It was also suggested that medicine information should be communicated directly between pharmacy staff and the prescriber, rather than involving RACF staff. To facilitate this, pharmacy staff could have input into medication regimen changes, they could visit RACFs while the prescriber is reviewing residents, and they could have access to electronic medicine records. Direct communication of medicine information between the pharmacy and pathology laboratories or hospitals was also felt to be beneficial.

“...I think direct communication with the doctor, if we can cut out the middle man, which is the nursing staff, I think that will cut out a lot of errors [DAA incidents].”

Pharmacist 5

“...we’re taking over the medication charts [medicine records] totally, so that...if they [prescriber] have changed the medication chart, we’re getting...it straight to us.” Pharmacist 6

It was suggested that prescribers could ensure medicine records are complete and accurate, they could notify RACF staff when they review resident medication regimens, and they could conduct resident reviews on specific and anticipated days each week. Participants also noted that communication could be facilitated with fewer prescribers servicing each RACF.

“...[on] just a couple of occasions this year I found instances where doctors have visited [the RACF], seen the patient, written up their notes, not communicated with [RACF] staff...[and I’ve] gone back to the notes later and found [that] they’ve actually changed something and they didn’t alert anybody...the doctors really do have to alert the [RACF] staff when they’re changing something.” Nurse 1

“Less numbers of doctors servicing a single facility [RACF]...the ones where there’s basically just one doctor, run so much better than the ones where there’s...15 [or] 20 different doctors...” Pharmacist 1

“...I’m really lucky that I have only six doctors to deal with...so I can actually personally say to them... ‘we want to change this...what do you think about this’...or ‘how about we do such and such’.” Pharmacist 6

Contributing factors related to knowledge and awareness

Participants discussed limitations in RACF and pharmacy staff medicine knowledge and awareness of workplace medicine issues.

It was identified that RACFs often employ PCAs instead of nurses to administer medicines, despite their limited qualifications. Additionally, RACF staff may not be able to identify all

DAA incident types that could occur, they may be unable to decipher medicine information, or they may be unfamiliar with resident medication regimens or pharmacy DAA preparation processes. It was noted that opportunities for RACF staff medicine education are limited or irregular, and staff may not attend if it is voluntary rather than compulsory.

“...nursing homes [are] moving like pharmacists are, we’ve put [pharmacy] technicians in our dispensaries, they’re putting PCAs in their nursing homes.”

Pharmacist 5

“Well I suppose the onus is on us to be vigilant [to identify DAA incidents], but that’s very tricky, depends on which staff are administering the medications, if they’re just having to count [medicines] and they’re not terribly aware of the appearance of a drug [i.e. PCAs].” Nurse 1

“And half the time the RNs or the [other RACF] staff can’t read what is written on the drug charts [medicine record] anyway, and they send it through [to the pharmacy] not knowing what the [medication regimen] change is, and if they fax it and we can’t read it, well I find out...[I ask them] what’s in the progress notes [other notes concerning the RACF resident], and if they can’t read what’s in the progress notes then you ring the doctor...” Pharmacist 3

“It’s interesting actually that we have our mandatory fire training, our mandatory physical handling of residents, but we don’t have mandatory ‘pharmacy issue’ training each year and yet I would have thought that was a primary concern.”

Nurse 1

It was also noted that pharmacy staff may have limited understanding of medicine stabilities once they are packed into DAAs and pharmacy technicians may not be aware of all the medicines available in the pharmacy for DAA packing.

“The rate of [medicine] degradation is minimal, I consider [when medicines are packed] in a blister pack, and once it’s [the DAA] sealed, it’s sealed anyway...so it’s a matter of weighing that up [minimal medicine degradation] against them not getting their medication at all.” Pharmacist 4

Strategies related to knowledge and awareness

It was suggested that RACF and pharmacy staff medicine knowledge could be improved through education and experience.

Participants indicated that medicine administration staff at RACFs should have an adequate level of medicine knowledge, should be familiar with resident medication regimens and workplace processes, and a nurse should be available to administer medicines out of original containers. It was also acknowledged that over time and through experience DAA checking may be facilitated, as staff become more familiar with medicines and the DAA incidents that can occur.

“...if you've got medication competent people caring, actually doing the care for the residents, who then take on the actual medication administration, they know the residents, they've become very familiar with their disease processes, with what they're taking, when they need to take what, and then they will become more familiar with the appearance of those medications and be more aware, for instance, if there are packaging errors [DAA incidents]...” Nurse 1

It was suggested that RACF staff could benefit from nurse- or pharmacist-facilitated education that covered the DAA preparation process, as well as medicine and DAA incident identification, and accurate medicine administration practices. Education should be compulsory, regular, involve all staff, and could be followed up with assessment. RACF participants also acknowledged their responsibility towards medicine knowledge and they appreciated the benefits of education.

“nurse educators inside the facility [RACF] where...a Div 1 [RN] is training the PCAs regularly...seems to make a big difference” Pharmacist 4

“...we assume the tablets are going to be correct and we're finding that they're not, so maybe it would be good for us all to learn how they're [DAAs, are] packed, how the system works, before we get it...” Nurse 2

“I suppose it's also just personal development...I think we're responsible for our own knowledge of what medications look like and what they're for...I suppose it's sort of up to us too.” Nurse 3

“...a couple of years ago was the best one [educational opportunity]...we had to do posters and things like that, it was really good...on dementia, yeah, learned a lot in that. Even though I've dealt with dementia and everything else, [I] still learnt a lot, you can always learn.” PCA

It was felt that pharmacy participants could benefit from education concerning DAA preparation, common DAA incidents that occur, strategies to reduce their occurrence, and what medicines can and cannot be packed into DAAs.

“...the whole thing is education, it’s pointing...out...these are your common errors [DAA incidents]...so that they’re [pharmacy staff] aware of them, so they can try and make sure they don’t happen...and these are...possibly better ways to do things...” Pharmacy technician

It was also suggested that prescribers could benefit from direction concerning RACF processes and medicine prescription writing.

“I think facilities [RACFs that] have their doctors groomed, and regular doctors, not allowing the families to take in their own family doctor in [to] the facility, makes a big difference.” Pharmacist 4

Contributing factors related to attitude

Participants often adopted a negative attitude or tone of response when discussing certain focus group topics. Some participants, or their workplace colleagues, appeared to have a less than positive attitude towards the DAA medicine supply service, DAA incidents, or the aged care team.

It was indicated that some pharmacists or pharmacy staff did not like checking DAAs and neither exercised care during DAA preparation nor respected DAA guidelines. Some pharmacists held little faith in the DAA service and the pharmacy technician seemed to, on occasion, shift responsibility for DAA incidents onto the pharmacist.

“...some of the pharmacists would love to go off...[DAA] checking. ...what’s worse than checking...” Pharmacist 6

“...the [DAA] packers pack so many [DAAs]...in a day that...there’s not probably the time and care...” Pharmacy technician

“You know what has to be done, you don’t need guidelines to tell you that.” Pharmacist 5

“Yeah I check mine [DAAs with medicine records at the RACF] once a month, regularly. I think we’re legally obliged to do 10% every three months...but we do more than that, if I did that, half the people [RACF residents] would be dead, honestly.” Pharmacist 5

“...and then the pharmacist’s checking...they should be picking it [DAA incident] up...that’s what they’re trained for.” Pharmacy technician

In some cases, participants were not motivated to discuss DAA incidents or strategies to reduce their occurrence, not all incidents were considered to be equally important, and it was not felt that incidents were a major issue in certain workplaces.

“But sometimes I allow foil to go through, if I check it [the DAA, and] I see foil [‘other’ incident]...I’d say it’s correct with the foil in it.” Pharmacist 4

“...some of these things [DAA incidents] are quite minor, compared to people just not getting their medicine...” Pharmacist 4

“We’ve found it’s better to have almost the same dose rather than no dose at all [if the RACF does not notify the pharmacy of correct medicine doses].” Pharmacist 1

Some pharmacists also appeared resigned to the fact that incidents of unsuitable packing were impossible to prevent.

“...because PCAs need everything packed [into a DAA]...you [the focus group moderator] say...we shouldn’t be packing this [moisture sensitive medicines], and it’s got to be packed.” Pharmacist 1

“The resident won’t get their medication...if you put the Risperdal Quicklets® [moisture sensitive] in a box [original medicine container], they won’t get it.” Pharmacist 4

Interprofessional strain between prescribers and staff at RACFs and pharmacies was described. In some cases, respect was not shown towards the aged care team and prescribers were portrayed as sometimes being incompetent and lazy.

“...sometimes I feel like we’re kind of two different worlds apart and you’ll ring a facility [RACF] and they just won’t, I guess, have time or understanding for the pharmacy...” Pharmacy technician

“...usually the nurses have to tell the doctors what to do...they just follow orders essentially...when the Div 1 [RN] is there, they’ll tell them...exactly what to do, what needs to be done.” Pharmacist 5

“...and the doctor doesn’t like to write scripts [medicine prescriptions].” Pharmacist 1

Nurse participants also appeared to have a less than favourable attitude towards aspects of the DAA medicine supply service. Some participants felt that pharmacy staff were responsible for DAA checking, rather than RACF staff, and some accepted rather than

challenged, the minimal requirement of PCAs to check medicines prior to administration (Chapter 3, Section 3.4).

“...we have done it in the past, when the new packs [DAAs] come up [from the pharmacy], you verify [check] them, but then that’s just repeating work that I think we shouldn’t really be doing...” Nurse 2

“...now that the onus for making an error [has] been taken away from us, by giving us an aid [DAA] which is supposed to be safer, I would like to feel that it actually was.” Nurse 1

“...even if it’s staff [PCAs] who are only expected to count [medicines before administering them], I think that probably you expect a greater level of intelligence than doing that...I mean you’re not going to hold them responsible if they do miss it [DAA incidents]...when they’re not required to [check medicines]...” Nurse 1

In many instances, the nurses and PCA were not motivated to discuss DAA incidents or acknowledge their occurrence. Some participants blamed pharmacy staff for DAA incidents and appeared more concerned with other workplace issues, such as staff not signing for medicines that had been administered. In some cases it was felt that incidents did not occur to a great extent in particular workplaces and examples were given when incidents were not followed up comprehensively.

“...I discuss it [the DAA incident] with the pharmacist as to why it’s occurred and it’s usually [the] pharmacist’s fault because it’s a regular [medicine] order.” Nurse 2

“I think overall it’s a very low percentage [of DAA incidents that occur in their workplace]...” Nurse 2

“...I never got to the bottom of it [DAA incident], I pulled the sachet off and pinned it to an incident report which I put under the manager’s door, because I thought it was something that he really needed to address with the pharmacy himself, personally, rather than just leaving it for the care coordinator and I never heard any feedback from that.” Nurse 1

Strategies related to attitude

The pharmacists and pharmacy technician suggested strategies to improve the professional relationship between themselves and their RACF colleagues.

It was mentioned that a team mentality could be adopted by working together, building rapport and having repeated contact with familiar staff members. Personality clashes could be addressed by rotating pharmacy staff who liaise with specific RACFs and by encouraging face-to-face interaction.

“...if you can somehow make them [RACF staff] feel like you are with them, part of them, they seem to be more helpful...I guess you just have to be really patient with them. ...even today, just getting an address out of them takes me five minutes...but...at the end...we got there and you know, everyone's happy.”

Pharmacist 2

“As pharmacies are getting bigger and there's more aged care facilities, I guess you're trying to have that personal contact, and that's something that my pharmacy is working on, sending people out to the homes [RACFs] just to put names to faces and just to...build relationships, because I find that once you've got a relationship you can ring a facility [RACF] and say...can you fax me through this full drug chart [medicine record] and you don't get ‘oh fine’, you get ‘sure no worries’...it makes such a big difference. So something that I guess...bridges the gap between the two.”

Pharmacy technician

“...I've had a problem with a few staff members and nursing homes...where they just don't get along well...then you just shift who deals with the nursing home...I just take the pharmacist with me, introduce them to the people [at the RACF]... ‘this is so and so, this is who you're working with, what are your problems?’ So once they...put a face to the name, it's amazing then how happy they are...[they] get along with each other.” Pharmacist 1

The importance of DAA incidents was sometimes acknowledged by participants. The PCA and pharmacy technician generally perceived that all incidents should be addressed, a number of pharmacists acknowledged that certain DAA incidents should not leave the pharmacy, and the nurse participants accepted the importance of their health care roles and at times also recognised that DAA incidents do occur.

“...any of those [DAA incidents] are a medication error, and an error is life threatening...you don't want any of them to happen...I always think...if it was my family member, you wouldn't want your family member to have one pill less or one pill extra.” Pharmacy technician

“...[I] get my [pharmacy] technician to change them [tablets] if it looks more like a three quarter than a half, or you know, just a quarter.” Pharmacist 2

“Because that’s why they’ve [residents] come into care [RACFs], because often they can’t manage their medications any more...they need some governance.” Nurse 2

4.3.2.3 Evaluation of researcher-suggested intervention strategies

Participants comprehensively evaluated the researcher-suggested intervention strategies that were presented during the focus group discussions (Section 4.2.2.3).

Education

The nurses, PCA and pharmacy technician liked the education session and pamphlet intervention strategy. It was suggested that education sessions could be scheduled during work times, conducted during regular staff meetings, and could include breaks and fun activities. It was felt that staff should be reminded to attend education and it should be mandatory, regular, repeated and remunerated. Education could be linked with health professional registration requirements and could include self-education components and assessment.

“What about a drug of the week education program?” Nurse 1

Participants suggested that pamphlets could be made attractive and interesting and could be followed-up with assessment to ensure that staff read them. Pamphlets could be provided to new staff, placed in staff rooms, and could provide guidance regarding DAA incident notification and rectification.

“I like the idea of the pamphlet, that’s really good...make that in your admission pack [for new staff] and then available in all areas [of the RACF], every year.” Nurse 2

The pharmacists, PCA and pharmacy technician also liked the posters.

“I think the poster is a great idea. We got a poster on constipation...that worked a treat. It was really, really good. ...it just needed a little bit of tweaking in the end, but I think visual cues are great.” Pharmacist 6

It was recommended that posters should present limited information that is clear and simple to read. They could be placed on the front of medicine record folders and in accessible workplace areas, such as on the wall of the DAA checking workstation or in the medicine

room. Participants felt that posters could be a constant reminder of information as they could be continually referred to. It was suggested that posters could be used to encourage interprofessional communication, as well as encourage staff to check DAAs before administration and be wary of medicine irregularities or DAA incidents.

“...our [DAA] packers each have their own workstation, it [the poster] could be up on the wall at their workstation, the pharmacist checking workstation...”

Pharmacy technician

“...with posters...they'd be constant reminders...it's one thing to sit there and do a training [session] and do well, but if you have a couple of weeks off and you forget it all...if you just had a poster, it would just be a constant reminder.”

Pharmacy technician

The CD-ROM strategy was highly favoured by both the pharmacy technician and PCA. Participants felt that the CD-ROM could be used at the workplace, the information it contained could be easily explained to staff who did not attend a group presentation, and the mixture of information and activities was engaging. It was suggested that an assessment questionnaire and a certificate of completion associated with the CD-ROM should be included. The CD-ROM could be delivered online or by the researchers during a staff meeting and it could also be used for new staff and delivered at repeat intervals as refresher education. It was felt that the information presented on the CD-ROM would remain relevant if it covered basic and important DAA issues, and it should be of less than 15 minutes duration to facilitate use and cause minimal work disruption.

“Our facility [RACF] would love this [CD-ROM].” PCA

“...[don't] make it too much longer, so that it is just a quick, sit down, 10 [or] 15 minutes on the computer...otherwise if it cuts into someone's day...like, my days are so busy that to stop and sit down and do something like this, if it took me an hour I'd spend the whole time thinking I have other things to do, so [it would be good] if it was just a quick 15 minutes.” Pharmacy technician

Participants also identified limitations of the suggested educational strategies. The nurses did not generally like the idea of a lanyard and were concerned that staff may not read the posters or pamphlets due to information overload.

“...you can have the posters and you'll look at it and think it's a pretty poster, but you may not take it in...” Nurse 2

“I get worried about paperwork though, because sometimes paperwork is handed out with...payslips, stapled to it [and marked as] essential reading...[but it’s] ripped off [and put] in the bin, and then you have the memo folders which people are expected to sign off and you look at them and there are three signatures, but I think we employ more than three staff, and also we have so many notices on our notice boards...” Nurse 1

Participants did not appreciate education that was scheduled during days of leave or travelling to attend single, short education sessions. It was noted that staff may not attend education without remuneration, staff that require education may not be those individuals that actually attend, and poor attendance could limit the effectiveness of education and waste the presenter’s time. Finally, education may already be conducted, though it may not be regular or specifically cover DAA incidents.

“And then someone actually broke the truth to us and said...if it's a voluntary education session, the [RACF] staff don't get paid, so they won't turn up. So often you're just giving a talk to about three or four people [and] you feel like you're just wasting your time.” Pharmacist 4

New or revised guidelines and protocols

RACF participants acknowledged that new or revised guidelines concerning DAA incidents and the DAA medicine supply service should be produced. Pharmacists liked the idea of new guidelines to replace existing ones that were considered to be impractical, ineffective and difficult to follow. It was suggested that a new guideline should be simple, easily understood and should cover the basic principles of DAA preparation. Participants wished for direction regarding which medicines should not be packed into DAAs and template job descriptions for the workplace.

“...[you need a] very practical, core down, basic system...for example...just get the alcoholic wipes and just wash your hands first, number one. ...you need to have a system which...you can give to a tech [pharmacy technician] and say ‘this is what you [are] expected to do’...if you look through the ones [guidelines] you’ve got now...they’ll read the first three lines and give up.” Pharmacist 4

There was concern, however, that more paperwork could get lost and it could be cumbersome trying to amend workplace guidelines.

“...we use checklists for our medication changes and we use checklists for everything at work, so I think that another checklist might...get lost...”

Pharmacy technician

A pharmacist conducting additional DAA checks at the RACF

This strategy was already employed in certain workplaces. Although the nurses liked this strategy, they acknowledged that its effectiveness could be limited by how frequently DAA incidents occurred. The pharmacists explained that this strategy was not cost-effective without remuneration, it would not reduce the occurrence of DAA incidents, and it could cause RACF staff to stop communicating medicine information to pharmacy staff.

“...I've been told by the [pharmacy] owners [that] it's just not practical...not affordable.” Pharmacist 3

“...[when I implemented this strategy, RACF staff] relied on me to come in and do all the changes [identify medication regimen changes], because they said ‘well it's your job isn't it’, so now I stopped doing it [visiting RACFs for additional DAA checking] and said...if you want the exchanges [updated DAAs] you have to send the stuff [medicine information] through. Then they started sending it through...”

Pharmacist 4

Stamp and bookmark

Most participants provided positive feedback on the stamp and bookmark strategy. It was suggested that the stamp could be placed in the resident's medicine notes, in the medicine record, on a removable sticky note, or on the DAA. It was also felt that the stamp could be used by all RACF staff and prescribers.

“I think that [stamp] would be good to leave out with the doctor, if a doctor comes in [to the RACF] to visit and asks for a medication chart [medicine record], he should be left with that [stamp], so that then if he leaves the building without communicating with staff, he's left that note there.” Nurse 1

It was suggested that the bookmark could easily transmit medicine information to large numbers of staff, could remind staff of important information upon returning from leave, and could be a constant reminder of medicine information.

“I think that [bookmark] would be really good...because sometimes [medication regimen] changes happen and if there's a few doctors that come through [the RACF] during the day and then accidentally you forget to hand over something [notify other RACF staff of information], at least...you'll have put the flag [bookmark] there and it alerts the next nurse on duty to follow it up.” Nurse 3

Participants did express concern that these strategies may not work if the prescriber was relied on to use them or if there were multiple prescribers servicing one RACF. It was noted that the bookmark could fall out or clutter the medicine record, there may not be enough space for it, and it could duplicate existing bookmarks that were already in use. Additionally, the medicine record may lack space for a stamp or it may become untidy if a stamp was used.

“...in our facility [RACF] we do have...short term antibiotic [bookmarks], and then I'm thinking...we've got another bookmark on top of that...I'm just wondering where we would actually put it...so that it's [medicine record] not so cluttered.”
Nurse 5

Communication logbook and sticker

The participants did not generally like the logbook and sticker strategy. Although the nurses explained that it could be a neater and simpler way of recording information and could assist with DAA checking, it was acknowledged that logbooks had not worked in the past. There was also concern that the logbook could add to workloads, could get lost or left behind at the wrong workplace, and the information it contained was already stored on facsimile records.

“The book [logbook] would get left and...it would be with us and not the pharmacist and [then we] think ‘why haven't they done that, oh, the book's sitting over there’...it was like a diary...it worked for a probably only a week or two, it really didn't work.” PCA

Medicine identification sheet

Participants generally liked the idea of a medicine identification sheet. It had the potential to assist RACF staff with identifying medicines quickly and addressing medication regimen changes, without pharmacy assistance. Participants suggested that it could be laminated and placed with the resident's RACF medicine record, close to their photograph, it could be printed at the pharmacy or ordered from external suppliers, and it could come in a hard copy or electronic format.

“...some of them [RACF staff] use the list of meds [medicine identification sheet]...as well as their...drug charts [medicine records] and they just sit them on...the inside cover of the drug chart, so then, as they get to [administering medicines for] each person, they can see what the medicines are, instead of having to look everything up.” Pharmacy technician

“I think it’s a great idea, I think it will reduce medication errors absolutely.”
Nurse 5

“I think it's a really good idea, especially if something needs to be withheld immediately...they might need to withhold a 5pm dose and [if] it's...3.30[pm], we're [pharmacy staff] not going to get out there [to the RACF] in time [to amend the DAA], something like that [medicine identification sheet] just makes it really easy [to identify]...‘this is the tablet that you're not to give tonight’...”
Pharmacy technician

While this strategy may be used in some workplaces, it may not be useful if medicine queries are already addressed by nurses and if DAA labels already have medicine descriptions. Participants expressed concern that this strategy would cost money, could contribute to staff workloads, and multiple daily medication regimen changes could limit its use. Additionally, some participants described unfavourable past experience with some externally supplied medicine identification sheets, where medicine pictures were found to be missing.

4.3.2.4 Barriers and facilitators to intervention implementation

Participants identified workplace barriers and facilitators to the implementation of general quality improvement (QI) interventions (Table 4.6).

Table 4.6 Barriers and facilitators to intervention implementation

Barrier to implementation	Facilitator to implementation
Resistance to change, fear of increased workloads, and fear of the unknown.	Explain the rationale behind interventions and potential positive impacts
Complacency, laziness and disinterest.	Force the uptake of interventions and update staff on their adherence
Deliberate sabotage	Adopt a positive attitude towards interventions
Staff preferences	Seek staff input and cooperation
Limited competency with technology or other technological limitations	Consider using technology or provide mandatory and remunerated training concerning the intervention
A lack of incentives	Provide incentives
Uncooperative prescribers	Provide instructions for prescribers
Negative past experiences	Implement simple interventions that are easily adopted and taught
Cost and human resource requirements	Trial interventions on a small scale
Pharmacy contract restrictions	Involve RACFs that are not part of large organisations

4.4 Discussion

This study phase set out to identify the perceptions of health professionals working in the RACFs and pharmacies involved in Phase 1. Their perceptions were sought on the types and frequencies of DAA incidents that occur in the workplace, contributing factors, and strategies to reduce their occurrence. These study findings can inform RACF and pharmacy workplaces that are attempting to improve their DAA medicine supply service.

Of the top five DAA incidents identified by survey respondents, three incidents, incorrect quantity, addition and medicine omission, featured in the top five identified by the Phase 1 DAA audits (Chapter 3, Section 3.3.1.3). It was difficult to separate those responses that related specifically to incidents of either incorrect medicine quantity or added medicine, therefore they were combined (Section 4.3.1.2). The similarity in the incidents perceived to occur by health professionals and those that were identified through researcher observation, partially validates the Phase 1 findings. Previous research has also identified omitted

medicines as a common DAA incident type.^{10, 11, 13} Lack of understanding by the survey respondents of what constitutes a DAA incident may explain the overall lack of concordance between these findings and the results from Phase 1. Additionally, the most common DAA incident identified in Phase 1, unsuitable packing, was not identified at all by the survey respondents. This may be explained by a lack of awareness of this type of DAA incident or limited ability to identify these medicines.

There is correlation between the frequency at which DAA incidents were identified in Phase 1, at every RACF DAA audit, and the perceptions of RACF staff. The majority of survey responses indicated that common DAA incident types were most frequently seen on a daily or weekly basis. However, the majority of pharmacy responses indicated that DAA incidents were most frequently seen on a monthly basis. If RACF staff do not communicate DAA incidents on every occasion to the pharmacy, this may explain the difference between the survey and Phase 1 findings. The focus group findings indicated that communication was not optimal within the aged care team and thus supports this theory. As previous literature has not attempted to identify health professionals' perceptions regarding DAA incident frequency of occurrence, the findings of this study cannot be compared. While Roberts *et al.* included an estimate of the proportion of DAAs experiencing an incident (1.39% of DAAs), obtained from directors of nursing, this figure cannot be compared to the findings of this study due to differences in the reporting of results.¹³

The focus group participants highlighted the importance of attention to medicine handling both during DAA preparation and medicine administration, and improved interprofessional verbal and written communication. Increased staff knowledge and awareness of workplace DAA issues and positive staff attitudes towards the aged care team and their medicine management roles, were also discussed. The survey findings also identified similar themes, with the exception of staff attitudes. As the focus groups allowed participants to discuss their feelings concerning the DAA medicine supply service in a comfortable environment amongst colleagues, this may have created an opportunity for discussion concerning interprofessional relationships. The survey provided limited space for comprehensive answers, and in contrast to the focus groups, did not provide an opportunity to discuss personal feelings amongst a group of peers in a supportive environment outside the workplace.¹⁰⁴

Both prescribers and RACF staff must recognise their pivotal role in ensuring current medicine information is communicated to pharmacy staff, to facilitate accurate DAA preparation. This is particularly important as medication regimen changes often occur at the RACF, though DAA preparation often occurs at the pharmacy. It is unlikely that significant

interprofessional interaction is present during traditional community pharmacy dispensing involving original medicine containers, and thus its influence on DAA incidents has not been extensively explored in pharmacy dispensing error studies.^{2, 4, 5, 9} In other studies, inefficient communication within workplaces and between RACF and pharmacy staff has been shown to potentially contribute to medicine errors¹²³⁻¹²⁶ and thus supports the study finding that interprofessional communication is an important intervention target. A Victorian Quality Council report also highlighted that ineffective communication in healthcare settings is an important risk factor for adverse patient events and attempts to improve communication are likely to optimise patient outcomes.¹²⁷ The Australian Commission on Safety and Quality in Health Care has provided a document to assist with communication involved in medicine prescribing and administration.¹²⁸

Pharmacy and RACF staff should compromise on DAA supply arrangements and agree that certain medicines be kept in their original containers for nurses to administer, thereby preventing unstable medicines from being packed into DAAs. Pharmacy guidelines⁶⁷ and research articles^{68, 70, 72-74} can be used to support this practice. DAA checking should also be regarded as a task that must be undertaken by staff at both RACFs and pharmacies, particularly as DAAs are often prepared at the pharmacy, while the original medicine record is held at the RACF. Interprofessional strain between pharmacy and RACF staff must also be addressed to facilitate the necessary close collaborations between the aged care team, for an efficient and accurate DAA medicine supply service.¹²⁷ Future interventions should address negative staff attitudes and interprofessional strain, as the DAA medicine supply service relies on the aged care team working closely together to ensure that DAAs are prepared accurately.

Focus group participants did not universally identify one researcher-suggested intervention strategy that would improve the DAA medicine supply service. All strategies suffered from disadvantages that could limit their potential for effective implementation, though advantages were still outlined. Heavy staff workloads, staff information overload, a lack of motivation to implement the strategy and impracticality, were recurring disadvantages. Development and implementation of a multifactorial intervention may be more favourable than a single strategy, as it may increase the chance that at least one intervention component is useful for a specific workplace. Multifactorial interventions designed to improve pharmacy-delivered health services have shown positive results.¹²⁹ Saini *et al.* developed a multifaceted intervention to facilitate pharmacist-delivery of specialised asthma care.¹²⁹ Through workshops, pharmacists were introduced to tools and documentation sheets for use in service delivery and were provided with self-study manuals containing material on asthma management.¹²⁹ Pharmacists provided positive feedback regarding this asthma

intervention.¹²⁹ A feedback questionnaire used to evaluate the self-study manuals showed that pharmacists rated them highly for readability, reader friendliness, content relevance and writing.¹²⁹ The intervention also improved clinical, humanistic, and economic patient outcomes, shown with significant reductions in asthma severity, as well as significant improvements in perceived control of asthma and asthma related knowledge scores, and medicine cost savings.¹²⁹

Some of the factors contributing to pharmacy dispensing errors and strategies to reduce their occurrence identified in the literature, are similar to those identified in this study.^{4, 89, 98, 99, 130-}

¹³² As DAA preparation may be considered a form of pharmacy medicine dispensing, this may explain the similarity in findings. However, this study is unique as it examines how communication between RACF and pharmacy staff may contribute to DAA incidents. Factors contributing to RACF medicine administration errors are also similar to the factors contributing to DAA incidents, identified in this study. Common medicine administration errors identified in RACFs include medicine omission, incorrect dose, incorrect medicine administration technique and incorrect time of administration.^{31-33, 133-135} Factors that have been reported as contributing to these errors include human error, inaccurate medicine records, heavy or busy workloads and interruptions, limited familiarity with resident medication regimens, limited knowledge regarding appropriate medicine administration techniques, transcriptions errors, and poor communication.^{31-33, 133-135} The similarity between the literature and this study points to the similarity in how medicines are handled in both processes; both situations require the removal of medicines from a primary container.

Strengths and limitations

Though survey sample sizes were relatively small, it was a strength that survey findings were triangulated with the Phase 1 DAA audit results (Chapter 3, Section 3.3.1.3) and were supported by the focus group discussions (Section 4.3.2). It is also a strength that the development of the Phase 3 intervention (Chapter 5, Section 5.3.1.1) was informed by individuals who worked at the RACFs and community pharmacies where the intervention was introduced (the Phase 1 workplaces). Additionally, the majority of survey respondents were in a position of leadership and could be expected to have a comprehensive understanding of DAA incidents that occur in their workplace.

Limitations associated with the focus groups were largely related to the sample sizes, the exclusion of prescribers, and the potentially limited experience participants may have had with DAA incidents.

Firstly, although participants were recruited in a similar way to the nurse and pharmacist recruitment process, it appeared that PCAs and pharmacy technicians were not as motivated to contribute their views and participate in the focus groups, as only two participants were recruited. It might, therefore, be possible that the views of these participants are not representative of other PCAs and pharmacy technicians. However, their comments were largely congruent with the pharmacist-only and nurse-only focus group findings, indicating that greater variability in responses may not have been identified with a larger group. Saturation of ideas was not a focus group objective, as it was not within the scope of this study to continually repeat the focus groups until no new ideas emerged, though it was necessary to identify perceptions from a range of individuals involved in different aspects of the DAA medicine supply service.

Prescriber perceptions concerning DAA incidents were not identified as they have limited involvement with DAA preparation and use. Additionally, focus group participant understanding of the factors contributing to DAA incidents and strategies to reduce their occurrence could have been influenced by a lack of personal experience of DAA incidents. Both dominant and reticent focus group participants were also encountered; the nurses and the PCA often required prompting, while the pharmacists and the pharmacy technician easily contributed to the discussions. This discrepancy may reflect the medicine-focussed topics of discussion and participants' relative knowledge of, and interaction with, medicines.

4.5 Conclusion

Consultations with health professionals involved in DAA preparation, supply and administration identified a number of factors contributing to DAA incidents that would benefit from QI, including medicine handling, communication, staff knowledge and awareness, and attitude. The importance of interventions that are multidisciplinary and multifactorial in nature was highlighted. The next chapter will describe how these findings, and the feedback generated from the researcher-suggested intervention strategies, were used to develop an evidence-based, stakeholder-informed intervention for RACFs and community pharmacies to improve the accuracy and suitability of DAA medicine packing and their DAA medicine supply service.

5 Phase 3 - Intervention development, introduction and initial evaluation

5.1 Summary

Although studies evaluating how accurately and suitably medicines are packed into DAAs have suggested strategies to reduce the occurrence of DAA incidents,¹⁰⁻¹³ they have neither developed nor introduced and evaluated a stakeholder-derived, evidence-based intervention for this purpose.¹⁰⁻¹³ This chapter describes how the results from the Phase 1 DAA audits (Chapter 3, Section 3.3.1.3) and the Phase 2 survey (Chapter 4, Section 4.3.1) and focus groups (Chapter 4, Section 4.3.2) were used to develop the Phase 3 intervention. The intervention comprised an education session and toolkit and was designed to reduce the occurrence of DAA incidents and improve the DAA medicine supply service. It was introduced to residential aged care facilities (RACFs) involved in Phase 1 and their affiliated community pharmacies, and was initially evaluated with a survey. In this thesis, the term ‘intervention’ refers to both the education session and toolkit. Alternatively, each component may be referred to separately.

5.2 Methods

5.2.1 *Intervention development*

5.2.1.1 Aim of developing the intervention

To develop an intervention to reduce the occurrence of DAA incidents and improve the DAA medicine supply service, involving DAAs supplied by Victorian community pharmacies to RACFs.

5.2.1.2 Developing and piloting the intervention

Some of the researcher-suggested intervention strategies presented to focus group participants in Phase 2 (Chapter 4, Section 4.2.2.3) were refined using the focus group feedback (Chapter 4, Section 4.3.2.3). Although some of these strategies were initially developed for only the RACF, they were later refined for either the RACF or community pharmacy, as the researchers felt that they had the potential to benefit both workplaces. Refined strategies included the education strategy (e.g. education sessions, posters, CD-

ROM), new or revised guidelines and protocols, the stamp and bookmark, and the medicine identification sheet. Strategies that were not used after the focus groups were conducted, included the educational pamphlets or lanyards, the suggestion of a pharmacist conducting additional DAA checks at the RACF, and the communication logbook and its accompanying sticker.

The refined strategies were sent to key individuals via post or email, in hard or soft copy, to generate further feedback. In some cases the strategies were personally presented to individuals, photographs were provided, or instructions on how they could be accessed through internet document storage services (e.g. DropboxTM) were outlined.

Key individuals who were sent the refined strategies included members of the research team, all 13 of the focus group participants, a member of the public with no expertise in pharmacy, and a Board Member of a Victorian RACF that was not part of the study. The refined strategies were also presented to representatives of the Australian Nursing Federation (ANF), the Pharmaceutical Society of Australia (PSA), the Victorian Pharmacy Authority and The Pharmacy Guild of Australia. All of these individuals provided feedback on the strategies, except for nine focus group participants who, in some cases, were too busy. The focus group participants who did provide feedback included two nurses, one pharmacist and the personal care assistant (PCA).

It was suggested that the content of the CD-ROM presentation should be simplified, self-assessment multiple-choice questions added, and photographs from the Monash University 'Pharmville' website included.¹³⁶ Printed text on any of the strategies was edited for syntax and grammar and the size of the bookmark was reduced so that it did not significantly protrude from medicine records. It was recommended that the stickers, a modification of the stamp strategy presented in the focus groups (Chapter 4, Section 4.2.2.3), should be printed on a white background with coloured text, rather than using coloured backgrounds with black text. It was suggested that a template DAA incident policy and procedure should be provided, along with the existing research articles and guidelines that were already included as strategies, and internet addresses should be available to access updated versions of the provided guidelines.

It was also decided that the intervention would include presenting the CD-ROM strategy in the form of an education session (Chapter 2, Section 2.2.3), to RACF and community pharmacy staff.

The final intervention was piloted in May 2012, comprising the 30 minute education session and the refined intervention strategies that formed a toolkit. One RACF and one community

pharmacy that were not involved in the study were introduced to the intervention. The intervention strategies were not modified following the pilot, however, it was suggested that the intervention could be introduced at a slower pace.

5.2.2 Intervention introduction

5.2.2.1 Aim of introducing the intervention

To introduce staff from RACFs involved in Phase 1 (Chapter 3, Section 3.3.1.1) and their affiliated community pharmacies to the intervention, comprising an education session and toolkit.

5.2.2.2 Selecting participants to be introduced to the intervention

Each of the 49 RACFs and the 14 recruited community pharmacies involved in the Phase 1 DAA audits (Chapter 3, Section 3.3.1.1) were invited by telephone, email, facsimile and posters (Appendix 19), to have the intervention introduced to their workplaces. Those pharmacies that were not recruited into the study but still supplied DAAs to the 49 RACFs, were also invited to receive the intervention, either directly or through their affiliated RACF.

All staff who were involved in the DAA medicine supply service were invited to attend the intervention introduction. Invited staff included nurses and PCAs, pharmacists and pharmacy technicians, prescribers, staff in a leadership role, as well as those responsible for quality improvement (QI), education, and DAAs in the workplace. Pharmacists were encouraged to attend at their affiliated RACF, while other community pharmacy staff could be introduced to the intervention at their pharmacy workplace.

5.2.2.3 Introducing the intervention

The PhD candidate introduced the intervention at participating workplaces between June and September 2012. The intervention, comprising a 30 minute education session and toolkit, was commonly introduced in workplace training rooms. The education session was facilitated by components of the toolkit, including the Microsoft PowerPoint® (Microsoft Corporation, Redmond, WA, USA) presentation contained on the CD-ROM and the handouts (Section 5.3.1.1).

The intervention was scheduled to be introduced on a day and at a time that was convenient for the workplace and where maximum staff attendance could be anticipated. This often

occurred in the early afternoon when pharmacy staff were able to have a break from their duties and when RACF staff working morning shifts were in the process of being replaced by those scheduled to work afternoon shifts. Except in two instances, the intervention was only introduced once per workplace. One pharmacy was introduced to the intervention twice, to accommodate their large number of staff. Similarly, one RACF was introduced to the intervention three times, to accommodate staff from three distinct residential units, located in separate buildings.

Those introduced to the intervention were provided with a certificate of attendance and were encouraged to ask questions about the intervention and inspect the toolkit components. The majority of workplaces received one toolkit, though up to three could be provided. This was usually given to the manager, QI staff member or DAA coordinator. Though each toolkit included a specific number of components, some components could be provided in greater quantity based on their availability and the needs of the workplace.

If the intervention was not introduced to pharmacies that supplied DAAs to the 49 RACFs from Phase 1 (Chapter 3, Section 3.3.1.1), they were given a personally delivered toolkit or their affiliated RACF was asked to pass it on. If workplaces only received a toolkit without the education session, the intervention was not considered to have been introduced at that workplace.

5.2.3 Survey

5.2.3.1 Survey aim

To identify health professionals' initial perceptions of the potential usefulness and effectiveness of the intervention, at reducing the occurrence of DAA incidents and improving the DAA medicine supply service.

5.2.3.2 Selecting participants for the survey

The survey was given to individuals who had been introduced to the intervention, at each RACF (Section 5.3.2.1) and at each recruited pharmacy (Chapter 3, Section 3.3.1.1). These individuals were selected by purposive and convenience sampling (Chapter 2, Section 2.4), as they could provide useful insight into the potential usefulness and effectiveness of the intervention that they had been introduced to. It was not necessary to individually recruit these individuals, as their affiliated workplace was recruited into the study and was deemed to be the study participant. Although permission was not obtained to collect data from non-

recruited pharmacies, it was not necessary to collect data from all pharmacies as the primary means for intervention evaluation was the DAA audits (Chapter 1, Section 1.6).

5.2.3.3 Developing and piloting the survey

Survey questions were derived from an understanding of the DAA medicine supply service that was informed from the literature (Chapter 1, Section 1.3) and the PhD candidate's experience as a pharmacist. Face and content validity (Chapter 2, Section 2.5) was assessed by two academic pharmacists from the research team. The questionnaire was piloted when the intervention was piloted (Section 5.2.1.2). Following the pilot, the questionnaire was simplified and edited for clarity, syntax and grammar.

The portrait-orientated, single page, structured questionnaire included nine open-ended questions, two mixed questions, 13 questions in association with a Likert scale, and space for further comments. A similar questionnaire was used at the *RACFs* (Appendix 20) and *pharmacies* (Appendix 21). Slight variations to question wording corresponded to the two different workplaces.

The questionnaire comprised three sections. The first section included demographic information about the respondent. The second section identified the potential usefulness of the toolkit over time, positive and negative aspects, uniqueness, and suggestions for improvement. The third section asked respondents to answer questions according to a Likert scale from one ('not at all') to five ('extremely' well).

The majority of questions explored the potential of the toolkit to reduce the occurrence of DAA incidents and improve the DAA medicine supply service. Only one Likert scale question directly referred to the usefulness of the education session. However, the education session was still sufficiently evaluated by the survey because it involved presenting the content of the CD-ROM presentation, which was a component of the toolkit.

5.2.3.4 Conducting the survey

After the intervention was introduced (Section 5.2.2.3), attendees were asked to complete and return a hard copy questionnaire before leaving the room, to prevent recall bias.

5.2.3.5 Analysing survey data

The data were managed with Microsoft Excel 2010® (Microsoft Corporation, Redmond, WA, USA) and Microsoft Word 2010® (Microsoft Corporation, Redmond, WA, USA).

Descriptive statistics arising from the quantitative responses, such as means, medians and frequencies were calculated with SPSS Statistics Version 19® (SPSS, Inc., Chicago, IL, USA).

5.3 Results

5.3.1 Intervention development

5.3.1.1 The intervention

The intervention comprised an education session and toolkit named: ‘Be alert and work together for medicine safety - dose administration aid (DAA) incident awareness toolkit’ (Table 5.1). It comprised a two ring binder with plastic pockets for each of the included components. An introductory letter provided an overview of the PhD study and the toolkit (Appendix 22) and four letters of support were included from the ANF (Appendix 23), The Pharmacy Guild of Australia (Appendix 24), the PSA (Appendix 25) and the Registrar from the Victorian Pharmacy Authority (Appendix 26). A contents page outlined the toolkit components, their purpose, and how each could be implemented in RACFs or community pharmacies.

The education session was facilitated by components of the toolkit, including the Microsoft PowerPoint® (Microsoft Corporation, Redmond, WA, USA) presentation contained on the CD-ROM and the handouts (Table 5.1).

Table 5.1 Toolkit components

Section	Toolkit component	Aim of the component	Implementation suggestion
1	Australian guideline ¹³⁷	To increase awareness of medicines that should not be packed into DAAs, including those with stability concerns.	Display on the wall of the RACF medicine room or the pharmacy DAA preparation or checking area
2	Australian research article ⁷⁴	To increase awareness of sodium valproate instability when packed into DAAs	Refer to this during DAA packing and checking at the pharmacy or RACF
3	Two each of A3 and A4 coloured posters (Appendix 27)	To increase awareness of DAA incidents, suggest that unstable medicines should be protected, and remind staff to check DAAs, keep accurate medicine records and communicate medicine information amongst the aged care team.	Display the A3 poster on the wall of the RACF medicine room or the pharmacy DAA preparation or checking area and place the A4 poster in the medicine record folder at the RACF or pharmacy
4,5	Ten laminated bookmarks (Appendix 28) and 260 stickers (Appendix 29)	To alert staff to medication regimen changes, encourage them to communicate medicine information, and check DAAs.	At the RACF or pharmacy, slot the bookmark at the top of the medicine record page and remove it once all staff are aware of the change and the DAA has been accurately packed. The sticker can be placed in the 'notes' section of the RACF or pharmacy medicine record, in close proximity to the changed medicine.
6	A CD-ROM with a 30-60 minute presentation (Appendix 30)	To increase awareness of DAA incidents, contributing factors and strategies to reduce their occurrence.	For self- or group-education of staff involved in the DAA medicine supply service, at the RACF or pharmacy. For single or repeat sessions, re-education following DAA incidents, or continuing professional development, and for new staff.

Table 5.1 continued

Section	Toolkit component	Aim of the component	Implementation suggestion
7	Template handout of the CD-ROM presentation slides with space for notes, and question (Appendix 31), answer (Appendix 32) and reflection (Appendix 33) handouts.	To provide assessment following the CD-ROM presentation and facilitate group discussion	Use during or after the CD-ROM presentation
8	Template certificates (Appendix 34)	To acknowledge attendance at, or completion of, the CD-ROM presentation.	Give to staff who attend an education session facilitated by the CD-ROM, or to those who use the CD-ROM for self-education.
9	A template medicine identification sheet (Appendix 35)	To assist with checking DAAs and DAA incident recording	These sheets can be used at the RACF or pharmacy and can be produced by the pharmacy for each RACF resident, upon every DAA delivery, or following medication regimen changes.
10	A template DAA incident policy and procedure (Appendix 36)	To assist with DAA checking, and DAA incident recording, communication, correction, evaluation and QI.	Modify this template to suit specific workplaces and refer to it at the RACF or pharmacy
11, 12	Australian DAA guidelines produced by pharmacy, nursing and Government bodies. ^{53, 54, 67, 77-79, 138-140}	To provide pharmacy- and RACF-specific direction regarding the DAA medicine supply service	Sections of the guidelines directly relating to DAAs were provided in hard copy, with the internet address where they could be accessed, and additional guidelines were also mentioned but not provided in hard copy. ^{141 142, 143} These guidelines were for the RACF or pharmacy.

5.3.2 *Intervention introduction*

5.3.2.1 *Introducing the intervention*

Five hundred and fourteen individuals were introduced to the intervention. There were 449 individuals who attended at a RACF (range: 2 to 34) and 65 who attended at a pharmacy (range: 1 to 21).

The intervention was introduced at 91.8% (45) of RACFs recruited in Phase 1 (Chapter 3, Section 3.3.1.1). Two RACFs did not respond to the PhD candidate within the requested timeframe and two RACFs withdrew from the study. Reasons for withdrawal included the manager currently had a heavy workload and did not believe that their DAAs suffered from incidents, it was believed that RACF staff would not attend an education session as education was already offered in abundance, and the DAAs were already audited by a community pharmacy.

Staff from 29 pharmacies, including the 14 recruited pharmacies, were introduced to the intervention either at their pharmacy workplace, at an affiliated pharmacy or at their affiliated RACF. One of the recruited pharmacies was still introduced to the intervention, even though they no longer supplied DAAs to any of the Phase 1 RACFs.

5.3.3 *Survey*

5.3.3.1 *Characteristics of survey participants*

Of the 514 individuals who were introduced to the intervention, the two attendees at one RACF were not provided with a questionnaire as they had to leave the education session upon its conclusion. Four hundred and thirty-five questionnaires were returned from the 512 individuals who were introduced to the intervention and were provided with a questionnaire (85.0% response rate). Respondents had worked with RACF DAAs for an average of 6.2 years (n=386, range: 1 month to 30 years) and both blister packs and sachets were represented in their responses. Table 5.2 outlines the profession or workplace role of the 418 respondents who answered this question.

Table 5.2 Profession or workplace role of survey respondents, n (%).

Profession or workplace role of respondents	Frequency n=418 respondents
Nurse (Division 1 or 2)	260 (62.2)
PCA	88 (21.1)
Pharmacist	37 (8.9)
Pharmacy technician	25 (6.0)
Pharmacy student/internship pharmacist	3 (0.7)
Other	5 (1.2)
Column total of percentages does not equal exactly 100% due to rounding	

The 435 respondents represented 43 RACFs and 13 pharmacies. As the questionnaire had to be completed and returned once the intervention had been introduced (Section 5.2.3.4), it was not within the scope of this study to collect completed questionnaires at a later time. No questionnaires were returned from one RACF as attendees were not able to complete them due to the immediate commencement of a second, unrelated education session. Additionally, no questionnaires were returned from one pharmacy, as attendees did not complete them in the time available.

In other cases, questionnaires were not completed if attendees had to leave the education session early or if they required more time to examine the toolkit. Some individuals did not complete the questionnaire if they were not involved in the DAA medicine supply service, though only those staff who had some involvement with DAAs should have attended (Section 5.2.2.2).

5.3.3.2 Likert scale responses

According to responses from the Likert scale questions (Table 5.3), the mean response for all 13 questions was between 3.8 and 4.2, indicating that the intervention had the potential to be ‘moderately’ or ‘very’ effective. Seventy eight point five per cent (321) of individuals who responded indicated that the toolkit was ‘very’ or ‘extremely’ useful for workplaces and 70.1% (298) indicated that it had the potential to reduce the occurrence of DAA incidents ‘very’ or ‘extremely’ well. For all Likert scale questions, less than or equal to 9.0% of all responses were classified as either ‘not at all’ or ‘somewhat’. The majority of responses (at least 91.1%) indicated that the toolkit could have a positive effect classified as

‘moderately, ‘very’ or ‘extremely’ well. Of the 363 people who responded, 84.6% found the education session ‘very’ or ‘extremely’ useful.

Table 5.3 Responses to the Likert scale questions, n (%).

Question	n	Not at all 1	Somewhat 2	Moderately 3	Very 4	Extremely 5	Mean (median)
How well do you think the toolkit will reduce the occurrence of DAA incidents?	425	4 (0.9)	25 (5.9)	98 (23.1)	211 (49.6)	87 (20.5)	3.8 (4.0)
How well do you think the toolkit will reinforce existing medicine management systems at your workplace?	426	1 (0.2)	18 (4.2)	90 (21.1)	214 (50.2)	103 (24.2)	3.9 (4.0)
How useful is the toolkit for your workplace?	409	0 (0)	19 (4.6)	69 (16.9)	220 (53.8)	101 (24.7)	4.0 (4.0)
How useful was the education session?	429	1 (0.2)	10 (2.3)	55 (12.8)	200 (46.6)	163 (38.0)	4.2 (4.0)
How well do you think the toolkit will improve...							
...the accuracy and suitability of DAA medicine packing?	426	1 (0.2)	24 (5.6)	77 (18.1)	215 (50.5)	109 (25.6)	4.0 (4.0)
...pharmacy medicine supply from DAAs/RACF medicine administration using DAAs?	423	2 (0.5)	24 (5.7)	98 (23.2)	200 (47.3)	99 (23.4)	3.9 (4.0)
...DAA checking <u>WITHIN</u> your workplace?	421	3 (0.7)	26 (6.2)	87 (20.7)	213 (50.6)	92 (21.9)	3.9 (4.0)
...communication <u>WITHIN</u> your workplace?	427	4 (0.9)	23 (5.4)	98 (23.0)	201 (47.1)	101 (23.7)	3.9 (4.0)
...communication <u>WITH</u> your affiliated RACF/pharmacy?	421	3 (0.7)	30 (7.1)	92 (21.9)	197 (46.8)	99 (23.5)	3.9 (4.0)
...the relationship <u>WITH</u> your affiliated RACF/pharmacy?	422	5 (1.2)	33 (7.8)	88 (20.9)	202 (47.9)	94 (22.3)	3.8 (4.0)
...awareness of DAA incidents?	426	2 (0.5)	15 (3.5)	82 (19.2)	207 (48.6)	120 (28.2)	4.0 (4.0)
...awareness of contributing factors to DAA incidents?	423	1 (0.2)	19 (4.5)	81 (19.1)	210 (49.6)	112 (26.5)	4.0 (4.0)
...awareness of strategies to prevent DAA incidents?	425	1 (0.2)	23 (5.4)	80 (18.8)	211 (49.6)	110 (25.9)	4.0 (4.0)
Row totals of percentages do not always equal exactly 100% due to rounding							

5.3.3.3 Usefulness of the intervention

In response to open-ended questions, on average, 261 respondents felt that their workplace would use or implement 72.5% of the toolkit in the short-term, 259 respondents felt that 74.7% would be used or implemented permanently and 212 respondents felt that 48.4% was new to existing workplace medicine management systems. One hundred and fifty-three respondents listed at least one specific toolkit component that they felt was most useful. Table 5.4 summarises the 190 responses.

Table 5.4 Most useful toolkit components, n (%).

Most useful toolkit component	Frequency n=190 responses
Bookmarks	71 (37.4)
Stickers	52 (27.4)
Posters	22 (11.6)
Guidelines (in general)	15 (7.9)
Medicine identification sheet	11 (5.8)
CD-ROM	7 (3.7)
Australian guideline (outlining medicines that should not be packed into DAAs) ¹³⁷	7 (3.7)
Handouts	3 (1.6)
Australian research article ⁷⁴	1 (0.5)
Template policy and procedure	1 (0.5)
Column total of percentages does not equal exactly 100% due to rounding	

Advantages of the toolkit

In response to open-ended questions, participants noted general advantages of the toolkit, including it:

- is clear, well explained, concise yet comprehensive, informative and relevant;
- is useful, user friendly, easily accessible and can be used quickly;
- is complete, compact and organised and includes visual components;
- provides guidance and formalises processes and protocols in writing;

- can be used over long time periods, as it provides a constant reminder of information;
- updates and increases awareness;
- educates, reinforces, refreshes and provides opportunities for reflection and revision;
- can be used for self-education or for educating all, or new staff; and
- can improve medicine administration and resident quality of care.

Disadvantages of the toolkit

In response to open-ended questions, participants noted general disadvantages of the toolkit, including it:

- is bulky and includes a large amount of reading material;
- may involve time and effort to use;
- may not be accessible to all staff if only one toolkit is provided per workplace, or if it is stored in an inaccessible location; and
- may not be applicable for every staff member or workplace, due to its generic nature, the fact that different workplaces are not all the same, and the fact that most RACFs already have structured procedures or systems in place.

Suggestions to improve the toolkit

In response to open-ended questions, participants gave suggestions to improve the toolkit. It could:

- be simplified and its information could be condensed into point form;
- be made available online or multiple toolkits could be provided per workplace, to increase accessibility;
- include more information regarding DAA checking and specific DAA types; and
- be improved through continuous monitoring, research, feedback and regular updates.

Comments regarding the education session

From a small number of written comments, eight respondents wrote about the education session.

“very good education session/study to improve the quality of care we provide in every RACF.” Registered nurse (RN)

“I very much enjoyed this session. It’s always good to learn something new and remind yourself of procedures that we do often.” Pharmacy student/internship pharmacist

Additionally, one respondent commented that it was a great presentation and a second positively commented on the PhD candidate who introduced the intervention.

In contrast, two respondents questioned the suitability of the education session for PCAs and mentioned that it may be more appropriate for pharmacy staff. A third respondent noted that the minimal staff attendance at their workplace when the intervention was introduced, may result in some staff not reading the toolkit and thus not being aware of its contents. Finally, one individual outlined that they could not comment on the toolkit as they felt that the education session was rushed and they would like to have more time to examine it.

5.4 Discussion

This study phase attempted to develop, introduce and provide initial evaluation of the potential of an intervention to reduce the occurrence of DAA incidents and improve the DAA medicine supply service, involving DAAs supplied by Victorian community pharmacies to RACFs. Overall, health professionals felt that the intervention would be very useful and the toolkit had the potential to reduce the occurrence of DAA incidents, as shown by survey responses. The practical suggestions and comments concerning the intervention could be used to refine it for wider use.

The intervention developed in this study can provide a framework for future policy makers such as the ANF, The Pharmacy Guild of Australia, the PSA and the Victorian Pharmacy Authority, to refer to, when suggesting ways to improve RACF and pharmacy medicine management systems.

Using the suggestions for improvement and advantages and disadvantages identified, the intervention can be refined and targeted for specific local settings. Both staff accessibility and the generic nature of the toolkit were two areas suggested for improvement. Providing multiple toolkits per workplace and including online components can allow for larger numbers of staff to access the toolkit at their convenience. Greater specificity for particular workplaces can also be achieved by tailoring the toolkit components to each workplace environment under consideration. Toolkit components could be made available in an electronic template form, allowing workplaces to modify the components based on their existing work practices. Toolkit components that are irrelevant for certain workplaces could also be removed, for example, the bookmarks designed for hard copy medicine records may

not be useful for RACFs where electronic medicine records are used. The education session can be improved by producing specific sessions for either the RACF or pharmacy workplace and delivering them over a longer time period.

Although it was identified that most workplaces already have structured medicine handling systems, the fact that DAA incidents were identified in previous research¹⁰⁻¹³ and in Phase 1 of this study (Chapter 3, Section 3.3.1.3), indicates that these systems are either not being adhered to, or are not adequately targeting this aspect of DAA supply. Future research could identify the systems in current use, evaluate their effectiveness, and compare evaluation findings to those of the intervention developed in this study (Chapter 6, Section 6.3).

Although published studies evaluating how well health professionals adhere to DAA medicine handling systems have not been identified, adherence to other QI systems has been described.¹⁴⁴ McIntosh *et al.* highlighted that Australian health professional adherence to community-acquired pneumonia treatment guidelines is problematic and national guidelines are often not followed.¹⁴⁴ A baseline audit of pneumonia management in patients presenting to Australian emergency departments showed that management varied and often did not correlate with guidelines.¹⁴⁴ Uptake of guidelines only improved following the implementation of an evidence-based, multifaceted educational intervention.¹⁴⁴ The intervention used by McIntosh *et al.* shared similar components to the intervention developed in this study (Section 5.3.1.1) and included:¹⁴⁴

- an audit report and automated feedback report that was generated in each hospital, for each audit;
- a generic Microsoft PowerPoint® (Microsoft Corporation, Redmond, WA, USA) presentation that described the study, presented feedback on the baseline audit data, and outlined guideline-based best practice points on pneumonia management;
- education sessions;
- generic letters to prescribers;
- wall poster prescribing prompts; and
- other prescribing prompts such as identification card tags and stickers, to facilitate calculation of the pneumonia severity index.

Published literature concerning the implementation and evaluation of multi-factorial educational interventions in the community pharmacy setting are scarce. As a result, it is difficult to compare the findings from this study, with other studies that have also examined pharmacists' perceptions of these interventions. Despite the lack of published research evaluating the impact of interventions designed to improve the DAA medicine supply

service, studies have shown positive findings when investigating the impact of education on aged care resident outcomes.¹⁴⁵⁻¹⁴⁸ These studies support the educational component of the intervention developed in this study. In a study by Roberts *et al.*, pharmacist-delivered medicine education for nurses showed positive effects on resident outcomes and led to potential medicine cost savings, and a reduction in medicine use without changes in morbidity or survival.¹⁴⁸ In a before-and-after study by Verrue *et al.*, a pharmacist-led educational intervention significantly reduced medicine preparation and administration error rates, as identified via direct observation ($p < 0.05$).¹⁴⁹ The intervention involved education concerning good medicine administration principles for RACF staff, plastic cards covering medicine administration, and checklists of inhaled medicine inhalation techniques.¹⁴⁹ Similarly to this study, the one and a half hour education session was interactive and facilitated by a researcher-developed Microsoft PowerPoint® (Microsoft Corporation, Redmond, WA, USA) presentation that included information based on a literature review and on the errors observed in the 'before' phase of the study.¹⁴⁹ Finally, a study by Ibsen *et al.*, showed reduced errors in medicine handling when pharmacists educated approximately 800 RACF staff about quality assurance associated with this RACF process.¹⁴⁵ Further evaluation of the intervention developed in this study could determine its impact on RACF resident outcomes, including adverse drug events (ADEs) following DAA incidents, as well the impact on medicine administration time, medicine administration errors, and any economic impact.

This study phase provides health professionals with practical suggestions to improve their DAA medicine supply service. This is comparable to studies that have identified potential factors contributing to pharmacy dispensing errors from original containers, but have not suggested specific tools or interventions to target identified errors.^{4, 130-132} Studies that have both implemented and evaluated interventions targeted at reducing dispensing errors in community or hospital pharmacies are limited.¹⁵⁰⁻¹⁵³ Successful strategies have included computerised medicine prescription entry and medicine interaction screening, barcode-assisted dispensing, and other automated dispensing strategies involving printers and computer software.¹⁵⁰⁻¹⁵³ Though DAA preparation can be considered a form of pharmacy medicine dispensing,¹³ interventions directed at this medicine supply service have not featured prominently in the published literature.

Strengths and limitations

It is a strength that a multicomponent intervention was inductively generated through multiple stakeholder forums. It is not surprising that the Likert scale questions led to positive findings, as the intervention was informed by health professionals (Chapter 4,

Section 4.2.1.2 and Section 4.2.2.2) who were directly involved in the DAA medicine supply service and who could contribute valuable insight into useful intervention strategies. It is a strength that feedback was sought from the very individuals for whom the intervention was designed and this feedback was successfully incorporated into the final intervention, as shown by the positive survey findings. It is not a limitation that the intervention was potentially evaluated by the same individuals who may have informed its development, as a significantly greater number of staff were involved in its evaluation (435 questionnaire respondents) than informed its development. However, it could be beneficial to trial the unmodified intervention, at workplaces outside of the study sample, to determine its transferability.

It is also a strength that staff from a large number of pharmacies and RACFs (74) were introduced to the intervention. This large sample was partially facilitated by the fact that only four RACFs withdrew from the study, from a total of 49 (Chapter 3, Section 3.3.1.1). Another strength is that a large number (435) of questionnaires were returned from individuals who were introduced to the intervention (85.0% response rate) and a variety of health professionals were represented. This large sample size was partially facilitated by some RACFs making it compulsory for staff to attend the intervention introduction at their workplace. These study strengths have increased the generalisability (Chapter 2, Section 2.7) of the questionnaire, although work of this nature is heavily context specific and caution is advised when applying the findings to other organisations.

Limitations associated with the intervention were identified. In a small number of cases, the intervention was introduced without the assistance of audio-visual facilities or it was introduced in less than 30 minutes due to staff time constraints. As attendance at the intervention introduction sessions was often voluntary, those staff who did not attend may not have been made aware of the intervention and this may impact on its eventual success. It may have also been a limitation that the intervention was only introduced over 30 minutes. It has been highlighted in the literature that educational interventions may be more effective with a greater investment of time.¹⁰⁶ Longer sessions may have allowed the PhD candidate to speak at a more leisurely pace, though this may have impacted on staff work schedules and consequently less staff may have been able to attend. It may also be a limitation that only one toolkit was provided to each RACF and if this was not stored in an area easily accessible by staff, then its usefulness could have been diminished. Additionally, the toolkit components were not specifically designed to be used with electronic medicine management systems, despite only a small number of RACFs using electronic medicine records. The toolkit components were designed simply, for workplaces to easily reproduce them using limited funds and time.

A number of limitations associated with the survey were also identified. It was not possible to accurately ascertain the total number of individuals who were introduced to the intervention or the total number of questionnaires provided, due to fluctuations in the number of staff who were introduced to the intervention at specific workplaces and a lack of questionnaire coding. The PhD candidate was also notified that a small number of individuals who were introduced to the intervention were not employees of the workplace but may have been visiting students or employees of an affiliated workplace, or they may not have been directly involved in the DAA medicine supply service. These individuals were not singled out and may have completed a questionnaire as the questionnaires were anonymous, though their opinions could still be considered useful. Some attendees also completed their questionnaires in consultation with others, rather than independently. Lastly, it could not be determined if responses that appeared low on the Likert scale occurred because respondents perceived that their workplace did not need the intervention or because they perceived that the intervention was not well designed.

5.5 Conclusion

This study phase demonstrated that a multifactorial intervention developed using aged care health professional input and introduced by a pharmacist, was favorably perceived by RACF and pharmacy staff. Survey respondents felt that the education session was useful and the toolkit had the potential to reduce the occurrence of DAA incidents and improve the DAA medicine supply service. Suggestions to improve the intervention can be used to refine it and to target it for local workplace issues. Objective assessment of the intervention is still required after a longer follow-up period to ascertain the sustainability of the intervention and its ability to quantitatively reduce the number of DAA incidents that occur. Research that assesses staff perceptions after a longer follow-up period is presented in Chapter 6. Chapter 6 also describes the findings of the Phase 4 DAA audits, used to evaluate whether the intervention actually reduced the number of DAA incidents identified, compared to the Phase 1 findings (Chapter 3, Section 3.3.1.3).

6 Phase 4 - Final evaluation of the intervention

6.1 Summary

This chapter describes the final evaluation of the intervention that was introduced in Phase 3 of this study to staff from 45 residential aged care facilities (RACFs) and 29 community pharmacies (Chapter 5, Section 5.3.2.1). The intervention, comprising an education session and toolkit, was evaluated for its ability to reduce the occurrence of DAA incidents and improve the DAA medicine supply service. Methods of evaluation included DAA audits, field notes, incident classifications and a survey. A comparison of the incident rates and risk categories of the DAA incidents identified in Phase 1 (Chapter 3, Section 3.3.1.3) and 4 (Section 6.3.1.2) were compared, to determine the impact of the intervention. The results presented in this chapter complement the survey findings from Phase 3 (Chapter 5, Section 5.3.3), by evaluating the intervention after a longer follow-up period, at least three months after the intervention was introduced to participating workplaces.

6.2 Methods

6.2.1 *Dose administration aid audits*

6.2.1.1 Audit aims

The audit aims were two-fold:

- to identify the types and frequency of DAA incidents that occur in blister pack and sachet DAAs supplied by Victorian community pharmacies, to RACFs introduced to the Phase 3 intervention (Chapter 5, Section 5.3.2.1); and
- to compare the DAA incident rates identified in Phase 4 (post-intervention), with those identified in Phase 1 (pre-intervention).

6.2.1.2 Selecting participants for the audits

The 45 RACFs where DAAs were audited were involved in both the Phase 1 DAA audits (Chapter 3, Section 3.3.1.1) and had been introduced to the Phase 3 intervention (Chapter 5, Section 5.3.2.1). To audit the DAAs at a particular RACF, it was not a requirement for their affiliated community pharmacy to have been introduced to the intervention. Of the 49

RACFs that were recruited in Phase 1, four RACFs were not introduced to the intervention and were thus excluded from Phase 4 of this study (Chapter 5, Section 5.3.2.1).

6.2.1.3 Conducting the audits

The PhD candidate conducted the DAA audits between September 2012 and January 2013, at least three months after the intervention was introduced to the RACFs (Chapter 5, Section 5.2.2.3). Three months was considered to be sufficient time for staff to implement the intervention components. If the affiliated community pharmacy was also introduced to the intervention, the DAA audits occurred three months after the last time that the intervention was introduced at either workplace.

The Phase 4 DAA audits were conducted according to the protocol followed in Phase 1 (Chapter 3, Section 3.2.1.4). Minor modifications were made to the Phase 1 DAA audit form to improve its ease of use and the clarity of information recorded (Appendix 37). For example, information fields were arranged vertically, running down the page, rather than horizontally. Additionally, a separate information field was included, to record the number of DAAs affected by a single DAA incident type. This information was previously collected as part of the general DAA incident description.

6.2.1.4 Analysing audit data

The data were coded and entered as per the protocol followed in Phase 1 (Chapter 3, Section 3.2.1.6) and were managed with Microsoft Excel 2010® (Microsoft Corporation, Redmond, WA, USA). SPSS Statistics Version 19® (SPSS, Inc., Chicago, IL, USA) was used to calculate descriptive statistics such as means and frequencies. Pearson's Chi-squared test was used to determine the statistical significance of any difference in DAA incident rates identified pre- and post-intervention.

6.2.2 Field notes

6.2.2.1 Aim of the field notes

To identify which toolkit components were implemented at RACFs and pharmacies that had been provided with the toolkit and if staff reported that the toolkit was useful.

6.2.2.2 Selecting participants for the field notes

Field notes were recorded at the RACFs and pharmacies that had been provided with the toolkit, whether they had been introduced to the intervention or not, as these workplaces could provide useful insight into the actual usefulness of the toolkit.

6.2.2.3 Recording the field notes

Around the time of the Phase 4 DAA audits, a check was made to see if toolkit components were implemented at workplaces and staff were spoken to about the toolkit.

6.2.2.4 Analysing field note data

The data were managed with Microsoft Word 2010® (Microsoft Corporation, Redmond, WA, USA).

6.2.3 *Incident classifications*

6.2.3.1 Aims of the incident classifications

The aims of classifying the incidents were two-fold:

- to classify the DAA incidents identified from the Phase 1 (Chapter 3, Section 3.3.1.3) and 4 DAA audits (Section 6.3.1.2) according to their potential risk of causing an adverse event in the RACF resident; and
- to compare the risk categories of DAA incidents identified in Phase 4 (post-intervention), with those identified in Phase 1 (pre-intervention).

6.2.3.2 Classifying the incidents

The risk classification scale for geriatric ambulatory care medicine-related problems (MRPs) was used.¹⁰⁹ This scale was adapted by Elliott and Woodward, from The Society of Hospital Pharmacists of Australia (SHPA) risk classification system.¹⁰⁹ The validity of this scale was established in Elliott and Woodward's study by a geriatrician and two clinical and academic pharmacists with experience in developing and using risk assessment scales.¹⁰⁹

The DAA incidents identified from the Phase 1 and 4 DAA audits were each classified according to their potential risk of causing an adverse event in the RACF resident. To ensure internal validity, all of the DAA incidents were classified by a single pharmacist researcher,

the PhD candidate. Both the *severity* and *likelihood* of the most probable adverse event that could occur if each identified DAA incident was transferred to the RACF resident, was determined. Using these two codes, a final five-point risk category from insignificant to catastrophic, was identified.

As the DAA incidents identified in this study did not reach the RACF resident, it was important to consider the *likelihood* of an adverse event occurring, to ensure that the final classification was not overestimated. For consistency and to reduce subjectivity, each DAA incident was considered in isolation and did not have the potential to be repeated outside of the DAA auditing day. This held true despite the fact that multiple DAA incident types may have occurred within a single DAA and in some cases, it was perceived that a DAA incident was very likely to be repeated the following week. Additionally, only those adverse events that could occur in the next two weeks were considered in the incident classifications. To reduce bias, the final risk category was only determined after all the DAA incidents had first been coded according to severity and likelihood.

The original Phase 1 (Appendix 12) and Phase 4 DAA audit forms (Appendix 37), eMIMS,¹¹⁹ internet access to medicine product information, medicine manufacturer storage recommendations, a research article⁷⁴ and pharmacy references or guidelines,^{67, 137} were used during the classifications.

6.2.3.3 Analysing incident classification data

The data were managed with Microsoft Excel 2010® (Microsoft Corporation, Redmond, WA, USA). SPSS Statistics Version 19® (SPSS, Inc., Chicago, IL, USA) was used to calculate descriptive statistics, such as frequencies, and Pearson's Chi-squared test was used to determine the statistical significance of any difference in the risk categories assigned to the incidents identified pre- and post-intervention.

6.2.4 Survey

6.2.4.1 Aim of the survey

To identify health professionals' perceptions of the usefulness and effectiveness of the toolkit a minimum of three months after it was introduced to the workplace.

6.2.4.2 Selecting participants for the survey

The survey was sent to one staff contact, at each of the 45 RACFs and 14 community pharmacies that had been recruited in Phase 1 (Chapter 3, Section 3.3.1.1) and were introduced to the intervention (Chapter 5, Section 5.3.2.1). Two of the 14 pharmacies were sent the questionnaire even though they no longer serviced any of the 45 RACFs, as they had still been introduced to the intervention and may have provided DAAs to other RACFs outside of the study. Staff contacts were selected using purposive and convenience sampling methods (Chapter 2, Section 2.4) as they could provide insight into the usefulness and effectiveness of the intervention that had been introduced to their workplace and had been in contact with the researchers previously. The survey only sought preliminary data from one person, who was usually in a position of leadership, at each participating workplace to complement the other methods of intervention evaluation (Section 6.2). It was not necessary to individually recruit these individuals, as their affiliated workplace was recruited into the study and was deemed to be the study participant.

6.2.4.3 Developing the survey

The Phase 3 survey (Chapter 5, Section 5.2.3.3) was modified and then used in Phase 4. Question wording was changed to evaluate the toolkit after it had been implemented, as opposed to before it had been implemented. Suggested answers were also provided for a few questions that were previously open-ended. For example, when respondents were asked to identify toolkit components that were implemented, the actual toolkit components were listed for ease of response. A similar questionnaire was used at the *RACFs* (Appendix 38) and *pharmacies* (Appendix 39). Slight variations in the wording of questions corresponded to the two different workplaces. Face and content validity (Chapter 2, Section 2.5) was assessed by two academic pharmacists from the research team.

The final questionnaire included six open-ended and six mixed questions, along with 12 Likert scale questions and an open-comment field. This survey did not evaluate the education session as it had been at least three months since the intervention had been introduced to workplaces and the education sessions had been previously evaluated by the Phase 3 survey (Chapter 5, Section 5.2.3.3).

6.2.4.4 Conducting the survey

The survey was sent to RACFs and pharmacies via email or facsimile, a few days after the DAA audits had been conducted at a specific RACF. One reminder was sent approximately

one month later and was followed-up with a posted certificate to acknowledge study participation of the workplace.

6.2.4.5 Analysing survey data

The data were managed with Microsoft Word 2010® (Microsoft Corporation, Redmond, WA, USA) and Microsoft Excel 2010® (Microsoft Corporation, Redmond, WA, USA). SPSS Statistics Version 19® (SPSS, Inc., Chicago, IL, USA) was used to calculate descriptive statistics, such as means and frequencies.

6.3 Results

6.3.1 *Dose administration aid audits*

6.3.1.1 Characteristics of audit participants

A total of 2,389 DAAs were audited, supplied by 39 Victorian community pharmacies, for 983 residents living in 45 RACFs. The four RACFs that were excluded from the study were located in outer metropolitan Melbourne (2 RACFs), inner metropolitan Melbourne (1) and rural Victoria (1).

The DAAs audited at:

- 37 of the 45 RACFs (82.2%) were supplied from the same pharmacy as in Phase 1;
- four of the 45 RACFs (8.9%) were mostly supplied from the same pharmacy, except for one or two DAAs that were supplied from a new pharmacy; and
- four (8.9%) RACFs were supplied from a different pharmacy.

A total of seven new community pharmacies were represented in the Phase 4 DAA sample, compared to Phase 1.

Staff from 27 of the 39 pharmacies (69.2%) were introduced to the intervention in Phase 3 (Chapter 5, Section 5.3.2.1) at their pharmacy, at an affiliated pharmacy, or at their affiliated RACF. The remaining 12 pharmacies (30.8%) were not introduced to the intervention, though the toolkit was still given to them directly (2 pharmacies, 5.1%) or left with their affiliated RACF to pass on (10, 25.6%).

Of the DAAs audited, 79.5% (1,899) were blister packs and 20.5% (490) were sachets. Blister packs alone were audited in 32 RACFs (71.1%), sachets alone were audited in nine RACFs (20.0%) and both DAA types were audited in four RACFs (8.9%). In this sample,

the blister packs were prepared both manually and via automation, in contrast to the manually prepared blister packs audited in Phase 1 (Chapter 3, Section 3.3.1.2).

The average resident whose DAAs were audited was female (68.8% of all residents audited), 85 years old (range: 33-106), took seven regularly packed medicines (range: 1-20), and had an average of two DAAs (range: 1-15), or an average of three blister packs (range: 1-15) or one sachet DAA (range: 1-4).

6.3.1.2 Overall incident rates

Seven hundred and seventy incidents in 502 DAAs, were identified, resulting in an overall DAA incident rate of 21.0% (502/2,389). DAAs for 407 residents (41.4% of all residents audited) contained incidents.

The overall incident rate is reduced to 16.7% of DAAs (400/2,389) if the 102 DAAs affected **only** by unsuitable medicine packing are removed from the sample. As more than one incident type may occur in a single DAA, the number of DAAs experiencing unsuitable packing, among other incident types, is greater (152, Table 6.1) than the number of DAAs **only** experiencing the incident type of unsuitable packing (102).

Table 6.1 outlines the 17 predetermined DAA incident types, their frequency of occurrence, and statistically significant differences between the Phase 1 and Phase 4 DAA incident rates. The most commonly identified DAA incidents included unsuitable packing (27.9% of all incidents identified), inaccurate division (26.6%), ‘other’ incident (15.1%), addition (12.5%) and incorrect time interval (4.8%). The incident types can also be collapsed into five main categories:

- 27.9% of all incidents were classified as unsuitable packing;
- 15.9% were classified as incorrect or missing medicines, including incidents of incorrect formulation and form, addition, and unauthorised brand substitution;
- 31.3% were classified as incorrect dose, including incidents of incorrect quantity, strength and frequency of administration, and inaccurate or incorrect division;
- 6.4% were classified as incorrect dose schedule, including incidents of incorrect time, time interval, or day, and inappropriate division; and
- 18.6% were classified as ‘other’ incidents, including damage.

Table 6.1 Frequency of incident types and the proportion of DAAs affected, n (%).

DAA incident type	DAAs affected by a specific incident type compared to the total number of DAAs audited			Frequency of a specific incident type compared to the total number of incidents identified		
	Phase 1 n=3,959 DAAs audited	Phase 4 n=2,389 DAAs audited	Direction of change if significant	Phase 1 n=684 incidents identified	Phase 4 n=770 incidents identified	Direction of change if significant
Unsuitable packing	227 (5.7)	152 (6.4)		343 (50.1)	215 (27.9)	Decrease p<0.001
Addition	52 (1.3)	78 (3.3)	Increase p<0.001	67 (9.8)	96 (12.5)	
Incorrect quantity	28 (0.7)	15 (0.6)		37 (5.4)	15 (1.9)	Decrease p<0.001
Omission	25 (0.6)	12 (0.5)		36 (5.3)	12 (1.6)	Decrease p<0.001
Damage	35 (0.9)	26 (1.1)		35 (5.1)	27 (3.5)	
'Other'	31 (0.8)	107 (4.5)	Increase p<0.001	34 (5.0)	116 (15.1)	Increase p<0.001
Inaccurate division	26 (0.7)	163 (6.8)	Increase p<0.001	28 (4.1)	205 (26.6)	Increase p<0.001
Incorrect strength	23 (0.6)	10 (0.4)		23 (3.4)	12 (1.6)	Decrease p<0.05
Incorrect time interval	19 (0.5)	30 (1.3)	Increase p<0.001	22 (3.2)	37 (4.8)	
Incorrect time	18 (0.5)	7 (0.3)		21 (3.1)	12 (1.6)	
Incorrect formulation	12 (0.3)	13 (0.5)		13 (1.9)	13 (1.7)	

Table 6.1 continued

DAA incident type	DAAs affected by a specific incident type compared to the total number of DAAs audited			Frequency of a specific incident type compared to the total number of incidents identified		
	Phase 1 n=3,959 DAAs audited	Phase 4 n=2,389 DAAs audited	Direction of change if significant	Phase 1 n=684 incidents identified	Phase 4 n=770 incidents identified	Direction of change if significant
Incorrect division	12 (0.3)	3 (0.1)		12 (1.8)	3 (0.4)	Decrease p<0.05
Incorrect form	4 (0.1)	0 (0)		5 (0.7)	0 (0)	Decrease p<0.05
Incorrect frequency of administration	3 (0.1)	6 (0.3)		4 (0.6)	6 (0.8)	
Incorrect day	2 (0.1)	0 (0)		3 (0.4)	0 (0)	
Unauthorised brand substitution	1 (<0.1)	1 (<0.1)		1 (0.1)	1 (0.1)	
Inappropriate division	0 (0)	0 (0)		0 (0)	0 (0)	
	The Phase 1 and Phase 4 columns above, do not equal the total number of DAAs with an incident in each respective phase (n=457 DAAs in Phase 1 and n=502 DAAs in Phase 4), as multiple incident types were often identified within a single DAA.			Column totals of percentages do not equal exactly 100% due to rounding		

Incidents were detected in 20.6% (391/1,899) of blister packs and 22.7% (111/490) of sachets. Of the 770 incidents identified, 564 incidents involved blister packs and 206 involved sachets. As the sample of blister packs included those prepared both manually and via automation, it is neither possible nor within the scope of this study, to separate the DAA incident rates by method of preparation (Chapter 3, Section 3.4). The majority of incidents were not isolated, but were repeated within a specific time interval an average of five times.

6.3.1.3 Incident rates by location and medicine class

Between 25 and 117 DAAs were audited at each of the 45 RACFs participating in the DAA audit. All RACFs had at least one DAA with an incident, with an incident rate ranging from 4.7% up to 52.5% of all DAAs audited at the RACF.

A range of 1-323 DAAs was audited from the 39 pharmacies that supplied the 45 RACFs. In the two pharmacies with an incident rate of 0% and in the three pharmacies with a 100% incident rate, fewer than nine DAAs were audited. In the remaining 34 pharmacies, incident rates ranged from 4.7% to 52.5% of all DAAs audited.

Of the DAAs audited from regional Victoria, 26.1% (59/226) had an incident, followed by 22.2% (115/519) of the DAAs from inner metropolitan Melbourne, 20.8% (273/1313) from outer metropolitan Melbourne and 16.6% (55/331) from rural Victoria.

Of the 571 DAA incidents where a medicine class was noted, Table 6.2 outlines those involved. The three medicine classes most commonly involved in incidents (nervous system, cardiovascular system, and alimentary tract and metabolism) may reflect the fact that these were also the three most commonly packed. Sodium valproate, metoprolol and oxazepam were the top three medicines involved in incidents.

Table 6.2 Medicine classes involved in DAA incidents, n (%).

Medicine class involved in incidents	Frequency n= 571 incidents
Nervous system	296 (51.8)
Cardiovascular system	146 (25.6)
Alimentary tract and metabolism	41 (7.2)
Blood and blood forming organs	26 (4.6)
Systemic hormonal preparations (excluding sex hormones and insulins)	25 (4.4)
Antiinfectives for systemic use	21 (3.7)
Musculo-skeletal system	9 (1.6)
Dermatologicals	2 (0.4)
Respiratory system	2 (0.4)
Antineoplastic and immunomodulating agents	2 (0.4)
Genitourinary system and sex hormones	1 (0.2)
Column total of percentages does not equal exactly 100% due to rounding	

6.3.1.4 Comparison of incident rates pre- and post-intervention

The *primary aim* (Chapter 1, Section 1.6) of this study was to determine if the Phase 3 intervention (Chapter 5, Section 5.3.1.1) reduced the overall DAA incident rate identified in Phase 1 (Chapter 3, Section 3.3.1.3), when the DAA audits were repeated in Phase 4 (Section 6.2.1.3). The overall DAA incident rate identified in Phase 4 (Section 6.3.1.2) was significantly higher (21.0%, $p < 0.001$) than the incident rate identified in Phase 1 (11.5%) (Chapter 3, Section 3.3.1.3).

Of the two secondary aims (Chapter 1, Section 1.6), *the first aim* was to identify if the intervention reduced the proportion of DAAs that were affected by a specific incident type. Incidents of addition, inaccurate division, incorrect time interval and ‘other’ incidents occurred significantly ($p < 0.001$) more frequently in Phase 4, compared to Phase 1 (Table 6.1). Significant decreases in the occurrence of any incident type were not seen, when considering the proportion of DAAs affected by a specific incident type.

The second of the two secondary aims (Chapter 1, Section 1.6) was to identify if the intervention reduced the frequency of occurrence of specific incident types compared to the total number of incidents identified. Incidents of inaccurate division and ‘other’ incidents

occurred significantly more frequently ($p<0.001$) (Table 6.1). However, six DAA incident types occurred significantly less frequently, including unsuitable packing ($p<0.001$), incorrect quantity ($p<0.001$), omission ($p<0.001$), incorrect strength ($p<0.05$), incorrect division ($p<0.05$) and incorrect form ($p<0.05$).

6.3.2 Field notes

6.3.2.1 Field note records

Field notes were taken concerning all 45 RACFs and 15 of the affiliated community pharmacies that were provided with the toolkit. The remaining 24 (out of 39) pharmacies that supplied DAAs to the RACFs (Section 6.3.1.1) were not able to be contacted within the study time frame.

At 21 RACFs (46.7% of those audited), either a staff member was able to list at least one specific toolkit component that was being used or it was observed to be in use during the DAA audit. The poster was being used in all 21 RACFs and the bookmarks or stickers were being used in eight RACFs (Chapter 5, Section 5.3.1.1). At two RACFs, staff said that the toolkit was being used, but a specific component was not identified. Medicine identification sheets were being used by some RACFs that may have been produced as a result of the toolkit template (Chapter 5, Section 5.3.1.1). Some RACF staff members who were approached had neither seen or heard of the toolkit nor been introduced to the intervention (Chapter 6, Section 6.3.1.1). Other individuals had been introduced to the intervention, but had not seen the toolkit since.

At seven pharmacies (17.9% of those who supplied DAAs to the 45 RACFs) either a staff member was able to list at least one specific toolkit component that was being used or it was observed to be in use during the DAA audit. The poster was being used in all seven pharmacies. Staff at one pharmacy said that the toolkit was useful, but a specific component was not identified.

At the remaining 22 RACFs and seven pharmacies where field notes were recorded, either staff said that the toolkit was not being used or they had not seen it recently, or no toolkit components were observed in use.

Specific factors identified by the RACF or pharmacy staff, or observed during the DAA audit, may explain why toolkit components were not being used. These factors included:

- the toolkit was being stored in the staff room or in a personal office;

- the toolkit was forgotten about;
- the toolkit did not fit with workplace policies or was not deemed to be useful;
- similar toolkit components had been tried in the past and had not been effective;
- there had been recent changes in managerial staff;
- staff who were approached were new to the workplace;
- staff had been, or were currently, on leave;
- the workplace was in a phase of transition and staff had been busy;
- there was poor communication amongst staff regarding the toolkit;
- staff were described as being resistant to change;
- it was not considered necessary to implement the toolkit as staff felt that the pharmacy provided an adequate service;
- necessary discussions amongst staff members had yet to occur;
- managerial approval to use the toolkit was pending;
- one pharmacy had given the toolkit to their affiliated RACF; and
- one pharmacy had only recently received the toolkit from their affiliated RACF.

6.3.3 Incident classifications

6.3.3.1 Risk categories

The most common risk category assigned to the DAA incidents identified in Phase 1, was 'minor' (32.2% of all Phase 1 DAA incidents, n=220) (Table 6.3), closely followed by 'major' (30.6%, n=209). The most commonly occurring risk category assigned in Phase 4 was 'minor' (47.1% of all Phase 4 DAA incidents, n=363).

Compared to Phase 1, in Phase 4 there were statistically significant decreases in the proportion of DAA incidents that were classified as 'major' or 'moderate' risk, and statistically significant increases in the proportion of DAA incidents that were classified as 'minor' or 'insignificant' risk ($p<0.001$).

Table 6.3 Risk categories of the incidents identified in Phase 1 and 4, n (%).

Risk category	Phase 1		Phase 4		Direction of change if significant
	Frequency n = 684 incidents	Most common DAA incident type per risk category	Frequency n = 770 incidents	Most common DAA incident type per risk category	
Insignificant	87 (12.7)	‘Other’ - 30 (34.5% of insignificant incidents)	157 (20.4)	‘Other’ - 115 (73.2)	Increase p<0.001
Minor	220 (32.2)	Unsuitable packing - 67 (30.5)	363 (47.1)	Inaccurate division - 168 (46.3)	Increase p<0.001
Moderate	166 (24.3)	Unsuitable packing - 84 (50.6)	110 (14.3)	Unsuitable packing - 51 (46.4)	Decrease p<0.001
Major	209 (30.6)	Unsuitable packing - 192 (91.9)	134 (17.4)	Unsuitable packing - 116 (86.6)	Decrease p<0.001
Catastrophic	2 (0.3)	Incorrect quantity - 2 (100.0)	6 (0.8)	Incorrect strength - 3 (50.0)	
Column totals of percentages do not equal exactly 100% due to rounding					

6.3.4 Survey

6.3.4.1 Characteristics of survey participants

Eleven questionnaires were returned, from nine RACFs (20.0% response rate) and two pharmacies (14.3% response rate). Respondents had worked with RACF DAAs for an average of 8.4 years and included nine nurses and two pharmacists. Ten individuals referred to blister packs in their responses, while one questionnaire related to sachets.

6.3.4.2 Likert scale responses

According to the Likert scale responses (Table 6.4) the mean response for the majority of questions (91.7% of questions, n=11) was between 3.2 and 3.7, indicating that the toolkit was ‘moderately’ effective. Just over half of respondents (54.6%, n=6) felt that the toolkit reduced the occurrence of DAA incidents, and was useful for their workplace (54.5% of respondents), ‘very’ or ‘extremely’ well. The toolkit improved the accuracy and suitability of DAA medicine packing according to 81.9% (9) of respondents, ‘moderately’, ‘very’ or ‘extremely’ well. A maximum of two respondents (18.2%) for any of the 12 Likert scale questions, felt that the toolkit did not achieve its aim.

Table 6.4 Responses to the Likert scale questions (n=11 for each question), n (%).

	Not at all 1	Somewhat 2	Moderately 3	Very 4	Extremely 5	Mean (median)
How well do you think the toolkit reduced the occurrence of DAA incidents?	1 (9.1)	4 (36.4)	0 (0)	4 (36.4)	2 (18.2)	3.2 (4)
How well do you think the toolkit reinforced existing medicine management systems at your workplace?	0 (0)	1 (9.1)	3 (27.3)	5 (45.5)	2 (18.2)	3.7 (4)
How useful was the toolkit for your workplace?	0 (0)	2 (18.2)	3 (27.3)	6 (54.5)	0 (0)	3.4 (4)
How well do you think the toolkit improved...						
...the accuracy and suitability of DAA medicine packing?	1 (9.1)	1 (9.1)	4 (36.4)	3 (27.3)	2 (18.2)	3.4 (3)
...pharmacy medicine supply from DAAs/RACF medicine administration using DAAs?	1 (9.1)	3 (27.3)	2 (18.2)	3 (27.3)	2 (18.2)	3.2 (3)
...DAA checking <u>WITHIN</u> your workplace?	0 (0)	4 (36.4)	0 (0)	6 (54.5)	1 (9.1)	3.4 (4)
...communication <u>WITHIN</u> your workplace?	1 (9.1)	4 (36.4)	3 (27.3)	2 (18.2)	1 (9.1)	2.8 (3)
...communication <u>WITH</u> your affiliated RACF/pharmacy?	1 (9.1)	2 (18.2)	1 (9.1)	5 (45.5)	2 (18.2)	3.5 (4)
...the relationship <u>WITH</u> your affiliated RACF/pharmacy?	2 (18.2)	0 (0)	4 (36.4)	4 (36.4)	1 (9.1)	3.2 (3)
...awareness of DAA incidents?	1 (9.1)	0 (0)	3 (27.3)	6 (54.5)	1 (9.1)	3.5 (4)
...awareness of contributing factors to DAA incidents?	0 (0)	2 (18.2)	2 (18.2)	6 (54.5)	1 (9.1)	3.5 (4)
...awareness of strategies to prevent DAA incidents?	0 (0)	1 (9.1)	3 (27.3)	5 (45.5)	2 (18.2)	3.7 (4)
Row totals of percentages do not always equal exactly 100% due to rounding						

6.3.4.3 Usefulness of the toolkit

In response to open-ended questions, on average, 11 respondents felt that 42.2% of the toolkit was used or implemented in their workplace in the short term, 11 felt that 58.5% will be used or implemented permanently, and 10 felt that 50.5% was new to their workplace existing medicine management system.

Ten respondents listed at least one specific toolkit component (n=22, Chapter 5, Section 5.3.1.1) that was implemented in their workplace (Table 6.5).

Table 6.5 Implemented toolkit components, n (%).

Implemented toolkit component	Frequency n=22 responses
Posters	8 (36.4)
Bookmarks	4 (18.2)
Stickers	3 (13.6)
Medicine identification sheet	3 (13.6)
CD-ROM	2 (9.1)
Guidelines (general)	1 (4.5)
Handouts	1 (4.5)
Column total of percentages does not equal exactly 100% due to rounding	

Respondents listed reasons why particular toolkit components were not implemented, including:

- adequate systems were already in place and they shared similarities with the toolkit components;
- similar components were already in use, such as stickers and bookmarks;
- similar toolkit components were unsuccessfully used in the past;
- the toolkit components did not match organisational policies and procedures;
- it was felt that not all toolkit components required implementation, because a few specific components were sufficient;
- there were time, resource and space implications; and
- changes to existing systems may have negative consequences.

Only one suggestion to improve the toolkit was provided. It was suggested that the toolkit could be tailored to specific RACFs according to their policies.

All respondents indicated where the toolkit was stored at their workplace. At the pharmacy it was stored in the DAA packing area (1 respondent) and dispensary (1). At the RACF, it was stored in an office (3), such as the clinical care coordinator or manager's office, the medicine room (3), or the nurses station (3).

All 11 respondents indicated other staff who were aware of the toolkit, including nurses (8 respondents), management staff (5), pharmacists (2), personal care assistants (PCAs, 1), pharmacy technicians (1), and 'all staff' (1).

6.4 Discussion

The aim of this study phase was to evaluate how effectively the intervention introduced in Phase 3, comprising the education session and toolkit (Chapter 5, Section 5.3.1.1), reduced the occurrence of DAA incidents identified in Phase 1 (Chapter 3, Section 3.3.1.3) and improved the DAA medicine supply service. Although the field notes and survey specifically evaluated the toolkit, the DAA audits and incident classifications evaluated the impact of the intervention as a whole. This research describes the impact of an evidence-based intervention that was introduced to a large study sample and was both quantitatively and qualitatively evaluated.

It was found that the overall DAA incident rate increased significantly from 11.5% pre-intervention to 21.0% of all DAAs audited post-intervention ($p < 0.001$). The DAA incident types of inaccurate division, addition, incorrect time interval and 'other' all increased significantly in Phase 4 as a proportion of the DAAs affected, compared to Phase 1 ($p < 0.001$). There was a greater than sixfold increase in the DAAs affected by inaccurate division and a greater than threefold increase in those affected by 'other' incidents that included the inadvertent packing of unknown objects or fluff. These findings may have contributed to the increased overall DAA incident rate identified in Phase 4. The DAA audits that were conducted pre- and post-intervention, with the aim to highlight problems and introduce possible solutions, demonstrated that there is a problem with the packing of DAAs that needs to be addressed. The relatively large numbers of RACFs and the widespread geographic location enables the results of this study to be generalised to the wider population.

The increased frequency of inaccurate division and 'other' incidents could be explained by the fact that these incidents occurred more commonly in Phase 4, compared to Phase 1. It is

difficult to confirm this without visiting the pharmacies and examining their specific DAA preparation processes, to determine if, and how, processes changed post-intervention compared to pre-intervention. It is also possible that the DAA audits were conducted more conservatively in Phase 4, compared to Phase 1, despite following the Phase 1 DAA auditing protocol and clarifying auditing issues with one of the research assistants who was involved in Phase 1.

A greater number of inaccurately divided tablets may have been recorded due to more conservative judgment when determining whether a tablet was inaccurately divided or not. In Phase 1, this subjectivity may have been offset by conferring with the research assistant (Chapter 3, Section 3.2.1.5), however, the PhD candidate who conducted all the Phase 4 DAA audits designed the study and undertook a large proportion of the Phase 1 audits. To address this issue, future DAA audits should include more objective methods of determining inaccurate tablet division. For example, an inaccurately divided tablet can be recorded as an incident if it represents three quarters of a tablet instead of a half, or half a tablet instead of one quarter. In this study, the incident type of 'incorrect division' encompassed incidents of this nature. Additionally, photographs could be taken of all potentially inaccurate tablet divisions and then later discussed amongst the research team.

Despite the fact that a foreign object and fluff were recorded as incidents in one and two cases respectively in Phase 1, there is a possibility that the majority of these issues were not recorded as incidents in this phase. This may explain why they appear to have occurred more commonly in Phase 4. Future DAA audits should include more objective methods of determining 'other' incidents by stipulating the minimum size of fluff and foreign objects that are to be considered a DAA incident.

The fact that DAA incidents did not occur less frequently post-intervention when considering the total number of DAAs affected, may indicate either that the intervention did not target the source of the problem, or that staff are entrenched in work practices that may take continued or multiple interventions to modify and improve. It will be important in the future to develop an intervention to target the specific DAA incident types identified in this study, with a specific focus on the pharmacy. Inadequate DAA checking may need to be targeted as many incidents, such as addition or incorrect time interval, should have been detected in the pharmacy. An intervention implementation plan that involves interaction with staff on multiple occasions, to modify existing work practices, may also be beneficial.

It was found, however, that the frequency of specific DAA incident types significantly decreased as a proportion of the total number of DAA incidents identified. Incidents of unsuitable packing, incorrect quantity and omission occurred significantly less frequently in

Phase 4, compared to Phase 1 ($p < 0.001$). Incidents of incorrect strength, incorrect medicine form and incorrect division also occurred significantly less frequently ($p < 0.05$).

As the intervention involved both an education session and a 12 component toolkit (Chapter 5, Section 5.3.1.1), it is difficult to determine which component may have mostly contributed to the findings described above. This is compounded by the fact that the majority of the intervention did not specifically target the DAA incidents identified in Phase 1. Instead, the intervention largely focused on general aspects of the DAA medicine supply service, such as DAA medicine checking and interprofessional communication, as these were identified by the Phase 2 survey (Chapter 4, Section 4.3.1.3) and focus groups (Chapter 4, Section 4.3.2.2) as factors contributing to DAA incidents. In support of the survey and focus group findings, the Victorian Quality Council has also highlighted the importance of interprofessional communication as a quality improvement intervention target, and has indicated that ineffective communication is a significant contributing factor to medicine errors and patient harm.¹²⁷ Future research should investigate the actual contribution of ineffective interprofessional communication to DAA incident occurrence.

Due to its high frequency of occurrence in Phase 1 (Chapter 3, Section 3.3.1.3), the incident of unsuitable packing was specifically targeted by the poster and CD-ROM component of the toolkit. As the poster was the most commonly implemented toolkit component, identified by the field notes (Section 6.3.2.1) and survey (Section 6.3.4.3), this may explain why unsuitable packing occurred significantly less frequently in Phase 4 (Section 6.3.1.2) as a proportion of the total incidents identified. It is likely that the poster was commonly implemented due to its relative ease of use and the fact that posters are often used in RACF and community pharmacy workplaces as a form of education.

It was also found that the DAA incidents identified in Phase 4 were generally of a lower risk category than those incidents identified in Phase 1. This may be explained by the different frequencies at which specific DAA incident types occurred in each of the two phases. Compared to Phase 4, unsuitable packing occurred significantly more frequently in Phase 1 and was usually classified as a major risk, as it often involved sodium valproate tablets that can potentially destabilise seizure control when packed into DAAs.⁷⁴ Conversely, inaccurate division and 'other' incidents occurred significantly more frequently in Phase 4. These incidents were often classified as a minor and insignificant risk, respectively, as minor variations in tablet quantities or fluff and foreign objects were perceived to have a low risk of causing adverse events.

It is concerning that eight DAA incidents were classified as catastrophic (Section 6.3.3.1). Although the difference in frequency of catastrophic incidents pre- and post-intervention

was not statistically significant, possibly due to their low frequency of occurrence, they can still lead to major consequences in the resident. Catastrophic incidents have the potential to cause major temporary injury or morbidity requiring hospital admission, or major permanent injury or morbidity with or without hospitalisation.¹⁰⁹ The eight cases identified across Phases 1 and 4 involved digoxin, sotalol and sodium valproate. Incidents of incorrect frequency of administration, incorrect quantity and incorrect strength were identified. These findings show that there is potential for RACF residents to be exposed to major harm if certain DAA incidents are not detected before medicine administration. These incidents should have been detected before the DAA left the pharmacy, indicating a lapse in checking procedures. The importance of evaluating DAA medicine supply systems and developing interventions to reduce the occurrence of DAA incidents is further highlighted with these findings.

Of the most commonly occurring DAA incident types assigned to each risk category, the frequent appearance of unsuitable packing may reflect the fact that it was the most commonly occurring incident identified in both Phase 1 and 4 (Section 6.3.1.2). In Phase 4, the presence of inaccurate division and 'other' as the most common DAA incidents assigned to the 'minor' and 'insignificant' risk categories respectively, may reflect the fact that they were the second and third most commonly occurring incident types identified in Phase 4.

Future interventions targeting the DAA medicine supply service should consider the survey responses and field notes that outlined why toolkit components were not implemented. The field notes indicated that staff-related issues were a major factor, including staff being busy or on leave and use of the toolkit requiring staff approval. The survey findings also indicated that a major disadvantage of the toolkit was its generic nature. Only one intervention was developed for the RACFs and pharmacies involved in this study. The intervention did not specifically target particular workplaces or consider local DAA incident issues, existing medicine management systems, or established policies and procedures. This may also explain why the overall DAA incident rate did not decrease in Phase 4, compared to Phase 1, in conjunction with the fact that the intervention did not specifically target particular DAA incident types to a significant extent. The survey also showed that the toolkit was sometimes stored in personal offices and not all staff were aware of it. Future interventions could be designed to address specific workplace issues and to ensure staff have access to, and are aware of, the intervention. It may also be useful to develop separate, but complementary, interventions for RACF and pharmacy staff. This may enable specific issues, such as accurate tablet halving, checking procedures, and concentration to be targeted to pharmacy staff, and communication and medicine record issues to be targeted to RACF staff.

RACF and pharmacy staff who completed the questionnaire felt that the toolkit had a positive overall impact in their workplace and was perceived to be reasonably useful. Likert scale responses indicated that the toolkit reduced the occurrence of DAA incidents, increased the accuracy and suitability of DAA medicine packing, and was useful for workplaces at least ‘moderately’ well. These findings indicate that to some extent, the toolkit was perceived to have successfully improved the DAA medicine supply service and has the potential to be used as a model for future intervention studies targeted at this service.

There is currently no published research that has developed an evidence-based intervention to specifically target DAA incidents and improve the DAA medicine supply service. However, a comparison between this study and others that have evaluated interventions targeting other pharmacy-based practices can still occur, particularly as DAA preparation can be considered a form of medicine dispensing.¹³ James *et al.* examined whether an automated dispensing system could reduce the occurrence of dispensing errors that had not left the hospital pharmacy.¹⁵⁴ Similarly to the focus of this study, James *et al.* examined the effect of an intervention on pharmacy dispensing errors.¹⁵⁴ In contrast to this study, the overall rate of dispensing errors significantly reduced post-intervention (0.3%) compared to pre-intervention (0.6%) ($p < 0.0001$), perhaps explained by its impact on mental workload and stressors,¹⁵⁴ its specificity for the medicine dispensing process at the pharmacy, and its focus on only one workplace. Intervention compatibility to existing needs, values and routines, can promote implementation,¹⁰⁶ and compatibility may be achieved when interventions are specifically designed for singular workplaces. This specificity is in contrast to the generic intervention developed in this study (Chapter 5, Section 5.3.1.1). Fitzpatrick *et al.*’s automated dispensing system implemented in a hospital pharmacy also showed a 16% reduction in dispensing errors identified at the final checking stage.⁹² The authors noted that the reduction in errors associated with selecting the wrong medicine or strength could be explained by the fact that the dispensing system was designed to correctly select medicine products.⁹²

Verrue *et al.*’s review of pharmacist-involved interventions targeting RACF medicine prescribing can highlight the potential success of these types of interventions,¹⁵⁵ where pharmacists were involved in medicine reviews, multidisciplinary teams, and educating prescribers, nurses and other RACF staff about medicine use.¹⁵⁵ The eight reviewed trials showed mixed evidence for intervention effectiveness, though it was acknowledged that greater pharmacist involvement in RACFs may increase prescriber and nurse medicine knowledge and awareness.¹⁵⁵ Additionally, two of the four studies that only involved pharmacists in the intervention, did result in positive outcomes.¹⁵⁵ Positive findings were found when pharmacists established professional relationships, conducted problem-based

nurse education, participated in medicine reviews, and consulted with the resident and carer.¹⁵⁵ Significant positive differences were seen in prescribed and administered medicines, medicine changes, resident falls, and cost savings.¹⁵⁵ Although features of these interventions shared similarities with the intervention developed in this study, they resulted in overall positive outcomes.¹⁵⁵ This difference may be explained by their choice of outcome measures, primarily targeting medicine prescribing,¹⁵⁵ as opposed to the present study that primarily aimed to reduce the occurrence of DAA incidents. It is possible that interventions of this nature may be more successful at improving medicine prescribing issues in RACFs, rather than reducing the occurrence of DAA incidents.

It has been shown that the intervention developed in this study has the potential to benefit DAA medicine supply services and should be refined using the evaluation findings detailed in this and previous chapters. When outlining qualities of best practice and strategies for improvement, medicine management policies and guidelines should consider that DAA incidents can occur and should contemplate the principles of the intervention developed in this study.

Strengths and limitations

A number of strengths and limitations of the present study phase can be identified. It is a strength that a large number of RACFs and pharmacies were involved in the final evaluation of the intervention. Forty-five RACFs were retained in the study and involved in the Phase 4 DAA audits, from a recruited total of 49 (Chapter 3, Section 3.3.1.1). This low attrition rate demonstrates that the intervention was not burdensome on RACFs and that further research can feasibly be conducted in this setting. Additionally, the DAA audit repeated in Phase 4, validated the Phase 1 DAA incident rate findings and showed that the high incident rate identified was not an aberration, but the result of a careful DAA auditing process that was guided by protocols.

A limitation of this study phase includes potential confounders that could have influenced the intervention, as a result of the before-and-after study design. Potential confounding factors included changes in pharmacy or RACF staff, changes in DAA preparation methods, and changes in DAA supplying pharmacies.

Staff changes between Phase 1 and 4 may have influenced how DAAs were checked, how well DAA incidents were identified and ultimately how accurately DAAs were prepared. If staff changes occurred after the Phase 3 intervention was introduced (Chapter 5, Section 5.2.2.3), staff may not have been aware of the intervention and may not have implemented its components. Additionally, not all staff at each workplace were introduced to the

intervention. In most cases, the intervention was only introduced once per workplace, on the assumption that staff would communicate with each other about the high rates of DAA incidents identified and strategies proposed to reduce the incident rate. Staff from 12 pharmacies (30.8% of the pharmacies supplying DAAs to the Phase 4 RACFs) were also not introduced to the intervention at all, though their workplace was still provided with a toolkit.

It is also possible that RACF staff did not see DAA incidents as their responsibility (Chapter 4, Section 4.3.2.2), but that of the supplying pharmacy, and thus did not actively engage in the intervention. The Theory of Planned Behaviour (Chapter 2, Section 2.2.3) supports this idea, as it describes how an individual's behaviour is influenced by their intention to perform that behaviour and their attitude concerning the behaviour.^{106, 108} In Verrue *et al.*'s study, a pharmacist-led educational intervention concerning RACF medicine administration practices targeted a process that RACF staff are specifically involved in, and for which they would be expected to feel responsible.¹⁴⁹ This may explain the positive outcomes of their study, including significantly reduced medicine preparation and administration error rates ($p < 0.05$).¹⁴⁹

A few pharmacies had also significantly changed how their DAAs were prepared and some RACFs had changed the format of their medicine records. Some blister packs audited in Phase 4 were prepared via automation, instead of manually, and some RACFs incorporated electronic medicine records into their medicine management processes. Automated DAA preparation may be postulated to improve the accuracy of DAA medicine packing, however, the high incident rates observed in the audited sachets from this study would suggest that automation may not reduce the occurrence of DAA incidents. Additionally, seven new DAA supplying pharmacies (17.9% of all pharmacies) were represented in the Phase 4 DAA sample, compared to Phase 1, though they contributed only 138 DAAs (5.8%) to the total DAA sample audited.

It was a limitation that minimal resident medical information was recorded during the DAA audits and was thus not available for the incident classifications. Information that was not recorded included the current health status of the resident, their co-morbidities and medicine indications. Due to the large number (1,454) of DAA incidents identified in this study, it was impractical to record this information. Future research should consider how to feasibly record this information, to allow for more informed DAA incident classifications. Some DAA incident information was also not comprehensively recorded on the DAA audit forms, such as the extent or nature of inaccurately divided tablets (e.g. under- or over-dosing) and the extent of damaged medicines. Although photographs were taken of some DAA

incidents, this did not routinely occur and they were therefore not used for the incident classifications.

6.5 Conclusion

This study phase has highlighted the importance of ongoing and wide-scale evaluation of established pharmacy medicine supply services. It recorded high rates of incidents in DAAs supplied by Victorian community pharmacies for RACFs, both before and after the introduction of a multifactorial intervention to target these incidents. Although the intervention did not reduce the overall DAA incident rate, certain DAA incident types did occur less frequently post-intervention and the overall risk associated with the DAA incidents decreased.

Health professionals provided generally positive feedback regarding the toolkit's impact on their workplaces, though reasons why it was not implemented should also be considered. This component of the intervention was therefore perceived by health professionals to improve the DAA medicine supply service to some extent. It was identified that the generic nature of the intervention and elements of subjectivity associated with certain aspects of the Phase 4 DAA audits may have influenced the higher overall DAA incident rate identified post-intervention. Future research should conduct wide-scale evaluation studies and produce interventions that are targeted for local settings and that have greater specificity for particular DAA incidents. The next chapter summarises the study and its findings and provides direction for further research in this area.

7 Summary, recommendations and conclusion

7.1 Summary

Dose administration aids (DAAs) are widely used in Australian residential aged care facilities (RACFs)¹³ and in the community, to organise medicines according to the day of the week and time of the day in which they must be taken. These devices are often relied on by RACF staff to manage the large amount of medicines used by their residents.^{22, 31, 156} Older residents of RACFs are vulnerable to medicine-related problems (MRPs)³¹ and Australian RACFs are increasingly employing staff other than nurses to be involved in resident care⁴³ and to administer medicines. As a result, it is important that medicine systems used in RACFs, such as DAAs, are continually evaluated to ensure that they meet expected high standards of safety, quality and efficacy.

In Australia, DAAs are commonly supplied by community pharmacies. Medicines may be packed into the DAA from their original containers, either manually or via automation, at the community pharmacy or at a DAA packing company. Without regard to the method or location of preparation, the supplying community pharmacist is responsible for the accuracy and suitability of the final DAA that is supplied to the RACF.⁷⁷

DAA medicine packing has not been extensively studied in either an Australian or international context. The limited available literature has shown that medicines may be inaccurately or unsuitably packed into DAAs, termed DAA incidents.¹⁰⁻¹³ Study design limitations were identified in the available studies (Chapter 1, Section 1.4.2) and none appeared to comprehensively and systematically examine contributing factors or describe strategies suggested by health professionals, to reduce the occurrence of DAA incidents. Additionally, there is no published literature describing inductively derived interventions aimed at improving this DAA medicine supply service and reducing the occurrence of DAA incidents (Chapter 1, Section 1.4.4). The overall aim of this study, conducted in four phases, was to determine the extent of DAA incidents in a large-scale Victorian sample of RACF DAAs and if problems were identified, as expected from previous literature, to introduce an evidence-based, stakeholder-derived intervention, targeted at this medicine supply service.

To determine the types and frequencies of incidents occurring in DAAs supplied by 40 Victorian community pharmacies to 49 RACFs, DAA audits were conducted (Chapter 3, Section 3.2.1). Following the audits, a survey (Chapter 4, Section 4.2.1) and three focus groups (Chapter 4, Section 4.2.2) were used to identify health professionals' perceptions

regarding the factors contributing to DAA incidents and potential strategies to reduce their occurrence.

These findings informed the development of a multifactorial intervention, comprising a 30 minute education session and 12 component toolkit (Chapter 5, Section 5.3.1.1). The toolkit included a guideline outlining what medicines should not be packed into DAAs, a research article concerning sodium valproate instability within DAAs, posters, bookmarks and stickers for the medicine record, a CD-ROM with a presentation, a handout with the CD-ROM presentation slides, a question, answer and reflection handout, template certificates, a medicine identification sheet, a DAA incident policy and procedure, and DAA guidelines for the RACF or pharmacy environment. The intervention was introduced to staff from 45 of the RACFs involved in the DAA audit, and from 29 of their affiliated community pharmacies. A survey was used to evaluate health professionals' initial perceptions of the potential usefulness and effectiveness of the intervention (Chapter 5, Section 5.2.3).

The intervention was then evaluated more extensively (Chapter 6, Section 6.2) by:

- repeating the DAA audits in 45 of the 49 RACFs (where the intervention was introduced), to determine if the number of DAA incidents reduced post-intervention;
- taking field notes, to record which toolkit components were implemented and staff perceptions regarding the toolkit usefulness;
- classifying the DAA incidents according to a risk category, to determine if there was a change in the overall risk associated with incidents identified post-intervention compared to pre-intervention; and
- conducting a survey, to determine health professional perceptions of the toolkit after a longer follow-up period.

The intervention did not reduce the overall DAA incident rate post-intervention (Chapter 6, Section 6.3.1.4). The incident rate increased significantly from 11.5% to 21.0% of all DAAs audited ($p<0.001$). The number of DAAs affected by particular incident types did not decrease, while significant increases were seen in the number of DAAs affected by incidents of addition, inaccurate division, incorrect time interval and 'other' incidents ($p<0.001$) (Chapter 6, Section 6.3.1.4).

Certain DAA incident types, however, occurred significantly less frequently post-intervention when compared to the total number of DAA incidents identified. These incidents included unsuitable packing ($p<0.001$), incorrect quantity ($p<0.001$), omission ($p<0.001$), incorrect strength ($p<0.05$), incorrect division ($p<0.05$) and incorrect form

($p < 0.05$). The DAA incidents identified post-intervention were also of a lower risk category than those identified pre-intervention (Chapter 6, Section 6.3.3.1). There were significant decreases in the proportion of DAA incidents that were classified as ‘major’ or ‘moderate’ risk and significant increases in those classified as ‘minor’ or ‘insignificant’ risk ($p < 0.001$). Additionally, health professionals felt that the intervention had the potential to be, or was, useful and effective (Chapter 5, Section 5.3.3 and Chapter 6, Section 6.3.4).

Confounding factors may have influenced the higher DAA incident rate in Phase 4, such as changes in the RACF or pharmacy workplace that could not be controlled with a before-and-after study design (Chapter 6, Section 6.4). Additionally, the intervention’s lack of specificity for the RACF or pharmacy workplace, specific workplace issues or existing medicine management systems, and the particular DAA incident types identified in the DAA audits, were identified as limitations.

While the generalisability of these findings is limited by the specific workplace environments of the study sample, this study has both attempted to address a shortcoming of the DAA medicine supply service, being the occurrence of DAA incidents, and comprehensively evaluate the impact of the resulting intervention that was developed.

7.2 Recommendations

The results of this study indicate that there are limitations with the current system of DAA medicine supply from Victorian community pharmacies to RACFs. DAA incidents of inaccurate and unsuitable packing have been shown to occur in current systems and it is therefore recommended that DAA services are regularly evaluated and targeted interventions developed.

Despite introducing an intervention, the two DAA audits in this study conducted pre- and post-intervention, identified relatively high rates of incidents in DAAs supplied by Victorian community pharmacies to RACFs. This significant problem may be widespread and a larger, nationwide multi-centre audit is required, to validate these findings and determine the extent of DAA incident occurrence across Australia.

This study has developed an intervention template that can be refined using evaluation findings (Chapter 5, Section 5.3.3 and Chapter 6, Section 6.3). Future research could use the principles and components of the intervention developed in this study and implement them in a large representative sample of RACFs and community pharmacies throughout Australia. Using similar methods of evaluation such as DAA audits, surveys, field notes and incident classifications, comparison can occur with the findings from this study.

Additionally, future interventions should target specific DAA incidents and the pharmacy DAA preparation process. A limitation of the intervention developed in this study was its generic nature (Chapter 6, Section 6.4). Although it considered health professional perceptions of contributing factors to incidents and strategies to reduce their occurrence, identified by surveys and focus groups (Chapter 4, Section 4.3.1.3, Section 4.3.1.4 and Section 4.3.2.2), the intervention did not focus on specific workplace environments or focus on specific DAA incident types, other than unsuitable packing. Improving interprofessional communication was a major focus of the intervention (Chapter 5, Section 5.3.1.1), though if this was not the major cause of the incidents identified, it may not have reduced the occurrence of DAA incidents. There is the potential that an intervention designed more specifically for the pharmacy workplace and specifically focussing on the DAA packing and checking process, could have reduced the overall incident rate identified post-intervention. This is supported by the fact that incidents of unsuitable packing occurred less commonly post-intervention, compared to pre-intervention, when considering the total number of DAA incidents identified. This was the only specific DAA incident type that was significantly targeted via intervention components, including the poster and a section of the CD-ROM presentation (Chapter 5, Section 5.3.1.1). Further research could investigate how significantly DAA preparation processes at the pharmacy contribute to the occurrence of DAA incidents. Additionally, interventions that are more targeted for specific workplace environments, such as the RACF or pharmacy, and specific workplace issues, could more successfully reduce the occurrence of DAA incidents and improve the DAA medicine supply service.

A limitation identified in this study was the difficult and subjective nature of identifying certain incident types such as inaccurate tablet division and 'other' incidents. Future DAA audits should incorporate protocols that allow for more objective determination of these incidents.

An evaluation of DAAs provided to individuals living in the community could also enable comparisons between medicine supply services that do, and do not, involve a multidisciplinary health care team. Community users of DAAs do not have a health professional support network as extensive as that seen in RACFs and could benefit from evaluation of their medicine supply services.

Finally, incidents in both blister packs, more commonly prepared manually, and sachets that are prepared via automation, were identified. Though it is generally perceived that automation may be more accurate, as opposed to systems largely relying on human input, a larger proportion of sachets experienced incidents compared to blister packs in this study.

One possible explanation for this finding could be that human-driven processes are still involved in the automated preparation of sachets, leading to the identified incident rate. Further research is needed to explore how frequently specific DAA incident types occur in sachets prepared via automation and the source of these incidents.

7.3 Conclusion

This study has identified that DAA incidents of inaccurate and unsuitable medicine packing occur in a large number of DAAs supplied by Victorian community pharmacies to RACFs. The importance of regularly evaluating this medicine supply service and introducing targeted quality improvement interventions has been highlighted. The multifactorial, evidence-based, stakeholder-derived intervention that was introduced to RACFs and community pharmacies in this study did not reduce the overall DAA incident rate identified post-intervention, compared to pre-intervention. However, some positive aspects of the intervention were highlighted through a variety of evaluation methods. Staff at the workplaces where the intervention was introduced generally perceived that it could reduce the occurrence of DAA incidents and improve the DAA medicine supply service. Additionally, the overall risk associated with incidents identified post-intervention was lower than the overall risk associated with incidents identified pre-intervention. Lastly, though the total number of identified incidents increased post-intervention, the frequency of some specific DAA incident types decreased in occurrence when compared to the total number of DAA incidents identified.

Even though the intervention development was informed by health professionals, it may not have achieved its primary outcome due to its overall lack of specificity for the RACF or pharmacy workplace and for specific DAA incident types. Further research should investigate this limitation in more detail.

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Appendices

Appendix 1: Approval of study by Monash University Human Research Ethics Committee



MONASH University

Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

Date: 15 November 2010
Project Number: CF10/1108 - 2010001253
Project Title: A review of dose administration aids: Improving medicine management
Chief Investigator: Dr Safeera Hussainy
Approved: From: 15 November 2010 to 15 November 2015

Terms of approval

1. The Committee has granted a privacy exemption for this research under The Statutory Guidelines on Research issued for the purposes of HPP 1.1(e)(iii) and 2.2(g)(iii) – *Health Records Act 2001 (Vic)* and Section 95A of the *Privacy Act 1988*.
2. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. **Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.**
3. Approval is only valid whilst you hold a position at Monash University.
4. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
5. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
6. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
7. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
8. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
9. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
10. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
11. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
12. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

Professor Ben Canny
Chair, MUHREC

Cc: Assoc Prof Jennifer Marriott; Ms Julia Gilmartin; Mr Rohan Elliott; Prof Peteris Darzins

Postal – Monash University, Vic 3800, Australia
Building 3E, Room 111, Clayton Campus, Wellington Road, Clayton
Telephone +61 3 9905 5490 Facsimile +61 3 9905 3831
Email muhrec@monash.edu.au <http://www.monash.edu.au/researchoffice/human/>
ABN 12 377 614 012 CRICOS Provider #00008C

Appendix 2: Approval of study by Barwon Health research office



Office for Research
Telephone: 03 5226 7920
Facsimile: 03 5226 7906
e-mail: HREC@BarwonHealth.org.au



The Geelong Hospital,
Ryrie Street P.O. Box 281
Geelong Victoria 3220

Correspondence:

Ms Julia Gilmartin
PhD candidate at Monash
Department of Pharmacy Practice
Centre for Medicine Use and Safety
Faculty of Pharmacy and Pharmaceutical Sciences
Monash University (Parkville Campus)
381 Royal Parade
PARKVILLE VIC 3052

LOW RISK APPROVAL STATEMENT

HREC Project Number 11/16
Site Barwon Health
Date Approved 6/04/2011
Principal Investigator Julia Gilmartin
Title: A review of dose administration aids: Improving medicine management
Co investigators Dr. Safeera Hussainy (supervisor), Associate Professor Jennifer Marriott, Rohan Elliott, Peteris Darzins, Denise van den Bosch
Student names

Thank you for submitting the above for our consideration. Phase I of your project to determine the accuracy of dose administration aids and to evaluate any identified medication discrepancies associated with the aids is approved and you may commence. Approval is granted on the basis that this is a low risk project, as defined by the "National Statement on Ethical Conduct in Human Research" sections 2.1.6 to 2.1.7.

Your obligations under this approval include notifying the Committee of any intent to deviate from the approved protocol and of the occurrence of any untoward events. You may submit an amendment for review of future phases of your project under this initial application.

Since you are not a Barwon Health employee, but will be accessing patient information on the Barwon Health premises, we require that you and any research assistants coming on site complete a privacy, confidentiality and security agreement (see attachment).

Please note that your final report is due on completion and in the interim progress reports are due annually on the anniversary of your approval.

06/04/2011

Project Number 11/16

1 of 2

Should you require any further information concerning the Committee's approval of your research or have any concerns regarding the reporting requirements please contact the Office for Research on 03 5226 7920.

In all future correspondence regarding your study please quote the Project Number and full title of your research project.

On behalf of the Committee, best wishes for your project.



Mary Lou Chatterton, Pharm.D.
Chair, Research Review Committee

Barwon Health operates in accordance with the "National Statement on Ethics Conduct in Human Research", National Health and Medical Research Council, 2007

Cc: Maree Townsend

06/04/2011

Project Number 11/16

2 of 2

Appendix 3: Approval of study by Ballarat Health Services and St John of God Healthcare Human Research Ethics Committee

Ballarat Health Services & St John of God Healthcare HREC
Phone: 03 53204278
Email: diannes@bhs.org.au



Dr Safeera Hussainy
Principal supervisor
Centre for Medicine Use and Safety
Faculty of Pharmacy and Pharmaceutical Sciences
381 Royal Parade
Parkville 3052

16 December 2010

Dear Dr Hussainy

Study title: A review of dosage administration aids: Improving medicine management.

HREC Reference Number: HREC/10/BHSSJOG/71

Decision of the HREC sub-committee

The HREC sub-committee has approved the above application on the basis of the information provided and recognition of prior ethical review. This approval is valid from the 16th December 2010.

Approval

Approval is given in accordance with the research conforming to the *National Health and Medical Research Council Act 1992* and the *National Statement on Ethical Conduct in Human Research (2007)*.

Exemption

The HREC Sub-committee endorses the exemption to residents' right to privacy and confidentiality under The Statutory Guidelines on Research issued for the purposes of HPP 1.1(e)(iii) and 2.2(g)(iii) – Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988

Approved documents

Documents reviewed and approved by the subcommittee were:

Document	Date
Application: Monash HREC	
Covering Letter: email	09 December 2010
Participant Information Sheet/Consent Form: Residential care facility	
Summary/Synopsis	01 August 2010
BHS privacy and confidentiality agreement: signed Julia Gilmartin	13 December 2010

The following conditions of approval apply:

Protocol Amendments

Any changes to the protocol must be submitted to the HREC for approval and should be accompanied by a summary outlining the reasons for the change together with an indication of any ethical implications. Two copies of amended documents must be provided: one with the amended version number or date clearly stated in the footer and another clearly highlighting the amended text.

Project Reports

The committee require that you provide notification of the project commencement date, annual progress reports, notification of conclusion and a copy of the final report and any publications arising from the project.

Please quote the reference number from the title of this letter in all correspondence.

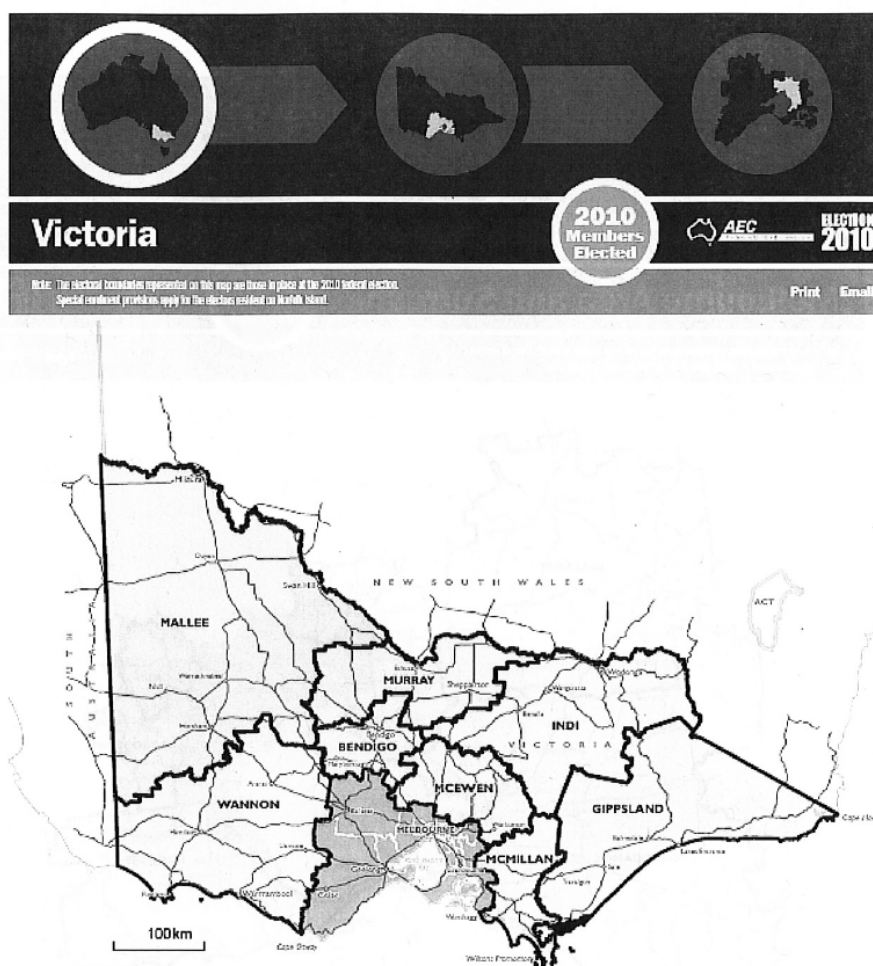
The HREC wishes you and your colleagues every success in your research.


Yours sincerely



Dr Susan Joy Shea
Secretary
Ballarat Health Services & St John of God Healthcare HREC

Appendix 4: Maps of the 2010 Victorian federal electorates

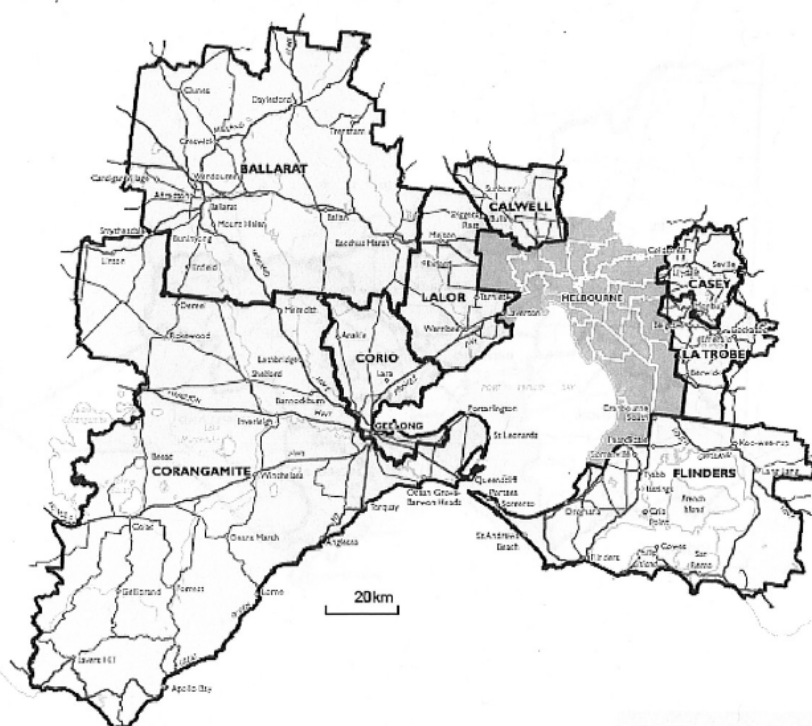


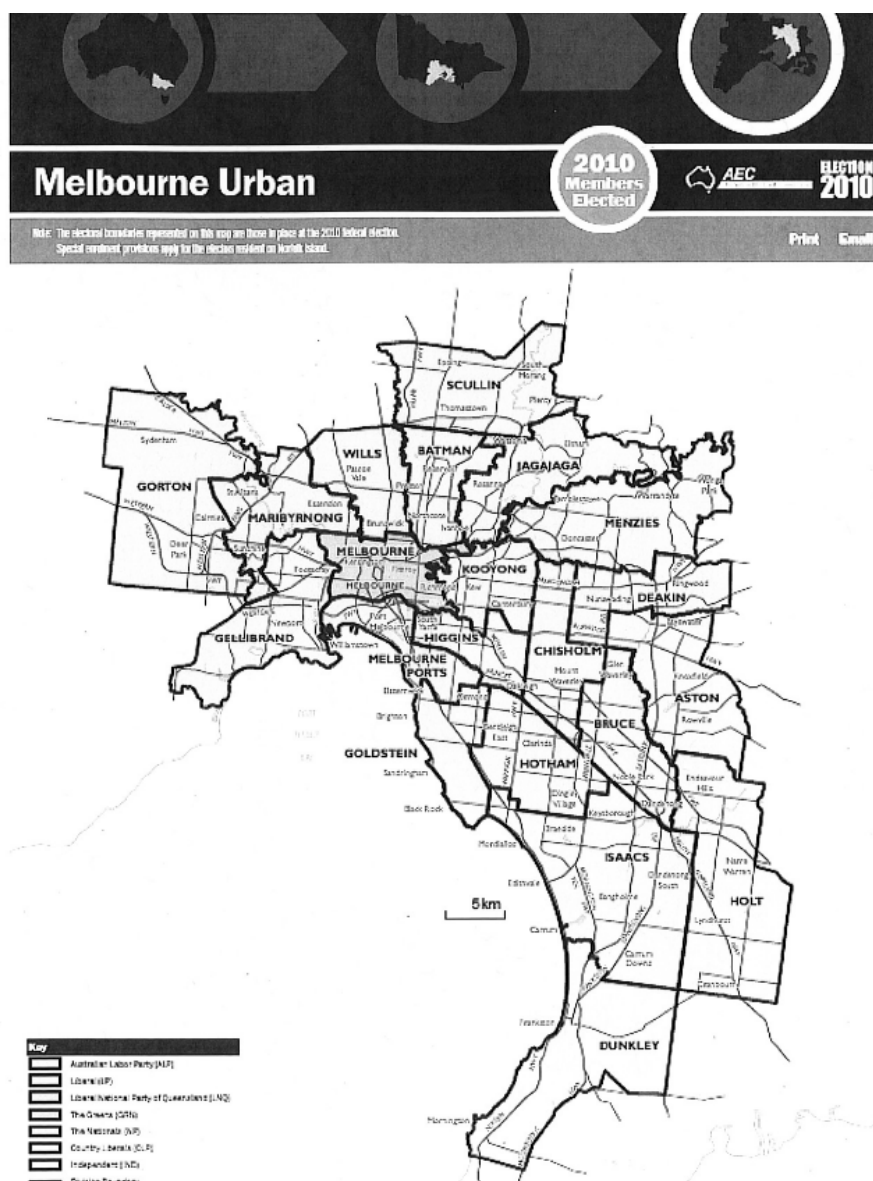


Melbourne Area and Surrounds **2010 Members Elected**

Note: The electoral boundaries represented on this map are those in place at the 2010 federal election. Special provisions apply to the electors resident on Norfolk Island.

Print Email





Appendix 5: Residential aged care facility letter of invitation



Letter of Invitation

Name of Residential Aged Care Facility:
Address:

Attention: Director of Nursing/ Residential Aged Care Facility Director, Proprietor or Manager

RE: Dose Administration Aid Research Project

Project Title: "A Review of Dose Administration Aids: Improving Medicine Management"

Dear

I am writing to you regarding a research project being conducted by the Centre for Medicine Use and Safety at the Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, into the accuracy of dose administration aids (DAAs) packed for residential aged care facility (RACF) residents. This project will form part of the research towards attainment of the degree of Doctor of Philosophy (PhD).

The aim of the research is to determine the accuracy of DAAs, supplied by pharmacies or automated packing plants, to RACF residents. DAAs packed manually or via automated means will be examined. It is anticipated that the results of this project will assist in the construction of an intervention/guideline/protocol to improve the DAA packing accuracy and thus ensure RACF residents are receiving the correct medicines according to their medicine records. Currently, there has been little research done in this area in Australia.

We are seeking expressions of interest from RACFs as potential participants for this project, which is planned to begin in January 2011. We have obtained approval from the Monash University Human Research Ethics Committee for this project.

It is expected that RACFs and their residents will not be disadvantaged or put at risk in this project. The project involves recording and comparison of residents' medicine records and DAAs so identification of discrepancies (incidents) can occur. As neither experimental designs or treatments are being applied to residents, nor will residents' identities be retained, individual residents are not considered participants in this project and will not be required to provide informed consent. The independent work of the student researcher and/or other project staff, to be completed alone and conducted on-site, is estimated to be around 5-10 minutes for every DAA. If an incident is detected, up to 10 minutes is required of the RACF to verify each incident, notify the responsible packing location and undergo any standard incident reporting procedures already in place at the RACF. This comparison of DAAs and medicine records will occur on 2 separate occasions approximately 12-15 months apart, to allow for an intervention (such as the development of a new guideline or protocol to be used in DAA packing and/or administration) to be implemented at the RACF and/or pharmacy and/or automated packing plant during that time.

For your convenience I have included with this invitation, an explanatory statement, permission letter and consent form. Should you wish to participate in this project, please fill in the relevant details on both the consent form and permission letter and return them in the reply-paid envelope supplied, to Julia Gilmartin in the Department of Pharmacy Practice.

Should you have any questions about the project please feel free to contact me. Additionally, my academic supervisors, Dr Safeera Hussainy and A/Prof Jennifer Marriott, will also be available to answer any questions you may have.

I look forward to hearing from you soon.

Sincerely,

Julia Gilmartin
Pharmacist and PhD Candidate
Department of Pharmacy Practice
Centre for Medicine Use and Safety
Faculty of Pharmacy and Pharmaceutical Sciences, Monash University

[Redacted signature]

Dr Safeera Hussainy
Lecturer, Academic Supervisor
Department of Pharmacy Practice
Centre for Medicine Use and Safety
Faculty of Pharmacy and Pharmaceutical Sciences, Monash University

[Redacted signature]

A/Prof Jennifer Marriott
Associate Professor, Academic Supervisor
Department of Pharmacy Practice
Centre for Medicine Use and Safety
Faculty of Pharmacy and Pharmaceutical Sciences, Monash University

[Redacted signature]

Appendix 6: Residential aged care facility explanatory statement

MONASH University



Explanatory Statement – Residential Aged Care Facilities

Project title:

A Review of Dose Administration Aids: Improving Medicine Management

This information sheet is for you to keep.

My name is Julia Gilmartin B.Pharm (Hons) and I am conducting a research project with Dr Safeera Hussainy and Associate Professor Jennifer Marriott at the Centre for Medicine Use and Safety, Department of Pharmacy Practice, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University. I am conducting this research project towards a Doctor of Philosophy at Monash University. This means that I will be writing a thesis, which is the equivalent of a short book/ several journal articles and reports. We presently do not have project funding.

Why did you choose this particular person/group as participants?

We have obtained the contact details of the residential aged care facilities (RACFs) we approach from publicly available databases on-line or telephone directories, The Aged Care Standards and Accreditation Agency, The Divisions of General Practice or via professional body meetings/seminars attended by health professionals. The RACFs approached have been asked to participate because they utilise dose administration aids (DAAs) in the medicine management of their residents, which have been packed by pharmacies or automated packing plants.

The aim/purpose of the research

The aim of this project is to determine the accuracy of manually or automatedly packed DAAs, supplied to RACFs in metropolitan/regional Victoria, by pharmacies or automated packing plants. Accuracy of DAAs will be determined by identifying incidents, that is, comparing them to the RACF residents' medicine records and recording the number and nature of discrepancies that have occurred, as well as identifying packed medicines that should not be packed according to relevant pharmaceutical guidelines and medicines that are damaged, incorrectly halved or altered in an inappropriate way. An intervention will then be devised and implemented at pharmacies and/or automated packing plants and/or RACFs to reduce the DAA packing incident rate. The success of the intervention will be investigated by a second comparison of packed DAAs alongside RACF resident medicine records. I am conducting this research to validate our hypothesis that incidents occur in DAAs supplied to RACFs and that a difference in incident rates exist between those DAAs packed via automation and those packed manually. This will in turn improve the accuracy of DAA delivered medicines to RACF residents.

Possible benefits

The benefit to RACFs from participation in this project will be a potential increase in the accuracy of DAAs that are utilised in the medicine management of their residents, through

the development of an intervention/guideline/protocol that addresses the issue of DAA packing incidents.

What does the research involve for your facility?

Phase 1 (out of a total of 3 Phases) participation:

At the first visit to the facility, the RACF will be required to orientate the student researcher and/or other project staff to their medicine management systems, in particular, their DAA service provision, DAAs and resident medicine records. A questionnaire may be used to assist in the orientation of the researchers to the medicine management systems, in particular, DAA service provision.

A student researcher and/or other project staff will then work independently to compare packed DAAs against resident medicine records and document any incidents and other relevant medicine-related information (photographs of DAA out-lays may be taken if needed).

Any identified incidents will be notified to the RACF, which will then verify the incident and notify the responsible DAA packing location for correction. In this way, no identified incident will be transferred to the RACF resident.

Phase 2 (out of a total of 3 Phases) participation:

An intervention (such as the development of a new guideline or protocol to be used in DAA packing and/or administration) will be devised and implemented to improve the accuracy of packed DAAs.

A questionnaire may be used to evaluate the intervention.

Phase 3 (out of a total of 3 Phases) participation:

Repeat Phase 1 to determine if the intervention improved the accuracy of packed DAAs.

How much time will the research take at your facility?

Phase 1 and 3 participation:

Orientation to the facility is estimated to take up to 1 hr when the student researcher and/or other project staff are welcomed on-site for the first time. If a questionnaire is used for this purpose, it is anticipated to take approximately 5-10 minutes to complete.

Independent DAA and medicine record examination by the student researcher and/or other project staff is estimated to take up to 5-10 minutes per DAA (to be completed in Phase 1 and repeated in Phase 3). The student researcher and/or other project staff will complete this task alone, unless an incident is detected.

Resident medicine record examinations against DAAs will occur over 1 to 2 days at the RACF, on two separate occasions up to 15 months apart. The total duration of Phase 1 and 3 respectively for the whole study, will be up to 6 months. The total data collection period for the whole study is anticipated to occur over 2 years.

Involvement of the RACF if an incident is identified is estimated to take up to 10 minutes per identified incident (which may follow the standard operating procedures already established at the RACF).

Phase 2 participation:

Involvement of the RACF in intervention implementation is estimated to take up to 1 hour on two separate occasions, which may form part of a morning tea or an existing scheduled staff meeting.

The total duration of Phase 2 for the whole study will be up to 6 months.

If a questionnaire is used to evaluate the intervention, it is anticipated to take approximately 10 minutes to complete.

Inconvenience/discomfort

It is expected that RACFs and their residents will not be disadvantaged or put at risk of harm in this project. All data collected will be de-identified. The involvement of an employer and their RACF in this study will not put at risk the employment of any individual, if they were found to be involved in an incident.

Payment

There is no financial incentive involved for this project.

Can I withdraw from the research?

Being in this project is voluntary and you are under no obligation to consent to participation. If you do consent to participate, you may withdraw at any time, however, any incident recording or other documentation that has occurred prior to your withdrawal will be kept on record. This will comprise anonymous data.

Confidentiality

In documenting incidents, as well as DAA and medicine record information, residents will not be identified by any means (e.g. name or room number) in the documentation. The names of participating RACFs will not be disclosed and only group data reported.

Storage of data

Storage of the data collected will adhere to the University regulations and will be kept on University premises in a locked cupboard/filing cabinet for 5 years. A report of the project may be submitted for publication, but individual RACFs and their residents will not be identifiable in such a report. All reported information will be de-identified and RACFs/pharmacies/automated packing plants will not be identified by name.

Use of data for other purposes

It is not intended that this data be used for any other purpose from which it is primarily obtained.

Results

If you would like to be informed of the aggregate research finding, please contact myself or my supervisors (see below). The findings will be accessible after all data is collated.

If you would like to contact the researchers about any aspect of this study, please contact myself and/or the Chief Investigators:	If you have a complaint concerning the manner in which this research CF10/2208 – 2010001253 is being conducted, please contact:
<p>Julia Gilmartin B.Pharm (Hons) PhD Candidate Centre for Medicine Use and Safety, Monash University. [REDACTED]</p> <p>Dr Safeera Hussainy Lecturer, Academic Supervisor Centre for Medicine Use and Safety, Monash University. [REDACTED]</p> <p>Associate Professor Jennifer Marriott Academic Supervisor. Centre for Medicine Use and Safety, Monash University. [REDACTED]</p>	<p>Executive Officer, Human Research Ethics Monash University Human Research Ethics Committee (MUHREC) Building 3e Room 111 Research Office Monash University VIC 3800</p> <p>[REDACTED]</p>

Thankyou.

Julia Gilmartin B.Pharm(Hons)

Appendix 7: Residential aged care facility consent form

Consent Form – Residential Aged Care Facilities

A Review of Dose Administration Aids: Improving Medicine Management

NOTE: This consent form will remain with the Monash University researcher for their records

I agree to take part in the Monash University research project specified above. I have had the project explained to me, and I have read the Explanatory Statement, which I keep for my records. I understand that agreeing to take part means that:

I agree to allow the researcher to:

have access to the premises ☐ Yes ☐ No

have access to residents' medicine records ☐ Yes ☐ No

have access to residents' dose administration aids ☐ Yes ☐ No

speak to staff ☐ Yes ☐ No

inform/consult staff in regards to identified dose administration aid incidents ☐ Yes ☐ No

make de-identified records, of information obtained from the dose administration aids packed for residents and their medicine records and other relevant medicine-related information, for the purpose of comparison and incident detection ☐ Yes ☐ No

speak to staff regarding an intervention/guideline/protocol designed to improve the dose administration aid service provision ☐ Yes ☐ No

take completely de-identified photographs of DAAs and medicine records for the purpose of incident detection and ease of recording ☐ Yes ☐ No

and

I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project without being penalised or disadvantaged in any way.

and

I understand that any data that the researcher extracts from the discussions with staff and resident medicine records and dose administration aid comparisons, for use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

and

I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party.

and

I understand that data from the discussions with staff and medicine records and dose administration aid comparisons, will be kept in secure storage and accessible to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research and I understand that the involvement of the residential aged care facility in this study will not put at risk the employment of any individual, if they were found to be involved in an incident.

Participant's name

Signature

Date

<p>If you would like to contact the researchers about any aspect of this study, please contact myself and/or the Chief Investigators:</p>	<p>If you have a complaint concerning the manner in which this research CF10/2208 – 2010001253 is being conducted, please contact:</p>
<p>Julia Gilmartin B.Pharm (Hons) PhD Candidate Centre for Medicine Use and Safety, Monash University. [REDACTED]</p> <p>Dr Safeera Hussainy Lecturer, Academic Supervisor Centre for Medicine Use and Safety, Monash University. [REDACTED]</p> <p>Associate Professor Jennifer Marriott Academic Supervisor. Centre for Medicine Use and Safety, Monash University. [REDACTED]</p>	<p>Executive Officer, Human Research Ethics Monash University Human Research Ethics Committee (MUHREC) Building 3e Room 111 Research Office Monash University VIC 3800</p> <p>[REDACTED]</p>

Appendix 8: Permission letter

Permission Letter

(This form may be copied onto an organisation letterhead if desired)

Permission Letter for “A Review of Dose Administration Aids: Improving Medicine Management”

_____ <insert date>

Julia Gilmartin B.Pharm (Hons)
Centre for Medicine Use and Safety
Department of Pharmacy Practice
Faculty of Pharmacy and Pharmaceutical Sciences
381 Royal Parade Parkville
MONASH UNIVERSITY VIC 3052
[REDACTED]

Dear Julia Gilmartin,

Thank you for your request for

_____ <insert facility/organisation> to be involved in the above-named research.

I have read and understood the Explanatory Statement regarding the research (Project number: CF10/2208 – 2010001253) and hereby give permission for this research to be conducted.

<Please include any stipulations / clauses the Company / Organisation may have about involvement in the project>.

Yours Sincerely,

<insert signature of CEO/Manager/Director of Nursing/Proprietor/Director (anyone who has the authority to give permission)>

_____ <insert name of the above signatory>

_____ <insert signatory's position>

Appendix 9: Pharmacy letter of invitation



Letter of Invitation

Attention: Pharmacy proprietor/manager

RE: Dose Administration Aid Research Project

Project Title: "A Review of Dose Administration Aids: Improving Medicine Management"

Dear (Pharmacy proprietor/manager),

I am writing to you regarding a research project being conducted by the Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, into the accuracy of dose administration aids (DAAs) packed for residential aged care facility (RACF) residents. This project will form part of the research towards attainment of the degree of Doctor of Philosophy (PhD).

The aim of the research is to determine the accuracy of DAAs, supplied by pharmacies or automated packing plants, to RACF residents. DAAs packed manually or via automated means will be examined. It is anticipated that the results of this project will assist in the construction of an intervention/guideline/protocol to improve the DAA packing accuracy and thus ensure RACF residents are receiving the correct medicines according to their medicine records. Currently, there has been little research done in this area in Australia.

We are seeking expressions of interest from pharmacies as potential participants for this project, which is planned to begin in January 2011. We have obtained approval from the Monash University Human Research Ethics Committee for this project.

It is expected that pharmacies and RACF residents will not be disadvantaged or put at risk in this project. The project involves recording and comparison of residents' medicine records and DAAs, to occur at the RACFs, so identification of discrepancies (incidents) can occur. As neither experimental designs or treatments are being applied to residents, nor will residents' identities be retained, individual residents are not considered participants in this project and will not be required to provide informed consent. The independent work of the student researcher and/or other project staff, to be completed alone and conducted on-site at the RACFs, is estimated to be around 5-10 minutes for every DAA. If an incident is detected, the responsible pharmacy will be notified and up to 10 minutes is required to verify each incident, notify the responsible packer and undergo any standard incident reporting procedures already in place at the pharmacy. This comparison of DAAs and medicine records will occur on 2 separate occasions approximately 12-15 months apart, to allow for an intervention (such as the development of a new guideline or protocol to be used in DAA packing and/or administration) to be implemented at the RACF and/or pharmacy and/or automated packing plant during that time.

For your convenience I have attached to this invitation an explanatory statement, permission letter and consent form. Should you wish the pharmacy to participate, please complete, sign and send both the consent form and permission letter in the reply-paid envelope supplied, to Julia Gilmartin in the Department of Pharmacy Practice. Should you have any questions about the project please feel free to contact me. Additionally, my academic supervisors, Dr

Safeera Hussainy and A/Prof Jennifer Marriott, will also be available to answer any questions you may have.

I look forward to hearing from you soon.

Sincerely,

Julia Gilmartin
Pharmacist and PhD Candidate
Department of Pharmacy Practice
Centre for Medicine Use and Safety
Faculty of Pharmacy and Pharmaceutical Sciences, Monash University

[Redacted]

Dr Safeera Hussainy
Lecturer, Academic Supervisor
Department of Pharmacy Practice
Centre for Medicine Use and Safety
Faculty of Pharmacy and Pharmaceutical Sciences, Monash University

[Redacted]

A/Prof Jennifer Marriott
Associate Professor, Academic Supervisor
Department of Pharmacy Practice
Centre for Medicine Use and Safety
Faculty of Pharmacy and Pharmaceutical Sciences, Monash University

[Redacted]

Appendix 10: Pharmacy explanatory statement

MONASH University



Explanatory Statement – Pharmacies

Project title:

A Review of Dose Administration Aids: Improving Medicine Management

This information sheet is for you to keep.

My name is Julia Gilmartin B.Pharm (Hons) and I am conducting a research project with Dr Safeera Hussainy and Associate Professor Jennifer Marriott at the Centre for Medicine Use and Safety, Department of Pharmacy Practice, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University. I am conducting this research project towards a Doctor of Philosophy at Monash University. This means that I will be writing a thesis, which is the equivalent of a short book/ several journal articles and reports. We presently do not have project funding.

Why did you choose this particular person/group as participants?

We have obtained the contact details of the pharmacies by asking the residential aged care facilities (RACFs) whom they supply dose administration aids (DAAs) to, to pass-on the study information to their packing pharmacies, so the pharmacy can contact the researchers if they would like to participate in the study, from publicly available databases on-line or telephone directories and from professional body meetings/seminars attended by health professionals. The pharmacies we approach have been asked to participate because they provide packed DAAs for the medicine management of RACF residents.

The aim/purpose of the research

The aim of this project is to determine the accuracy of manually or automatedly packed DAAs, supplied to RACFs in metropolitan/regional Victoria, by pharmacies or automated packing plants. Accuracy of DAAs will be determined by identifying incidents, that is, comparing them to the RACF residents' medicine records and recording the number and nature of discrepancies that have occurred, as well as identifying packed medicines that should not be packed according to relevant pharmaceutical guidelines and medicines that are damaged, incorrectly halved or altered in an inappropriate way. An intervention will then be devised and implemented at pharmacies and/or automated packing plants and/or RACFs to reduce the DAA packing incident rate. The success of the intervention will be investigated by a second comparison of packed DAAs alongside RACF resident medicine records. I am conducting this research to validate our hypothesis that incidents occur in DAAs supplied to RACFs and that a difference in incident rates exist between those DAAs packed via automation and those packed manually. This will in turn improve the accuracy of DAA delivered medicines to RACF residents.

Possible benefits

The benefit to pharmacies from participation in this project will be a potential increase in the accuracy of DAAs that are packed for the medicine management of RACF residents, through the development of an intervention/guideline/protocol that addresses the issue of DAA packing incidents.

What does the research involve for your pharmacy?

Phase 1 and 3 (out of a total of 3 Phases) participation:

At the first visit to the facility, the pharmacy will be required to orientate the student researcher and/or other project staff to their medicine management systems, in particular, their DAA service. This is to enable examination of the DAA packing environment. Specific residents' DAAs and medicine record comparisons will not occur at the pharmacy. A questionnaire may be used to assist in the orientation of the researchers to the medicine management systems, in particular, DAA service provision.

The pharmacy will be notified and asked to verify any incidents that are identified at the RACF. In this way, incidents can be corrected and not transferred to the RACF resident.

Phase 2 (out of a total of 3 Phases) participation:

An intervention (such as the development of a new guideline or protocol to be used in DAA packing and/or administration) will be devised and implemented to improve the accuracy of packed DAAs.

A questionnaire may be used to evaluate the intervention.

How much time will the research take at your pharmacy?

Phase 1 and 3 participation:

Orientation to the pharmacy is estimated to take up to 1 hr when the student researcher and/or other project staff are welcomed on-site for the first time. If a questionnaire is used for this purpose, it is anticipated to take approximately 5-10 minutes to complete.

Involvement of the pharmacy if an incident is identified is estimated to take up to 10 minutes per identified incident (which may follow standard operating procedures already established at the pharmacy).

Resident medicine record examinations against DAAs will occur over 1 to 2 days at the RACF, on two separate occasions up to 15 months apart. The total duration of Phase 1 and 3 respectively for the whole study, will be up to 6 months. The total data collection period for the whole study is anticipated to occur over 2 years.

Phase 2 participation:

Involvement of the pharmacy in intervention implementation is estimated to take up to 1 hour on two separate occasions, which may form part of a morning tea or an existing scheduled staff meeting.

The total duration of Phase 2 for the whole study will be up to 6 months.

If a questionnaire is used to evaluate the intervention, it is anticipated to take approximately 10 minutes to complete.

Inconvenience/discomfort

It is expected that pharmacies and RACF residents will not be disadvantaged or put at risk of harm in this project. All data collected will be de-identified. The involvement of an employer and their pharmacy in this study will not put at risk the employment of any individual, if they were found to be involved in an incident.

Payment

There is no financial incentive involved for this project.

Can I withdraw from the research?

Being in this project is voluntary and you are under no obligation to consent to participation. If you do consent to participate, you may withdraw at any time, however, any incident recording or other documentation that has occurred prior to your withdrawal will be kept on record. This will comprise anonymous data.

Confidentiality

In documenting incidents, as well as DAA and medicine record information, residents will not be identified by any means (e.g. name or room number) in the documentation. The names of participating pharmacies will not be disclosed and only group data reported.

Storage of data

Storage of the data collected will adhere to the University regulations and will be kept on University premises in a locked cupboard/filing cabinet for 5 years. A report of the project may be submitted for publication, but individual pharmacies and RACF residents will not be identifiable in such a report. All reported information will be de-identified and RACFs/pharmacies/automated packing plants will not be identified by name.

Use of data for other purposes

It is not intended that this data be used for any other purpose from which it is primarily obtained.

Results

If you would like to be informed of the aggregate research finding, please contact myself or my supervisors (see below). The findings will be accessible after all data is collated.

If you would like to contact the researchers about any aspect of this study, please contact myself and/or the Chief Investigators:	If you have a complaint concerning the manner in which this research CF10/2208 – 2010001253 is being conducted, please contact:
<p>Julia Gilmartin B.Pharm (Hons) PhD Candidate Centre for Medicine Use and Safety, Monash University. [REDACTED]</p> <p>Dr Safeera Hussainy Lecturer, Academic Supervisor Centre for Medicine Use and Safety, Monash University. [REDACTED]</p> <p>Associate Professor Jennifer Marriott Academic Supervisor. Centre for Medicine Use and Safety, Monash University. [REDACTED]</p>	<p>Executive Officer, Human Research Ethics Monash University Human Research Ethics Committee (MUHREC) Building 3e Room 111 Research Office Monash University VIC 3800</p> <p>[REDACTED]</p>

Thank you.

Julia Gilmartin B.Pharm(Hons)

Appendix 11: Pharmacy consent form

Consent Form – Pharmacy

A Review of Dose Administration Aids: Improving Medicine Management

NOTE: This consent form will remain with the Monash University researcher for their records

I agree to take part in the Monash University research project specified above. I have had the project explained to me, and I have read the Explanatory Statement, which I keep for my records. I understand that agreeing to take part means that:

I agree to allow the researcher to:

have access to the premises ☐ Yes ☐ No

speak to staff ☐ Yes ☐ No

inform/consult staff in regards to identified dose administration aid incidents ☐ Yes ☐ No

make de-identified notes in relation to the dose administration aid service provision ☐ Yes ☐ No

speak to staff regarding an intervention/guideline/protocol designed to improve the dose administration aid service provision ☐ Yes ☐ No

and

I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project without being penalised or disadvantaged in any way.

and

I understand that any data that the researcher extracts from the discussions with staff and resident medicine records and dose administration aid comparisons, for use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

and

I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party.

and

I understand that data from the discussions with staff and medicine records and dose administration aid comparisons, will be kept in secure storage and accessible to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent

to it being used in future research and I understand that the involvement of the pharmacy in this study will not put at risk the employment of any individual, if they were found to be involved in an incident.

Participant's name

Signature

Date

<p>If you would like to contact the researchers about any aspect of this study, please contact myself and/or the Chief Investigators:</p>	<p>If you have a complaint concerning the manner in which this research CF10/2208 – 2010001253 is being conducted, please contact:</p>
<p>Julia Gilmartin B.Pharm (Hons) PhD Candidate Centre for Medicine Use and Safety, Monash University. [REDACTED]</p> <p>Dr Safeera Hussainy Lecturer, Academic Supervisor Centre for Medicine Use and Safety, Monash University. [REDACTED]</p> <p>Associate Professor Jennifer Marriott Academic Supervisor. Centre for Medicine Use and Safety, Monash University. [REDACTED]</p>	<p>Executive Officer, Human Research Ethics Monash University Human Research Ethics Committee (MUHREC) Building 3e Room 111 Research Office Monash University VIC 3800 [REDACTED]</p>

Appendix 12: Phase 1 dose administration aid audit form

Patient details form (print clearly in red/blue)

1.RA initials:	Date: / /	2. Phase:	3.RACF code (I/O/R/P):
4.Record #:	5.Type of DAA: blister sachet dosette other:		
6.Source group:	Special DAA features:		
7.# individual units for ONE patient for ONE week that you audit (one unit is 1 blister pack or 1 sachet pocket):			
8. Sachets: ___ morn () ___ lunch () ___ dinner () ___ bedtime ()			

Patient details

9.Age:	10.Gender: M / F
Other patient info:	

MOST CURRENT RACF medicine record

Regular packed medicines

	Drug	Brand	Strength	Can't ID	Description / not checked/ notes
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					
32					

Incident details**REMEMBER PHOTOS- RECORD #/ RA INITIALS/ RACF CODE!**

Incident # 1	11. Drug	Brand	Strength	Form	Dose	Frequency	Time	Brand subs (Y/N)
Info from:								
RACF record								
The DAA								
Incident details:								
12. Day:		13. Time:						
14. What the erroneous medicine was being used for:			15. Single/isolated incident: Y / N			16. # of times occurred in one dose interval (e.g. lunch):		
17. # of times occurred in 1 blister pocket or 1 sachet square:			18. # of times occurred in 1 whole blister pack:			19. # of times occurred in one week's supply for one patient:		
20. RACF staff notified: Y / N			21. DAA source notified? Y / N					
22. Error by RA: Y / N			23. Error by RN: Y / N			24. Error by DAA source: Y / N		
Reason/cause for the incident (and source of this info):								
Outcome:								
Incident # 2	25. Drug	Brand	Strength	Form	Dose	Frequency	Time	Brand subs (Y/N)
Info from:								
RACF record								
The DAA								
Incident details:								
26. Day:		27. Time:						
28. What the erroneous medicine was being used for:			29. Single/isolated incident: Y / N			30. # of times occurred in one dose interval (e.g. lunch):		
31. # of times occurred in 1 blister pocket or 1 sachet square:			32. # of times occurred in 1 whole blister pack:			33. # of times occurred in one week's supply for one patient:		
34. RACF staff notified: Y / N			35. DAA source notified? Y / N					
36. Error by RA: Y / N			37. Error by RN: Y / N			38. Error by DAA source: Y / N		
Reason/cause for the incident (and source of this info):								
Outcome:								

Incident # 3	39.Drug	Brand	Strength	Form	Dose	Frequency	Time	Brand subs (Y/N)
Info from:								
RACF record								
The DAA								
Incident details:								
40.Day:		41.Time:						
42.What the erroneous medicine was being used for:			43.Single/isolated incident: Y / N			44.# of times occurred in one dose interval (e.g. lunch):		
45.# of times occurred in 1 blister pocket or 1 sachet square:			46.# of times occurred in 1 whole blister pack:			47.# of times occurred in one week's supply for one patient:		
48.RACF staff notified: Y / N			49.DAA source notified? Y / N					
50.Error by RA: Y / N			51.Error by RN: Y / N			52.Error by DAA source: Y / N		
Reason/cause for the incident (and source of this info):								
Outcome:								
Incident # 4	53.Drug	Brand	Strength	Form	Dose	Frequency	Time	Brand subs (Y/N)
Info from:								
RACF record								
The DAA								
Incident details:								
54.Day:		55.Time:						
56.What the erroneous medicine was being used for:			57.Single/isolated incident: Y / N			58.# of times occurred in one dose interval (e.g. lunch):		
59.# of times occurred in 1 blister pocket or 1 sachet square:			60.# of times occurred in 1 whole blister pack:			61.# of times occurred in one week's supply for one patient:		
62.RACF staff notified: Y / N			63.DAA source notified? Y / N					
64.Error by RA: Y / N			65.Error by RN: Y / N			66.Error by DAA source: Y / N		
Reason/cause for the incident (and source of this info):								
Outcome:								

Appendix 13: Phase 2 residential aged care facility questionnaire

DAAs refer to Dose administration aids such as blister packs or sachets

1	Please highlight which DAA type your answers below will relate to.	Blister pack DAAs Sachet DAAs Other_____
2	List the top 3 most common packing errors seen within DAAs.	1. 2. 3.
3	How often would you see each of the above mentioned packing errors? (please type in the number and highlight the units of measurement)	1. _____ times per week/month/year 2. _____ times per week/month/year 3. _____ times per week/month/year
4	List 3 actual causes of DAA packing errors that you know of.	1. 2. 3.
5	What do you perceive are 3 potential causes of DAA packing errors?	1. 2. 3.
6	What have you done to reduce errors in DAA packing?	
7	What is one suggestion to reduce errors in DAA packing?	
8	When are errors usually identified (as soon as they arrive on-site or during medicine administration etc)?	
9	Per month, how often do you perceive DAAs are found with errors?	
10	In your facility, what are the occupational groups of staff who administer DAAs to residents?	
11	What is the qualification of the staff member most commonly involved in DAA medicine administration?	
12	What are the most useful guidelines/documents that you have referred to when you incorporated DAAs into your facility?	
13	On average, how often does a prescriber review resident medicine records at your facility?	
14	On average, how often does a prescriber make changes to resident medicine records at your facility?	
15	How (e.g. via phone/fax/email) are the DAA packers told of medicine record changes?	
16	When are the DAA packers told of medicine record changes after a change has been made to medicine records?	Immediately Within 24 hours Within 48 hours Other_____
17	Who (e.g. DON/nurse/doctor) tells the DAA packer of medicine record changes?	
18	Are the DAA packers regularly updated on resident medicine record information OR only when changes occur?	
19	How are medicine record changes dealt with if the DAA has been supplied to the facility?	
20	How often does a Pharmacist visit the facility?	

Appendix 14: Phase 2 pharmacy questionnaire

Instructions:

DAA = Dose Administration Aids (blister packs and sachets)

RACFs = Residential Aged Care Facilities

Place your answers in the correct column relating to 'Blister packs' or 'Sachets'. If your facility prepares both blister packs and sachets, please fill in both columns. If your answer relates to both blister packs and sachets please write this in the 'Both' column.

If you supply DAAs to more than one RACF, please answer questions in general terms, that is, what occurs on average (or you may list several answers).

1	Highlight/type-in all DAA forms which you supply to RACFs	Blister pack	Sachets	Other _____
		Blister pack	Sachets	Both
2	List the top 3 most common packing errors seen within DAAs that have left the pharmacy (either the errors have been identified by staff at the RACF or by a pharmacist at the RACF)	1. 2. 3.	1. 2. 3.	1. 2. 3.
3	How often would each of the above mentioned packing errors occur? (please type-in how often the errors occur and highlight the units of measurement)	1.____(day/week/month/year) 2.____(day/week/month/year) 3.____(day/week/month/year)	1.____(day/week/month/year) 2.____(day/week/month/year) 3.____(day/week/month/year)	1.____(day/week/month/year) 2.____(day/week/month/year) 3.____(day/week/month/year)

4	When would these errors be identified (e.g. while the pharmacist checks at the RACF or the RACF staff identify the error)	1. 2. 3.	1. 2. 3.	1. 2. 3.
5	List 3 actual causes of DAA packing errors that you know of	1. 2. 3.	1. 2. 3.	1. 2. 3.
6	What do you perceive are 3 potential causes of DAA packing errors?	1. 2. 3.	1. 2. 3.	1. 2. 3.
7	What has your pharmacy done to reduce errors in DAA packing?			
8	What is one suggestion to reduce errors in DAA packing?			
9	Per month, how often do you perceive DAAs are found with errors at your pharmacy during packing?	____times per month	____times per month	____times per month
10	If your pharmacy conducts DAA checking at the RACF, per month, how often do you perceive DAAs are found with errors at the RACF by the pharmacist?	____times per month	____times per month	____times per month
11	Per month, how often do you perceive DAAs are found with errors at the RACF by RACF staff?	____times per month	____times per month	____times per month
12	At your pharmacy, what are the occupational groups of staff who handle DAAs?			
13	At your pharmacy, what are the occupational groups of staff that pack DAAs?			
14	What is the qualification of the staff member most commonly involved in DAA packing?			
15	What is the qualification of the staff member most commonly involved in DAA checking?			

16	What are the most useful guidelines/documents that you have referred to when you incorporated DAAs into your pharmacy?			
17	Briefly outline your pharmacy's standard operating procedure (SOP) for DAA checking (e.g. what documents are used to check DAA accuracy, how does checking occur etc)			
18	Where are DAAs checked once they are packed? (e.g. at pharmacy, at RACF, both etc)			
19	How much time passes from when the DAAs are first packed (without being checked), and when they are first used at the RACF? (please type-in how much time passes and highlight the units of measurement)	_____(hours/days/weeks)	_____(hours/days/weeks)	_____(hours/days/weeks)
20	How much time passes from when the DAAs are last checked, and when they are first used at the RACF? (please type-in how much time passes and highlight the units of measurement)	_____(hours/days/weeks)	_____(hours/days/weeks)	_____(hours/days/weeks)
21	Where are DAAs stored in the pharmacy once they are packed? (e.g. cupboard, temperature controlled room)			
22	Where are DAAs stored at the RACF upon delivery? (e.g. cupboard, temperature controlled room)			
23	Briefly outline your pharmacy's SOP for DAA error reporting			
24	Briefly outline your pharmacy's SOP for DAA error rectification			
25	Briefly outline your pharmacy's SOP for DAA error recording			

26	Are RACF residents medicine records (held at your pharmacy) updated at regular pre-determined intervals OR only when changes occur OR both?			
27	How often are RACF residents medicine records (held at your pharmacy) updated? (please write the number in and highlight the units of measurement)	____(day/week/month/year)	____(day/week/month/year)	____(day/week/month/year)
28	Briefly outline your pharmacy's SOP for recording RACF medicine record changes that your pharmacy is notified of			
29	On average, how often are you notified of medicine record changes from the RACF? (please write the number in and highlight the units of measurement)	____(day/week/month/year)	____(day/week/month/year)	____(day/week/month/year)
30	How does the RACF inform you of medicine record changes? (e.g. via phone/fax/email)			
31	How long after a medicine record change at the RACF occurs, is your pharmacy notified? (highlight)	Immediately Within 24 hours Within 48 hours Other_____	Immediately Within 24 hours Within 48 hours Other_____	Immediately Within 24 hours Within 48 hours Other_____
32	Who tells your pharmacy of medicine record changes? (e.g. director of nursing/nurse/doctor)			
33	How does your pharmacy deal with medicine record changes if the DAA has already been supplied to the RACF?			
34	How often does a Pharmacist visit the RACF? (please write the number in and highlight the units of measurement)	____(day/week/month/year)	____(day/week/month/year)	____(day/week/month/year)

Demographic information	
35	<div> <div> Apart from RACFs, who else does your pharmacy prepare DAAs for? (highlight) </div> <div> Community users Hospital Other: _____ </div> </div>
36	<div> <div> How many RACFs do you provide DAAs to? (highlight) </div> <div> <u>1</u> <u>2</u> <u>3 or more</u> </div> </div>
37	<div> <div> Are the majority of your RACF DAA users high or low care? (highlight) </div> <div> High Low Unsure </div> </div>
38	<div> <div> Are DAAs prepared onsite or offsite? (highlight) </div> <div> Onsite Offsite If offsite, please state where e.g. at RACF: </div> </div>
39	<div> <div> Are your DAAs packed manually or via automation? (highlight) </div> <div> <div> 1. DAA type: blister/sachet/other: _____ <div>Packing method: manual/automated</div> </div> <div> 2. DAA type: blister/sachet/other: _____ <div>Packing method: manual/automated</div> </div> </div> </div>
40	<div> <div> How often does your pharmacy prepare DAAs? (highlight) </div> <div> daily/weekly/monthly </div> </div>

Appendix 15: Focus group letter of invitation



Letter of Invitation

Attention: Focus Group participant

RE: Dose Administration Aid Research Project

Project Title: "A Review of Dose Administration Aids: Improving Medicine Management"

Dear (Focus Group participant),

I am writing to you regarding a research project being conducted by the Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, into the accuracy of dose administration aids (DAAs) packed for residential aged care facility (RACF) residents. This project will form part of the research towards attainment of the degree of Doctor of Philosophy (PhD).

The aim of the research is to determine the accuracy of DAAs, supplied by pharmacies and automated packing plants, to RACF residents. DAAs packed manually or via automated means will be examined. It is anticipated that the results of this project will assist in the construction of an intervention/guideline/protocol to improve the DAA packing accuracy and thus ensure RACF residents are receiving the correct medicines according to their medicine records. Currently, there has been little research done in this area in Australia.

We are seeking expressions of interest from practicing Doctors, Registered Nurses, Pharmacists, RACF staff and automated packing plant staff as potential participants for Focus Groups. If you agree to participate in a Focus Group, it would involve up to 2 hours of your time in a convenient location to discuss issues relevant to your professional practice and the provision of DAA services and medicine management in the elderly. Some of the topics that will be discussed in the Focus Group include: the factors contributing to DAA packing incidents and incidents related to medicine administration from DAAs; processes in place to reduce these incidents; and suggestions for a future intervention to reduce incidents in packed DAAs. Your time would be required during the day or of an evening, and is planned to occur in January/February/March of 2012. We have obtained approval from the Monash University Human Research Ethics Committee for this project. Your time will be rewarded with \$100 per 2 hour session attended.

It is expected that Focus Group participants will not be disadvantaged or put at risk in this project. All information recorded and reported from Focus Groups will be de-identified.

In the event that individuals interested in participating, outnumber those required for Focus Groups, a random selection of Focus Group participants will be sought.

For your convenience I have attached to this invitation a 'contact details' slip. Should you wish to accept this invitation as a Focus Group participant, please complete the 'contact details slip' and return it in the reply paid envelope supplied, to Julia Gilmartin in the Department of Pharmacy Practice. Should you have any questions about the project please feel free to contact me. Additionally, my academic supervisors, Dr Safeera Hussainy and A/Prof Jennifer Marriott, will also be available to answer any questions you may have.

I look forward to hearing from you soon.

Sincerely,
Julia Gilmartin
Pharmacist and PhD Candidate
Department of Pharmacy Practice
Centre for Medicine Use and Safety
Faculty of Pharmacy and Pharmaceutical Sciences, Monash University



Dr Safeera Hussainy
Lecturer, Academic Supervisor
Department of Pharmacy Practice
Centre for Medicine Use and Safety
Faculty of Pharmacy and Pharmaceutical Sciences, Monash University



A/Prof Jennifer Marriott
Associate Professor, Academic Supervisor
Department of Pharmacy Practice
Centre for Medicine Use and Safety
Faculty of Pharmacy and Pharmaceutical Sciences, Monash University



Appendix 16: Focus group explanatory statement

MONASH University



Explanatory Statement – Focus Group participants

Title:

A Review of Dose Administration Aids: Improving Medicine Management

This information sheet is for you to keep.

My name is Julia Gilmartin B.Pharm (Hons) and I am conducting a research project with Dr Safeera Hussainy and Associate Professor Jennifer Marriott at the Centre for Medicine Use and Safety, Department of Pharmacy Practice, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University. I am conducting this research project towards a Doctor of Philosophy at Monash University. This means that I will be writing a thesis, which is the equivalent of a short book/ several journal articles and reports. We presently do not have project funding.

Why did you choose this particular person/group as participants?

We have obtained the contact details of the Doctors, Pharmacists, Registered Nurses, other residential aged care facility (RACF) staff and automated packing plant staff we approach from attendance at The Divisions of General Practice meetings, or other professional body meetings/seminars attended by health professionals, from affiliation with the RACFs, pharmacies and automated packing plants involved in the project (either through the student researcher and/or other project staff personally meeting the potential participant or by the facility passing-on the details of the project to potentially interested participants), through contacts of Investigators and publicly available databases on-line or telephone directories. The Doctors, Pharmacists, Registered Nurses, other RACF staff and automated packing plant staff we approach have been selected as they have the required level of expertise, through educational qualifications and professional practice experience, to participate in the Focus Groups.

The aim/purpose of the research

This project will be conducted in 3 phases, involving RACFs, pharmacies, automated packing plants, Panel Meeting participants and Focus Group participants. The Focus Groups will occur in Phase 2 of the project. The aim of this project is to determine the accuracy of dose administration aids (DAAs) packed manually or via automation and supplied to RACFs in metropolitan/regional Victoria, by pharmacies or automated packing plants. In Phase 1 the accuracy of DAAs will be determined by identifying incidents, that is, comparing them to the RACF residents' medicine records and recording the number and nature of incidents that have occurred, as well as identifying packed medicines that should not be packed according to relevant pharmaceutical guidelines and medicines that are

damaged, incorrectly divided or altered in an inappropriate way. An intervention will then be devised in Phase 2 and implemented at pharmacies and/or automated packing plants and/or RACFs to reduce the DAA packing incident rate. The success of the intervention will be investigated by a second comparison of packed DAAs alongside RACF resident medicine records in Phase 3. I am conducting this research to validate our hypothesis that incidents occur in DAAs supplied to RACFs and that a difference in incident rates exist between those DAAs packed via automation and those packed manually. This will in turn improve the accuracy of DAA delivered medicines to RACF residents.

Possible benefits

There may be no direct benefit to the Focus Group participants from involvement in this project, however, contribution to the Focus Group discussions on issues related to DAA incident causes and suggestions to improve DAA packing will contribute to a potential increase in the accuracy of DAAs that are packed for the medicine management of RACF residents. This will occur through the development of an intervention/guideline/protocol that addresses the issue of DAA packing incidents.

What does the research involve for you?

Participation in the Focus Groups will involve discussion of the potential and actual causes of DAA packing incidents and medicine administration incidents which involve DAAs and devising an intervention to reduce this incident rate. Focus Groups will be audio-recorded for later transcription and analysis.

How much time will the research take?

If you choose to participate in the Focus Groups, you will be required to attend 1 Focus Group of up to 2 hours duration. The total duration of Phase 2 for the whole study (which includes the Focus Groups) will be up to 6 months. The total data collection period for the whole study is anticipated to occur over 2 years.

Inconvenience/discomfort

It is expected that Focus Group participants will not be disadvantaged or put at risk of harm in this project. All data collected will be de-identified.

Payment

The financial incentive for your participation will be a payment of \$100 per 2 hour Focus Group session attended.

Can I withdraw from the research?

Being in this project is voluntary and you are under no obligation to consent to participation. If you do consent to participate, you may withdraw at any time, however, any recording of Focus Group discussions that has occurred prior to your withdrawal will be kept on record. This will comprise anonymous data.

Confidentiality

In documenting and reporting on Focus Group discussions, participants will not be identified by name in the documentation.

Storage of data

Storage of the data collected will adhere to the University regulations and will be kept on University premises in a locked cupboard/filing cabinet for 5 years. A report of the project may be submitted for publication, but individual Focus Group participants and RACF residents will not be identifiable in such a report. All reported information will be de-identified and RACFs/pharmacies/automated packing plants and Focus Group participants will not be identified by name.

Use of data for other purposes

It is not intended that this data be used for any other purpose from which it is primarily obtained.

Results

If you would like to be informed of the aggregate research finding, please contact myself or my supervisors (see below). The findings will be accessible after all data is collated.

If you would like to contact the researchers about any aspect of this study, please contact myself and/or the Chief Investigators:	If you have a complaint concerning the manner in which this research CF10/2208 – 2010001253 is being conducted, please contact:
<p>Julia Gilmartin PhD Candidate Centre for Medicine Use and Safety, Monash University. [REDACTED]</p> <p>Dr Safeera Hussainy Lecturer, Academic Supervisor Centre for Medicine Use and Safety, Monash University. [REDACTED]</p> <p>Associate Professor Jennifer Marriott Academic Supervisor. Centre for Medicine Use and Safety, Monash University. [REDACTED]</p>	<p>Executive Officer, Human Research Ethics Monash University Human Research Ethics Committee (MUHREC) Building 3e Room 111 Research Office Monash University VIC 3800</p> <p>[REDACTED]</p>

Thank you.

Julia Gilmartin B.Pharm(Hons)

Appendix 17: Focus group consent form

Consent Form – Focus Group(s)

Title:**A Review of Dose Administration Aids: Improving Medicine Management**

NOTE: This consent form will remain with the Monash University researcher for their records

I agree to take part in the Monash University research project specified above. I have had the project explained to me, and I have read the Explanatory Statement, which I keep for my records. I understand that agreeing to take part means that:

I agree to participate in a Focus Group that will involve discussing the potential and actual causes of dose administration aid packing incidents and medicine administration incidents while utilising dose administration aids, and devising an intervention to reduce this incident rate ☐ Yes ☐ No

I agree to allow the Focus Group to be audio-taped and transcribed ☐ Yes ☐ No

and

I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project without being penalised or disadvantaged in any way.

and

I understand that any data that the researcher extracts from the Focus Group(s) for use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

and

I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party.

and

I understand that data from the Focus Group(s) will be kept in a secure storage and accessible to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.


Participant's name

Signature



Date

<p>If you would like to contact the researchers about any aspect of this study, please contact myself and/or the Chief Investigators:</p>	<p>If you have a complaint concerning the manner in which this research CF10/2208 – 2010001253 is being conducted, please contact:</p>
<p>Julia Gilmartin B.Pharm (Hons) PhD Candidate Centre for Medicine Use and Safety, Monash University. [REDACTED]</p> <p>Dr Safeera Hussainy Lecturer, Academic Supervisor Centre for Medicine Use and Safety, Monash University. [REDACTED]</p> <p>Associate Professor Jennifer Marriott Academic Supervisor. Centre for Medicine Use and Safety, Monash University. [REDACTED]</p>	<p>Executive Officer, Human Research Ethics Monash University Human Research Ethics Committee (MUHREC) Building 3e Room 111 Research Office Monash University VIC 3800 [REDACTED]</p>

Appendix 18: Focus group recruitment poster

MONASH University 


Are you a **personal care worker/carer**
who handles, prepares or administers medicines from
blister packs or sachets for use in aged care facilities?



We'd love to hear your suggestions on how
to improve this system of medicine management!

To join a 2 hour discussion group
at Monash University in Parkville
for one evening in February 2012 please email:
julia.gilmartin@monash.edu

Your valuable contribution to the study "A review of dose
administration aids: Improving medicine management" will
be greatly appreciated and we'd like to thank you for your
participation with a gift voucher.

MONASH University 

Are you a **pharmacy technician/assistant**
who handles or prepares
blister packs or sachets for use in aged care facilities?


We'd love to hear your suggestions on how
to improve this system of medicine management!

To join a 2 hour discussion group
at Monash University in Parkville
for one evening in February 2012 please email:
julia.gilmartin@monash.edu

Your valuable contribution to the study "A review of dose
administration aids: Improving medicine management" will
be greatly appreciated and we'd like to thank you for your
participation with a gift voucher.



Appendix 19: Intervention introduction poster

MONASH University



Educational Presentation

For all staff who handle Dose Administration Aids (DAAs- blister packs and sachets) used for medicine administration



- For nurses, carers, pharmacists, technicians, prescribers etc
- 30 minute Pharmacist-delivered presentation
- Results of a Victoria-wide evaluation of DAAs prepared by pharmacies and used in aged care facilities
- Quality improvement ideas to increase the accuracy and appropriateness of medicines packed within DAAs and improve medicine handling
- Certificate of attendance

Date: _____

Time: _____

Venue: _____

For more details contact your manager/coordinator or email:
julia.gilmartin@monash.edu

This is a Monash University initiative from the research study
"A review of dose administration aids: Improving medicine management"

Appendix 20: Phase 3 residential aged care facility questionnaire

DAA - refers to dose administration aid e.g. blister packs and sachets
DAA incident - refers to inaccurate or inappropriate DAA medicine packing
RACF - refers to residential aged care facility
Toolkit - refers to the 'BE ALERT AND WORK TOGETHER' for medicine safety Dose Administration Aid (DAA) Incident Awareness Toolkit designed to reduce DAA incidents and given to RACFs via an education session

1	I am a (please circle) Div 1 Nurse Div 2 Nurse/Enrolled Nurse Carer/Personal Care Worker Other:					
2	I have worked with RACF DAAs for _____ years					
3	My answers below will relate to (please circle) Blister packs Sachets Both Other _____					
4	What percentage of the Toolkit would your RACF use/implement in the <u>short term</u> ? _____ %					
5	What percentage of the Toolkit would your RACF use/implement <u>permanently</u> ? _____ %					
6	What percentage of the Toolkit is new to your RACF's existing medicine management systems? _____ %					
7	Name the most useful component of the Toolkit					
8	Name the least useful component of the Toolkit					
9	Name 1 advantage of the Toolkit					
10	Name 1 disadvantage of the Toolkit					
11	How can the Toolkit be improved?					
For the questions below, place a tick the column that your answer relates to						
	<table border="1"> <tr> <td>Not at all (1)</td> <td>Somewhat (2)</td> <td>Moderately (3)</td> <td>Very (4)</td> <td>Extremely well (5)</td> </tr> </table>	Not at all (1)	Somewhat (2)	Moderately (3)	Very (4)	Extremely well (5)
Not at all (1)	Somewhat (2)	Moderately (3)	Very (4)	Extremely well (5)		
12	How useful is the Toolkit for your RACF?					
13	How well do you think the Toolkit will improve the accuracy and appropriateness of DAA medicine packing?					
14	How well do you think the Toolkit will reduce the occurrence of DAA incidents?					
15	How well do you think the Toolkit will improve RACF medicine administration using DAAs?					
16	How well do you think the Toolkit will improve DAA checking <u>WITHIN</u> your RACF?					
17	How well do you think the Toolkit will improve communication <u>WITHIN</u> your RACF?					
18	How well do you think the Toolkit will improve communication <u>WITH</u> your pharmacy?					
19	How well do you think the Toolkit will improve the relationship <u>WITH</u> your pharmacy?					
20	How well do you think the Toolkit will improve awareness of DAA incidents?					
21	How well do you think the Toolkit will improve awareness of contributing factors to DAA incidents?					
22	How well do you think the Toolkit will improve awareness of strategies to prevent DAA incidents?					
23	How well do you think the Toolkit will reinforce existing RACF medicine management systems?					
24	How useful was the education session provided by the researchers?					

PLEASE TURN OVER PAGE TO WRITE ANY FURTHER COMMENTS

Appendix 21: Phase 3 pharmacy questionnaire

DAA - refers to dose administration aid e.g. blister packs and sachets
DAA incident - refers to inaccurate or inappropriate DAA medicine packing
RACF - refers to residential aged care facility
Toolkit - refers to the 'BE ALERT AND WORK TOGETHER' for medicine safety Dose Administration Aid (DAA) Incident Awareness Toolkit designed to reduce DAA incidents and given to RACFs via an education session

1	I am a (please circle) Pharmacist Pharmacy Technician Pharmacy Student/Intern Other: _____					
2	I have worked with RACF DAAs for _____ years					
3	My answers below will relate to (please circle) Blister packs Sachets Both Other _____					
4	What percentage of the Toolkit would your pharmacy use/implement in the <u>short term</u> ? _____%					
5	What percentage of the Toolkit would your pharmacy use/implement <u>permanently</u> ? _____%					
6	What percentage of the Toolkit is new to your pharmacy existing medicine management systems? _____%					
7	Name the most useful component of the Toolkit					
8	Name the least useful component of the Toolkit					
9	Name 1 advantage of the Toolkit					
10	Name 1 disadvantage of the Toolkit					
11	How can the Toolkit be improved?					
For the questions below, place a tick the column that your answer relates to						
	<table border="1"> <tr> <td>Not at all (1)</td> <td>Somewhat (2)</td> <td>Moderately (3)</td> <td>Very (4)</td> <td>Extremely well (5)</td> </tr> </table>	Not at all (1)	Somewhat (2)	Moderately (3)	Very (4)	Extremely well (5)
Not at all (1)	Somewhat (2)	Moderately (3)	Very (4)	Extremely well (5)		
12	How useful is the Toolkit for your pharmacy?					
13	How well do you think the Toolkit will improve the accuracy and appropriateness of DAA medicine packing?					
14	How well do you think the Toolkit will reduce the occurrence of DAA incidents?					
15	How well do you think the Toolkit will improve pharmacy medicine supply from DAAs?					
16	How well do you think the Toolkit will improve DAA checking <u>WITHIN</u> your pharmacy?					
17	How well do you think the Toolkit will improve communication <u>WITHIN</u> your pharmacy?					
18	How well do you think the Toolkit will improve communication <u>WITH</u> your RACF?					
19	How well do you think the Toolkit will improve the relationship <u>WITH</u> your RACF?					
20	How well do you think the Toolkit will improve awareness of DAA incidents?					
21	How well do you think the Toolkit will improve awareness of contributing factors to DAA incidents?					
22	How well do you think the Toolkit will improve awareness of strategies to prevent DAA incidents?					
23	How well do you think the Toolkit will reinforce existing pharmacy medicine management systems?					
24	How useful was the education session provided by the researchers?					

PLEASE TURN OVER PAGE TO WRITE ANY FURTHER COMMENTS

Appendix 22: Toolkit introductory letter

MONASH University



Attention: person responsible for staff education/quality improvement/DAAAs

Thank-you for your continued support of the Monash University Study:

‘A review of dose administration aids: Improving medicine management’

This study aims to improve medicine administration at residential aged care facilities (RACFs) and medicine supply from pharmacies, by auditing, evaluating and improving the accuracy and appropriateness of dose administration aid (DAA) medicine packing. These DAAs (e.g. blister packs and sachets) organise medicines according to the day of the week and time of the day in which they must be taken or administered.

Study results from our 2011 DAA audit (that is likely to have involved your RACF or pharmacy), survey and focus groups, have informed the development of a quality improvement Toolkit:

‘BE ALERT AND WORK TOGETHER’ for medicine safety

Dose Administration Aid (DAA) Incident Awareness Toolkit

This Toolkit is designed to improve the accuracy and appropriateness of DAA medicine packing and is targeted at RACFs who use DAAs, and pharmacies who supply DAAs to RACFs.

This Toolkit will be formally unveiled at a Pharmacist-delivered education session at your RACF or pharmacy. **Approximately 3 months after this education, it is hoped that your RACF or pharmacy will be involved in a follow-up DAA audit to evaluate the effectiveness of this Toolkit.**

I encourage you to peruse this Toolkit, share the tools and information with your colleagues who also handle DAAs and implement the provided tools and suggestions into your everyday practice. **Please tell your RACF and pharmacy about the Toolkit and ask them to contact me if they would like one** [REDACTED]). Additionally, please contact me if you have any queries about this Toolkit or the Monash University study, or would like to request more Toolkit components.

Please take some time to read the 4 letters of support for this Toolkit from the Australian Nursing Federation, The Pharmacy Guild of Australia, the Pharmaceutical Society of Australia and the Registrar from the Victorian Pharmacy Authority (located behind this introductory letter).

I hope this Toolkit will be a valuable resource for providing optimal medicine services in your RACF or pharmacy and I look forward to keeping you updated as the study progresses.

Kind regards,

Julia Gilmartin

Pharmacist and PhD Candidate, Centre for Medicine Use and Safety, Monash University (Parkville)

Appendix 23: Australian Nursing Federation letter of support



australian
nursing federation

10 May 2012

Ms Julia Gilmartin
Project Officer
Dose Administration Toolkit Project
Department of Pharmacy Practice
Monash University Centre for Medicine Use & Safety

Dear Ms Gilmartin

Dose Administration Aid Toolkit Project

The Australian Nursing Federation (ANF) is pleased to endorse the *Dose Administration Aid Toolkit* developed by Monash University.

With a membership of over 214,000 the ANF is the largest professional and industrial organisation in Australia for nurses, midwives and assistants in nursing. Given a large cohort of our members work in the residential and community aged care sectors, our organisation has an intense interest in quality use of medicines for older people. We recognise that medicines management in these sectors increasingly involves the use of dose administration aids.

Recently we revised our *Nursing Guidelines for the Management of Medicines in Aged Care*, which is jointly produced with Royal College of Nursing, Australia (soon to become the Australian College of Nursing). This document clearly outlines the scope of practice and responsibilities of registered and enrolled nurses in medicines management, including administration, and, the role of assistants in nursing which is legally confined to assisting people self-administer their medicines from pre-packaged dose administration aids.

The *Dose Administration Aid Toolkit* should prove to be a valuable resource for improving quality use of medicines for the Australian community, health care professionals and other care workers, and health and aged care facilities. On completion of the Toolkit program ANF registered and enrolled nurse members will be able to include this on their portfolio for mandatory continuing professional development requirements (http://www.anf.org.au/html/resources_edonline.html).

Should you require any additional information or wish to discuss this matter further please contact Julianne Bryce, Senior Federal Professional Officer, on (03) 9602 8500 or julianne@anf.org.au.

Yours sincerely

Lee Thomas
Federal Secretary

The industrial and professional organisation for nurses and midwives in Australia

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Unit 3, 28 Eyre Street Kingston ACT 2604 Australia
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(T) + 61 2 6232 6533 (F) + 61 2 6232 6610
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ANF Journals
Australian Nursing Journal
Australian Journal of Advanced Nursing
anj@anf.org.au ajn@anf.org.au
ASN 41 816 898 298

www.anf.org.au

Appendix 24: The Pharmacy Guild of Australia letter of support



The Pharmacy
Guild of Australia

2 May 2012

Julia Gilmartin
Centre For Medicine Use and Safety
Monash University
381 Royal Parade
Parkville Vic 3052

Email: Julia.gilmartin@monash.edu

Dear Ms Gilmartin

Letter of support for the research project: "A review of dose administration aids: Improving medicine management".

The Pharmacy Guild of Australia (the Pharmacy Guild) would like to extend our support to the research project "A review of dose administration aids: Improving medicine management".

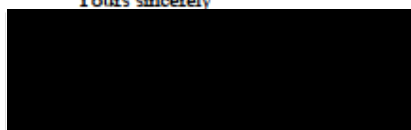
The Pharmacy Guild is a membership organisation representing the owners and interests of independent community pharmacies in Australia. It exists to maintain community pharmacy's status as a primary provider of health care to the community through the optimum use of medicines, medicine management and related services.

Community pharmacists work in a collaborative partnership with other health care professionals to ensure that patients receive a safe and quality service. As the prime source of information and advice, they also provide a range of professional services.

The proposed project has the potential to significantly improve medication use and safety in Residential Aged Care Facilities.

I would like to congratulate you on this study, wish you success and look forward to working with you in this important area of Quality Use of Medicines.

Yours sincerely



Maurice V Sheehan
Branch Director

Victoria
'Guild House' Level 2, 40 Burwood Road Hawthorn VIC 3122
telephone: + 61 3 9810 9999 · facsimile: + 61 3 9819 2542
e-mail: info@vic.guild.org.au · Internet: www.guild.org.au/vic

Appendix 25: Pharmaceutical Society of Australia letter of support



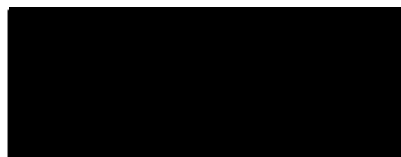
29 May 2012

Dear Colleagues,

I am very pleased to refer to you the project 'A review of dose administration aids: Improving medicine management' being conducted by Ms Julia Gilmartin at Monash University. As a pharmacist, Ms Gilmartin is building her expertise in this field through her extensive study in medication safety associates with dose administration aids. She has since developed a tool kit to be used in pharmacies to minimise many of the potential risks identified in her project.

I urge you to be involved in this project and be part of the team in utilising and evaluating these valuable tools, so that the profession may learn and advance our practice through practitioner involvement in these research initiatives.

Yours sincerely,



Mark Feldschuh
Victorian President
Pharmaceutical Society of Australia

Appendix 26: Victorian Pharmacy Authority letter of support

Dear Julia

Thank you for recently providing me with a presentation on the Toolkit which will be an important quality improvement initiative. Dose Administration Aids continue to increase in use with the increasing number of older Australians taking regular medications but frequently with increased confusion regarding dose timing and other compliance issues.

The main components of kit will assist pharmacists and their staff in providing medications to residential care facilities, providing information sessions to often untrained staff in aged care settings, to families supporting family members and in provision of services within the pharmacy.

I congratulate you and your team on this initiative and enthusiastically support the work and look forward to its implementation across a wide range of stakeholders in the provision of medications to those in need of dose administration aids.

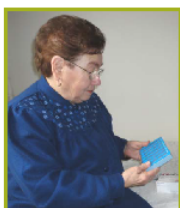
Yours sincerely

Stephen Marty

Registrar

Victorian Pharmacy Authority

Appendix 27: Toolkit poster



‘BE ALERT and WORK TOGETHER’ for medicine safety

Dose Administration Aid (DAA) Incident Awareness Toolkit - Poster

BE ALERT

DAA incidents can occur e.g. inaccurate or inappropriate medicine packing within blister packs and sachets (see photos below)

Inspect the **DAA** for incidents

Check the **DAA** with updated aged care facility medicine records



Keep unstable medicines in their original containers or consider other protective packing options e.g. pack in foil

e.g. moisture sensitive sodium valproate (see mottled tablet on the left)

See the Pharmaceutical Society of Australia's Appendix 5: Examples of medicines which should not be packed in DAA

WORK TOGETHER

Keep accurate and updated records and promptly communicate

all medicine information (e.g. **DAA** incidents and medicine changes)

To the aged care facility, pharmacy and prescriber

For action, correction, evaluation, prevention

Aged Care Facility (Phone/Email/Fax) _____

Photo
of main
contact
person

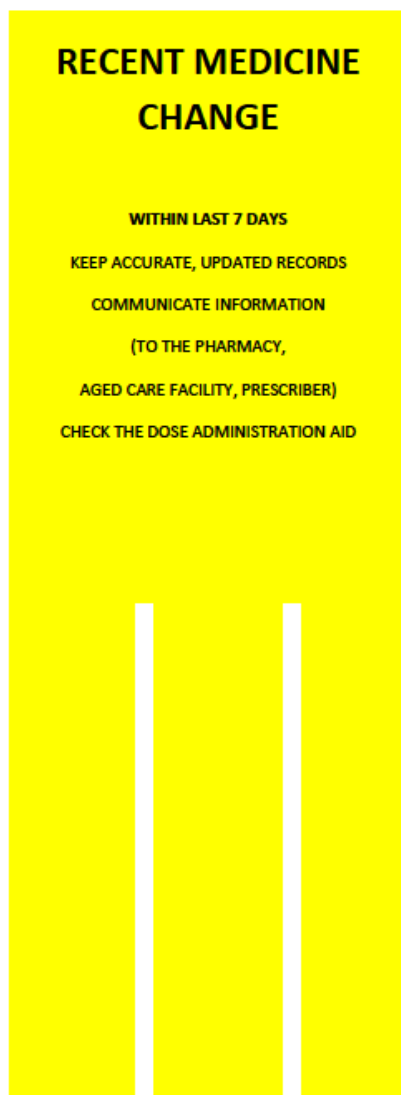
Pharmacy (Phone/Email/Fax) _____

Photo
of main
contact
person

Prescriber (Phone/Email/Fax) _____

Photo
of main
contact
person

Appendix 28: Toolkit bookmark



Appendix 30: Compact disk-read only memory presentation slides



Pharmacy and Pharmaceutical Sciences

'BE ALERT AND WORK TOGETHER'
for medicine safety
Dose Administration Aid (DAA)
Incident Awareness Toolkit CD-ROM



Developed in conjunction with the
Monash University study:

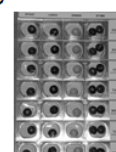
**"A review of dose administration aids:
Improving medicine management"**

© Julia Gilmartin 2012

Definitions

▪ Dose Administration Aids (DAAs)

- Blister packs and sachets that organise medicines according to the day of the week and time of the day in which they must be taken or administered.
- DAAs may be packed by hand or machine.
- Pharmacies usually prepare and supply DAAs to residential aged care facilities (RACFs).



▪ Residential Aged Care Facilities (RACFs)

- Provide accommodation and support for older people e.g. medicine administration using DAAs.

▪ DAA incidents

- May occur when a DAA is packed inaccurately according to the medicine record (e.g. medicines are missing) or inappropriately (e.g. damaged medicines are packed).

Purpose and Objectives of this CD-ROM

▪ Purpose

- To improve RACF medicine administration and pharmacy medicine supply by improving how accurately and appropriately medicines are packed in DAAs.

▪ Learning objectives

On completion of this presentation, participants will be able to:

- identify types of DAA incidents,
- understand causes of DAA incidents,
- recognise ways to prevent DAA incidents.



How to use this CD-ROM

▪ Who

- All RACF and pharmacy staff who handle DAAs for RACFs.

▪ When:

- New staff,
- re-education following DAA incidents,
- continuing professional development.



▪ How:

- 30-60 minutes of education,
- present to a group or self-education,
- assess knowledge learned from this presentation with question and reflection handouts (provided in the DAA Toolkit - see person responsible for staff education/quality improvement/DAAs).

Outline

1. Background
2. DAA incidents
3. Causes of DAA incidents
4. Prevention of DAA incidents



| 5

1. Background

- **Results from a Monash University study are included in this presentation**
 - **'A review of dose administration aids: Improving medicine management'** aims to improve RACF medicine administration and pharmacy medicine supply with a focus on DAAs.
 - Pharmacy-supplied DAAs (blister packs and sachets) were compared to the RACF medicine records to identify how accurately and appropriately medicines were packed.
 - **DAA incidents were identified, including:**
 - mismatch between the DAA and medicine record,
 - medicines unsuitable for packing according to pharmaceutical guidelines (e.g. unstable medicines),
 - damaged medicines,
 - inappropriately altered/divided medicines.
 - A survey and focus groups with RACF and pharmacy staff identified contributing factors and potential ways to prevent DAA incidents.



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1. Background

- Overall results of the study

- 3,959 DAAs from 49 Victorian RACFs and 40 pharmacies were audited.
- The average patient was: female, 85 years old and taking an average of 7 regularly packed medicines (within DAAs).
- Overall, 11.6% of DAAs had incidents (see previous slide for DAA incident definition).
- Staff perceived DAAs to be more accurate than these findings and identified many contributing factors and ways to prevent DAA incidents (presented later in this CD-ROM).
- **DAA incidents were found in both blister packs (packed by hand) and sachets (packed by machine). Therefore, both DAA types can benefit from quality improvement.**

1. Background

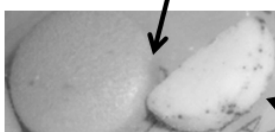
- The top 5 DAA incident types found in the study

- 1st Medicines that are unsuitable for packing into DAAs according to pharmaceutical guidelines (50.1% of all DAA incidents)
 - 2nd Incorrectly added medicines (9.8%)
 - 3rd Incorrect medicine quantity packed (5.4%)
 - 4th Missing medicines (5.3%)
 - 5th Damaged medicines (5.1%)
- Look out for these DAA incidents so they can be corrected and prevented.
 - These DAA incidents can be found by checking the DAA with the medicine record or by inspecting the DAA for DAA incidents.

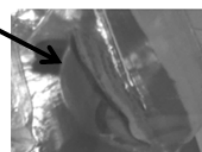
1. Background

▪ The most common DAA incident found in the study

- Medicines that are unsuitable for packing into DAAs according to pharmaceutical guidelines:
 - e.g. sodium valproate (Epilim®, Valpro®) used for conditions like epilepsy, bipolar mood disorder and nerve pain,
 - these medicines may be unstable when removed from their original containers and
 - packed in DAAs without foil,
 - packed in DAAs with poorly cut foil (exposing the medicine).



mottled sodium valproate tablet



1. Background

▪ The most common DAA incident found in the study

- Check that unstable medicines are kept in their original container and are not packed in the DAA or:
 - pack the medicine into the DAA with protective foil,
 - consider other ways to supply these medicines,
 - notify responsible staff if necessary.
- Consider the company medicine information, guidelines and research that suggest certain medicines, such as sodium valproate, should **not** be packed into DAAs:
 - Pharmaceutical Society of Australia guidelines, Appendix 5: Examples of medicines which should not be packed in DAA.
 - Llewelyn VK, Mangan MF, Glass BD. Stability of sodium valproate tablets repackaged into dose administration aids. *Journal of Pharmacy and Pharmacology* 2010; (62): 838-843.

2. DAA incidents

- **DAA incidents can occur so BE ALERT AND WORK TOGETHER!**
 - All staff at the RACF and pharmacy who are involved in aged care DAA medicine supply should have an active role in the DAA service, to ensure best patient care.
 - **BE ALERT** for DAA incidents:
 - inspect the DAA,
 - check the DAA with updated RACF medicine records.
 - **WORK TOGETHER:**
 - keep accurate and updated records and promptly communicate DAA incidents and medicine changes to the RACF, pharmacy and prescriber,
 - for action, correction, evaluation and prevention,
 - know where these records must be made (e.g. DAA incident book at your workplace) and who to communicate this information to.

2. DAA incidents

- **All DAA incidents are important**
 - Don't ignore a DAA incident, because it may harm the patient.
 - Consider why the DAA incident occurred and address these factors.
- **The next 5 slides describe the types of DAA incidents that may occur**
 - Look out for these DAA incidents when checking DAAs.
- **Question 1**
 - What types of incidents can be found in DAAs?



2. DAA incidents

- **Medicines unsuitable for packing according to pharmaceutical guidelines, occurs when:**
 - **Unstable medicines are packed into DAAs** - dispersible, dissolvable, in poorly sealed foil.
- **Incorrect or missing medicines occurs when medicines are:**
 - **Added** - when ceased, added everyday when they are 'when required', a wrong combination tablet or extra tablets are packed, a combination tablet is packed when only one medicine is on the medicine record, tablet dust/pieces are packed.
 - **Missing** - every day or sporadically, or a single medicine is packed instead of a combination tablet.
 - **Changed for a brand that is not equivalent** (e.g. warfarin) **or against the prescriber's wishes** ('do not substitute' is on the medicine record).
 - **Incorrect form** - e.g. tablet versus capsule.
 - **Incorrect formulation** - e.g. normal release versus long-acting medicine.
 - **Incorrect patient name on the DAA label**

2. DAA incidents

- **Incorrect dose occurs when medicines are:**
 - **Damaged** - major damage, minor damage to special tablet coatings, discoloured/contaminated with smudges, melted.
 - **Divided when it's formulation doesn't allow it** - e.g. special-release tablet coating.
 - **Divided incorrectly** - e.g. halved when it should be a whole tablet.
 - **Divided inaccurately**
 - **Incorrect frequency of administration** - e.g. packed once daily instead of twice daily.
 - **Incorrect tablet quantity** - added or missing tablets.
 - **Incorrect strength** - of single or combination tablets.

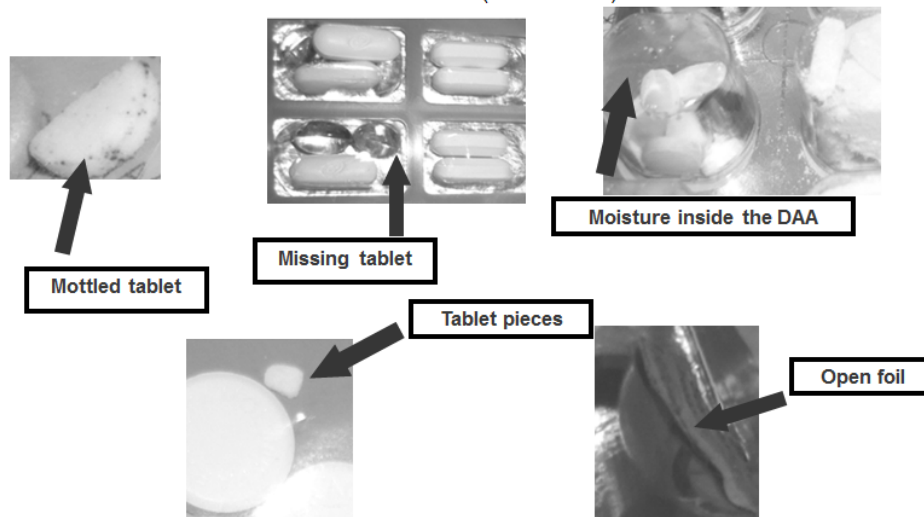


2. DAA incidents

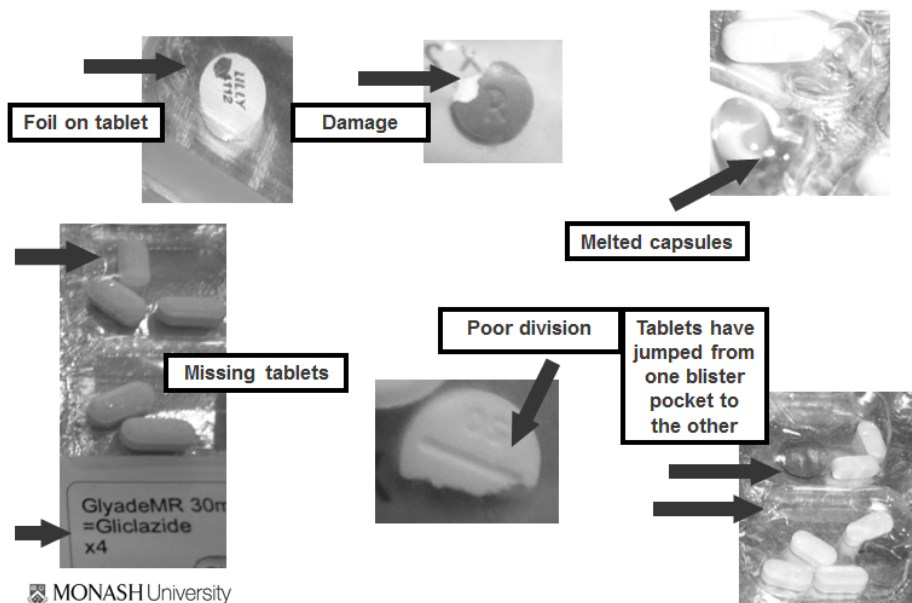
- **Incorrect dose schedule occurs when medicines are:**
 - **Packed on the incorrect day of the week**
 - **Packed at the incorrect time of day** - e.g. breakfast versus lunch, or at a meal time that doesn't correspond to the time on the medicine record.
 - **Not packed at a specific special time** - e.g. antibiotics or Parkinson's Disease medicines are not packed at the specific time on the medicine record or are packed at a meal time that doesn't match the time on the medicine record.
- **'Other' incidents occur when medicines are:**
 - **Packed with foreign objects** - foil, fluff, paper, hair, water, or the DAA is too full to accurately identify medicines.

2. DAA incidents

Look for DAA incidents in these next 2 slides (click mouse)



2. DAA incidents



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2. DAA incidents

- The next 2 slides describe what may happen to the patient if DAA incidents are not corrected before medicines are administered
 - Elderly patients rely on RACF and pharmacy staff to provide accurate and appropriately packed medicines for their medical conditions.
 - Be confident that you can provide this high level of care when handling DAAs.
 - Consider this when handling DAAs and checking for DAA incidents.
- Question 2
 - How can DAA incidents potentially harm the patient?



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2. DAA incidents

- If DAA incidents are not corrected before medicines are administered:
 - DAA incidents may destabilise medicine levels in the body, leading to poorly treated health conditions or adverse medicine effects.
 - They may also lead to swallowing difficulties, confusion (about the unfamiliar medicine packing) or poor quality medicine administration.

2. DAA incidents

How can these DAA incidents potentially harm the patient? (click mouse)



What would happen if Kang's anti-epileptic sodium valproate tablets were packed in the DAA without foil and they absorbed moisture?



What would happen if there were extra tablet pieces in Phyllis' DAA and you crushed them with her other medicines?



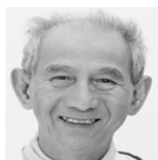
What would happen if Peter is missing one of his Parkinson's Disease tablets?



What would happen if Shirley swallowed pieces of foil that were packed into her DAA incorrectly?

2. DAA incidents

How can these DAA incidents potentially harm the patient? (click mouse)



**DAA incident:
unsuitable medicine
packing (unstable
medicines)**

The medicine levels in his body may destabilise and his epilepsy may not be well controlled.



**DAA incident:
wrong medicine**

She would be swallowing the tablet pieces along with her other medicines. This may have an effect on her health depending on what the tablet pieces were.



**DAA incident:
wrong dose**

The medicine levels in his body may destabilise and his Parkinson's Disease may not be well controlled.



**DAA incident:
'other' incident**

She may become distressed when she notices it.

3. Causes of DAA incidents

- The next 4 slides outline factors that may cause DAA incidents
 - Identify whether these factors exist in your workplace and address them to prevent DAA incidents.
- The entire health care team can contribute to DAA incidents occurring:
 - the pharmacy, RACF, prescriber, medicine manufacturing company, DAA packing company, the government/regulatory bodies, the patient and their family and the hospital.
- Question 3
 - What RACF and pharmacy factors may cause DAA incidents?



3. Causes of DAA incidents

- **Training**
 - Staff have medicine knowledge gaps and limited understanding of medicine processes (e.g. DAA medicine administration and checking); and training is poorly facilitated.
- **Communication**
 - Communication within the health care team is: lacking, ineffective, not comprehensive or timely, suffers from technology failures; and medicine records are inaccurate or incomplete.
- **Attitude**
 - Professional relationships are poor within the health care team, staff are not professional, helpful or motivated for training and skill improvement. They are dismissive of DAA incidents, quality improvement, accountability and job responsibilities and processes.

3. Causes of DAA incidents

- **Quality improvement**
 - Is not formalised or facilitated (e.g. it is difficult to develop, staff lack ideas and it is not routinely considered).
- **Money**
 - Is lacking for service reimbursement and restricts quality improvement.
- **Medicine handling**
 - Medicine administration, DAA packing and checking is careless, inaccurate, difficult and is restricted by time constraints.
- **Staff factors**
 - E.g. human error, reduced staff volume and non regular staff.

3. Causes of DAA incidents

All individuals and workplaces involved with DAAs
have the potential to cause DAA incidents



3. Causes of DAA incidents

- Consider DAA incidents in your workplace
- Reflection 1
 - What was the last DAA incident you saw and how do you think it could have harmed the patient?
- Reflection 2
 - Consider 2 factors in your workplace that may have contributed to this type of incident.
- Reflection 3
 - Consider 1 way that you may have contributed to this type of incident.
- Reflection 4
 - Consider 1 way that your colleagues may have contributed to this type of incident



4. Prevention of DAA incidents

- **The next 3 slides outline ways to prevent DAA incidents**
 - Consider implementing these ideas in your workplace to prevent DAA incidents.
- **The entire health care team can be targeted to prevent DAA incidents including:**
 - the pharmacy, RACF, prescriber, medicine manufacturing company, DAA packing company, the government, patient and the hospital.
- **Question 4**
 - What RACF and pharmacy factors can be targeted to prevent DAA incidents?



4. Prevention of DAA incidents

- **Training**
 - Facilitate relevant training to increase skill levels e.g. regarding medicine knowledge and medicine processes such as DAA medicine administration and checking.
- **Communication**
 - Facilitate communication within the health care team, enforce it and ensure it is comprehensive, prompt and timely; incorporate technology and provide an audit trail; include communication of policies, DAA incidents and medicine information; and update medicine records and include information to assist with medicine handling (e.g. DAA medicine administration, packing and checking).
- **Attitude**
 - Improve relationships within the health care team; collaborate with and respect staff; acknowledge the importance of DAA incidents, quality improvement and training; improve accountability; and improve attitudes towards the importance of staff health care roles and responsibilities.

4. Prevention of DAA incidents

- **Quality improvement**
 - Facilitate and enforce quality improvement; consider incorporating technology, guidelines and policies (e.g. regarding DAA incidents) into the workplace.
- **Money**
 - Allocate for service reimbursement (e.g. pharmacy services) and quality improvement (e.g. education).
- **Medicine handling**
 - Medicine administration, DAA packing and checking should be comprehensive and accurate and staff should pay close attention to detail during medicine processes; the workload should be shared and could be assisted with systems, technology and role allocation.
- **Staff factors**
 - Consider regular staff, increasing staff volume and the presence of authority positions (to direct queries to and seek assistance from).

4. Prevention of DAA incidents

- **The next 3 slides describe practical tips to prevent specific DAA incidents in your workplace**
 - Consider these general practical tips:
 - pack DAAs carefully according to updated RACF medicine records.
 - **(BE ALERT)** inspect the DAA for incidents or poor quality packing and check the DAA with the updated RACF medicine records
 - » carefully check the entire DAA at the pharmacy during and after DAA packing and at the RACF before medicine administration,
 - **(WORK TOGETHER)** keep accurate and updated records and promptly, accurately and comprehensively communicate DAA incidents and medicine changes to the RACF, pharmacy and prescriber.
 - consult the prescriber and make records of any medicine changes.

4. Prevention of DAA incidents

- **Medicines unsuitable for packing according to pharmaceutical guidelines**
 - Refer to pharmaceutical packing guidelines.
 - Consult:
 - your RACF/pharmacy about different medicine supply/packing options,
 - your prescriber about prescribing stable medicines for DAA packing,
 - your prescriber if you choose to pack unstable medicines (make a record of this).
 - Keep medicines in their original container for qualified staff to administer (e.g. similar to administering eye drops and creams).
 - Pack medicines in their carefully cut foil and ensure the foil is not swallowed.
 - Pack DAAs close to the supply date and store away from light, in temperature controlled rooms.
 - Use 'non-packed' alerts e.g. write 'non-packed' on the medicine record and on the DAA for medicines that are not packed in the DAA.
- **Incorrect dose**
 - Consider special formulation properties of medicines before dividing.
 - Divide medicines carefully and accurately.
 - Ensure the accurate strength of combination medicines are packed in the DAA.

4. Prevention of DAA incidents

- **Incorrect or missing medicine**
 - Ensure combination tablets are packed accurately according to the medicine record.
 - Pack DAAs to a high standard and remove tablet dust/pieces.
 - Ensure medicine records have complete information e.g. medicine form such as tablet/capsule and special tablet properties such as long-acting.
- **Incorrect dose schedule**
 - Ensure medicines are packed according to the time on the medicine record.
 - When packing at meal times, consider the time meals are given at the RACF.
 - Ensure antibiotics and Parkinson's Disease medicines are packed according to the time on the medicine record and include those times on the DAA.
- **'Other' incidents**
 - Avoid overfilling DAAs.

4. Prevention of DAA incidents

- The next 2 slides will help you to consider DAA incident prevention in your workplace
- **Reflection 5**
 - Consider 1 way that your workplace has tried to prevent DAA incidents.
- **Reflection 6**
 - Consider 1 reason why the idea in Reflection 5 was successful or not.
- **Reflection 7**
 - Consider 1 idea that your workplace should implement to prevent DAA incidents.
- **Reflection 8**
 - Consider 1 way that your workplace can ensure your idea in Reflection 7 is successful at preventing DAA incidents.

4. Prevention of DAA incidents

- **Keep a DAA incident diary for the next 7 days**
 - Record 1 DAA incident you find in your workplace
 - e.g. packing unstable medicines.
 - Record 1 reason why this has occurred
 - e.g. RACF staff are not aware of different supply/packing options.
 - Record 1 way to prevent this DAA incident
 - e.g. pack the medicine in it's carefully cut foil in the DAA.
 - Consider how this idea can be implemented in your workplace to ensure it is successful
 - e.g. discuss this different packing option with RACF and pharmacy staff.
- At the end of the 7 days** present this idea to the person responsible for quality improvement/DAA's.



4. Prevention of DAA incidents

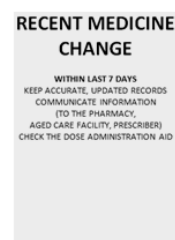
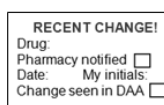
- A quality improvement Toolkit has been given to your RACF or pharmacy, titled:

‘BE ALERT AND WORK TOGETHER’ for medicine safety
Dose Administration Aid (DAA)
Incident Awareness Toolkit
- The Toolkit contents may prevent DAA incidents in your workplace:
 - use them as they are, or modify them for your workplace,
 - come up with your own Toolkit contents to improve DAA handling (e.g. DAA checking, and recording and communication of DAA incidents and medicine changes).



4. Prevention of DAA incidents

- The Toolkit contents include:
 - guidelines and studies regarding medicines unsuitable for DAA packing,
 - posters (remind staff to check DAAs and communicate medicine information),
 - bookmarks and stickers (alert staff to medicine record changes and remind them to follow it up).



4. Prevention of DAA incidents

- The Toolkit contents include:
 - this CD-ROM and handouts (for education),
 - template certificates (for completing/attending this CD-ROM presentation),
 - template medicine identification sheet (consider asking your pharmacy for this to assist with DAA packing and checking),
 - template DAA incident policy and procedure,
 - RACF and pharmacy specific DAA guidelines.

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4. Prevention of DAA incidents

- Consult RACF and pharmacy DAA guidelines for more information

www.psa.org.au	<ul style="list-style-type: none"> • Professional practice standards version 4, 2010 (Standard 7: Dose Administration Aids Service). • Guidance and checklists for DAA service delivery. • Self assessment worksheet for the professional practice standards version 4. • Guidelines and standards for pharmacists - Dose Administration Aids service (also known as 'dose administration service guidelines').
www.health.gov.au	<ul style="list-style-type: none"> • Guiding principles for medication management in the community - June or July 2006 (Guiding principle 3 - Dose Administration Aids). • Guidelines for medication management in residential aged care facilities - 3rd Edition (Recommendation 9 - Dose Administration Aids).
www.pharmacyboard.gov.au	<ul style="list-style-type: none"> • Guidelines on specialised supply arrangements.
www.health.vic.gov.au	<ul style="list-style-type: none"> • Resource kit to enable implementation of the APAC guidelines for medication management in residential aged care facilities - Sept 2006. • Public sector residential aged care services bulletin - Sept 2006.
www.anf.org.au	<ul style="list-style-type: none"> • The use of DAAs by nurses - ANF guidelines. • The use of DAAs by nurses - ANF position statement.
www.pdl.org.au	<ul style="list-style-type: none"> • Guide to good dispensing chart.

Test yourself

- **Question 1:** There are only a couple of DAA incident types that may occur in DAAs.
A) True B) False
- **Question 2:** Both the RACF and pharmacy may contribute to DAA incidents.
A) True B) False
- **Question 3:** You should only target the RACF when preventing DAA incidents.
A) True B) False
- **Question 4:** It is important to consider different supply/packing options for unstable medicines.
A) True B) False
- **Question 5:** All RACF and pharmacy staff should play an active role in the DAA service, including checking the DAA.
A) True B) False
- **Question 6:** DAA incidents and medicine changes should be recorded and communicated to the RACF, pharmacy and prescriber.
A) True B) False

Test yourself

- Question 1: False
- Question 2: True
- Question 3: False
- Question 4: True
- Question 5: True
- Question 6: True



Congratulations!

- You have completed the:

'BE ALERT AND WORK TOGETHER' for medicine safety

**Dose Administration Aid (DAA)
Incident Awareness Toolkit CD-ROM**

- Remember to use the information you have learnt in your daily practice!
- Ask the person responsible for staff education/quality improvement/DAA's to see the DAA Toolkit and for a certificate of completion/attendance for this presentation.
- Acknowledgements: to the Monash University Pharmacy and Pharmaceutical Sciences Pharmville educational website and Monash University staff for supplying some photos used in this presentation and the individuals who evaluated this Toolkit.

Appendix 31: Toolkit question handout

Question Handout

Also refer to 'Answers' Handout

Question 1: List 4 types of incidents that can be found in DAAs.

1. _____
2. _____
3. _____
4. _____

Question 2: For each of the above incidents, list one way it could harm the patient.

1. _____
2. _____
3. _____
4. _____

Question 3: For each incident in Question 1, list one factor that may cause this DAA incident.

1. _____
2. _____
3. _____
4. _____

Question 4: For each incident in Question 1, list one way it can be prevented.

1. _____
2. _____
3. _____
4. _____

Appendix 32: Toolkit answer handout

Answer Handout

2. DAA incidents

- **All DAA incidents are important**
 - Don't ignore a DAA incident, because it may harm the patient.
 - Consider why the DAA incident occurred and address these factors.
- **The next 5 slides describe the types of DAA incidents that may occur**
 - Look out for these DAA incidents when checking DAAs.
- **Question 1**
 - What types of incidents can be found in DAAs?



2. DAA incidents

- **Medicines unsuitable for packing according to pharmaceutical guidelines, occurs when:**
 - **Unstable medicines are packed into DAAs** - dispersible, dissolvable, in poorly sealed foil.
- **Incorrect or missing medicines occurs when medicines are:**
 - **Added** - when ceased, added everyday when they are 'when required', a wrong combination tablet or extra tablets are packed, a combination tablet is packed when only one medicine is on the medicine record, tablet dust/pieces are packed.
 - **Missing** - every day or sporadically, or a single medicine is packed instead of a combination tablet.
 - **Changed for a brand that is not equivalent** (e.g. warfarin) **or against the prescriber's wishes** ('do not substitute' is on the medicine record).
 - **Incorrect form** - e.g. tablet versus capsule.
 - **Incorrect formulation** - e.g. normal release versus long-acting medicine.
 - **Incorrect patient name on the DAA label**

2. DAA incidents

- **Incorrect dose occurs when medicines are:**
 - **Damaged** - major damage, minor damage to special tablet coatings, discoloured/contaminated with smudges, melted.
 - **Divided when it's formulation doesn't allow it** - e.g. special-release tablet coating.
 - **Divided incorrectly** - e.g. halved when it should be a whole tablet.
 - **Divided inaccurately**
 - **Incorrect frequency of administration** - e.g. packed once daily instead of twice daily.
 - **Incorrect tablet quantity** - added or missing tablets.
 - **Incorrect strength** - of single or combination tablets.

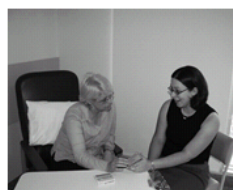


2. DAA incidents

- **Incorrect dose schedule occurs when medicines are:**
 - **Packed on the incorrect day of the week**
 - **Packed at the incorrect time of day** - e.g. breakfast versus lunch, or at a meal time that doesn't correspond to the time on the medicine record.
 - **Not packed at a specific special time** - e.g. antibiotics or Parkinson's Disease medicines are not packed at the specific time on the medicine record or are packed at a meal time that doesn't match the time on the medicine record.
- **'Other' incidents occur when medicines are:**
 - **Packed with foreign objects** - foil, fluff, paper, hair, water, or the DAA is too full to accurately identify medicines.

2. DAA incidents

- **The next 2 slides describe what may happen to the patient if DAA incidents are not corrected before medicines are administered**
 - Elderly patients rely on RACF and pharmacy staff to provide accurate and appropriately packed medicines for their medical conditions.
 - Be confident that you can provide this high level of care when handling DAAs.
 - Consider this when handling DAAs and checking for DAA incidents.
- **Question 2**
 - How can DAA incidents potentially harm the patient?



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2. DAA incidents

- **If DAA incidents are not corrected before medicines are administered:**
 - DAA incidents may destabilise medicine levels in the body, leading to poorly treated health conditions or adverse medicine effects.
 - They may also lead to swallowing difficulties, confusion (about the unfamiliar medicine packing) or poor quality medicine administration.

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3. Causes of DAA incidents

- **The next 4 slides outline factors that may cause DAA incidents**
 - Identify whether these factors exist in your workplace and address them to prevent DAA incidents.
- **The entire health care team can contribute to DAA incidents occurring:**
 - the pharmacy, RACF, prescriber, medicine manufacturing company, DAA packing company, the government/regulatory bodies, the patient and their family and the hospital.
- **Question 3**
 - What RACF and pharmacy factors may cause DAA incidents?



3. Causes of DAA incidents

- **Training**
 - Staff have medicine knowledge gaps and limited understanding of medicine processes (e.g. DAA medicine administration and checking); and training is poorly facilitated.
- **Communication**
 - Communication within the health care team is: lacking, ineffective, not comprehensive or timely, suffers from technology failures; and medicine records are inaccurate or incomplete.
- **Attitude**
 - Professional relationships are poor within the health care team, staff are not professional, helpful or motivated for training and skill improvement. They are dismissive of DAA incidents, quality improvement, accountability and job responsibilities and processes.

3. Causes of DAA incidents

- **Quality improvement**
 - Is not formalised or facilitated (e.g. it is difficult to develop, staff lack ideas and it is not routinely considered).
- **Money**
 - Is lacking for service reimbursement and restricts quality improvement.
- **Medicine handling**
 - Medicine administration, DAA packing and checking is careless, inaccurate, difficult and is restricted by time constraints.
- **Staff factors**
 - E.g. human error, reduced staff volume and non regular staff.

4. Prevention of DAA incidents

- **The next 3 slides outline ways to prevent DAA incidents**
 - Consider implementing these ideas in your workplace to prevent DAA incidents.
- **The entire health care team can be targeted to prevent DAA incidents including:**
 - the pharmacy, RACF, prescriber, medicine manufacturing company, DAA packing company, the government, patient and the hospital.
- **Question 4**
 - What RACF and pharmacy factors can be targeted to prevent DAA incidents?



4. Prevention of DAA incidents

- **Training**
 - Facilitate relevant training to increase skill levels e.g. regarding medicine knowledge and medicine processes such as DAA medicine administration and checking.
- **Communication**
 - Facilitate communication within the health care team, enforce it and ensure it is comprehensive, prompt and timely; incorporate technology and provide an audit trail; include communication of policies, DAA incidents and medicine information; and update medicine records and include information to assist with medicine handling (e.g. DAA medicine administration, packing and checking).
- **Attitude**
 - Improve relationships within the health care team; collaborate with and respect staff; acknowledge the importance of DAA incidents, quality improvement and training; improve accountability; and improve attitudes towards the importance of staff health care roles and responsibilities.

4. Prevention of DAA incidents

- **Quality improvement**
 - Facilitate and enforce quality improvement; consider incorporating technology, guidelines and policies (e.g. regarding DAA incidents) into the workplace.
- **Money**
 - Allocate for service reimbursement (e.g. pharmacy services) and quality improvement (e.g. education).
- **Medicine handling**
 - Medicine administration, DAA packing and checking should be comprehensive and accurate and staff should pay close attention to detail during medicine processes; the workload should be shared and could be assisted with systems, technology and role allocation.
- **Staff factors**
 - Consider regular staff, increasing staff volume and the presence of authority positions (to direct queries to and seek assistance from).

Appendix 33: Toolkit reflection handout

Reflection Handout

No answers provided

Reflection 1: What was the last DAA incident you saw and how do you think it could have harmed the patient?

DAA incident: _____

How it could have harmed the patient: _____

Reflection 2: List 2 factors in your workplace that may have contributed to the DAA incident in Reflection 1.

1. _____

2. _____

Reflection 3: List 1 way that you may have contributed to the DAA incident in Reflection 1.

1. _____

Reflection 4: List 1 way that your colleagues may have contributed to the DAA incident in reflection 1.

1. _____

Reflection 5: List 1 strategy that your workplace has implemented to prevent DAA incidents.

1. _____

Reflection 6: List one reason why the strategy in Reflection 5 was successful or not.

1. _____

Reflection 7: List 1 strategy that your workplace should implement to prevent DAA incidents.

1. _____

Reflection 8: List 1 way that your workplace can ensure your strategy in Reflection 7 is successful at preventing DAA incidents.

1. _____

Appendix 34: Toolkit certificates

<p style="text-align: center;">Certificate of Completion</p> <p style="text-align: center;">Congratulations</p> <hr style="width: 20%; margin: auto;"/> <p style="text-align: center;">for completing the</p> <p style="text-align: center;">‘BE ALERT AND WORK TOGETHER’ for medicine safety</p> <p style="text-align: center;">Dose Administration Aid (DAA) Incident Awareness Toolkit CD-ROM</p> <p>Date:</p> <p>Workplace name:</p> <p>Person responsible for staff education/quality improvement/DAA:</p> <p>Approximate duration of education (30-60 minutes):</p>
--

<p style="text-align: center;">Certificate of Attendance</p> <p style="text-align: center;">Congratulations</p> <hr style="width: 20%; margin: auto;"/> <p style="text-align: center;">for attending the</p> <p style="text-align: center;">‘BE ALERT AND WORK TOGETHER’ for medicine safety</p> <p style="text-align: center;">Dose Administration Aid (DAA) Incident Awareness Toolkit CD-ROM</p> <p style="text-align: center;">presentation</p> <p>Date:</p> <p>Workplace name:</p> <p>Person responsible for staff education/quality improvement/DAA:</p> <p>Approximate duration of education (30-60 minutes):</p>
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Appendix 35: Toolkit medicine identification sheet

Medicine Identification Sheet

Resident Details

Name: Mrs Phyllis Dawson Sex: F DOB: 3/8/35 Room: 2B (Magnolia Wing) Facility: The Nursing Home, Pharmville



Date of photo: 5/2/12

Regular DAA Packed Medicines

DAA refers to dose administration aid e.g. blister pack or sachet

Brand name	Losec®	Norvasc®	APO Simvastatin®
Generic/drug name	Omeprazole	Amlodipine	Simvastatin
Strength	20mg	10mg	40mg
Dose	1 daily 0800 (Breakfast)	1 daily 1200 (Lunch)	1 daily 2000 (Bedtime)
Colour of packed medicine	Pink	White	Orange
Picture of packed medicine			
Picture of different medicine brand/generic (may be written on medicine record)			

TURN OVER TO RECORD DAA INCIDENT DETAILS

DAA Incident Details

DAA incident refers to inaccurate or inappropriate DAA medicine packing

RACF refers to residential aged care facility

Date identified	5/2/12						
Who identified	Sally Smith						
Medicine round	Breakfast (0800)						
Patient name	Phyllis Dawson						
Medicine (drug, strength)	Omeprazole, 20mg						
DAA incident description	Half a tablet packed when it should be 1 whole tablet						
Staff notified at RACF (name, position, date)	Mary Brown, RN, 5/2/12						
Staff notified at pharmacy (name, position, date)	Alice Jones, Pharmacist, 5/2/12						
RACF action	Return DAA to pharmacy this morning (0900)						
Pharmacy action	Send new DAA to RACF this evening (1700)						
DAA incident recorded and details provided to RACF and pharmacy staff responsible for evaluation (Y/N)	Y						

Appendix 36: Toolkit policy and procedure

Workplace name: The nursing home/the pharmacy

Document title: Template policy and procedure for DAA incidents

Version: 1	Last updated: 26/05/12	Next review: 26/05/13
Updated by: Jane Doe (manager)	Approved by: Mark Smith (owner)	Collaborated with: May Stamp (care coordinator) Alice Jones (quality improvement) John Damp (pharmacist)

Date issued to staff: 27/05/12

Definitions

- **DAA** refers to dose administration aid (e.g. blister packs or sachets).
- **DAA incident** refers to inaccurate or inappropriate DAA medicine packing including:
 - inappropriately packed medicines according to pharmaceutical guidelines
 - incorrect or missing medicines
 - incorrect dose
 - incorrect dose schedule
 - ‘other incidents’ e.g. quality control incidents such as the packing of foil, paper, hair.
- **RACF** refers to residential aged care facility.

Purpose

- To outline the course of action following a DAA incident identified in the workplace.
- To identify, record and communicate DAA incidents for the purpose of prevention.

Scope

- **This covers:** DAA incidents that are identified before or after medicine administration to the patient.
- **This does not cover:** medicine administration incidents (errors due to the incorrect administration of medicines despite accurate and appropriate DAA medicine packing).

Applies to

- **This applies to:** all staff who have a significant role in DAA handling e.g. packing, checking and administration of medicines.
- **This does not apply to:** staff who do not handle DAAs or are only involved in the logistics of DAA handling e.g. transport and storage.

References

- Pharmacy and RACF specific guidelines in the 'BE ALERT AND WORK TOGETHER' for medicine safety DAA Incident Awareness Toolkit (see the person responsible for staff education/quality improvement/DAAAs).

Compliance requirements

- All staff who this document applies to must comply with this policy and procedure in its entirety.
- Staff who do not comply with this document must undergo a period of re-training and assessment (e.g. re-familiarisation of this document and asked questions about it).

Audit requirements

- Every 6 months during a staff meeting or medicine management training session this document will be discussed with regular staff to ensure it is known and understood.
- This document will be discussed with new staff upon their employment at the workplace.
- Every month DAA incident records will be evaluated to ensure this document is being followed.

Responsibilities

- **Role:** registered nurse/pharmacist.
- **Responsibility**
 - Conduct competency and knowledge assessment regarding this document at regular intervals (e.g. 6 monthly for all staff), upon employment for new staff and when staff have not complied with this document.
- **Role:** registered nurse/enrolled nurse/personal care worker/pharmacist/pharmacy technician.
- **Responsibility**
 - Checking
 - During and after DAA packing and prior to medicine administration staff will:
 - inspect the entire DAA for DAA incidents,
 - check the DAA with the updated RACF medicine record.
 - Recording
 - Any identified DAA incidents will be promptly, accurately and completely recorded in a specific DAA incident record book located in the medicine room/DAA preparation area. It is important to record all DAA incidents that occur to encourage quality improvement and prevention.
 - The DAA incident record book will be easily accessible to all staff and will be shown to all staff to ensure its location and procedure for use is known.

- Staff will be trained on the types of DAA incidents that may occur.
- Communicating
 - Any identified DAA incidents will be promptly, accurately and completely communicated to the RACF, pharmacy and prescriber.
 - It is important to communicate DAA incidents soon after their identification e.g. before the end of a medicine shift/DAA packing sequence.
 - It is important to communicate in person or via the telephone to allow comprehensive communication.
 - All staff will be aware of the primary contact person at the RACF, pharmacy and the prescriber to ensure streamlined communication of DAA incidents.
- Correction
 - DAAs with incidents will be returned to the pharmacy for correction and a new DAA supplied within 24 hours.
- Evaluation
 - DAA incident records will be regularly (e.g. monthly) evaluated for DAA incident contributing factors and strategies for prevention.
 - All staff will comment on DAA incident contributing factors and strategies for prevention via the DAA incident record book.
 - DAA incident evaluation will be communicated at medication advisory committee (MAC) meetings.
- Quality improvement
 - Following evaluation of DAA incidents, contributing factors will be addressed immediately.
 - Strategies to prevent DAA incidents will be trialled on a regular basis (e.g. every 3 months).
 - The RACF and pharmacy will regularly discuss DAA incident records (e.g. every 3 months) to consider strategies for prevention.

Reference to other existing policies and procedures in the workplace

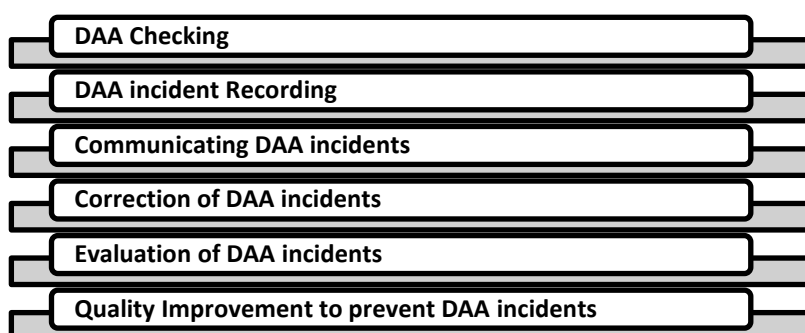
- Also refer to other policies and procedures at the RACF and pharmacy regarding medicine administration and errors/incidents.

Sample DAA incident record book template

(Records are to be made by staff identifying the DAA incident)

Date	<i>5/2/12</i>
Name	<i>Sally Smith</i>
Medicine round	<i>Breakfast (0800)</i>
Patient name	<i>Phyllis Dawson</i>
Medicine (drug, strength)	<i>Omeprazole, 20mg</i>
Incident description	<i>Half a tablet packed when it should be 1 whole tablet</i>
Staff notified at RACF (name, position, date)	<i>Mary Brown, RN, 5/2/12</i>
Staff notified at pharmacy (name, position, date)	<i>Alice Jones, Pharmacist, 5/2/12</i>
RACF action	<i>Return DAA to pharmacy this morning (0900)</i>
Pharmacy action	<i>Send new DAA to RACF this evening (1700)</i>
DAA incident recorded and details provided to RACF and pharmacy staff responsible for evaluation (Y/N)	<i>Y</i>
Contributing factors to DAA incident	<i>Medicine change not communicated to pharmacy</i>
Strategies to prevent DAA incident	<i>Communicate medicine changes promptly to pharmacy when they occur and provide a copy of the entire medicine record for reference</i>

Flowchart for management of DAA incidents



Appendix 37: Phase 4 dose administration aid audit form

Patient details form

RA initials	JU (1)
Date	/ /
Phase	2 nd audit (re-audit) (2)
RACF code	
Record #	
DAA type	B (1) S (2) Both (3)
Pharmacy code	
DAA features:	unit (1) multi (2) combo (3)
Other (single pack for B/L/D etc):	Other:
# individual DAA units for ONE patient for ONE week that you audit (REGULAR MEDS)	#B packs _____ #S squares (1 st roll) _____ #S squares (2 nd roll) _____
Sachet times (roll 1)	() () () () () () () () () ()
Sachet times (roll 2)	() () () () () () () () () ()
YOB	
Gender	M (1) F (2)
Other patient info:	

B L D Be

MOST CURRENT RACF medicine record

REGULAR DAA packed medicines

	Drug / Brand	Strength	Can't ID (description)	Checked? (tick)	If not packed in a DAA remove from list. If not checked, where is it and why?
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					

Incident photo details: **Date** **Record #** **RACF code** **Incident #**

Incident details

Incident # :					
	Drug	Brand	Strength	Form	Dose / Frequency / Time
RACF record					
The DAA					
Incident details:					
Day:		Time:		What the erroneous medicine was being used for:	
Single/isolated incident			Y (1) N (2)		
# of times occurred in one dose interval (e.g. lunch)					
# of times occurred in 1 blister pocket or 1 sachet square					
# of times occurred in 1 whole blister pack					
# of times occurred in one week's supply for one patient					
# packs/rolls affected					
# packs/rolls affected (compared to other incidents)			DIFF SAME NA		
RACF staff shown			Y N NA		
Error by RN			Y N unsure NA		
RACF/pcy staff reported			Y N		
Error by RA			Y N		
Reason/cause for the incident (and source of this info):					
Outcome/pcy response:					

Incident # :					
	Drug	Brand	Strength	Form	Dose / Frequency / Time
RACF record					
The DAA					
Incident details:					
Day:		Time:		What the erroneous medicine was being used for:	
Single/isolated incident			Y (1) N (2)		
# of times occurred in one dose interval (e.g. lunch)					
# of times occurred in 1 blister pocket or 1 sachet square					
# of times occurred in 1 whole blister pack					
# of times occurred in one week's supply for one patient					
# packs/rolls affected					
# packs/rolls affected (compared to other incidents)			DIFF SAME NA		
RACF staff shown			Y N NA		
Error by RN			Y N unsure NA		
RACF/pcy staff reported			Y N		
Error by RA			Y N		
Reason/cause for the incident (and source of this info):					
Outcome/pcy response:					

Incident # :					
	Drug	Brand	Strength	Form	Dose / Frequency / Time
RACF record					
The DAA					
Incident details:					
Day:		Time:		What the erroneous medicine was being used for:	
Single/isolated incident			Y (1) N (2)		
# of times occurred in one dose interval (e.g. lunch)					
# of times occurred in 1 blister pocket or 1 sachet square					
# of times occurred in 1 whole blister pack					
# of times occurred in one week's supply for one patient					
# packs/rolls affected					
# packs/rolls affected (compared to other incidents)			DIFF SAME NA		
RACF staff shown			Y N NA		
Error by RN			Y N unsure NA		
RACF/pcy staff reported			Y N		
Error by RA			Y N		
Reason/cause for the incident (and source of this info):					
Outcome/pcy response:					

Incident # :					
	Drug	Brand	Strength	Form	Dose / Frequency / Time
RACF record					
The DAA					
Incident details:					
Day:		Time:		What the erroneous medicine was being used for:	
Single/isolated incident			Y (1) N (2)		
# of times occurred in one dose interval (e.g. lunch)					
# of times occurred in 1 blister pocket or 1 sachet square					
# of times occurred in 1 whole blister pack					
# of times occurred in one week's supply for one patient					
# packs/rolls affected					
# packs/rolls affected (compared to other incidents)			DIFF SAME NA		
RACF staff shown			Y N NA		
Error by RN			Y N unsure NA		
RACF/pcy staff reported			Y N		
Error by RA			Y N		
Reason/cause for the incident (and source of this info):					
Outcome/pcy response:					

Appendix 38: Phase 4 residential aged care facility questionnaire

DAA	= dose administration aid e.g. blister packs and sachets
DAA incident	= inaccurate or inappropriate DAA medicine packing
RACF	= residential aged care facility
Toolkit	= 'BE ALERT AND WORK TOGETHER' for medicine safety Dose Administration Aid (DAA) Incident Awareness Toolkit designed to reduce DAA incidents and given to RACFs via an education session
Please highlight or type answers	

1	I am a:	Div 1 Nurse	Div 2 Nurse/Enrolled Nurse	Carer/Personal Care Worker	Other:	
2	I have worked with RACF DAAs for:	_____ years				
3	My answers below will relate to:	Blister packs	Sachets	Both	Other _____	
What percentage of the Toolkit...						
4	...did your RACF use/implement in the <u>short term</u> ?	_____ %				
5	...will your RACF use/implement <u>permanently</u> ?	_____ %				
6	...was new to your RACF's existing medicine management systems?	_____ %				
7	What components of the Toolkit were implemented at your RACF?					
	Posters	Bookmarks	Stickers	CD-ROM	Medicine identification sheet	
	Other (e.g. guidelines/article/handouts/policy/procedure):					
8	What components of the Toolkit were NOT implemented at your RACF?					
	Posters	Bookmarks	Stickers	CD-ROM	Medicine identification sheet	
	Other (e.g. guidelines/article/handouts/policy/procedure):					
9	Why were those components NOT implemented?					
10	How can the Toolkit be improved?					
11	Where is the Toolkit currently stored/kept at your RACF?					
	Front office	Staff room	Medicine room	Nurses station	Other:	
12	Who is currently aware of the Toolkit at your RACF?					
	Nurses(Div1/Div2)	Carers/Personal care workers	Management staff	All staff	Other:	
For the questions below, place a number in the column that your answer relates to		Not at all	Somewhat	Moderately	Very	Extremely well
How well do you think the Toolkit...		(1)	(2)	(3)	(4)	(5)
13	improved the accuracy and appropriateness of DAA medicine packing?					
14	reduced the occurrence of DAA incidents?					
15	improved RACF medicine administration using DAAs?					
16	improved DAA checking <u>WITHIN</u> your RACF?					
17	improved communication <u>WITHIN</u> your RACF?					
18	improved communication <u>WITH</u> your pharmacy?					
19	improved the relationship <u>WITH</u> your pharmacy?					
20	improved awareness of DAA incidents?					
21	improved awareness of contributing factors to DAA incidents?					
22	improved awareness of strategies to prevent DAA incidents?					
23	reinforced existing RACF medicine management systems?					
24	How useful was the Toolkit for your RACF?					

Further comments:

Appendix 39: Phase 4 pharmacy questionnaire

DAA	= dose administration aid e.g. blister packs and sachets
DAA incident	= inaccurate or inappropriate DAA medicine packing
RACF	= residential aged care facility
Toolkit	= 'BE ALERT AND WORK TOGETHER' for medicine safety Dose Administration Aid (DAA) Incident Awareness Toolkit designed to reduce DAA incidents and given to RACFs via an education session
Please highlight or type answers	

1	I am a:	Pharmacist	Pharmacy Technician	Pharmacy Student/Intern	Other:	
2	I have worked with RACF DAAs for:	_____ years				
3	My answers below will relate to:	Blister packs	Sachets	Both	Other _____	
What percentage of the Toolkit...						
4	...did your pharmacy use/implement in the <u>short term</u> ?	_____ %				
5	...will your pharmacy use/implement <u>permanently</u> ?	_____ %				
6	...was new to your pharmacy's existing medicine management systems?	_____ %				
7	What components of the Toolkit were implemented at your pharmacy?					
	Posters	Bookmarks	Stickers	CD-ROM	Medicine identification sheet	
	Other (e.g. guidelines/article/handouts/policy/procedure):					
8	What components of the Toolkit were NOT implemented at your pharmacy?					
	Posters	Bookmarks	Stickers	CD-ROM	Medicine identification sheet	
	Other (e.g. guidelines/article/handouts/policy/procedure):					
9	Why were those components NOT implemented?					
10	How can the Toolkit be improved?					
11	Where is the Toolkit currently stored/kept at your pharmacy?					
	Front office	Staff room	Dispensary	DAA packing area	Other:	
12	Who is currently aware of the Toolkit at your pharmacy?					
	Pharmacists	Pharmacy technicians	Management staff	All staff	Other:	
For the questions below, place a number in the column that your answer relates to						
		Not at all (1)	Somewhat (2)	Moderately (3)	Very (4)	Extremely well (5)
How well do you think the Toolkit...						
13	improved the accuracy and appropriateness of DAA medicine packing?					
14	reduced the occurrence of DAA incidents?					
15	improved pharmacy medicine supply from DAAs?					
16	improved DAA checking <u>WITHIN</u> your pharmacy?					
17	improved communication <u>WITHIN</u> your pharmacy?					
18	improved communication <u>WITH</u> your RACF?					
19	improved the relationship <u>WITH</u> your RACF?					
20	improved awareness of DAA incidents?					
21	improved awareness of contributing factors to DAA incidents?					
22	improved awareness of strategies to prevent DAA incidents?					
23	reinforced existing pharmacy medicine management systems?					
24	How useful was the Toolkit for your pharmacy?					
Further comments:						