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PHARMACISTS IN RESIDENTIAL AGED CARE FACILITIES (PiRACF) STUDY

FINAL EVALUATION REPORT

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The University of Canberra acknowledges the Ngunnawal people, traditional custodians of the lands where Bruce Campus is situated. We wish to acknowledge and respect their continuing culture and the contribution they make to the life of Canberra and the region. We also acknowledge all other First Nations Peoples on whose lands we gather.

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This is the final report of Phase 1 of the Pharmacist in Residential Aged Care Facilities (PiRACF) study, which was supported by funding from the Australian Capital Territory's Primary Health Network through the Australian Government's Primary Heath Network Program. The Pharmacist in Residential Aged Care Facilities (PiRACF) study and evaluation were undertaken by researchers from the Health Research Institute at the University of Canberra, and the economic evaluation was conducted by researchers from the Australian National University's National Centre for Epidemiology and Population Health. Phase 2 outcomes will be presented in the Phase 2 report, due 30 March 2023.

The research team would like to acknowledge and thank residential aged care managers, staff, residents, families and carers as well as on-site pharmacists, general practitioners, prescribers and health care professionals who participated in the study. We are also grateful for the time and invaluable insights that the Study Governance Committee provided.

The research team acknowledges the contribution of the following members on the project (in alphabetical order):

- Dr Danish Ahmad, research officer, assisted with data cleaning and analysis of pharmacist diary data.
- Ms Miranda Batten, PhD candidate, assisted with the evaluation of the study.
- Associate Professor Liliana Bulfone assisted with the economic evaluation of the study.
- Dr Michael Dale, senior data manager, managed the data for the project.
- Ms Mei Davey, research officer, assisted with data collection, data entry and qualitative data analysis.
- Professor Rachel Davey was a study Chief Investigator.
- Mr Ibrahim Haider, PhD candidate, analysed the medication and non-medication outcomes.
- Dr Jane Koerner, senior research officer, project managed the study.
- Associate Professor Sam Kosari was a study Chief Investigator.
- Professor Emily Lancsar lead the economic evaluation of the study.
- Dr Syarifah Liza Munira, research fellow, conducted the economic evaluation of the study.
- Professor Mark Naunton was a study Chief Investigator.
- Ms Sarah Nikro, administration officer, assisted with data collection and data entry.
- Associate Professor Theo Niyonsenga, contributed to the conceptualisation of the statistical analyses.
- Dr Sundus Nizamani, research officer, assisted with data cleaning and analysis of pharmacist diary data.
- Mr Rahanan Sathiyakuar, research officer, assisted with data collection.
- Mr Thomas Vasey, research officer, assisted with quantitative data analysis.

The opinions expressed are those of the authors and do not necessarily reflect those of the funding body.

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SUMMARY

Older people living in residential aged care facilities (RACFs) are at increased risk of medication-related harm due to high rates of co-morbidities and inappropriate medication use. Medication-related adverse events in older adults, including aged care residents, are the leading cause of hospitalisation, incurring a significant cost to the health care system.[1] Given the high rate of reported medication-related problems in RACF residents in Australian studies, optimising medication management is important in reducing the likelihood of adverse health outcomes resulting from medications.

The recent final report of the Royal Commission into Aged Care Quality and Safety has highlighted problems relating to medication management and has made several recommendations, including increasing access to allied health professionals, including pharmacists. In Australia, there is a growing recognition that a more integrated approach for pharmacists' involvement in RACF residents' medication management is required, one which goes well beyond existing residential medication management reviews and quality use of medicines services is.

The Australian Government, recognising the importance of this issue, recently announced funding for community and on-site pharmacists into residential aged care from 2023 to improve medication safety. The Pharmacists in RACFs (PiRACF) study will provide an evidence base to inform the effectiveness and implementation of on-site pharmacist in residential aged care model to improve medication management for RACF residents and reduce medication-related adverse outcomes.

This is the final report of Phase 1 of the PiRACF study, which was supported by funding from the Australian Capital Territory's Primary Health Network through the Australian Government's Primary Heath Network Program.

A NEW MODEL OF INTERDISCIPLINARY CARE

Our study was a cluster randomised controlled trial (cRCT) in RACFs in the ACT to examine the impact of this model of care on the appropriateness of medication use. A mixed-methods design was used to evaluate implementation, adherence, collaboration, and normalisation of this model of care. Additionally, an economic evaluation was performed to examine the cost-effectiveness of integrating pharmacists into RACFs, based on the primary outcome of the trial, reduction in the proportion of residents prescribed regular use of Potentially Inappropriate Medications (PIMs); in addition, a cost-consequence analysis of the intervention based on the secondary outcomes was conducted.

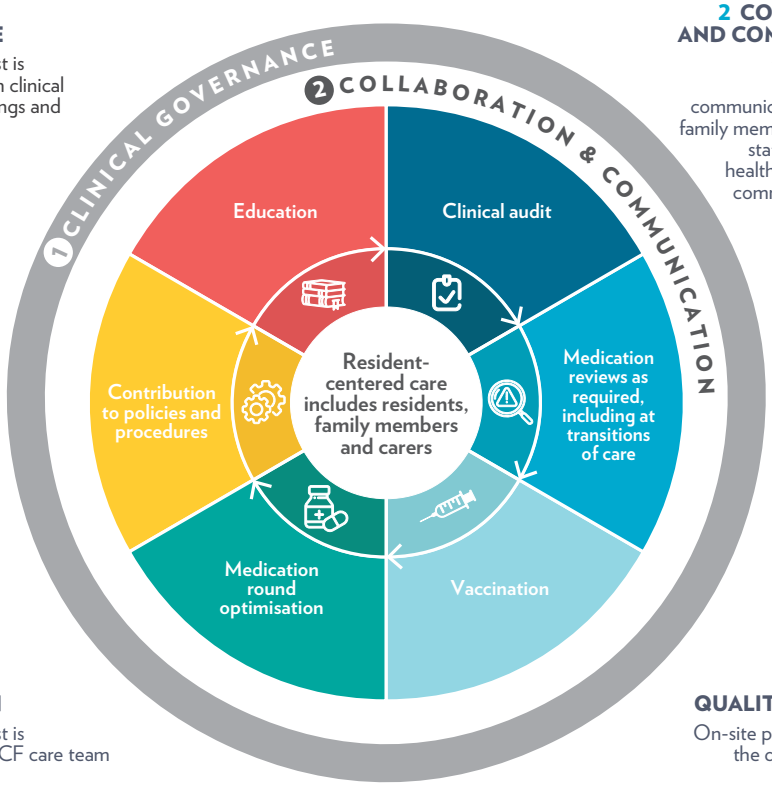
The PiRACF cRCT study aimed to examine a new model of interdisciplinary care in RACFs, with an on-site pharmacist working alongside staff as a member of the RACF care team to improve medicine management quality and safety. The on-site pharmacist was employed by RACFs and integrated into the RACF care team, working with residents, family members, carers, RACF managers and staff, and general practitioners, prescribers and other health care professionals.

In Phase 1 of this study, 23 of the 25 RACFs In the ACT were invited to participate in the study (2 were ineligible due to their participation in a pilot study of the intervention). Of these, 15 agreed to participate and were blindly randomised into intervention (7 RACFs) and control (8 RACFs) groups.

On-site pharmacists were employed in RACF sites for 12 months and conducted a range of medication management activities (see figure below). They worked as part of RACF care teams, collaborating with general practitioners and other prescribers (nurse practitioners, geriatricians, and other specialists), allied health professionals, and community and hospital pharmacists.

1 CLINICAL GOVERNANCE
On-site pharmacist is actively involved in clinical governance meetings and processes

2 COLLABORATION AND COMMUNICATION
On-site pharmacist collaborates, and communicates with residents, family members, carers, facility staff, GPs, prescribers, health care professionals, community and hospital pharmacists



INTEGRATION
On-site pharmacist is integratedinto RACF care team

QUALITY AND SAFETY
On-site pharmacist improves the quality and safety of medicine use

The primary outcome of this study was to reduce the extent of PIM prescribing. PIMs are a proxy measure for appropriateness of prescribing, which represents an ideal level of care and is reliable in predicting adverse events.[2] PIMs are associated with adverse outcomes for older individuals, including hospitalisations, falls, fractures, cognitive decline, delirium, stroke, and cardiovascular events. Phase 1 used a cRCT to assess the impact of the intervention on the main outcome by comparing baseline with endpoint data grouped by intervention and control facilities. Secondary outcomes were focused on quality use of medicine indicators and health service utilisation.

An economic evaluation was conducted in Phase 1 to assess the cost effectiveness integrating pharmacists into RACFs and cost-consequence of the intervention, based on the primary outcome, as well as a cost-consequence analysis of the intervention based on the secondary outcomes. Phase 2 will roll out the intervention to the RACFs that were not part of the cRCT or were control groups in the RCT and will include an evaluation of education and implementation materials. The RE-AIM framework was used to report on essential program elements and implementation in both phases.[3, 4]

ON-SITE PHARMACISTS REDUCED PRESCRIBING OF POTENTIALLY INAPPROPRIATE MEDICINES

In total, 1668 residents were involved in the study, with females making up 61.4% of the sample, and 45.5% of residents having a dementia diagnosis at baseline and 51.0% at endpoint.

FINDING ONE: The principal result of the intervention was that the activities carried out by the on-site pharmacist were responsible for a reduction in the extent of PIM prescribing. This means that the likelihood of a resident being prescribed one or more PIM was half (OR: 0.501) in aged care facilities with an on-site pharmacist compared to those with no on-site pharmacist.

FINDING TWO: The intervention resulted in a reduction in the dose of antipsychotic prescribed for residents (measured by chlorpromazine equivalent daily dose), and a reduction in resident's mean anticholinergic burden score in the intervention group compared to control.

FINDING THREE: There was no change observed in other secondary outcomes. These included health service usage (number and length of hospitalisations, and number of emergency department transfers) and quality indicators (number of falls, total number of medications, number of psychotropics, medication incident reports, and documentation of allergies and adverse drug reactions). There were no statistically significant differences observed between the intervention and control groups.

FINDING FOUR: On-site pharmacists were normalised as part of routine practice in RACFs. The quantitative and qualitative evaluation findings illustrate that prescribers, RACF managers, nursing staff, on-site pharmacists, and residents and family members found the potential for on-site pharmacists to become part of routine practice and 'normalised' in RACFs. Managers and RACF nursing staff, as well as some prescribers, stated that having on-site pharmacists helped to reduce their workloads. By being located on-site, they could interact with residents and family members and provided them with medication information and support. This study identified a positive interprofessional collaborative working relationships between on-site pharmacists and prescribers, managers and nursing staff. Collaboration between on-site pharmacists, prescribers, and RACF managers and nursing staff was more broadly supported by close proximity (the on-site pharmacist being on site and readily accessible). This increased opportunities for informal regular interactions and increased the likelihood of the on-site pharmacists and team members working together collaboratively. This was particularly important as prescribers needed to see the benefit of having the on-site pharmacist before deciding to collaborate with them.

> *it's really gone from, you know, six or seven [complaints] in a month to zero* [Manager 6.1]

> *more confident to have those [medication management decision making] discussions [with doctors and specialists] and know what sorts of questions I need to ask and know what I should be aiming for* [Family Member 3.1]

Potential barriers to establishing and maintaining interprofessional collaborative working relationships included limited opportunities to interact face-to-face with prescribers, not taking an active role in making connections and building relationships, not being in close physical proximity (such as sitting and working near facility staff) and RACF factors such as staff and management turnover.

> *There wasn't very much of that proactivity and getting [them] to focus on this, or focus on that, or to try to — what we needed [them] to do.* [RACF manager]

> *we can get all those problem like a potential PIMs, pick it up and document it and everything, but we don't have a prescribing authority or anything like that. It has to be from the doctors and that's a problem.* [On-site pharmacist 2]

FINDING FIVE: The economic evaluation estimated the average cost to a health care provider of integrating an on-site pharmacist in RACFs to be $56,286.18 per RACF per year, which equates to an average cost per resident of $622.58. No statistically significant difference was identified across the two arms of the trial in the use of other health care resources. The economic analysis calculated the incremental cost of integrating a pharmacist into a RACF to be $6,842 per resident avoiding the use of a PIM with a regular administration schedule. This incremental cost effectiveness ratio (ICER) is difficult to interpret in the absence of knowing what the impact of avoiding administration of at least one regularly prescribed PIM means for a resident. Interpretation is further complicated by the absence of a cost effectiveness threshold in relation to a resident avoiding use of a regularly prescribed PIM. As such, it is difficult to determine if this ICER of $6,842 per PIM avoided can be considered cost effective or good value from an economic point of view.

RECOMMENDATIONS FOR ROLLING OUT ON-SITE PHARMACISTS NATIONALLY

This study showed the PiRACF model reduced inappropriate medication prescribing and had organisational benefits for RACFs in improving medication management. Based on these findings, the PiRACF study team proposes that residential aged care stakeholders, including governments and providers, consider the following recommendations:

RECOMMENDATIONS

1. **Roll out the on-site pharmacist model nationally to improve medication management for RACF residents.**
2. **Promote an understanding of the on-site pharmacist role among stakeholders, including consumers (residents, families and carers), pharmacists, general practitioners and prescribers, health care professionals, and RACF organisations and staff.**
3. **Ensure that the on-site pharmacist and facilities are provided with on-going support to orient pharmacists and RACF staff to the activities and role of the on-site pharmacist.**
4. **Explore and address workforce issues that arise from the need to train and recruit pharmacists.**
5. **Explore options for a nationally recognised professional pharmacy body to coordinate, upskill and train pharmacists to enhance their clinical skills and knowledge about aged care facilities' operations and processes.**
6. **Explore models of pharmacists using telehealth for RACFs in rural and remote areas.**
7. **Conduct further studies to examine implementation of this model. In particular, the full-time equivalent required, effective inclusion in clinical governance processes, appropriate evaluation and quality indicators, and role development and integration require further investigation.**
8. **Future economic evaluations are required to be able to determine if integrating on-site pharmacists into RACFs is cost effective in the ACT or nationally. Such studies should include rigorous capture of time spent on medication management by RACF staff. The study should be appropriately powered to detect significant differences in this outcome as a difference in this outcome would be a key driver of the determination of whether the intervention is cost saving. Such studies should also elicit the impact of avoiding the regular use of a PIM on resident outcomes such as quality of life to enable generation of incremental cost per QALY to determine if integrating on-site pharmacists into RACFs is cost effective.**

1

INTRODUCTION

RATIONALE

Australia's population is ageing rapidly. In Australia in 2017–18, there were 234,800 permanent residents in aged care,[5] and this number will increase as the demand for residential aged care increases. Residents in residential aged care facilities (RACFs) have complex co-morbidities and are prescribed large numbers of different medications.[6] This increases the risk of medication-related problems and adverse drug events, including hospitalisation.[7] About 20–30% of all hospital admissions in people aged 65 years and over are medication related.[8] Older people living in RACFs are the highest users of medicines and are therefore at greatest risk of medication-related harm.

Adverse medication events occur in as many as three out of four aged care residents and are a major contributor to unplanned hospitalisations.[6] The Pharmaceutical Society of Australia's report on medication safety highlights inappropriate medicine use in residential aged care as a major concern.[9] The report stated that 98% of people living in RACFs have at least one medication-related problem and up to 80% are prescribed potentially inappropriate medications (PIMs). In addition, 17% of unplanned hospital admissions by people living in RACFs are caused by a prescription of inappropriate medicine. Problems in RACFs have also been highlighted by the Royal Commission into Aged Care Quality and Safety. The Royal Commission's final report recommended that medication management be improved through medication reviews and increasing the role of allied health professionals, including pharmacists, to improve residents' care and service quality.[10] The Australian Medical Association recently highlighted the urgent need to increase the number of health care professionals in RACFs.[11]

This study aims to examine a new model of interdisciplinary care in RACFs, with an on-site pharmacist working alongside staff as a member of the care team, to improve medicine management and prevent medication-related adverse health outcomes. A similar model of care is currently being examined in a large-scale study in the UK, as a result of recommendations by the UK Royal Pharmaceutical Society.[12] A UK study reports that for every £1 invested in this care model, £2.38 could be released from the medicines budget, in addition to the potential savings from reduced hospitalisations.[13] This model of care, however, has not yet been examined in Australia, and more evidence is needed regarding its effectiveness. This is the final report of Phase 1 of the Pharmacist in Residential Aged Care Facilities (PiRACF) study, which was supported by funding from the Australian Capital Territory's Primary Health Network through the Australian Government's Primary Heath Network Program.

PROPOSED MODEL OF CARE

Having an on-site pharmacist employed by the RACF has the potential to address some of the issues relating to medication management and safety and will enable more frequent face-to-face communication and collaboration between RACF residents, families, RACF staff, and residents' care teams. This model of care will potentially lead to greater understanding of resident-specific medication management, better communication between RACF staff regarding decisions made about treatments, and improved medication coordination with other health professionals, including visiting general practitioners (GPs). Having an on-site pharmacist as part of the RACF care team, as opposed to visits currently provided by pharmacists undertaking residential medication management reviews (RMMRs), may improve medication policies and procedures and may enable them to regularly follow up with residents, care staff, and prescribers (including GPs, nurse practitioners, geriatricians, and specialists). It may also build the rapport necessary to assess co-morbidities for residents with chronic diseases, including behavioural and psychological symptoms of dementia, and develop trust and communication with carers and nurses to help implement medication management plans.

Pharmacists conduct activities to improve medication management in RACF settings and benefit residents by optimising their pharmacotherapy, leading to improved health outcomes for residents, increased collaboration between RACF staff and health care professionals, and strengthened quality improvement in RACFs.

Pharmacists in RACFs work within their scope of practice as registered pharmacists. Their activities include (but are not limited to):

- medication reviews, where a pharmacist reviews residents' medications at any time, including following a clinical audit or at transition of care, such as when residents enter the facility, return from hospital, are diagnosed with a new condition, or have their medications changed
- clinical audits of residents' medication charts, including risk assessments for PIMs and other high-risk medications, such as psychotropics, opioids, and antibiotics
- providing advice to RACF staff, residents, and families on residents' medication management, including, follow up
- immunising staff against influenza
- reconciling residents' medications at transition of care, to ensure new medication regimes are correctly updated in residents' records and that residents and staff are aware of changes
- optimising the process of administering medicines during medication rounds, to improve efficiencies and reduce nursing time spent on administering medicines to residents
- improving residents' clinical documentation, to ensure allergies documentation and diagnoses are up to date
- participating in residents' case conferences (multidisciplinary consultations with residents, families, RACF staff, GPs, and other health care professionals)
- developing and updating medication management policies and procedures in RACFs, such as medication storage, disposal of medicines, and psychotropic medicines reporting
- training, upskilling, and educating RACF staff about medication management through individual and group education sessions
- liaising with prescribers and other health care professionals, to improve residents' medication management
- undertaking professional development
- collecting study-related data, such as pharmacist activity diaries.

On-site pharmacists' activities in RACFs are detailed in **Figure 1**.

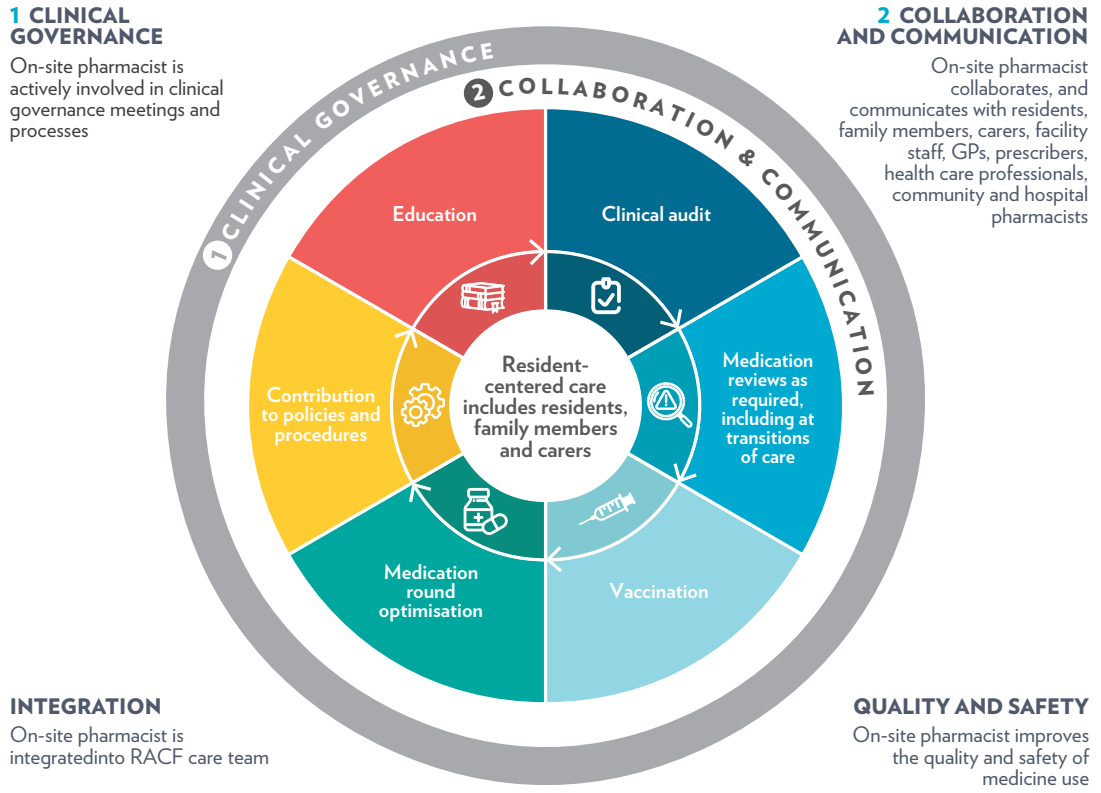


FIGURE 1. On-site pharmacist in RACFs — activities and processes in the model of care

The PiRACF study proposes a new model for health care delivery whereby pharmacists become integrated members of RACFs care teams. Their expertise in medication management, pharmacotherapy, and care coordination complement the skills of RACF nursing and care staff and health care professionals. Integrating pharmacists into RACFs has the potential to strengthen collaboration in interdisciplinary care teams. These communication, support, collaboration, and coordination roles are not currently funded under existing Residential Medication Management Review (RMMR) and quality use of medicine (QUM) services provided in RACFs.

The key differences between current pharmacist activities in RACFs (RMMR and QUM services) and the activities of the pharmacists in the on-site pharmacist PiRACF model are summarised in **Table 1**.

TABLE 1. Key components and activities of existing pharmacist services and the on-site pharmacist model

Key component	Existing pharmacist services provided to RACFs	The on-site pharmacist in RACF service model
Service structure, governance, and funding	• RMMR and QUM activities are conducted by pharmacist on visitational basis. • Pharmacist works independently as a contractor. • Funded by Australian Government Department of Health.	• Pharmacist is employed by the RACF, reports to the facility manager, and is incorporated into RACFs' care teams. • Pharmacist works within RACFs' clinical governance structures, including those defined in Aged Care Quality Standards, to achieve resident and facility level goals. • Not currently funded — RACFs fund the position.*
Multidisciplinary care team (including resident and family)	• Pharmacist is not incorporated into the RACF care team. They visit RACF at regular intervals, provide medication advice to GPs (and nursing staff) through RMMRs, and provide quality improvement projects that are often one-off education sessions to staff members. Some providers provide online support.	• Pharmacist is incorporated into the RACF care team, which includes the resident and family, GPs and prescribers, nurses, and care staff. The pharmacist is available on site at RACFs to manage the needs of residents according to care plans and goals of care. The pharmacist includes residents and their families into discussion and decision-making regarding residents' medication management, provides education to residents and families about medications and treatment options, and participates in case conferences with them.
Reciprocal interdependence	• Pharmacist provides medication review as an add-on service to help GPs with prescribing. However, they are not integrated into the RACF care teams.	• Multidisciplinary team members, including RACF staff, prescribers, health care professionals and residents and family members, engage in shared decision making and work together to achieve goals. • Pharmacist's role is well defined within the RACF, with medication management-related activities designated to the on-site pharmacist. Their role complements the skills and expertise of the existing RACF care staff. • Pharmacist's activities include resident medication review and reconciliation and coordination of medication-related issues across multiple prescribers. Activities at the facility level include establishing of collaborative medication management protocols; committing to ongoing education; reviewing and updating medication-related policies and procedures; and conducting ongoing quality improvement activities.
Communication	• Pharmacist communicates medication-related issues about individual residents to GPs, usually through the RMMR report. GPs communicate medication changes to RACF nurses.	• Pharmacist communicates and coordinates medication-related issues directly with GPs, nurses, carers, residents, community pharmacy, and hospital.
Collaboration	• Pharmacist usually collaborates with GPs to conduct RMMR.	• Pharmacist collaborates with nurses, aged care staff and management, GPs and prescribers, community pharmacy, and hospital.
Sharing and access to information	• Pharmacist may have limited access to resident's clinical records held by GP.	• Pharmacists have access to residents' records, current medication lists, information about allergies, lab results, notes, procedures, and discharge summaries.
Coordinated care/ outcomes	• Pharmacist provides initial once-off advice and opinion (supplemented by two follow ups, if required) to GPs through RMMRs and are not generally involved in implementing medication management changes.	• Residents' goals and outcomes are coordinated within the team of nurses, carers, pharmacist, GPs and prescribers, and health care professionals. Pharmacist is involved in providing advice to GPs and prescribers and the RACF care team and are also involved in implementing residents' care plans and goals of care.

Notes: GP=general practitioner, QUM=quality use of medicines, RMMR=residential medication management reviews. * In the 2022–23 budget, the Department of Health and Aged Care announced $345.7 million over four years to improve medication management and safety for aged care residents through on-site pharmacists and community pharmacy services. This responds to a recommendation by the Royal Commission into Aged Care Quality and Safety. **www.health.gov.au/sites/default/files/documents/2022/04/budget-2022-23-residential-aged-care-quality-and-safety-assuring-access-to-multidisciplinary-care-and-maintaining-effective-quality-audits.pdf**

STUDY AIMS, OUTCOMES AND KEY PERFORMANCE INDICATORS

The on-site pharmacist model of care was studied in a small pilot study in 2017.[14, 15, 16, 17, 18] The preliminary findings indicated that the addition of an on-site pharmacist to the RACF team resulted in:

- improved influenza vaccination rates for staff and residents in RACFs[17]
- improved medication administration and clinical documentation in RACFs[17]
- efficiencies for RACFs, resulting in cost savings (unpublished data)
- potential hospital avoidance (a 0.4 full-time equivalent (FTE) pharmacist added to the nursing team in a 100-bed RACF prevented four potential hospital admissions over 6 months) (unpublished data)
- providing education for nursing and care staff to improve the quality use of medicines and reduce medication administration errors.[16]

The current PiRACF study evaluated a new model of integrated care in RACFs. The PiRACF study includes two phases. Phase 1 was a cluster randomised controlled trial (cRCT) (seven intervention sites and eight control sites) and is the focus of this report. Phase 2 will be a roll out of the intervention to control sites and RACFs in the ACT that did not participate in the cRCT or the pilot study, and will be reported on in 2023.

The primary outcome of this study was to reduce the extent of PIM prescribing. PIMs are a proxy measure for appropriateness of prescribing, which represents an ideal level of care and is a reliable predictor of adverse events.[2] PIMs are associated with potentially adverse outcomes for older individuals, including hospitalisations, falls, fractures, cognitive decline, delirium, stroke, and cardiovascular events. Secondary outcomes were focused on other quality use of medicine indicators and health service utilisation. A peer-reviewed paper of the protocol was published in 2021 (**Appendix 1**).

The secondary objectives were to evaluate if the new model of care reduces emergency department (ED) presentations and unplanned hospital admissions of RACF residents, use of psychotropic medicines in RACF residents, and falls.

In addition, we assessed whether this new model increases:

- other quality use of medicines indicators, including number of residents' regular and pro re nata (PRN — when necessary) medicines and staff influenza vaccination
- quality improvement activities in RACFs, such as improving policies in response to medication incidents
- interactions between pharmacists, RACF management and staff, GPs and prescribers, and other allied health professionals.

The PiRACF study outcomes and key performance indicators (KPIs), as outlined in the CHN-UC contract, are presented in Findings.

The PiRACF study aligns with several Department of Health aged care quality improvement and medications management guidelines. This includes performance standards that aged care organisations have been required to comply with from 1 July 2019, outlined in the national Aged Care Quality Standards.[19] These standards aim to improve the quality and safety of care delivered to consumers of aged care services. Two standards are addressed by the objectives of this study:

- Standard 3: Personal care and clinical care — that organisations deliver 'safe and effective personal and clinical care in accordance with consumer's needs, goals and preferences to optimise health and well-being'.
- Standard 4: Services and supports for daily living — that organisations provide 'safe and effective services that supports daily living that optimise the consumer's independence, health, well-being and quality of life'.[20]

The study also aligns with medications management principles outlined in the Department of Health's 'Guiding principles for medication management in residential aged care facilities', including Guiding Principles, Information Resources, Selection of Medicines, Medication Charts, Medication Review and Medication Reconciliation and Evaluation of Medication Management.[21]

In its 2022 budget, the Australian Government announced $345 million in funding to implement community and on-site pharmacists into residential aged care from 2023 to improve medication safety in aged care. The outcomes of the PiRACF study will provide an evidence base to inform the effectiveness and implementation of the on-site pharmacist in residential aged care model to improve medication management.

STUDY DESIGN

Phase 1 of the study was a cRCT with both quantitative and qualitative analysis to investigate the primary and secondary outcomes, study fidelity, process evaluation and costs associated with the intervention.

SAMPLE SIZE

A review of medication safety in 2013 by the Australian Commission on Safety and Quality in Health reported that the prevalence of PIM use in the aged care population was 40–50%.[8] The Beers Criteria is used widely in aged care research as an indicator for medications use, to improve the effectiveness and safety of prescription practices for geriatric patients.

Prevalence of PIM use using Beers criteria has been reported by several studies in Australian aged care facilities: Harrison et. al. found 81.4% of aged care residents (533 residents from 17 RACFs in SA, NSW, WA and Qld) had been exposed to one PIM.[22] In 2014, 49.5% of the older patients discharged from hospital into RACFs had at least one PIM.[23] In a sample of RACF residents with dementia, 56.4% had at least one PIM.[24]

A meta-analysis of 33 studies showed that PIMs are significantly associated with hospitalisation in the older population and that the risk is further increased in those who had two or more PIMs compared to those would had only one.[25] In an Australian 2010 study, pharmacists' involvement in a home medicine review of older community patients reduced exposure to PIMs from 40% to 28%.[26] A Belgian RCT showed pharmacists' involvement in geriatric care reduced the prevalence of PIMs from 25% to 3.1%, although a similar change was observed in the control group.[27] A cRCT aimed at deprescribing inappropriate medications in community dwelling older adults in Canada showed that following pharmacists' medication reviews, 43% of patients in the intervention group discontinued PIMs compared to 12% in the control group.[28]

From these studies, we estimated that a sample size of 1188 residents from a minimum of 13 RACFs sites was required for the cRCT, based on the assumption that pharmacists will reduce the prevalence of PIMs by 20%, with an intra-cluster correlation coefficient of 0.05, and a cluster size of 93 residents per RACF.

Recruitment

The study included RACFs residents and families, on-site pharmacists involved in implementing the new model, RACF management and care staff, and GPs and other allied health professionals working with RACFs.

The Phase 1 cRCT was a staggered design with a duration of 12 months. Sites started between March 2020 and January 2021, and thus the last site finished in January 2022.

At study commencement, there were 25 RACFs in the ACT. Of these, 23 were invited to participate in Phase 1; the two sites that participated in the pilot study were excluded. The study team approached the facilities in multiple ways, including contacting RACFs managers, CEOs, and head offices by phone, email, online meetings, and in-person meetings to explain the potential benefits of the project and to encourage RACFs to participate. Of the 15 RACFs that responded to the expression of interest, seven sites were randomly allocated (by an independent third party) to receive the on-site pharmacist intervention, and eight were allocated to the control arm and had no on-site pharmacist.

Eight of the 23 facilities declined to participate — the most common reason was lack of interest from the area manager or head office, despite facility managers wanting to be involved. Other responses included lack of capacity or not seeing the study outcomes as relevant to the RACF. Some facilities did not provide a rationale for non-participation.

To be eligible for inclusion in the study, RACFs had to be accredited in the ACT, agree to provide data to the research team, and agree to employ an on-site pharmacist for 2–2.5 days a week, depending on the number of beds, for 12 months (intervention group only).

To be employed in RACFs, pharmacists had to:

- have a current pharmacist registration with Australian Health Professional Registered Agency (AHPRA), the Australian Association of Consultant Pharmacy or a similar accreditation
- have a minimum of 1 year of pharmacy practice experience
- be authorised to administer vaccinations
- be able to liaise and work with other health care professionals and perform managerial, administrative, and other duties as required for the role.

A purposive sample of RACF staff in the control and intervention groups was invited to participate in surveys and interviews to discuss medications management and engagement with the model of care, including facility managers, directors of nursing, team leaders, registered nurses, enrolled nurses, and care workers.

A purposive sample of GPs, prescribers, and other allied health professionals working with intervention pharmacists was invited to participate in surveys and interviews to discuss medications management and engagement with the model of care. A purposive sample of residents and family members who interacted with the pharmacist and who were able to give consent were invited to participate in interviews to discuss engagement with the pharmacist.

Phase 1 RACFs were recruited in staggered clusters, randomised 1:1 with each RACF as the unit of randomisation into either a control or intervention arm. Control group RACFs had no additional on-site pharmacist and only the usual government-funded RMMR and QUM services. Intervention sites had an on-site pharmacist employed by the RACF in addition to 'usual' care.

RACFs with a bed size that was below the ACT average of 101.2 beds were allocated an on-site pharmacist with 0.4 FTE, and RACFs above the average were allocated 0.5 FTE. The on-site pharmacist's role was to help improve the quality use of medicines and undertake activities that are within their current scope of practice as a registered pharmacist with the AHPRA.

DATA COLLECTION

Facility mangers were asked to provide demographic data about the facility prior to baseline, including number of beds, number of RACF staff, and number of residents with dementia as per the Aged Care Funding Instrument. Baseline and second endpoint data included resident's demographics, diagnoses, and medication charts (See **Appendix 2**).

RACF staff helped the UC research team collect data from RACF digital (iCare, Inerva, Leecare, Manad) and paper records. Data on RACF residents' ED presentations, hospitalisations, and reasons for these were sought from ACT Health and Calvary Healthcare ACT. Callouts and transports of residents from RACF to hospital and return were sought from ACT Ambulance Service. Geriatric Rapid Acute Care Evaluation (GRACE) team visit data was requested from, but not provided by, Calvary HealthCare; thus RACF-collected data are reported for GRACE team visits.

Pharmacist activity data collected from RACFs in the intervention group were self-reported by pharmacists through an online diary, on a regular basis (see **Appendix 3** for survey).

The original protocol included collecting data on medication round timing and appropriateness of administration (crushing) by observing the average time in minutes spent on medication rounds, per resident, recorded at baseline and 12 months. Due to COVID-19, the study team was not able to have face-to-face contact with residents and this data was not collected.

On-site pharmacists, prescribers (including GPs), health professionals, and RACF staff were invited to participate in an interprofessional collaboration measurement instrument to understand the impact of the on-site pharmacist on interprofessional collaborative care within RACFs. Prescribers, health professionals, pharmacists, and RACF staff were invited to participate in a survey to understand the extent of new service model integration. Surveys are shown in **Appendix 4.1** and **Appendix 4.2**.

Interviews were conducted towards the end of the study with on-site pharmacists, RACF staff (RACF managers and nursing staff), prescribers (GPs and nurse practitioners), residents, and family members to collect qualitative data about their involvement and engagement with the new model, along with benefits and barriers of adoption and the potential for further wider implementation. Interview guides are attached as **Appendix 5.1**, **Appendix 5.2**, **Appendix 5.3**, **Appendix 5.4**, **Appendix 5.5**, and **Appendix 5.6**.

ETHICAL APPROVALS AND CONSIDERATIONS

This study was conducted in compliance with National Health and Medical Research Council guidelines and the World Medical Declaration of Helsinki and all amendments.[29, 30] Privacy and confidentiality of data complies with the *Federal Privacy Act 1988*, the *ACT Information Privacy Act 2014*, and the *ACT Human Rights Act 2004*. The study is registered with the Australian New Zealand Clinical Trials Group (ACTRN: ACTRN12620000430932). RACF staff and pharmacists were provided with information and induction into ethical considerations, including consent and management of data.

Ethical approval to conduct the study was obtained from the University of Canberra Human Research Ethical Committee (UC HREC Reference: 2007). Approval for hospitalisation and ambulance data was obtained from ACT Health Human Research Ethical Committee (ACT Health HREC Reference: 2019/ETH13453). Approval for hospitalisation data for data linkage was approved by Calvary Hospital Bruce (Calvary Hospital Reference: 30 -2019).

Each RACF agreed to participate in the study and provide resident data after being fully informed about the study. The study was given approval to seek consent to participate at the facility level, rather than the individual resident level. This follows National Health and Medical Research Council guidelines for Australia and is consistent with comparable studies.[29, 31]

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FINDINGS

DEMOGRAPHICS

RACFs

The demographics of RACFs involved in the Phase 1 cRCT are presented in **Table 2**. The study included a range of facility sizes and sites with and without dementia-specific wards. At the time of study commencement, there were 1978 RACF beds in the ACT. The number of permanent RACF residents enrolled in the Phase 1 cRCT (n= 1275 at baseline) was 64.5% of RACF residents in the ACT. National data [32] indicates that the mean bed size for a RACF in Australia is 74 beds (range: 2–333). AIHW data [33] indicate that nationwide, 54% of the RACF population have dementia. These data are broadly similar to the sample detailed in **Table 2** and **Table 3**, with a mean bed size 103 beds (range 21–207) and 41.8–49.9% with a dementia diagnosis. Similarly, a comparison of nationwide RACF staff workforces [34] indicates a mean number of staff per facility of approximately 103 personnel, which is broadly comparable to facilities in the study sample (82.2 staff per facility). Therefore, the results of this study are generalisable to the broader ACT population of RACF residents, and they are likely to be relevant to other Australian urban contexts. A peer-reviewed paper of the baseline findings was published in 2022 (**Appendix 6**).

TABLE 2. Details of RACFs in Phase 1 cRCT

Site	Group	Pharmacist FTE	No. of beds	No. of RACF care staff	No. of residents with dementia	Dementia-specific ward	Study period
Phase 1 (cRCT)							
1	Intervention	0.4					April 2020–April 2021
2	Intervention	0.5					June 2020–June 2021
3	Intervention	0.5					July 2020–July 2021
4	Intervention	0.4					August 2020–August 2021
5	Intervention	0.4					October 2020–October 2021
6	Intervention	0.4					December 2020–December 2021
7	Intervention	0.5					January 2021–January 2022
Mean (range)		0.44 (0.4–0.5)	103.4 (53–207)	95.3 (37–140)	43.1 (12–88)	4 of 7	-
8	Control	-					March 2020–March 2021
9	Control	-					March 2020–March 2021
10	Control	-					March 2020–March 2021
11	Control	-					July 2020–July 2021
12	Control	-					July 2020–July 2021
13	Control	-					August 2020–August 2021
14	Control	-					August 2020–August 2021
15	Control	-					August 2020–August 2021
Mean (range)			107 (21–176)	70.8 (3–143)	53.3 (13–149)	8 of 8	-

Notes: cRCT=cluster randomised controlled trial, FTE=full-time equivalent of the employed pharmacist, NS=not specified, RACF=residential aged care facility. Aggregated RACF details are shown.

TABLE 3. Comparison between PiRACF study sample characteristics (at baseline) and nationally representative data

Variable	Characteristic	PiRACF study N=1275	National data* N=179,993	P-value
Age (years)	65–69	25 (2.0%)	6290 (3.5%)	**0.001**
	70–74	93 (7.3%)	13,145 (7.3%)	
	75–79	117 (9.2%)	20,343 (11.3%)	
	80–84	213 (16.7%)	32,369 (18.0%)	
	85+	827 (64.9%)	107,840 (60.0%)	
Gender	Male	436 (34.2)	59,983 (33.3%)	0.513
	Female	839 (65.8)	120,004 (66.7%)	
Aboriginal and Torres Strait Islander status	Yes	6 (0.3)	1562 (0.9%)	0.167
	No	1247 (97.7)	178,300(99.1%)	
Preferred language	English	1044 (81.9)	160,669 (90.8%)	**< 0.001**
	Others	231 (18.1)	16,374 (9.2%)	

Notes: * Residents under 65 years were excluded from the national data. Statistically significant differences between PiRACF study and nationally representative data [35] are shown in bold text.

At the resident level, a comparison between national data [35] and baseline characteristics of the study sample indicate that both the gender and proportion of the population identifying as Aboriginal and/or Torres Strait Islander was similar. The PiRACF study sample had a substantially larger proportion (18.1% versus 9.2%) of individuals whose secondary language was not English. Compared to national data, there were significantly different age distributions (P=0.001), with the PiRACF sample overrepresented in older and underrepresented in younger age groups. Despite these differences, the sample RACFs are broadly comparable, in terms of resident characteristics, to the wider context of Australian RACFs.

Pharmacists

On-site pharmacists were recruited to the study through paid advertising and information distributed to relevant professional groups, including the Pharmaceutical Society of Australia, the Society of Hospital Pharmacists of Australia, and the Australian Association of Consultant Pharmacy. A total of 25 pharmacists responded to the expression of interest for Phase 1. Of these, 13 had the necessary experience and were shortlisted. Considering the shortage of pharmacists in the ACT with both vaccination and medication review accreditation, recruitment was difficult, and the final on-site pharmacist was recruited despite not having the desired qualifications. COVID-19 also impacted recruitment, with six candidate pharmacists withdrawing due to home-schooling commitments or hesitancy to work in residential aged care. All pharmacists who commenced in facilities completed their full term of employment (i.e., there were no resignations). Demographic characteristics of the pharmacists employed in Phase I are presented in **Table 4**, with national data [36] for gender and age provided for comparison purposes.

TABLE 4. Demographic characteristics of pharmacists employed in PiRACF study and comparative national data

Category	Characteristic	n of respondents (%)	AHPRA age categories	National data n=35,262*
Gender	Male	1 (16.7)	-	13,033 (37.0)
	Female	5 (83.3)	-	22,229 (63.0)
Age (years)	21–30	1 (16.7)	<25 to 29	7770 (37.3) *
	31–40	5 (83.3)	30 to 39	13,069 (62.7) *
Tertiary qualification	Bachelor's degree (B. Pharm)	6 (100)	-	-
	Postgraduate qualification	2 (33.3)	-	-
	MMR accreditation	5 (83.3)	-	-
Experience (years)	1–3	1 (16.7)	-	-
	4–6	0 (0)	-	-
	7–9	1(16.7)	-	-
	10+	4 (66.7)	-	-
Accredited immuniser	Yes	4 (66.7)	-	-
	No	2 (33.3)	-	-

Notes: MMR=medication management review. * Data from APHRA 2020–21 annual report, total sample n=35,262, restricted comparable age sample (ages < 25–39) n=20,839.

Pharmacist's activities

The number of medication review recommendations made by on site pharmacists, and their uptake by prescribers, is presented in **Table 5**. We found that 524 of 878 PIM-related recommendations were accepted by prescribers (59.7%). 980 of 1,025 recommendations not related to PIMs were accepted by prescribers (44.5%).

TABLE 5. Clinical medication review activities

Clinical medication review recommendations and outcomes		Count (% of total)
Number of PIMs identified and discussed with prescribers	Number of Medication review identified 1 PIM	310 (30.6)
	Number of Medication review identified 2 PIMs	123 (12.1)
	Number of Medication review identified 3 PIMs or more	66 (6.5)
	Not specified	379 (37.4)
	Total	**878 (100%)**
Recommendations related to PIMs accepted by prescribers	Medication(s) deprescribed	249 (47.5)
	Decrease in dose recommended and accepted	89 (17.0)
	Alternative medication(s) recommended and accepted	24 (4.6)
	Not specified	162 (30.9)
	Total	**524 (100%)**
Recommendations made not related to PIMs		1025
Recommendations not related to PIMs accepted by prescribers	Medication(s) deprescribed	253 (55.5)
	Alternative medication(s) recommended and accepted	47 (10.3)
	Decrease in dose recommended and accepted	81 (17.8)
	Increase in dose recommended and accepted	45 (9.9)
	Change(s) in dosage form and accepted	30 (6.6)
	Total	**456 (100%)**

Note: PIM=Potentially Inappropriate Medicine

The activities conducted by pharmacists are presented in **Table 6**. These activities are derived from online diaries that pharmacists were required to submit on a regular basis. Of the 4252 total activities performed by pharmacists, comprehensive medication reviews were the most common recorded activity (24.0%), followed by communication (23.4%), medication management related administrative tasks including S8 counting, recording and destruction, attending Medication Advisory Committee (MAC) and falls meetings, and updating progress notes and resident's records (19.6%), education activities (13.4%), and quality improvement activities (9.4%).

TABLE 6. Activities of on-site pharmacists in RACFs — Phase 1 and Phase 2

Activity	Activity subcategories	Phase 1 Frequency (%)
Medication management activities	Comprehensive medication review	1022 (100.0)
	Total	**1022 (24.0)**
Clinical audit activities	Psychotropics	60 (24.4)
	Medication chart audit	36 (14.6)
	PIMs	33 (13.4)
	Medication management including administration	19 (7.7)
	Opioids	19 (7.7)
	Medications requiring monitoring	14 (5.7)
	PRN	9 (3.7)
	Anticoagulants	8 (3.3)
	Residents at high risk of hospitalisation	7 (2.8)
	Antimicrobial	6 (2.4)
	Other	35 (14.2)
	Total	**246 (5.8)**
Communication activities	**Total number of communication activities**	**995 (23.4)**
	Who pharmacists communicated with:	
	RACF staff	462 (35.7)
	GP (including doctor's rounds)	206 (15.9)
	Community pharmacy	201 (15.5)
	Resident	131 (10.1)
	Resident's family	74 (5.7)
	Nurse practitioner	47 (3.6)
	Staff at GP reception	20 (1.5)
	Research staff	18 (1.4)
	Hospital and hospital pharmacy	1 (0.1)
	Other	135 (10.4)
	Total number persons communicated with	**1295 (100.0)**
Vaccination activities	Staff vaccination activities	23 (20.5)
	Resident vaccination activities	21 (18.8)
	Both staff and resident vaccination activities	4 (3.6)
	Other (e.g., preparation, administration)	64 (57.2)
	Total vaccination activities	**112 (2.6)**
	Number of staff vaccinated	225 (59.5)
	Number of residents vaccinated	155 (40.8)
	Total number of people vaccinated	**380 (100)**

TABLE 6. Activities of on-site pharmacists in RACFs — Phase 1 and Phase 2 *cont.*

Activity	Activity subcategories	Phase 1 Frequency (%)
Education activities	RACF staff-related education activities	
	General medication administration (e.g., medication round)	129 (22.6)
	Opioids/pain management	31 (5.4)
	Psychotropics	30 (5.3)
	Specific medical conditions (e.g., dementia/Parkinson's disease/diabetes)	30 (5.3)
	Inhalers/drops/ointments	18 (3.2)
	Medication crushing	16 (2.8)
	Allergies/side effects/interactions	12 (2.1)
	Medication dosing/timing/expiry/discontinuation	11 (1.9)
	Medication incidents	11 (1.9)
	Cytotoxics	10 (1.8)
	Medication storage	9 (1.6)
	PRNs	9 (1.6)
	Guidelines/policies	8 (1.4)
	Staff training topics (e.g., clinical skills)	8 (1.4)
	Medication changes	7 (1.2)
	Antibiotics	5 (0.9)
	Other (e.g., software/supplements/use of personal protective equipment)	15 (2.6)
	Total	**359 (62.9)**
	Self-education	76 (35.8)
	Residents and family education (group or individual)	94 (44.3)
	Other health care professionals	34 (16.0)
	External agencies	1 (0.5)
	Other (e.g., preparing presentations, education to student nurses)	7 (3.3)
	Total staff education activities	**571 (13.4)**
Quality improvement activities	Reviewing RACF policies and procedures and attending relevant meetings	80 (20.1)
	Ward stock related	79 (19.8)
	Medication rounds related	78 (19.6)
	Developing policies and procedures	79 (19.8)
	Schedule 8 related	25 (6.3)
	Reviewing medication incident report	13 (3.3)
	Other	44 (11.1)
	Total	**398 (9.4)**
COVID-19-related activities	Vaccination rollout	17 (27.0)
	Vaccination information (e.g., adverse effects)	12 (19.0)
	Administration of vaccination records (e.g., updating staff COVID-19 vaccination lists)	12 (19.0)
	Infection control/outbreak management	9 (14.3)
	COVID-19 administration for facility entry (e.g., risk entry forms)	6 (9.5)
	Staff training /meeting	5 (7.9)
	COVID-19 Care (e.g., counselling residents on impact of lockdown on mental health)	2 (3.2)
	Total	**63 (1.5)**
Medication management related administration activities	Clinical administration (e.g., S8 count, recording and destruction, MAC meeting, etc)	520 (62.4)
	Study-related administration (e.g., meeting with study team, on-line diary)	301 (36.1)
	Other administration	13 (1.6)
	Total	**834 (19.6)**
Other activities	Other activities (e.g., fire safety training, signing statutory declarations)	11 (0.3)
TOTAL		**4252**

Note: Values may not sum to subtotals or 100% due to rounding.

Residents

Characteristics of RACF residents (at baseline) are shown in **Table 7**. Within the sample, residents were typically older (62.3–68.4% in the 85 years+) and predominantly female (63.1–69.5%). Very few residents identified as Aboriginal or Torres Strait Islander, and few (<20%) spoke a second language. Most residents took 10 or more medications regularly, and co-morbidity was common, with only 10–12% of residents scoring a zero on the Charlson co-morbidity index (CCI). A dementia diagnosis was reported in 42–50% of residents, and the majority of residents took one or more PIM, with 13–17% taking three or more PIMs regularly. The gender distribution differed between control and intervention groups at baseline (P=0.017), with 63.1% of the control population female compared to 69.5% in the intervention group. A higher proportion of the control group reported speaking a second language ('secondary language'; 20.6% *vice* 14.8%, P=0.008). Dementia diagnoses were also more frequent in the control group (P=0.003, 49.9% *vice* 41.8%) than in the intervention group. Other baseline characteristics were not statistically significantly different at baseline.

TABLE 7. Baseline characteristics of RACF residents

Category	Characteristic	Control (%) (n=734)	Intervention (%) (n=541)	P value
Age (years)	65–69	21 (2.9)	4 (0.7)	0.051
	70–74	63 (8.6)	30 (5.5)	
	75–79	69 (9.4)	48 (8.9)	
	80–84	124 (16.9)	89 (16.5)	
	85+	457 (62.3)	370 (68.4)	
Gender	Male	271 (36.9)	165 (30.5)	**0.017**
	Female	463 (63.1)	376 (69.5)	
Aboriginal and Torres Strait Islander status	Yes	3 (0.4)	3 (0.6)	0.789
	No	717 (97.7)	530 (98.0)	
Secondary language	Yes	151 (20.6)	80 (14.8)	**0.008**
	No	583 (79.4)	461 (85.2)	
Number of regular medications	< 5	37 (5.0)	40 (7.4)	0.214
	5–9	202 (27.5)	131 (24.2)	
	≥ 10	495 (67.4)	370 (68.4)	
Charlson comorbidity index	0	89 (12.1)	56 (10.4)	0.374
	1	202 (27.5)	144 (26.6)	
	2	158 (21.5)	114 (21.1)	
	3+	285 (38.8)	227 (42.0)	
Dementia diagnosis	Yes	365 (49.9)	215 (41.8)	**0.003**
	No	371 (50.1)	315 (58.2)	
Number of PIMs instances per resident	0 PIMs	245 (33.4)	159 (29.4)	0.172
	≥ 1 PIMs*	487 (66.6)	382 (70.6)	
	≥ 2 PIMs*	257 (35.0)	192 (35.4)	
	≥ 3 PIMs*	95 (12.9)	92 (17.0)	

Notes: PIMs=potentially inappropriate medications. Statistically significant differences between control and intervention groups shown in **bold** text.
* PIMs categories ≥ 1 are inclusive categories (i.e., ≥ 1 PIMs includes data shown in ≥ 2 PIMs and ≥ 3 PIMs, and thus % values do not total 100%).

Analyses were conducted on subsamples of the overall resident study sample; thus, the *n* for each analysis (and within analyses) varies.

PRIMARY AND SECONDARY OUTCOMES

Medication-related outcomes

The primary outcome of the cRCT was to determine if the model of the on-site pharmacist in residential aged care improved appropriateness of prescribing for RACF residents, as determined by the prescribing of PIMs according to 2019 Beers criteria.[37] PIMs are a proxy measure for appropriateness of prescribing, which represents an ideal level of care and is reliable in predicting adverse events.[2] Medication-related secondary outcomes include prevalence and dose of antipsychotics and benzodiazepines (where doses are measured by chlorpromazine or diazepam, respectively), ACB score, and completeness of residents' allergy and adverse drug reaction documentation. Overall, primary and secondary outcomes indicate the quality of medication management and measures, which are important from public health, aged care industry, and resident perspectives.

Analyses of the medication-related outcomes were conducted using a sample that included individuals for whom medications data were available at baseline, endpoint, or both timepoints. The sample for these analyses was 1275 residents at baseline (control, 734 residents; intervention, 541 residents) and 1301 residents at endpoint (control, 681 residents; intervention, 620 residents). This approach was possible due to the manner by which the generalised linear mixed models statistical approach treats missing data.

Generalised linear mixed models were used to compare medicine-related outcome variables between intervention and control groups at baseline and endpoint. Different models were used based on the type of data analysed: logistic regression models were used for binary outcome variables, Poisson regression was used for discrete variables, and gamma distributions were used for continuous positively skewed variables. Random effects were used to account for clustering of residents within RACFs and repeated observation within residents. The intra-cluster correlation coefficient at baseline was calculated for primary outcome.[38] The model estimated the effects of group (control or intervention) and time (baseline and endpoint) on each outcome and the combination (interaction) of these effects. The approach adjusted for potential confounders including age, gender, dementia diagnosis, CCI, number of regular medications, level of care, and number of GRACE team visits. Two facilities had a concurrent educational intervention (the NPS MedicineWise intervention), which was also adjusted for as a potential confounder.[39] Missing values were infrequent (less than 1%) and were addressed via listwise deletion.

The descriptive data for these medication-related outcomes at baseline and endpoint of the study, in both the control and intervention groups, is shown in **Table 8**.

Table 9 shows the effects of the intervention on the primary and secondary medications-related outcomes, using both unadjusted and adjusted models. The study found a statistically significant reduction in the number of PIMs (primary outcome) in the intervention group compared to control group, which is consistent with the study hypothesis to improve quality of prescribing and medication management. There was also a statistically significant reduction in residents' mean ACB scale, and chlorpromazine equivalent dose of antipsychotic medications in the intervention group compared to the control group. There were no significant differences in number of regular medicines, adverse drug reaction documentation status, number of psychotropics and the dose of benzodiazepines between control and intervention groups.

TABLE 8. Descriptive statistics for medication-related outcomes at baseline and endpoint

Outcome *	Timepoint	Control (95% CI) n (baseline)=734 n (endpoint)=681	Intervention (95% CI) n (baseline)=541 n (endpoint)=620
Proportion of residents who were prescribed 1+ regular PIMs	Baseline	66.6% (63.1–70.0)	70.6% (66.6–74.4)
	Endpoint	67.0% (63.3–70.5)	60.8% (56.8–64.7)
Mean ACB scale score	Baseline	1.2 (1.1–1.3)	1.2 (1.1–1.4)
	Endpoint	1.1 (1.0–1.3)	0.9 (0.8–1.1)
Proportion of residents prescribed 1+ regular antipsychotic or benzodiazepine	Baseline	25.1% (22.0–28.4)	24.6% (21.0–28.4)
	Endpoint	23.8% (20.6–27.2)	18.4% (15.4–21.7)
Chlorpromazine equivalent daily dose per resident (mg)	Baseline	15.4 (11.9–19.1)	12.5 (9.0–16.0)
	Endpoint	15.2 (11.2–19.1)	8.64 (6.1–11.3)
Diazepam equivalent daily dose per resident (mg)	Baseline	0.8 (0.7–1.0)	0.8 (0.5–1.0)
	Endpoint	0.5 (0.3–0.6)	0.4 (0.3–0.6)
Number of regular medicines per resident	Baseline	9.9 (9.5–10.2)	10.0 (9.6–10.4)
	Endpoint	9.1 (8.8–9.5)	9.6 (9.3–10.0)
Proportion with complete ADR documentation	Baseline	97.4% (96.0–98.4)	95.6% (93.5–97.1)
	Endpoint	99.1% (98.1–99.7)	98.2% (96.8–99.1)

Notes: ACB=anticholinergic burden, ADR=adverse drug reaction, mg=milligram, PIM=potentially inappropriate medication.
* Proportions presented as % and continuous variables as means.

TABLE 9. Main effects from unadjusted and adjusted models of medication-related outcomes (reference category: controls at baseline)

Outcomes*	Unadjusted model: effect for the intervention at endpoint	p value	Adjusted model: effect for the intervention at endpoint	p value
Primary outcome:				
Proportion of residents who were prescribed 1+ regular PIMs (OR)	**0.595 (0.414–0.855)**	**0.005**	**0.501 (0.335–0.750)**	**0.001**
Secondary outcomes:				
Residents' ACB scale score (RR)	**0.832 (0.705–0.981)**	**0.028**	**0.800 (0.678–0.944)**	**0.008**
Proportion with one or more benzodiazepine or antipsychotic (OR)	0.732 (0.487–1.101)	0.134	0.676 (0.439–1.042)	0.076
Chlorpromazine equivalent daily dose (mg) per resident (β Coeff)	−0.198 (−0.405–0.008)	0.060	**−0.250 (−0.456–−0.043)**	**0.018**
Diazepam equivalent daily dose (mg) per resident (β Coeff)	−0.093 (−0.400–0.214)	0.551	−0.129 (−0.428–0.170)	0.397
Proportion with complete ADR documentation (OR)	1.127 (0.518–2.450)	0.763	1.109 (0.510–2.408)	0.794
Number of regular medicines per resident (RR)	1.033 (0.978–1.092)	0.243	1.029 (0.974–1.087)	0.313

Notes: ACB=anticholinergic burden, ADR=adverse drug reaction, Coeff=coefficient, OR=odds ratio, PIM=potentially inappropriate medication, RR=relative risk.
* In comparison to control over the period of study. Interaction term (intervention x endpoint). Adjusted model includes age, gender, presence/absence of a dementia diagnosis, CCI, number of regular medications, and presence/absence of concurrent NPS MedicineWise intervention. Baseline control n=734, intervention n=541, endpoint control n=681, intervention n=620.

The study also found reductions in the proportion of residents taking one or more benzodiazepine or anti-psychotic medication and in the diazepam equivalent daily dose. Although these effects were not statistically significant, the observed reduction in psychotropics will likely have a positive clinical value for residents.

Non-medication outcomes

Analyses of the non-medication outcomes were conducted using a sample that included all individuals who remained within the sample after standard exclusions were applied. These data were cross-sectional in nature (although collected over one year), and thus baseline and endpoint considerations were not relevant. The sample for these analyses was 1668 residents overall, with 771 residents in the intervention group and 897 residents in the control group. Economic analysis of the intervention (where relevant at a resident level) relied on this sample, but the primary outcome was assessed on the basis of those who were residents for the full year of the trial resulting in a sample of 890 residents overall (383 in the intervention group and 507 in the control group).

Non-medication related outcomes were treated similarly to medication-related outcomes, with the exception that these variables were cross-sectional in nature and thus lacked baseline and endpoint analyses. Additionally, the time spent within the RACF facility (in days) for each resident was used to account for different lengths of exposure to the intervention.

Data analysis was conducted using the Statistical Package for Social Sciences (SPSS, version 27.0; IBM Corp. Armonk, USA). Descriptive statistics were performed to report the mean, standard deviation for numeric variables, and proportion for categorical variables. Mann-Whitney-U tests and Chi-square tests were used for unadjusted comparison of (continuous and categorical, respectively) baseline demographic characteristics between control and intervention arms. For the final model, the level of significance was set at an alpha of 0.05; any observed result with an associated probability value less than 0.05 was considered statistically significant. Magnitudes of effects are described (where possible, for odds ratios, relative risk, and correlations) using the standardised scale of magnitudes developed by Hopkins.[40]

Non-medication related outcomes in this study focussed predominantly on health service usage (i.e., number of hospitalisations and length of stay (in days) in hospital, number of ED transfers), but also included number of falls (which are likely to precede and be causative of some ED transfers and hospitalisations) and number of medication incident reports (a measure of procedural documentation of incidents [i.e., administration and reporting quality/performance]). Descriptive statistics for these outcomes are provided in **Table 10**, with data provided for the whole sample as well as the control and intervention groups separately.

TABLE 10. Non-medication outcome descriptive statistics

	Whole sample		Control		Intervention	
Outcome	Mean (±SD) (n=1668)	Range	Mean (±SD) (n=897)	Range	Mean (±SD) (n=771)	Range
Number of hospital admissions	0.41 (0.92)	0–10	0.40 (0.97)	0–10	0.41 (0.87)	0–7
Length of hospital stay (days)	1.92 (8.33)	0–197	2.04 (9.96)	0–197	1.77 (5.89)	0–65
Number of falls	2.08 (5.09)	0–90	1.95 (3.96)	0–40	2.22 (6.15)	0–90
Number of Emergency Department transfers	0.52 (1.14)	0–16	0.49 (1.09)	0–10	0.55 (1.19)	0–16
Number of medication incident reports*	0.90 (3.08)	0–51	0.85 (3.62)	0–51	0.95 (2.30)	0–29

Notes: * n=1661 for whole sample and n=890 for control.

Table 11 shows the effects of the intervention on non-medication related outcomes. There were no statistically significant differences between the intervention and control groups observed, regardless of the presence or absence of adjustment for potentially confounding variables. Differences between intervention and control groups were generally very small. There was a small increase in falls in the adjusted model. Moderate increases in medication incident reporting were seen in both the unadjusted and adjusted models. As a result, despite the reduction in PIMs, chlorpromazine daily dose, and the residents' mean ACB scale score in the intervention group (**Table 9**), health service usage (as described by these measures) did not appear to be associated with a decrease. Except for medication incident reporting, most values clustered closely around 1.0, indicating small to very small effects of the intervention.

TABLE 11. Non-medication outcomes compared between control and intervention groups in unadjusted and adjusted models

Outcomes*	Unadjusted model	p value	Adjusted model	p value
Number of hospital admissions †	0.988 (0.739–1.320)	0.933	0.857 (0.528–1.390)	0.311
Length of hospital stay †	0.976 (0.598–1.592)	0.923	1.010 (0.434–2.353)	0.981
Resident's number of falls †	1.140 (0.689–1.888)	0.512	1.390 (0.827–2.337)	0.214
Number of Emergency Department transfers †	1.086 (0.804–1.468)	0.589	0.984 (0.611–1.586)	0.948
Number of medication incident reports ‡	1.987 (0.465–8.493)	0.927	2.104 (0.410–10.798)	0.892

Notes: * Compared with control over the period of study. Outcomes are expressed as the exponential of the model coefficient: that is, relative risk ratios. Adjusted model includes age, gender, presence/absence of a dementia diagnosis, CCI, number of regular medications, and presence/absence of concurrent NPS MedicineWise intervention, number of GRACE callouts, and level of care. † n=897 for control and n=771 for intervention. ‡ n=870 for control and n=771 for intervention.

The number of medication incident reports was higher in the intervention group compared to the control. However, there was a large amount of variation, so this difference was not statistically significant. Despite this, the size of the difference between groups (with residents in the intervention group approximately twice as likely to have medication incident reports) is such that it is possible that a real effect is occurring. This variable counts medication incident *reports*, rather than medication *incidents*. Therefore, either the incident rate or the reporting rate, or both, is increased. However, it is far more likely that this represents more complete incident reporting rather than an increase in the rate of incidents.

PROCESS EVALUATION

The RE-AIM evaluation implementation framework was used to report on essential program elements, including collaboration and sustainability of the on-site pharmacist model, to inform implementation and generalisability.[3, 4] Mapping of the RE-AIM framework against study outcomes is in **Appendix 7**.

The RE-AIM framework consists of five dimensions:

- **Reach** — assesses the number, proportion, and representativeness of individuals/organisations who participate in the service model.
- **Effectiveness** — assesses the effectiveness or efficacy of the service model on outcome measures and economic outcomes.
- **Adoption** — assesses the number, proportion, and representativeness of take up of the service model by target staff, settings, or institutions.
- **Implementation** — assesses the implementation of the service model's fidelity to the various elements, including consistency of delivery as intended.
- **Maintenance** — assesses the extent to which the service model becomes institutionalised or part of routine organisational practices and policies.

Program logic was developed to identify the study inputs, activities, and short-term, medium-term, and long-term outcomes (see **Appendix 8** for details).

Collaboration and normalisation was assessed using qualitative interviews with residents, family members, RACF manager, RACF nursing staff, on-site pharmacists, and prescribers (GPs and nurse practitioners), using framework analysis.[41] NVivo 20 (QSR International) was used to manage data and maintain a clear audit trail. Quantitative collaboration data were collected using surveys that were available digitally via the platform Qualtrics, with hard copies also available. The survey was adapted from the 14-item Physician-Pharmacist Collaboration Index (PPCI) survey for physicians. This survey has previously been tested among a small (n=340) cohort of primary care physicians in the US.[42] It is divided into three survey domains related to relationship initiation, trustworthiness, and role specification.[42]

Collaboration

Qualitative interviews

Forty-seven interviews were undertaken at intervention RACFs with GPs (n=7), nurse practitioners (n=2), RACF managers (n=7), registered nurses (n=9), enrolled nurses (n=1), on-site pharmacists (n=7), residents (n= 10), and family members (n=4). Interview length ranged from 14 minutes to 163 minutes. The median duration of interviews for prescribers, managers, nursing staff, residents, and family members was 38 minutes. For on-site pharmacists the median duration was 148 minutes. Participant characteristics are described in **Table 12**.

Qualitative interviews identified three dominant themes relating to integration and collaboration:

- the process of establishing relationships
- on-site pharmacist characteristics supportive of establishing and maintaining these relationships
- the perceived (or potential) benefit of the on-site pharmacist role.

TABLE 12. Semi-structured interview participant characteristics*

Position	Number of participants	Age (years)	Gender	Years at facility	Experience	Professional experience (years)
On-site pharmacist	6	≤ 40 (4, 66%) > 40 (2, 33%)	Female (5, 83%) Male (1, 17%)	< 1 (6, 100%)	• Experience conducting RMMR (2, 33%) • Community pharmacist experience supplying medications to RACF(s) (1, 17%) • Delivering QUM services (0, 0%)	< 5 (1, 17%) > 10 (5, 83%)
RACF manager	8*	≤ 50 (2, 25%) > 50 (6, 75%)	Female (6, 75%) Male (2, 25%)	≤ 1 (3, 37.5%) > 1 (5, 62.5%)	≤ 4 yrs (2, 25%) > 4 yrs (6, 75%)	≤ 15 (2, 25%) > 15 (6, 75%)
RACF nursing staff	9 RNs 1 EN	≤ 40 (5, 50%) > 40 (5, 50%)	Female (10, 100%)	≤ 4 (6, 60%) > 4 (4, 40%)	≤ 4 yrs (4, 40%) > 4 yrs (6, 60%)	≤ 6 (2, 20%) > 6 (8, 80%)
Prescribers	8 (7 GPs# 2 NPs)	≤ 40 (1, 12.5%) > 40 (7, 87.5%)	Female (4, 50%) Male (4, 50%)	≤ 2 (3, 37.5%) > 2 (5, 62.5%)	≤ 6 yrs (4, 50%) > 6 yrs (4, 50%)	≤ 8 (2, 25%) > 8 (6, 75%)
Resident	10	≤ 85 (5, 50%) > 85 (5, 50%)	Female (7, 70%) Male (3, 30%)	N/A	N/A	N/A
Family member	4	≤ 70 (2, 50%) > 70 (2, 50%)	Female (3, 75%) Male (1, 25%)	N/A	N/A	N/A

Notes: GP=general practitioners, NP=nurse practitioner, QUM=quality use of medicines, RMMR=residential medication management reviews, yrs=years of experience. # does not include characteristics of GP who was interviewed but elected not to disclose their characteristics * includes 7 interviewed RACF managers plus written feedback from 1 additional RACF manager, 6 on-site pharmacists interviewed (one at each of 7 sites, 1 on-site pharmacist [employed by 2 RACFs] interviewed twice).

The process of establishing relationships

Interview transcripts indicated that the process of establishing relationships between on-site pharmacists and prescribers, managers, and nursing staff most often fell to the on-site pharmacist; they needed to take a proactive approach. OSP 1 felt that they were 'the new kid of the block' [OSP 1], implying an obligation to build relationships and connections with others. Three on-site pharmacists mentioned that this process took 2 to 4 months. This is consistent with the insights of other professional groups, with one manager describing the first few months of their on-site pharmacist starting at their RACF as a 'teething period' [M1.1]. The process of establishing relationships was ongoing for most on-site pharmacists throughout the PiRACF study, most commonly due to RACF staff and management turnover across the RACFs.

Importance of face-to-face interactions

Establishing interprofessional collaborative working relationships was facilitated by face-to-face interactions with clinical staff, RNs, and prescribers. Co-located office arrangements with clinical staff and having the chance to meet prescribers were identified as ways in which this occurred. One on-site pharmacist described their experience of regularly attending medication rounds with a GP and it taking many months before the GP started to consider the on-site pharmacist's recommendations. Several on-site pharmacists found it challenging to establish relationships when there were limited opportunities to interact face-to-face with prescribers within RACFs.

Importance of incidental and informal interactions

Managers, nursing staff and on-site pharmacists highlighted that on-site pharmacists being in close physical proximity (such as sitting and working near RACF care staff members) facilitated interprofessional collaborative working relationships. As described by one on-site pharmacist, working in the same office space as senior nursing staff and management 'facilitates casual interactions and the relationship develops by itself' [OSP 6]. Ongoing interactions with RNs helped in developing trust and effective working relationships. Working on-site increased the likelihood of incidental interactions between on-site pharmacists and GPs.

On-site pharmacist characteristics supportive of establishing relationships

Participants generally described on-site pharmacists positively, with specific characteristics identified that helped the on-site pharmacist establish workplace relationships. On-site pharmacists were often characterised as friendly, adaptable, approachable, and having the 'right attitude to do something about it [medication management issues] without upsetting people' [Prescriber]. Several participants also acknowledged that it 'may have been different had it been a different person' [RACF manager]. Consequently, the potential impact of an on-site pharmacist being approachable and 'making an effort to say hi and good night to people' [OSP 3] was perceived by both on-site pharmacists and RACF care staff as important.

There were no instances where on-site pharmacists were described as unapproachable. One nurse practitioner said that their prescribing for one resident was questioned by an on-site pharmacist, but that when the nurse practitioner went through the therapeutic guidelines with the on-site pharmacist, the nurse practitioner found that it 'was a really valuable interaction. We each learned something' [Prescriber]. Subsequently, the nurse practitioner indicated that when they saw that on-site pharmacist again, 'I can walk up to them and ask a question and there's a mutual respect there' [Prescriber]. Pharmacists' proactivity and engagement were also identified as factors that affected their ability to develop relationships with RACF staff and prescribers. Less proactive on-site pharmacists were less likely to fully engage with prescribers and RACF managers. On-site pharmacists who did not have ongoing conversations with managers about the medication management activities they could help with meant that some RACF managers were not clear about their roles.

> *There wasn't very much of that proactivity and getting [them] to focus on this, or focus on that, or to try to — what we needed her to do.* [RACF manager]

Perceived (or potential) benefit of the on-site pharmacist role

Across the prescriber, manager, nursing staff, and on-site pharmacist interviews, participants consistently described the perceived (or potential) benefit of the on-site pharmacist role from their perspectives. Participants often said that their on-site pharmacist provided reassurance in relation to RACF medication management. Critically, GPs needed to see the benefit of the on-site pharmacist role prior to deciding whether to collaborate with them. Once GPs considered that the on-site pharmacist role to be beneficial, their relationships with on-site pharmacists often shifted from predominately on-site pharmacist-initiated to more of a two-way relationship. As described by one on-site pharmacist, 'now that the relationships are established [with GPs], I don't have to push at all' [OSP 1]. Some on-site pharmacists were also able to demonstrate an important role in increasing interprofessional care amongst the care team within RACFs, and there was no evidence to suggest that on-site pharmacists were perceived as encroaching upon the professional boundaries of the other health professionals interviewed.

Quantitative surveys

Quantitative surveys completed by prescribers (GPs and nurse practitioners), managers, and nursing staff (registered nurses and enrolled nurses) provided data on collaboration, which were interrogated using 2-tailed independent sample t-tests to identify changes in collaboration between on-site pharmacists, RACF staff, and prescribers at two time points: T1 was from 3 months after on-site pharmacist commencement in the role and T2 was from 9 months. Due to low numbers of survey responses from allied health care professionals and care staff, as well as lack of corresponding interview data, these groups were excluded from the analysis.

There were 33 completed surveys at T1 and 19 at T2, giving a survey response rate of 26% and 15%, respectively. At both time points, more nursing staff completed the PPCI surveys (n=22, n=9) than managers (n=8, n=5) and prescribers (n=3, n=5). Survey respondents were invited to provide a unique identifier response to enable survey responses at T2 to be linked to those at T1; however, only one participant from T1 also completed a survey at T2. Thus, T1 and T2 represent independent samples, rather than repeat measures. It is likely that the ACT COVID-19 lockdown from August 2021 contributed to the lower T2 survey response rate from the three remaining RACFs participating in the study. RACF staff turnover may have also been a contributing factor.

PPCI scores for all participants for T1 and T2 are shown in **Table 13**; a higher score represents a more established and committed interprofessional collaborative working relationship. The PPCI total scores at T1 and T2 suggest that positive interprofessional collaborative working relationships between on-site pharmacists and RACF care staff were established within 3 months and were maintained to at least 9 months. In addition, there was no difference in the PPCI total mean scores between T1 and T2 (P=0.96). Expressed as a percentage of the maximum scale scores, domain scores clustered universally at the high end of each scale. 'Relationship initiation and trustworthiness' was 86.1–91.9% and 'role specification' was 79.4–82.2% of the maximum scale values, respectively, indicating high to very high levels of initiation, trustworthiness, and role specification. The PPCI scores for both time points of this study are consistent with those in other studies conducted in inpatient [43, 44] and community settings.[42]

TABLE 13. Comparison of PPCI scores at T1 and T2 timepoints

PPCI score for all participants	PPCI Score range	T1 PPCI score (mean ± SD)	T2 PPCI score (mean ± SD)
Total PPCI score	14–98	83.7 ± 2.1	85.6 ± 2.1
PPCI domain scores			
Relationship initiation	3–21	18.1 ± 2.2	19.2 ± 2.2
Trustworthiness	6–42	36.8 ± 2.0	38.6 ± 2.1
Role specification	5–35	28.8 ± 2.0	27.8 ± 2.0

Note: PPCI=physician-pharmacist collaboration index. n=33 at T1 and n=19 at T2.

Normalisation

Normalisation (service integration) refers to the extent to which the intervention (on-site pharmacist) became part of routine practice within the intervention RACFs. The degree of normalisation of the on-site pharmacist role was assessed via semi-structured interviews and an adapted survey based on the 23 item NoMAD instrument. NoMAD has demonstrated good construct validity and face validity,[45] and it incorporates four constructs: coherence, cognitive participation, collective action, and reflexive monitoring.[46]

Each question was responded to on a 5-point Likert scale scored from 1 (strongly disagree) to 5 (strongly agree), except for responses to one question, 'The on-site pharmacist **disrupts** existing relationships', which were reverse-coded. Surveys were completed by prescribers (GPs and nurse practitioners), managers, and nursing staff (registered nurses and enrolled nurses), and mean response scores for individual questions and domains were calculated. Due to low numbers of survey responses from allied health care professionals and care staff as well as a lack of corresponding interview data, these groups were excluded from the analysis.

Qualitative interviews

Most participants at both the individual and team level described the on-site pharmacist's presence as beneficial. On-site pharmacists indicated that their managers were often key people to help drive the adaptation to the on-site pharmacist role becoming part of routine practice (i.e., being normalised). This on-site pharmacist considered their manager to be central in helping RACF staff realise and accept that the on-site pharmacist was to be '*integrated into their systems*' [OSP 1].

> *The on-site pharmacist was "able to take a long-term interest in residents and follow up medication-related matters for them over many weeks and months* [M5.1]

> *The general manager introduced me and said, "This is our onsite pharmacist. We're so happy and lucky to have her here. We wanna make the most of having her here, and please involve her in stuff".*
> [On-site pharmacist 1]

Some family members thought that it was beneficial for them to interact with the on-site pharmacist, whom they considered to be a potential 'broker'. As described by one family member, the on-site pharmacist *'had an in to the role of the RN, the role of the doctors, [OSP 3] had access to these people'* [FM3.1]. The perception was that the on-site pharmacist *'knew about them. [OSP 3] knew their roles, what the full nature of their roles'* which meant that *'I just felt that [OSP 3] was able to often tell me, 'Look, check [with] so and so'* [FM3.1]. For this family member, the on-site pharmacist could increase connections and enhance their communication with prescribers and RACF staff.

Prescribers, managers, and nursing staff considered working with the on-site pharmacist to be a legitimate part of their role. They were invested in working with the on-site pharmacist, although they were more likely to work collaboratively after the on-site pharmacist established a trusted relationship with them. As described by one on-site pharmacist, establishing these relationships was *'the foundation for anything else'* [OSP 6] they did within the RACF. This then helped increase the likelihood of prescribers listening to them and being *'far more likely to act'* [OSP 6] when medication recommendations were made.

Obviously if [OSP 1] made recommendations, it would be very sensible for me to listen to them and generally and act on them [GP1.2]

Most managers and nursing staff thought that the presence of the on-site pharmacist reduced their workload. As described by one nurse, the *'workload for us will be crazy now that OSP 1 is leaving'* [RN1.1]. There were, however, divergent views of on-site pharmacists' impact on prescriber workload, ranging from a noticeable reduction in workload and *'shorten[ing] our time spent onsite'* [GP1.1] through to contributing to a slight increase *'because OSP 6 will be scrutinising a lot of the medication, a lot more than I would'* [GP 6.1]. These varying views were not unexpected, given the on-site pharmacists' focus on medication management, inclusive of more regular medication reviews and clinical audits being undertaken compared to usual practice.

Most prescribers, managers, and nursing staff seemed to find it easy to integrate the new way of working with the on-site pharmacist into routine practice. Nursing staff consistently found it *'quite easy to adapt'* [RN4.1]. Likewise, a manager described how *'we just worked together and I can't see any of it being difficult'* [M1.1], reflective of the ease of on-site pharmacist normalisation. Some GPs also considered that it was easy to integrate working with the on-site pharmacist: *'I think it just happened. I don't think we tried to engineer it'* [GP1.2].

There was no perception that the on-site pharmacist role disrupted existing relationships. Instead, examples were provided where the on-site pharmacist was seen as facilitating communication. The on-site pharmacist's presence sometimes helped nursing staff to have better interactions with prescribers.

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when on-site pharmacist 5 is there ... we ask her to, you know, "Can you please help us talk to the GP?" ... having her there, it's very easy to interact with [the GP] because you've got that extra support [RN5.1]

Interview transcripts indicated that RACF management support of the on-site pharmacist role was sufficient. Support was improved when management was flexible in their operations, to ensure that the on-site pharmacist could attend and be involved in key medication management decision-making discussions, such as during medication advisory committee meetings, clinical staff meetings, and ad hoc multidisciplinary team discussions.

Overall, on-site pharmacists were well accepted and considered worthwhile across the intervention RACFs. Most residents and family members thought that on-site pharmacists were accepted, with *'everybody know[ing] who [the OSP] is. [The OSP]'s not on the outside looking in'* [R3.1]. Residents and family members who had regular interactions with on-site pharmacists were the most supportive. Interviewees were also broadly supportive of on-site pharmacists in RACFs, as articulated by one manager stating that the on-site pharmacist was *'invaluable'* [M4.1].

When reflecting upon the intervention and where the on-site pharmacist's impact was valued, one nurse described them as being able to undertake medication management activities which would have been time-consuming (e.g. the psychotropics register) and more difficult for RNs to complete. Additionally, one RACF manager described a reduction in management complaints at their facility, which they considered to be *'a big reflection'* [M6.1] of the on-site pharmacist's presence.

> *... helped us with the psychotropic register a lot. So I feel like if [the OSP] wasn't there, it would have taken us a lot of time and a lot of manpower to do that, but having [the OSP] there, it really helped us getting things on track* [RN 5.1]

> *it's really gone from you know six or seven [complaints] in a month to zero* [Manager 6.1]

Overall, most participants valued the presence of on-site pharmacists. Furthermore, residents, family members, nursing staff, and managers shared instances where the on-site pharmacist was able to provide specific medication management support. A powerful example was someone describing the admission of a family member into an RACF as a time *'full of misgivings... You always think you'd done the wrong thing. You think of how others are judging you'* [FM3.1]. This family member said this was *'such a crucial time for a pharmacist to be here when someone, a loved one, has just been placed into care and changes are being made to medication'* [FM3.1]. This family member then went on to describe the importance of speaking with the on-site pharmacist, which helped to increase their medication knowledge, thereby becoming more empowered:

> *proper discussions with doctors and my husband's specialists* [Family Member 3.1]

> *more confident to have those [medication management decision making] discussions [with doctors and specialists] and know what sorts of questions I need to ask and know what I should be aiming for* [Family Member 3.1]

The ongoing utility of the on-site pharmacist was actively demonstrated by two RACFs continuing to self-fund the role at their respective facilities, with the managers of the other five RACFs indicating that lack of funding was a barrier to retaining the role.

Quantitative surveys

Sixteen completed surveys (n=16) were returned from ten RACF nursing staff, three RACF managers, and three prescribers, with a survey response rate of 13%. The low survey response is likely a result of the ACT COVID-19 lockdown, which started in August 2021 and resulted in an increased workload for RACF staff.[47] The adapted survey findings are displayed in **Table 14**.

TABLE 14. Normalisation survey findings (n=16)

Normalisation survey data (modified NoMAD instrument survey domain and question responses)	Mean score (range 1–5)
Coherence	
I can see how having the on-site pharmacist at this facility differs from not having an on-site pharmacist	4.94
My colleagues (e.g. RACF staff, visiting general practitioners) and I have a shared understanding of the on-site pharmacist's purpose at this facility	4.81
I understand how the on-site pharmacist's role affects my work	4.88
I can see the potential beneficial impact of having the on-site pharmacist at this facility	5.00
Mean coherence domain score	**4.91**
Cognitive participation	
There are key people who drive working alongside the on-site pharmacist at this facility and get others involved	4.81
I believe that working with the on-site pharmacist is a legitimate part of my role	4.88
I am open to working collaboratively with the on-site pharmacist at this facility	5.00
I will continue to support the on-site pharmacist working at this facility	5.00
Mean cognitive participation score	**4.92**
Collective action	
I can easily integrate working with the on-site pharmacist into my work	4.94
The on-site pharmacist **disrupts** existing relationships (item score reversed)	4.25
I have confidence in my colleagues' ability to work with the on-site pharmacist	4.75
Facility management adequately supports the on-site pharmacist	4.94
Mean collective action score	**4.72**
Reflexive monitoring	
I am aware of reports about the work undertaken by the on-site pharmacist	4.75
My colleagues and I believe that having the on-site pharmacist working at this facility is worthwhile	4.75
Residents believe that having the on-site pharmacist working at this facility is worthwhile	4.44
I value the on-site pharmacist's impact at this facility	5.00
I can modify how I work with the on-site pharmacist to improve resident care which relates to medications	5.00
Feedback about the activities undertaken by the on-site pharmacist can be used to improve resident medication care in the future	5.00
Mean reflexive monitoring score	**4.82**

All survey respondents responded positively (i.e., agree or strongly agree) to survey questions relating to the coherence construct. This construct refers to how well respondents understand the role of the on-site pharmacist, the impact of the on-site pharmacist on the respondent's work, and the benefit of the on-site pharmacist. The mean coherence domain score was 4.91, indicating near universal highly positive (strongly agree) responses. All survey respondents saw the potential benefit of the on-site pharmacists at their RACF. These data are consistent with interviewee responses described above.

All survey respondents responded positively (i.e., agree or strongly agree) to survey questions that focussed on the cognitive participation construct. This construct refers to the willingness of the respondent to work with and support the on-site pharmacist. The mean cognitive participation domain score was 4.92, indicating near universal highly positive (strongly agree) responses. All survey respondents were open to working collaboratively with their on-site pharmacist and would continue to support them. These findings suggested that there were high levels of investment in the success and integration of the on-site pharmacist role amongst survey respondents. Again, these data are consistent with interviewee responses described above.

Most survey respondents responded positively (i.e., agree or strongly agree) to survey questions relating to the collective action construct. This construct refers to the ease of, confidence in, and support for the integration of the on-site pharmacist role, and also assessed any disruptive effects. With the exception of the response relating to the disruptive effects, respondents were near-universally strongly positive. However, regarding disruption, one respondent was ambivalent (neither agree nor disagree), and one strongly agreed that the introduction of the role was disruptive. This resulted in a lower (yet still high) response on this item (4.25/5) and thus a slightly lower mean score for the collective action domain (4.72/5). Despite this, a high proportion of survey respondents either strongly disagreed (50%, n=8) or disagreed (38%, n=6) that the on-site pharmacist disrupted existing relationships. Interview data did not contain instances where relationship disruption was attributed to the on-site pharmacist role. As such, the survey responses are broadly similar to interview outcomes, although they do flag the possibility of the on-site pharmacist role being disruptive in some instances.

All survey respondents responded positively (i.e., agree or strongly agree) to survey questions on the reflexive monitoring construct. This construct refers to the value ascribed to the work of the on-site pharmacist and to awareness of feedback and reporting processes. The mean reflexive monitoring domain score was 4.82, indicating near-universal highly positive (strongly agree) responses. All survey respondents strongly agreed that they valued the on-site pharmacist's impact, that they could modify their work processes that related to the on-site pharmacist to improve medication related resident care, and that feedback processes would result in improved care. These data are likewise consistent with interview responses.

These findings illustrate that survey respondents were strongly positive regarding the benefit of the on-site pharmacist position. Respondents were strongly positive regarding the integration of the role, with only one of sixteen respondents perceiving a disruptive effect. Given the near-universal positive nature of these findings, it is likely that the on-site pharmacist role would be well integrated into a RACF and quickly and (relatively) seamlessly become part of routine care in the facility.

Clinical governance

At the commencement of the study, RACF managers were invited to include on-site pharmacists in clinical governance processes, including MAC meetings, clinical meetings, and email groups, and to include pharmacists in notifications when residents entered the RACF, returned from ED or hospital, or commenced palliative care. Interview findings indicated that, for the most part, facilities incorporated on-site pharmacists into their clinical governance processes. Some facilities involved the on-site pharmacist by changing the MAC meeting date and also made efforts to include the on-site pharmacist in clinical and handover meetings.

> *We also invite, obviously, [OSP 2] to the MAC meeting. So, we have to have a three-monthly or a quarterly MAC meeting, medical advisory committee. So, that's kind of driven by myself ... but we try to get [OSP 2] involved with that meeting as well to really look at our overall usage, our antibiotic stewardship, obviously, our chemical restraints.* [Facility manager 2.1]

> *And at every meeting, we would mention that [Pharmacist 1] was still with us and explain if they had anything they'd like to talk to about, they could.* [Facility manager 1.1]

> *So the clinical meeting which is held maybe once a month, I occasionally attend if it's on a day that I'm there, but I found I actually get more out of the weekly toolbox meetings which cover the main at-risk patients and the main points from the week, so I attend those.* [On-site pharmacist 1]

> *They moved their MAC meetings so that I could attend, they've let me pick my days, they've let me pick my start and finish times, if I wanna come in early to do a morning med round review and come in to do that, I'm allowed to do that.* [On-site pharmacist 1]

On the other hand, some facilities were less successful in integrating on-site pharmacists into clinical governance processes. This may because the RACF manager did not invite the on-site pharmacist to MAC meetings or the MAC meeting was held on days the on-site pharmacist worked elsewhere. One on-site pharmacist was not generally on site when residents returned from hospital and did not successfully integrate themself into clinical care.

Interview data with on-site pharmacists and prescribers indicated that as well as inviting and involving on-site pharmacists in clinical governance processes, the communication skills of the on-site pharmacist were critical, as was engagement between the on-site pharmacist and RACF clinical manager.

> *My advice will be, number one, communicate to the facility management. Tell them what you can do about this and if it's possible just go through the study program folder. It's very comprehensive. It tells us what major activities we can conduct in the facility and how we can communicate that to the facility management to see if there's a problem we can do something.* [On-site pharmacist 2]

> *So I was the one that invited myself along to the first clinical meeting … I have to be quite proactive to get the communication channels going. And in the clinical meetings, I think that's been a big part of why they can see now that it's useful to have me here and that I can actually help them, so that relationship has changed the most, and now I would say they are probably the ones that utilise me the most.* [On-site pharmacist 6]

Usefulness of education materials and support

Prior to commencing in facilities, on-site pharmacists undertook online training in clinical topics that they were likely to encounter in aged care, such as pain management and behavioural and psychological symptoms of dementia. These materials were hosted on the Pharmaceutical Society of Australia's website (a list of videos is available in **Appendix 9**). The study team also conducted 3.5 hours of face-to-face or online training in study outcomes and activities, using materials developed for the project which included a site file for the on-site pharmacist and facility manager to integrate the on-site pharmacist into the RACF, a pharmacist tool kit outlining the Beers criteria and detailed information on how to undertake the activities, and a clinical notes folder to manage record keeping.

> *The trainings in the beginning, I think it was PSA trainings, they were helpful initially, just refreshing on all those topics.* [On-site pharmacist 5]

> *Yeah, so I remember picking on those folders and freaking out, actually, at the volume of what might have been in those folders, but when I had a look into that, it wasn't as bad <Laughs>.* [On-site pharmacist 3]

> *Yeah, I think that they're very good. They're actually comprehensive … I think that this is very, very good and valuable and that's — basically when I started doing the medication review for every resident, that's a tool I go to every single time.* [On-site pharmacist 2]

A gap in training, identified in the interviews, was palliative care training. On-site pharmacists also identified the need for additional resources to support their role in RACFs.

> *It was just that switch between going from community pharmacy to aged care where the focus is different in terms of medications, and then also that end of life care. That was quite a shock I think in the beginning for me.* [On-site pharmacist 3]

> *I think there's an opportunity for pharmacists to talk about advanced care planning because we're talking about medications and perhaps removing medications that kind of leads into that kind of conversation.* [On-site pharmacist 3]

But also just being a bit confronted by death and dying, like I had to face my own mortality a bit. It's like, yeah, there is end of life and we're caring for the people at the end of their life journey. I feel like I'm a bit more comfortable with that now, but at the beginning, it took up a lot of my thinking time. [On-site pharmacist 3]

... having the AMH (Australian Medicines Handbook) aged care companion, that really helped me in the beginning too, as a quick guide on particular disease states and what's usually prescribed or not prescribed in certain diseases. [On-site pharmacist 3]

Connections with other on-site pharmacists through catch ups and emails was also seen to be beneficial, although the Microsoft Teams app that connected on-site pharmacists was less so. This is reflected in the low number of posts on Teams.

They were fabulous. No, they were really good because they gave me the — from the study perspective, the kind of the goal of what the study was aiming to achieve in terms of reducing inappropriate medications and how to integrate a pharmacist within the health care team. Obviously, being a new role that people weren't familiar with yet, having that was like a support for me that the other pharmacists in the role are on the same page. [On-site pharmacist 7]

I think that first one where I got to meet — everybody was there, and when they go around and say, "What have you identified? What have you been able to implement? What have the barriers been?" Seeing that they align with what I've been doing was quite encouraging. [On-site pharmacist 7]

Look, I'll be honest with you. I've tried to use the online forum, but no one ever writes back. Can I say that? Is that allowed? <Laughs> Or it'll be a week and I'm like, "Oh, okay." So I feel like people are not using it, but I do look at it a lot, and then you know, for example, last week, I wrote that we had accreditation and then it took a week before I got a reply ... [On-site pharmacist 3]

Diary data indicated a small number of medication reviews use My Health Record for accessing resident's information or updating residents' records. Interviews with on-site pharmacists indicated that facility records created barriers to effective medication management.

I have tried to fax some reviews to external doctors, and I get the occasional fax back, or I don't get anything back but then I see the chart is changed, but to do any of these is a big administrative process because you have to fax the whole chart, then they have to print it all, it comes out of their fax machine, they then like annotate it, and then they have to send it back. So you end up with multiple copies of the med chart, and that really is an area of high risk because what if one RN is operating off one copy, and there's another copy in transit or somewhere else? [On-site pharmacist 3]

...what we're finding here at RACF 3 is sometimes a doctor or nurse practitioner will make a change on the med chart but it doesn't find its way to pharmacy. And so, it doesn't actually happen and it's something that I pick up but not always exactly timely. It'll be on a review or I'll be like, "Hang on, that was ceased but it's still on Leecare and we've been giving it –" and that is an issue that we've been looking at because the time — RNs crazy busy to fax that physical medication chart to the pharmacy and then the pharmacy rely on them to then update it in the system to come back on our system. So, there is a program that the nurse practitioner tells me called BESTmed that is live. The doctor makes a change and it goes straight to pharmacy. And I just feel like that would be a dream. [On-site pharmacist 3]

STUDY FIDELITY

Fidelity (the extent to which the intervention was delivered as intended) was assessed using Hasson's Conceptual Framework,[48] which appraises adherence against content, coverage, frequency, and duration domains (see **Figure 2**). Pharmacist diaries were assessed, a random sample of medications reviews were checked against resident charts, and interviews with RACF managers, nursing staff, on-site pharmacists, and prescribers were conducted to assess site engagement with the model of care. Sites were rated high, medium, or low fidelity based on this assessment.

Analysing the online pharmacist diaries demonstrated coverage across all activities conducted by the on-site pharmacists. Pharmacists were provided with activity targets, and minimum targets were met in clinical audits and quality improvement. However, pharmacists in six out of seven RACF sites offered vaccination services to RACF staff because one pharmacist did not have qualifications to conduct vaccinations. While the on-site pharmacist sought to undertake vaccination training, COVID-19 limited the availability of vaccination accreditation courses.

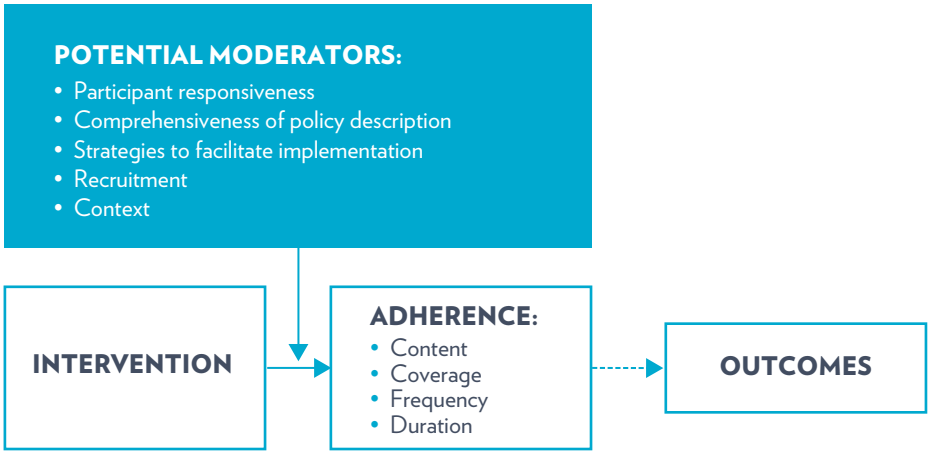

FIGURE 2. Assessment of fidelity and moderating factors from Hasson (originally from Carroll et al.)

Pharmacists were asked to keep a written copy of their medication reviews throughout the trial, with a target of at least 70% of residents having one or more medication reviews. At the end of the trial, pharmacists supplied 588 written medication review reports for 771 residents. 61.1% of residents had at least one medication review. Pharmacists self-reported conducting 1022 medication reviews via the pharmacist diaries, indicating that one-third of residents had more than one medication review due to the complexity of their medical conditions and medications.

A quality assessment was conducted on 10% of medication reviews by two accredited and experienced pharmacists using a checklist developed a priori by the study team. This builds upon the approach taken in the Care Home Independent Prescribing Pharmacist Study (CHIPPS) wherein a random sample of pharmaceutical care plans were reviewed for appropriateness by suitable experts.[49] The Intraclass Correlation Coefficient between the two accredited pharmacists was also assessed. Medication reviews in three RACFs were high quality, three were medium quality and one was low quality, with a rounded mean score for the quality assessment of all medication reviews of 3.5/5. The intraclass correlation coefficient was assessed to investigate the level of reliability between the two independent assessors and was found to be 0.922 (95%; CI:0.697–0.974), indicating excellent reliability between them.

Interview data were available on the context in RACFs as well as facilitators and barriers identified by on-site pharmacists and facility staff. Contextual issues affecting implementation included the high turnover and burdens experienced by staff in residential aged care, including COVID-19.

> *But it's the turnover of staff in general at RACF 3 and on a burgeoning aged care, is crazy. It's really high. So when I arrived, we had a care manager who started with me, and she wasn't here for very long. We went a long time without one and that was really hard, I think, for residents and staff. And we've had senior clinical manager, we've had three different ones.* [On-site pharmacist 3]

I think the Royal Commission has destroyed a lot of people and I think we're already seeing massive change in the ACT with managers leaving which is really, really sad and care staff reducing hours. Our permanent staff, a number of them have reduced hours and they're just burned out and exhausted because of this constant — there was the workload of COVID and there's increased acuity of our residents, I think, it's just damaged things. [Manager 4.1]

Well, across the board and some of it was the fault of lockdown because a lot of the staff were working part time in multiple sites and so they have to pick one, so we lost quite a lot of staff from that. [On-site pharmacist 6]

The biggest facilitators were effective communication, establishment of relationships between facility staff (including the facility manager, clinical manager, RNs), prescribers (GPs, nurse practitioners and geriatricians) and on-site pharmacists, and support from the facility manager. Previous experience in the on-site pharmacist role, in conducting RMMRs and working in pharmacies that supply RACFs, was seen as enabling undertaking of the role.

I think we were lucky in that respect. OSP 6 had already started at another facility before she started here. So she was actually working with — I can't remember what facility it is. So she'd already started there two months prior to coming here so we implemented pretty much what she was already doing at that other one here ... [Manager 6.1]

Well, I guess being accredited really helped because I already had an eye for looking at the list of medications and yeah, I think that without that, I would have had to get into the groove of reviewing medication charts. So that definitely helped, and I was doing home medicine reviews for similar aged cohorts so that definitely was a bonus, but aged care facility was completely new to me. [On-site pharmacist 3]

I guess with being accredited, we learn how to communicate with doctors <laughs>. [On-site pharmacist 4]

I guess, my knowledge of just the state regulations around controlled medicines was useful even though in nursing homes it can be a little bit different to what you used to in the community, but that was still helpful coming in. And obviously, just the knowledge of medications that you have as a pharmacist. And just, I guess, communication skills really, really important. [On-site pharmacist 3]

... because if I haven't worked as a supply pharmacist before, I might find this a little bit difficult, but I would start from the scratch because I don't know how the aged care system work. I don't know how this Webster-pack or this iCare system works. [On-site pharmacist 4]

Barriers highlighted by on-site pharmacists and RACF managers included differences in their understanding and expectations of the role (including the fact that the role was new for the on-site pharmacist and RACF), insufficient time, the COVID-19 lockdown, and difficulties with communicating with GPs, particularly given the number of GPs visiting some facilities and the fact that some GPs do not visit residents.

... on-site pharmacist was really good, she's experienced, but again, I think in hindsight, I think it would've been good for the pharmacists to actually have an idea or have them have a plan of they wanted to do to support us. I think a lot of the onus was put on us. A lot of the onus was put on us for us to tell them what we wanted them to do Clinical manager ... [Manager 7.1]

At first, I felt completely at sea and a bit lost and I struggled in the first month or two, to know what I needed to be doing, what KPIs I had. I didn't feel I have a very clear job description. The facility didn't know what my job was going to be either. So the first, probably, two months, I was actually struggling. [On-site pharmacist 1]

Education was seen as a missed opportunity in that staff were often not compelled to attend training sessions. Management encouraging staff to attend was seen as a way to facilitate greater staff engagement with education.

I think it would be much better if the management would allow her to actually do more education to the staff regarding medication administration. Currently, she wasn't given that much opportunity to give education … It would increase the knowledge of our staff members, and maybe increase our compliance … [RN 1.1]

… the only big negative was, if I'm gonna run an education session, at least someone should show up. And I don't know, I would put up memos, put it in the communication book, put up posters. So that one I think has to be supported from the top because the staff don't wanna stay and do something if they don't have to but I do think it benefits if they know more. [On-site pharmacist 1]

Facility managers, prescribers, and on-site pharmacists felt that there was not enough time to get to all the tasks, with education in particular not taken up due to this. Only one facility manager from a smaller facility stated that there would not be enough work for the on-site pharmacist to work fulltime.

… if she were here five days, I think we would have a lot more of that prompt reviewing of residents who were admitted and residents returning from hospital, those polypharmacy — no, not polypharmacy — antibiotic, like antimicrobial stewardship was a lot more 'cause she was really big on doing a lot of that and making sure that those all matched … [Manager 7.1]

It would have made an even greater impact if she was able to work more than two days per week to allow for greater follow up. E.g. if she sent an email on Friday, she could not follow up the response till the following Wed, five days later. Sometimes she needed to check emails from home on her days off and forward them on to us. [Manager 5.1]

… I think it's around probably more of that education component that we probably haven't tapped into enough. So, I'd almost see us running, if not weekly, definitely a monthly themed education session for our clinical team to help them understand, just even if it's around — for example, we have a couple of residents just on low dose methotrexate. So, making sure that we understand it's a chemotherapy product, it should be a non-handling or non-touch technique, the disposal, the waste management from a resident perspective. [Manager 2.1]

The COVID-19 lockdown affected on-site pharmacists' capacity to communicate with residents and GPs, as well as to conduct education with RACF staff.

The residents that are newly from hospital and from the community are in isolation, and I will have to wear full PPE to visit them, so I haven't seen any new residents lately since the lockdown until their 14 days is up. So it has impacted my ability to do medication reconciliations … [On-site pharmacist 6]

So we're not allowed to go out of zones. They've divided their facility into three zones and we have to stay in our zone. So I'm in the dementia ward and that means that I can't really visit the other residents. So the lockdown has affected one facility quite a lot and they've asked me to work from home one day a week, but this facility, they've blocked any outside visitors or volunteers, but the staff that are already here are encouraged to still provide maximum care to the residents. [On-site pharmacist 6]

So the way the facilities have dealt with it is quite different ...Yeah, we've still got all the GPs coming in. Last week, there were three that I saw come in on the two days I was there ... and the other facility is all telehealth, there's no doctors coming in, so it's very opposite. [On-site pharmacist 6]

Barriers included non-visiting GPs, the number of GPs attending residents in the RACF, and communication with GPs in general.

Yeah, and then it can be involved with multiple doctors. I don't know what happens in the other facilities but I think that's our biggest problem here. [On-site pharmacist 2]

... we can get all those problem like a potential PIMS, pick it up and document it and everything, but we don't have a prescribing authority or anything like that. It has to be from the doctors and that's a problem. [On-site pharmacist 2]

In my experience, I think the most difficult part is to communicate it to the doctors, and the hardest part is to get them to change something. [On-site pharmacist 2]

The components of fidelity for each intervention RACF were assessed using a scale of low, medium, and high. Of seven RACFs, one was assessed to have high fidelity, two were medium to high, two were low to medium, and one was low (**Table 15**).

TABLE 15. Summary of fidelity assessments

	Fidelity score			
Facility number	Diary activities	10% of medication reviews assessed for quality*	Interview data on level of adherence to the intervention as planned	Overall score
1	High	High	High	High
2	High	Med	Low	Low –Med
3	High	Med	High	Med–High
4	High	Low	Low	Low
5	High	Med	Low	Low–Med
6	High	High	Low–Med	Low–Med
7	High	High	Low	Med–High

ECONOMIC EVALUATION

Phase I of the PiRACF cRCT provided data on health care utilisation, changes in PIM prescription, and other QUM indicators such as falls and medication incidents, over 12 months. The cost effectiveness and cost-consequence analyses were conducted from a public health sector perspective. For the cost-effectiveness analysis, effectiveness was measured in terms of the primary outcome from the trial — proportion of residents avoiding use of PIMs on a regular basis (change from baseline in proportion of residents prescribed administration of at least one PIM on a regular basis). The cost-consequence analysis explored the incremental impact of the intervention (compared to the control arm) on the various secondary outcomes, to provide decision makers with greater clarity on potential benefits of the intervention beyond the primary outcome assessed in the trial. Costing of health care services assumed that all RACF residents have universal health care coverage for health care services given that all residents were Australian residents with access to Medicare. Description of the methods and complete findings are presented in the Economic Evaluation report in Appendix 11.

Resident-relevant outcomes such as the incidence of ED visits, hospitalisations and falls are more clinically meaningful outcomes than the rate of reduction in prescribing regular PIMs. However, the change in the prevalence of appropriate prescribing was considered to be a more direct and immediate outcome following pharmacist intervention.

Secondary outcomes were also assessed through the trial: i) medication-related incidents; ii) number of ED visits; iii) number of hospital admissions; and iv) change in clinical quality indicators at the resident level. Details of the clinical quality indicators are available in the full report of the economic evaluation provided as Appendix 11.

Utilisation and cost estimates

We followed the standard approach of identifying, quantifying, and valuing the resources used by applying unit prices. A time-use survey was sent to RACF managers at both intervention and control sites to measure the costs associated with time use of RACF staff for the same set of activities performed by the on-site pharmacists. Unit costs were obtained from national sources, such as the Fair Work Ombudsman[50, 51] and the ACT public sector nursing and midwifery enterprise agreement.[52]

Each intervention site was assigned an on-site pharmacist which activities were self-reported through a Qualtrics online diary. Their activities included: (i) medication review; (ii) clinical audit; (iii) communication; (iv) vaccination; (v) administrative tasks; (vi) education; (vii) quality improvement; and (viii) other activities. Vaccination activities were later excluded given the COVID-19 pandemic situation shifting the task from GPs to RACF staff, which may not be applicable in following years.

Total costs for the intervention and control groups were calculated to determine the average costs per facility-bed over 12 months. Intervention costs included time use of on-site pharmacists and RACF staff in managing medications. The RACF staff included facility and care managers, nursing staff (including registered nurses, nursing assistants, enrolled nurses, directors of nursing, and clinical nurse consultants), and care staff. Only costs that would be involved in the actual delivery of the intervention were included. Therefore, sunk costs of training on-site pharmacists (video material development time and 3 hours per session training) and costs associated with orientation of the intervention (2-hour orientation and resource material) were not included. The cost of an on-site pharmacist was estimated at $50 per hour plus 30% on-costs for 12 months. The cost per FTE pharmacist was estimated at $127,097.83. After removing costs related to vaccination tasks, costs per on-site pharmacist were divided by the number of beds per facility to produce the average cost per facility bed (over 12 months).

Resource use included utilisation of health services by each resident. The use of health services included ED visits, hospital admissions, ambulance services, and nursing triage assistance provided by the GRACE team.[53] Data on the use of primary care physicians were not collected and are therefore not included in the analysis. Medicine-related data were limited to number of PIMs prescription and secondary outcomes on PIM-related indicators (i.e., number of antipsychotic or benzodiazepine prescription, ACB score, number of regular medications, ADR documentation, and mean daily dose of chlorpromazine- and diazepam-equivalent medications). The unit costs of health care services and intervention costs were valued in 2021 Australian dollars. Details on unit costs applied in the economic analysis are available in the full report of the economic evaluation provided as Appendix 11. A discount rate was not applied given the 12-month time horizon examined by the trial.

The primary outcome (change in proportion of residents prescribed at least one regular PIM) was calculated for residents with exposure to the intervention or comparator for the full year of the trial. Other medication-related outcomes (i.e., proportion of residents prescribed at least one regular antipsychotic or benzodiazepine, number of regular medications, ACB scores) were estimated by the clinical trial team.

Statistical analysis

Analysis was undertaken using Stata (Version 17) and Python (Version 3). Average total counts and costs were calculated by facility bed in each group. The analysis included all residents and staff members for whom information was collected during the cRCT. The primary outcome (change in proportion of residents prescribed at least one regular PIM) included only residents with exposure to the intervention or comparator for the full year of the trial. All outcomes were checked for missing values, normality, and outliers.

The secondary outcomes presented in the cost-consequence analysis for medicine-related variables were generated using generalised mixed models (logistic, Poisson, and gamma distributed, as appropriate) to compare between intervention and control groups at baseline and endpoint.

Time spent on medication management was missing for nine of the fifteen RACFs (60%). These missing values were considered to be missing at random and imputed using a multiple imputation technique[54] using a Poisson regression distribution. The imputation procedure included predictors from the known covariates,[55] such as intervention/control status (categorical), total number of beds of the RACF (discreet), not-for-profit (categorical) and standalone (categorical) status of the RACF, and whether or not the RACF had a dementia ward (categorical).

Medication management costs were analysed at the facility level, while other health services costs were analysed at the resident level. Costs and outcomes are presented as means (over 12 months) and standard deviation per facility bed. Two-sample t-tests were conducted to examine the alternative hypothesis of statistically significant difference, and confidence intervals were calculated around the difference in means (intervention and control). A 5% alpha-level was taken to indicate statistical significance.

Intervention effectiveness

Table 16 shows the primary outcome, which is the change from baseline in the proportion of residents prescribed at least one regular PIM. The change from baseline in intervention sites (a 9.7% reduction) was greater than in control sites (0.6% reduction) resulting in a 9.1% incremental effect between the intervention and control groups.

TABLE 16. Primary outcome for PiRACF compared to usual care over 12 months

	Intervention (PiRACF)			Control (Usual care)			Difference in changes [95% CI] (Intervention – Control)
Item	Baseline	Endpoint	Change [95% CI]	Baseline	Endpoint	Change [95% CI]	
Proportion (%) of residents prescribed at least one regular PIM (SD)	69.5 (46.12)	59.8 (49.09)	−9.7 [2.92–16.39]	−65.7 (47.52)	65.1 (47.71)	−0.6 [−5.26–6.45]	−9.1 [6.04–12.10]

Note: Calculations were based on residents with full exposure of the trial, having paired baseline and endpoint data (n=890).

Costs of intervention and health care service use

On average (over 12 months), on-site pharmacists spent 10.03 (± 3.40) hours per facility bed undertaking medication management tasks (**Table 17**). Time spent by RACF staff was 48.26 hours (95% CI: −116.15; 19.63, P=0.14) less compared to control sites. The difference between the intervention and control arms was not statistically significant. No statistically significant differences were found between the intervention and control groups for use of ambulance services, GRACE services, ED visits, and hospital admissions (**Table 17**).

TABLE 17. Health service utilisation (12 months – per facility bed) – all residents

Resource item	Intervention (PiRACF)	Control (usual care)	Difference [95% CI] (intervention – control)
Intervention – medication management			
On-site pharmacists* (hours)	10.03 (3.40)	N/A	10.03 [6.88–13.17]
RACF staff (hours)	64.50 (13.10)	112.77 (81.18)	-48.26 [−116.15–19.63]
Ambulance service (attendances)	0.69 (0.37) (n=474)	0.52 (0.13) (n=424)	0.17 [−0.17–0.50]
GRACE service (attendances)	1.20 (0.74) (n=806)	0.92 (0.92) (n=850)	0.28 [−0.63–1.20]
ED visits (attendances)	0.67 (0.29) (n=435)	0.53 (0.11) (n=431)	0.14 [−0.12–0.41]
Hospitalisation admissions (episodes)	0.50 (0.20) (n=336)	0.46 (0.10) (n=369)	0.046 [−0.15–0.24]

Note: All data are reported as mean (SD) per facility bed (over 12 months). * 5% alpha-level

In this trial, the average cost to the health care provider of integrating an on-site pharmacist in a RACF was $56,286.16 per annum, which equated to an average cost per resident of $622.58. No statistically significant difference was identified across the two arms of the trial in the use of other health care resources. Although there is potential for a reduction in time spent by RACF staff on medication management in RACFs with an integrated pharmacist, the sample of RACFs in the trial that provided data for this parameter was very small (three RACFs in each arm), which meant that detection of a statistical difference in this factor was improbable. Despite the comprehensive collection of data concerning the attendance of residents to emergency departments and hospitalisation admissions over a year (e.g., due to falls, medication incidents, etc.), a statistically significant difference in the use of these resources was not observed in this trial. Therefore, the economic analysis does not apply any cost offsets against the costs of integrating pharmacists into RACFs. The incremental cost of resources used over 12 months per facility bed was $622.58. The result is equivalent to $6,842 per resident avoiding the use of a regular prescribed PIM (**Table 18**).

TABLE 18. Cost of resources used (over 12 months, per facility bed)

Resource item	Cost per facility bed*		Difference [95% CI] (Intervention – Control)
	Intervention (PiRACF)	Control (usual care)	
On-site pharmacist (SD)	$622.58 (209.92)	–	$622.58 [428.44–816.72]

Notes: *Costs are reported as mean (SD) per facility bed over 12 months, in 2021 Australian dollars. 95% CI for between group differences are shown within brackets. There was no statistically significant difference for other health care services such as RACF staff time, ambulance service, GRACE service, hospitalization and ED visits; therefore costs across the two arms for these resources are expected to be equivalent and cancel each other out. They were therefore not included in the analysis shown.

For the cost-effectiveness analysis, effectiveness was measured in terms of the primary outcome – proportion of residents avoiding use of PIMs on a regular basis (change from baseline in proportion of residents prescribed administration of at least one PIM on a regular basis). Costs to the health care system included the cost of the integration of an on-site pharmacist in RACF, RACF staff time-spent on delivering medication management, as well as other health care services such as ambulance services, GRACE services, ED visits and hospitalisation admissions.

An incremental cost-effectiveness ratio (ICER) was computed by comparing the incremental costs and incremental outcomes of the intervention and control groups. Results were expressed as incremental cost per resident avoiding use of at least one regular PIM. Mean estimates were used, and confidence intervals and sensitivity analysis indicating the robustness and validity of the results were also used. To address the uncertainty in the data from the missing values of RACF staff time use, a sensitivity analysis was conducted using a complete case analysis [56, 57] for the missing RACF staff time-spent data.

The ICER of integrating on-site pharmacists in RACFs was $6,842 per resident avoiding the use of a regularly prescribed PIM (**Table 19**).

TABLE 19. Incremental cost-effectiveness analysis for PiRACF compared to usual care over 12 months

	Total costs	Total effect (% prescribed ≥ 1 regular PIM)
Intervention (PiRACF)	$622.58	-9.7%
Control (Usual Care)	0	-0.6%
Increments	$622.58	-9.1%
ICER	$6,842 per resident avoiding the use of a PIM with a regular administration schedule	

Note: Costs are in 2021 Australian dollars. Effects are presented as absolute change between proportions.

A cost-consequence analysis (CCA), based on a public health perspective, was used to provide more information on the incremental impact (compared to the control arm) of the intervention on the disparate secondary outcomes. The CCA was complemented by a balance sheet containing a descriptive comparison based on the CCA to provide a more representative reflection of the impact of an on-site pharmacist on QUM in RACFs.

There was no statistically significant difference in non-medication outcomes such as ED visits, hospital admissions, medication incidents, falls, and deaths. Secondary outcomes for the intervention group were poorer for non-medicine related variables, except for average number of deaths (**Table 20**), and were better for medicines-related variables, except for number of regular medicines per resident and diazepam-equivalent daily dose per resident (**Table 21**). The medication outcomes did not show a statistically significant difference. However, when an adjusted model was fit to the data, using relative risk ratio and gamma distributed logistic regression as per communication with the clinical trial team, results for mean ACB scale scores and chlorpromazine equivalent daily dose per resident showed a statistically significant difference (p=0.008 and p=0.018, respectively).

TABLE 20. Summary of consequences: Non-medicine related outcomes in intervention and control facilities (reported in units of average per facility-bed over one year)

Item	Intervention (PiRACF)	Control (usual care)	Intervention – Control (95% CI)
ED visits (SD)	0.67 (0.29) (N=435)	0.53 (0.11) (N=431)	0.14 [−0.12–0.41]
Hospital admissions (SD)	0.50 (0.20) (N=336)	0.46 (0.10) (N=369)	0.05 [−0.15–0.24]
Medication incidents (SD)	1.42 (1.86) (N=731)	0.85 (1.21) (N=756)	0.57 [−1.24–2.37]
Falls (SD)	2.74 (1.29) (N=1715)	2.08 (1.14) (N=1749)	0.66 [−0.69–2.01]
Deaths (SD)	0.20 (0.06) (N=129)	0.22 (0.06) (N=183)	-0.01 [−0.08–0.06]

TABLE 21. Summary of consequences: Medicine related outcomes in control and intervention facilities

	Intervention (95% CI)			Control (95% CI)			
Item	Baseline (N=541)	Endpoint (N=620)	Change	Baseline (N=734)	Endpoint (N=681)	Change	Difference in changes
Proportion (%) of residents prescribed at least one regular antipsychotic or benzodiazepine (SD)	24.6 (43.1)	18.4 (38.8)	-6.2 [-10.94 – 1.46]	25.1 (43.4)	23.8 (42.6)	-1.3 [-5.78 – 3.18]	-4.9 [-12.55 – 2.75]
Mean ACB Scale Score	1.21 (1.66)	0.94 (1.49)	-0.27 [-0.45 – -0.09]	1.21 (1.80)	1.14 (1.66)	-0.07 [-0.25 – 0.11]	-0.2 [-0.45 – 0.05] ◊
Number of regular medicines per resident	10.00 (4.72)	9.64 (4.49)	-0.36 [-0.89 – 0.17]	9.85 (4.93)	9.11 (4.35)	-0.73 [-1.23 – -0.25]	0.37 [-0.35 – 1.09]
Chlorpromazine equivalent daily dose per resident, in mg	12.46 (41.64)	8.64 (32.32)	-3.82 [-8.03 – 0.39]	15.42 (49.89)	15.18 (52.51)	-0.25 [-5.58 – 5.10]	-3.57 [-10.37 – 3.23] ◊
Diazepam equivalent daily dose per resident, in mg	0.77 (2.76)	0.43 (1.73)	-0.34 [-0.60 – -0.08]	0.84 (2.49)	0.48 (1.89)	-0.36 [-0.59 – -0.13]	0.02 [-0.33 – 0.37]
Proportion (%) with complete ADR documentation	95.6 (20.6)	98.2 (13.2)	2.6 [0.63 – 4.57]	97.4 (15.9)	99.1 (9.4)	1.7 [0.32 – 3.08]	0.90 [-2.04 – 3.84]

Notes: Proportions presented as % and continuous variables as means. ACB=Anticholinergic Burden, ADR=Adverse Drug Reaction, mg=milligram, PIM=Potentially Inappropriate Medication. ◊ results showed a p value < 0.05 when an adjusted model was fit to the data

The average cost to the health care provider of integrating an on-site pharmacist in RACFs in this trial was $56,286.18 per RACF per year. A balance sheet comparing the incremental impact of the intervention compared to the control arm, across the secondary outcomes, is presented in **Table 22**.

TABLE 22. Cost consequence analysis balance sheet of on-site pharmacists in RACFs

In favour of intervention (PiRACF)	In favour of usual care
Resident's ACB Scale score	
Chlorpromazine equivalent daily dose per resident (mg)	
Neither in favour of nor against intervention	
• Number of regular medicines per resident	
• Proportion (%) of residents prescribed at least one regular antipsychotic or benzodiazepine	
• Diazepam equivalent daily dose per resident (mg)	
• ED visits	
• Hospital admissions	
• Medication incident reports	
• Average number of falls per facility bed	
• Average number of deaths per facility bed	
• RACF staff time-use	
• Proportion with complete ADR	

Notes: Outcomes in favour of intervention were based on whether the change between baseline and endpoint were statistically significantly better in intervention than in the control group, and vice versa. Outcomes neither in favour of nor against PiRACF are those with no statistically significant difference between intervention and control groups.

Sensitivity analysis

A sensitivity analysis was performed based on the subset of residents who had data both at baseline and at the one-year endpoint to ensure that the conclusions of the analyses presented with the results above are robust. The mean age of the subgroup was 86.7 (SD: 7.96). Baseline characteristics for the subgroup in both arms were similar with respect to gender and Aboriginal and/or Torres Strait Islander status. The imbalances observed in the total population (in proportion reporting English as a second language and proportion with a dementia diagnosis) were also observed in the subgroup. Consistent with the analyses shown in the results section, the sensitivity analysis also showed that no statistically significant differences were found between the intervention and control groups for use of ambulance services, GRACE services, ED visits and hospital admissions for the subgroup of residents exposed to the intervention or control for the full year of the trial (**Table 23**), which indicates that the conclusions based on the results presented in the results section above are robust.

TABLE 23. Health service utilisation (over 12 months, per facility bed) — for subgroup of residents with full exposure of the trial

Resource item	Intervention (PiRACF)	Control (usual care)	Difference [95% CI] (intervention – control)
Ambulance service	0.29 (0.12) (n=200)	0.29 (0.09) (n=217)	-0.00 [-0.13–0.12]
GRACE service	0.66 (0.47) (n=462)	0.58 (0.57) (n=514)	0.08 [-0.49–0.66]
ED visits	0.32 (0.15) (n=211)	0.30 (0.08) (n=235)	0.01 [-0.13–0.16]
Hospitalisation admissions	0.25 (0.10) (n=170)	0.26 (0.08) (n=202)	-0.016 [-0.15–0.24]

Note: All data are reported as mean (SD) per facility bed (over 12 months). * 5% alpha-level

Six facilities (three in each of the study arms) provided data on time that RACF staff spent on medication management activities. Missing data for the other nine facilities was imputed using a multiple imputation methodology. A sensitivity analysis that considers a complete case analysis (i.e., based directly on data from the six facilities with complete RACF staff time-use data) was conducted. The results showed that the difference across the two arms of the trial for time RACF staff spent on medication management activities on average per facility-bed (over one year) was not statistically significant (**Table 24**). This is consistent with the findings presented in **Table 23**.

TABLE 24. Complete case analysis — RACF staff time-use in undertaking the same medication management tasks as the on-site pharmacists (reported in average hours per facility-bed over one year)

RACF staff time-use	Intervention (PiRACF)	Control (usual care)	Difference [95% CI] (intervention – control)
Base case (multiple imputation method)	64.50 (13.10)	112.77 (81.18)	−48.26 [−116.15–19.63]
Sensitivity analysis (complete case analysis, N=6)	54.37 (12.35)	108.32 (75.69)	-53.96 [−227.94–120.05]

We also performed a sensitivity analysis around the upper and lower 95% confidence limits of the change in percentage of residents prescribed at least one PIM. We found that the ICER ranged from $5,145 to $10,307 per change in proportion of residents prescribed at least one regular PIM (**Table 25**).

TABLE 25. Sensitivity analysis — ICER upper and lower bound of primary outcome

	Change in % of residents prescribed at least one PIM			ICER — upper bound	ICER — lower bound
	Base case	Upper bound	Lower bound		
Sensitivity analysis — ICER	9.1	12.10	6.04	$5,145	$10,307

STUDY OUTCOMES AND KEY PERFORMANCE INDICATORS

CHN set targets for study outcomes in the CHN–UC contract, before commencement of the study (**Table 26**).

All targets were met, except for the target to reduce hospitalisations and 70% of residents to have completed a Medication Review in intervention sites. This may be due to the mixed adherence to the model in some sites or the short duration of the intervention.

TABLE 26. PiRACF study outcomes and key performance indicators and targets as per the CHN-UC contract, with findings

Intended outcomes	Indicators to achieve outcomes	Target as per CHN-UC contract
Clinical outcomes — Pharmacists employed to deliver quality, safe and appropriate use of medications	• Number of RACFs receiving funds to employ a pharmacist • Number and full-time equivalent pharmacists employed to deliver the model • Number of RACF clients receiving pharmacist services • Number of 1st time medication reviews completed • Reduction in the use of anti-psychotic medications • Reduction in use of benzodiazepines • Reduction in chemical restraints • Increase in vaccination rates of residents and staff	a. All eligible RACF in the ACT have been contacted and been given the opportunity to participate in the programme → **Target met** **At commencement of the study, there were 25 RACFs in the ACT and all were invited to participate in the study.** b. Of those participating RACFs, after 12 months of enrolling in the study — an average 70% of RACF residents have undergone at least one medication review by the pharmacist → **Target not met** **480 of 771 residents (62.3%) received at least one formal medication review. Pharmacist diaries recorded 1022 (132%) medication review activities indicating that 1/3 of residents received more than 1 medication review.** c. After 12 months of enrolling in the study there has been a 2% reduction n from baseline in the number of anti-psychotic medications prescribed in those RACFs with higher prevalence of use of anti-psychotics (>20%) → **Target met** **In Facilities with a high (>20%) prevalence of chemical restraint, the Intervention group demonstrated a 8.2% reduction over baseline and a 12.1% reduction over the control group change.** d. After 12 months — 2% reduction from baseline in chemical restraints as defined by use of anti-psychotics and benzodiazepine in those RACFs with high prevalence of chemical restraints (>20%) → **Target met** **In Facilities with a high (>20%) prevalence of chemical restraint, the Intervention group demonstrated a 7.6% reduction over baseline and a 7.3% reduction over the control group change**
Clinical outcomes — reduction of medication related problems for residents	• Reduced frequency of hospital admissions • Reduced frequency of emergency department presentations	a. 12 month — overall 4% reduction in hospital presentation as defined by the composite number of hospital admission / readmission/ED visit, determined by available RACF data such as residents leave days → **Target not met** **There was no reduction in ED or hospital admissions.**
Operational — RACFs have the capability to better manage medications	• Number of quality improvement activities undertaken in the period (Qualitative description)	a. 12 month — at least 6 quality improvement activities undertaken by each employed pharmacist in each RACF → **Target met** **OSPs conducted a total of 398 (range 17 to 113 each) quality improvement activities over the 12 months, an average of 56.9 activities per OSP.**
Operational — Service integration	• Evidence of increased and improved interactions between pharmacists, RACFs, general practitioners and allied health professionals including utilisation of My Health Records and other digital health innovations	b. Qualitative interviews with key stakeholders conducted by 12 months, to assess interprofessional interaction with pharmacist and other key health care professionals → **Target met** **The evaluation findings indicate the OSP role would be well integrated into the RACF and quickly and (relatively) seamlessly become a part of routine care in the RACF.**

TABLE 26. PiRACF study outcomes and key performance indicators and targets as per the CHN-UC contract, with findings *cont.*

Intended outcomes	Indicators to achieve outcomes	Target as per CHN-UC contract
Operational — Service sustainability	• Evidence to support recommendations regarding future sustainability of the model	a. As part of final evaluation report and program report **→ Target met** **2 of 7 facilities decided to continue funding the OSP at the end of the cRCT. In the 2022 Budget, the Commonwealth Government announced $345m in funding to implement community and on-site pharmacists into residential aged care from 2023 to improve medication safety.** b. Direct cost consequences of employing an on-site pharmacist will be reported **→ In favour of intervention — Target met** i. Resident's ACB Scale score ii. Chlorpromazine equivalent daily dose per resident (mg) **→ In favour of usual care — Target not met** **→ Neither in favour of or against intervention — Target not determined** • Diazepam equivalent daily dose per resident (mg) residents prescribed at least one regular antipsychotic or benzodiazepine • Proportion (%) of Number of regular medicines per resident • ED visits • Hospital admissions • Medication incidents • Falls • Average number of deaths per facility bed • RACF staff time-use • Proportion with complete ADR

DISCUSSION

MAIN OUTCOMES

Reduction in PIMs

This study examined the effectiveness and implementation of on-site pharmacist in residential aged care model to improve the medication management for RACF residents. Integrating on-site pharmacists in RACFs reduced the proportion of residents who were prescribed one or more regular PIMs, which is a positive outcome for residents and the health care system. PIMs, as defined by the Beers Criteria, is used widely in aged care research as an indicator for quality of prescribing. Use of PIMs is associated with an increased risk of hospitalisation in the older population, with elevated risk for those taking more than one PIM. PIMs are also associated with other potential adverse outcomes in older individuals, including falls, fractures, cognitive decline, delirium, stroke, and cardiovascular events. This reduction in PIMs occurred because of activities conducted by the on-site pharmacist in addition to, rather than instead of, standard (usual) care which includes RMMR and QUM services. RMMRs were conducted in both the control and intervention groups. Our study has not investigated the question of replacing RMMRs with the on-site pharmacist model of care.

Other inappropriate prescribing or high-risk medications decreased in the intervention group (compared with controls). ACB- and chlorpromazine-equivalent daily dose reduced significantly. Although diazepam daily dose equivalent and proportion of residents with one or more benzodiazepine or antipsychotic did not reach the threshold for statistical significance, they had decreased in comparison with the control group.

Experience level of on-site pharmacists

In this study, on-site pharmacists were typically experienced (66% had more than 10 years of pharmacy experience) and well qualified, with most being accredited immunisers and MMR-accredited and one-third having postgraduate educational qualifications. In a broader rollout of the on-site pharmacist model, to retain the level of effect demonstrated here, on-site pharmacists deployed into RACFs may need to have similar levels of experience and education as the sample of on-site pharmacists in this study. Further investigation may confirm whether these characteristics are necessary; however, the study evaluation findings indicate that this may be the case.

On-site pharmacists in this study were also employed directly by the RACFs, and as a result they were typically well integrated into the RACF care teams. It is uncertain whether a different employment model would retain the positive effects seen in this study. Without the RACF directly controlling their employment, the on-site pharmacist may not be able to integrate into the RACF care team and their ability to focus on the specific needs of the RACF may be impaired, reducing the effect of the on-site pharmacist on critical outcomes.

Increase in medication incident reports

The most notable effect of on-site pharmacists on non-medication related outcomes was a substantial increase in medication incident reports, although this increase was not statistically significant due to high facility-to-facility variability. We interpret this result as a substantial increase in the accuracy and frequency of reporting in some facilities (those where reporting may have been relatively poorer), due to a positive workplace culture in incident reporting.[58, 59] However, this interpretation requires confirmation in future studies.

No change in non-medication outcomes

There were no meaningful changes in non-medication related outcome (e.g. falls, hospitalisation) over the year-long intervention. Given the improvements in medication-related outcomes, some subsequent 'knock-on' benefit was expected. However, it is possible that the intervention was not long enough to see this effect. It may be also possible that in some RACFs, the pharmacist did not deliver the model of care as planned. The study fidelity assessment showed three out of seven RACFs had a fidelity score of medium or high, and four RACFs received a scores of low to medium. The potential reasons for low fidelity score in some RACFs may be related to pharmacists not being fully integrated into the facility clinical governance processes, or the on-site pharmacist, RACF staff and GPs were not able to develop strong collaborative relationships quickly enough during the study period to make an impact. As the role was being implemented for the first time, it is possible that it may require more time and effort from the on-site pharmacist and RACF staff to develop effective working relationships and utilise the full capacity of pharmacists to improve medication management within the facilities. It is also possible that the dose required to achieve significant outcomes was not reached and that some facilities may require an increased pharmacist FTE in order to effectively manage resident's medicines.

Pharmacist characteristics and role establishment

The PiRACF model requires incidental and informal face-to-face interactions. It also needs a proactive on-site pharmacist who can establish workable and sustainable relationships with members of the RACF care team, despite structural challenges such as high staff and management turnover, and who can demonstrate the relevance of the on-site pharmacist role to prescribers. Although the PiRACF model creates the opportunity for face-to-face and informal/incidental interactions by default, the need for the on-site pharmacist to be confident enough, and capable enough, to proactively create the necessary links with other team members reinforces earlier comments that the experience and education level of the on-site pharmacist may be a critical factor in intervention success. The majority of on-site pharmacists in this study were experienced and well qualified and thus well placed to take a proactive approach to forming and managing interprofessional relationships. The study on-site pharmacist capabilities in this regard are reflected in the universally high scores for 'relationship initiation' in the quantitative PPCI survey, as well as high overall PPCI score and scores on other domains both early (within 3 months) after on-site pharmacist commencement and later in the on-site pharmacist engagement period. Less well-experienced and well-qualified on-site pharmacists may have been less capable in meeting this requirement.

This issue has implications for recruitment of pharmacists for any broader rollout of the on-site pharmacist model. Well-educated and experienced pharmacists seem ideal to the task but may not be available in numbers, as these characteristics would likely be desirable for most pharmacist positions in many employment contexts. There may be work force capacity issues in finding enough of the ideal 'type' of pharmacist (experienced, well qualified, and confident enough to operate successfully in a novel and challenging environment) for the on-site pharmacist role.

Although on-site pharmacists were required to be active in establishing their role, an important finding was that prescribers, managers, and nursing staff did not consider the on-site pharmacist as an encroachment on their roles. This outcome speaks to both the sensitivity with which study on-site pharmacists develop their interprofessional relationships with these prescribers, managers and nursing staff and to the latent need for the on-site pharmacist skillset in the RACF environment. Again, however, the possibility of perception of encroachment exists, and broader use of the on-site pharmacist model should be cognizant of the need to minimise such perceptions.

Time required to establish good working relationships

Few previous studies have investigated the timeframes required to establish a positive working relationship between on-site pharmacists and prescribers, managers and nursing staff. [42, 44] We found that it took 2–4 months, which has implications for future adopters of this on-site pharmacist model of care: time must be allowed for the necessary relationships to be developed before any positive effects can be seen. Future research may be useful to explore how these relationships are maintained over a longer period.

Despite the timeframe required, RACF staff, managers and prescribers were near universal in their acceptance of the on-site pharmacist role. The very high levels of role understanding and acceptance, perception of value, integration, and modification of work practices to facilitate collaboration, and the relatively low levels of concern regarding disruption of existing relationships, indicate that the on-site pharmacist role and services can become normalised relatively quickly. The almost complete absence of negative comments regarding normalisation and integration is a strong indicator that wider rollout is unlikely to suffer from issues regarding a broader acceptance of the role and services or resistance to uptake from within the RACF care team.

Economic evaluation

The average cost of the PiRACF intervention to the health care provider was $56,286.16 per annum, which equated to an average cost per resident of $622.50, with the incremental cost of integrating a pharmacist into a RACF to be $6,842 per resident avoiding the use of a regularly prescribed PIM. These costs are not offset by associated reductions in non-medication related outcomes (i.e., hospitalisations). However, the sample of RACFs in the trial that provided data for this parameter was very small (three RACFs in each arm), and as a result this difference is not statistically significant and should be interpreted with some caution.

The economic evaluation estimated the incremental cost effectiveness ratio (ICER) to be $6,842 per PIM avoided. It is difficult to determine whether this can be considered cost effective or good value for money in the absence of knowing what the impact of avoiding administration of at least one PIM regularly means for a resident. We also do not have a clear cost effectiveness threshold in terms of PIMs avoided. For these reasons further research is needed which ideally collects data on the implications of PIMs avoided on resident outcomes such as quality of life. From such data quality adjusted life years (QALYs) and an incremental cost per QALY can be generated allowing the question of whether integrating an on-site pharmacist in RAFs is cost effective to be more readily determined.

CHALLENGES

The outcomes of the PiRACF study have been achieved despite several substantial challenges, each of which may have muted the overall effect of an on-site pharmacist.

COVID-19 impacted the study in several ways. RACF operations were affected by the potential risk to residents, staff, and visitors, and the requirements to implement Commonwealth and ACT Health guidelines. In the early stages of the pandemic, this involved multiple changes in policy and procedures within a short timeframe, which limited RACFs' abilities to engage with the study team or on-site pharmacists. Medication round timing observations could not be conducted due to the Chief Health Officer's Public Health Direction (dated 23 March 2020) which prevented face-to-face data collection. Medications round timing is a secondary outcome that could have contributed to the economic evaluation, however its absence is not critical. On-site pharmacists were also affected, with some candidates declining offered positions in RACFs due to COVID-19 home-schooling commitments. A small number of RACFs requested that pharmacists work from home, denying the on-site pharmacist the face-to-face and incidental contacts identified as important to sound integration into the RACF care staff and making it harder for on-site pharmacists to establish critical relationships. Some required on-site pharmacists to only work at one site, affecting pharmacists' working hours and earning capacity. As a result, recruitment of on-site pharmacists was substantially delayed, with RACF employment likely perceived as 'higher risk' and thus less appealing than would have been the case prior to the COVID-19 outbreak.

On-site pharmacists within the PiRACF study highlighted several issues: lack of consistency in how and which psychotropics RACFs report for quality and safety reporting; difficulties in contacting and communicating with GPs; difficulties in accessing the Australian Immunisations Register to upload immunisations certificates; and lack of guidance regarding the process for on-site pharmacists to conduct COVID-19 vaccinations. High turnover of facility managers, care managers, and RNs resulted in some difficulties in involving pharmacists in medication management processes such as medicine advisory and other RACF committees.

A number of limitations have been identified that frame the interpretation of study findings:

- New Aged Care Quality Standards that included reporting of chemical restraints came into effect in July 2019, which overlapped with study outcomes for psychotropic use.
- NPS MedicineWise conducted a dementia in aged care project at two sites, which had the potential to confound results relating to the use of psychotropic medications. To address this, the analysis controlled for the presence of the NPS MedicineWise interventions in medication-related and non-medication related outcomes. The lack of statistically significant outcomes for the NPS MedicineWise intervention in the adjusted models suggests that this intervention did not confound our main findings.
- The evaluation survey had limited generalisability, low survey response rates, and potential for participant recall and positivity bias.
- For the economic evaluation, data relating to time spent on medication management by RACF staff was missing for nine (60%) of the fifteen RACFs. Thus, conclusions regarding comparative costs of RACF staff time spent on medication management should be considered speculative. Future studies should include rigorous capture of time spent on medication management by RACF staff and that they elicit the impact of avoiding the regular use of a PIM on resident outcomes such as quality of life.
- This study only included RACFs located in the ACT, a metropolitan area. Further research should examine this model in rural, regional, and remote locations and contexts. The enablers, barriers, potential indicators, and developing strategies required to adapt the on-site pharmacist model to local contexts of primary care in different regions are important elements that determine the sustainability of this model and need further study.

CASE STUDIES

These case studies show how on-site pharmacists use their medication management skills and knowledge to address residents' issues through collaboration and communication with residents and families, RACF staff, and GPs.

Case study 1 A GP with a patient at an intervention facility contacted the on-site pharmacist requesting an urgent medication review for the resident, and the on-site pharmacist was able to provide this in a timely way. The GP also sent a referral to the RMMR pharmacist, but this incurred a delay due to the time that the referral process usually takes.

Having an on-site pharmacist improved timely access in managing medication issues, particularly in urgent circumstances.

Case study 2 A facility has a resident with insulin-dependent diabetes who is also resistant to medication and blood glucose checks due to dementia. Staff were required to do finger prick checks three times daily and administer medications several times a day. The on-site pharmacist, in collaboration with the GP, discussed alternative medications to reduce the burden and frequency of medication administration. The resident was started on sensors for monitoring blood glucose levels, but staff did not know how to use this product. The on-site pharmacist taught RNs how to use and replace the sensors and showed care staff how to be aware of the sensor during tasks such as showering and changing.

The resident is no longer refusing medications and seems more comfortable.

Case study 3 Facility managers requested clarification on whether on-site pharmacists can conduct COVID-19 vaccination. Currently, provision of COVID vaccinations in RACFs is through a project funded by the Department of Health. Only RACFs that have applied and been approved can have pharmacist-delivered COVID-19 vaccinations. The study team sought clarification from the ACT Health Chief Health officer on the approval and registration process for on-site pharmacists to conduct COVID-19 vaccinations.

Resident vaccination activities are beyond the original remit of the study, but shows the increased scope for on-site pharmacists' activities in RACFs.

REVISED SERVICE MODEL

Based on the study findings, we propose a revised service model that includes updated pharmacist activities and mechanisms for embedding pharmacists into RACFs (**Table 27**).

Additional documents to support embedding on-site pharmacists in RACFs are attached in the appendixes:

- Position description for RACFs to use for employing on-site pharmacists (**Appendix 11.1**)
- Pharmacist's activities and orientation checklist for RACFs and on-site pharmacists to use to embed the pharmacist into the facility (**Appendix 11.2**)
- Introductions to RACF staff (**Appendix 11.3**), GPs and health professionals (**Appendix 11.4**), and residents, families and carers (**Appendix 11.5**)

TABLE 27. Revised on-site pharmacist activities in RACFs

Activity	
Medication reviews	Review medications, screen for PIMs, communicate with prescriber, follow up and keep notes, at these time points: • Upon resident's admission to RACF • After a resident returns from ED or hospital, after being prescribed new medication, when a resident has declining health, and after referral to palliative care • At regular intervals • When a resident is identified at a clinical meeting to have deteriorating health • When a resident is referred to palliative care • When a resident has a fall or experiences frequent falls • When a medication causes adverse effects or symptoms • If a resident, family member or carer requests a medication review • When a speech pathologist identifies the need for medication dose form modification for a resident
Clinical audits	Conduct clinical audits to identify residents most at risk of medication related problems and hospitalisations, on the following classes of medications: • PIMs • Anticoagulants (due to falls risk, to ensure dose is adjusted according to renal function, for residents taking aspirin, and for other indications) • Polypharmacy audit report (also to identify falls risk) • PPI — in particular high dose PPI • Antimicrobial audit (for reporting, to ensure there is supporting indication including pathology, to check dose and duration of treatment, to check renal function, NAPS survey benchmarking) • PRN usage (e.g. past 4 months) • Opioids • Insulin administration • Prolia audit (including timing, and supporting blood tests) • Non-packed medication • Medication storage • Medication chart • Expiry date audit • Chart audits to ensure diagnoses and ADR are up to date
Medication round optimisation	Observe medication rounds and dose-form modification (crushing) to identify potential problems, and: • Take action to address problem in a collaborative manner • Provide education to staff • Develop relevant procedures and checklists (such as trolley check)
Education	Conduct ad-hoc and regular, planned education with group and individual RACF staff, residents and carers, for example: • Insulin and diabetes management • Psychotropics and chemical restraints • S8 medicines, including legislation • Inhaler and eye drop administration and storage • Cytotoxic medications and handling • Educate residents on their medications and what they are for

TABLE 27. Revised on-site pharmacist activities in RACFs *cont.*

Activity	
Quality improvement	Review and improve medication management policies and procedures including: • Update medication management policies and procedures • Ensure S8 medicines are used, stored and disposed of according to legislation • Attend and take an active role in MAC meetings • Set up processes to review new admissions and transitions of care • Ensure the on-site pharmacist is added to the clinical team email list
Other activities	Conduct other relevant medication management activities, including: • Participate in case conferences with GPs • Have discussions with GPs/prescribers when medicines are changed • Establish relationships with GPs — make an appointment to meet and be introduced to all GPs • Assist with COVID vaccines, antiviral supply and education • Liaise with hospitals and community pharmacies • Liaise with pharmaceutical manufacturers • Assist RNs with S8 destruction

Based on the PiRACF study findings, the following actions have been identified for on-site pharmacists to embed themselves into clinical governance processes in the facility. An orientation checklist and guidance have been developed to support this — see **Appendix 11.2**.

Upon commencement in RACFS, and in an ongoing way, the on-site pharmacist should:

- Proactively build relationships with GPs and prescribers and outline their role by attending doctor rounds or making a time to meet or talk with GPs and prescribers
- Attend and actively participate in MAC meetings
- Attend clinical meetings (e.g. weekly) and follow up on residents with declining health or who have returned from ED or hospital
- Proactively talk to RACF managers and staff about medication management activities that on-site pharmacists can help with (e.g. announcements at staff and clinical meetings as well as emails)
- Work closely with clinical care managers
- Proactively build relationships with staff.

The following actions have been identified for RACF managers and staff to integrate on-site pharmacists into the workflow in the facility:

- Facilitate on-site pharmacist to attend relevant committees (e.g. MAC, quality, falls, Antimicrobial Stewardship)
- Invite the on-site pharmacist to attend clinical meetings and include them in clinical email lists and notifications
- Give on-site pharmacist a specific time to present on medicine management topics at clinical and staff meetings
- Encourage staff to attend education sessions run by the on-site pharmacist
- Give on-site pharmacists space to contribute to resident newsletters
- Involve on-site pharmacists in assessing staff medication competencies assessment and education
- Involve pharmacists to review and address medication incidents and provide necessary education
- Seek systematic ways to involve on-site pharmacist in reviewing resident's medications at transitions of care, such as when a resident enters the facility, returns from ED or hospital, when a resident has declining health, or commences palliative care

RECOMMENDATIONS FOR NATIONAL ROLLOUT

The PiRACF study found that the on-site pharmacist model reduced inappropriate medication use and had benefits for RACFs, including saving staff costs. Based on these findings, the study team proposes that residential aged care stakeholders, including governments and providers, consider the following recommendations:

RECOMMENDATIONS

1. **Roll out the on-site pharmacist model nationally to improve medication management for RACF residents.**
2. **Promote an understanding of the on-site pharmacist role among stakeholders, including consumers (residents, families and carers), pharmacists, general practitioners and prescribers, health care professionals, and RACF organisations and staff.**
3. **Ensure that the on-site pharmacist and facilities are provided with on-going support to orient pharmacists and RACF staff to the activities and role of the on-site pharmacist.**
4. **Explore and address workforce issues that arise from the need to train and recruit pharmacists.**
5. **Explore options for a nationally recognised professional pharmacy body to coordinate, upskill and train pharmacists to enhance their clinical skills and knowledge about aged care facilities' operations and processes.**
6. **Explore models of pharmacists using telehealth for RACFs in rural and remote areas.**
7. **Conduct further studies to examine implementation of this model. In particular, the full-time equivalent required, effective inclusion in clinical governance processes, appropriate evaluation and quality indicators, and role development and integration require further investigation.**
8. **Future economic evaluations are required to be able to determine if integrating on-site pharmacists into RACFs is cost effective in the ACT or nationally. Such studies should include rigorous capture of time spent on medication management by RACF staff. The study should be appropriately powered to detect significant differences in this outcome as a difference in this outcome would be a key driver of the determination of whether the intervention is cost saving. Such studies should also elicit the impact of avoiding the regular use of a PIM on resident outcomes such as quality of life to enable generation of incremental cost per QALY to determine if integrating on-site pharmacists into RACFs is cost effective.**

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ACRONYMS

ACT	Australian Capital Territory
ADR	adverse drug reaction
AHPRA	Australian Health Practitioner Regulation Authority
CCI	Charlson co-morbidity index
cRCT	cluster randomised controlled trial
FTE	full-time equivalent
MAC	medication advisory committee
PIM	potentially inappropriate medication
PRN	pro re nata — when necessary
QUM	quality use of medicines
RACF	residential aged care facility
RMMR	residential medication management review

APPENDICES

APPENDIX 1. PROTOCOL PAPER

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Trials

STUDY PROTOCOL Open Access

Integrating pharmacists into aged care facilities to improve the quality use of medicine (PiRACF Study): protocol for a cluster randomised controlled trial

Sam Kosari[1*], Jane Koerner[2], Mark Naunton[1], Gregory M. Peterson[1,3], Ibrahim Haider[2], Emily Lancsar[4], David Wright[5], Theo Niyonsenga[2] and Rachel Davey[2]

Abstract

Background: Medication management in residential aged care facilities is an ongoing concern. Numerous studies have reported high rates of inappropriate prescribing and medication use in aged care facilities, which contribute to residents' adverse health outcomes. There is a need for new models of care that enhance inter-disciplinary collaboration between residential aged care facility staff and healthcare professionals, to improve medication management. Pilot research has demonstrated the feasibility and benefits of integrating a pharmacist into the aged care facility team to improve the quality use of medicines. This protocol describes the design and methods for a cluster randomised controlled trial to evaluate the outcomes and conduct economic evaluation of a service model where on-site pharmacists are integrated into residential aged care facility healthcare teams to improve medication management.

Methods: Intervention aged care facilities will employ on-site pharmacists to work as part of their healthcare teams 2 to 2.5 days per week for 12 months. On-site pharmacists, in collaboration with facility nurses, prescribers, community pharmacists, residents and families will conduct medication management activities to improve the quality use of medicines. Aged care facilities in the control group will continue usual care. The target sample size is 1188 residents from a minimum of 13 aged care facilities. The primary outcome is the appropriateness of prescribing, measured by the proportion of residents who are prescribed at least one potentially inappropriate medicine according to the 2019 Beers Criteria. Secondary outcomes include hospital and emergency department presentations, fall rates, prevalence and dose of antipsychotics and benzodiazepines, Anticholinergic Cognitive Burden Score, staff influenza vaccination rate, time spent on medication rounds, appropriateness of dose form modification and completeness of resident's allergy and adverse drug reaction documentation. A cost-consequence and cost-effectiveness analysis will be embedded in the trial.

Discussion: The results of this study will provide information on clinical and economic outcomes of a model that integrates on-site pharmacists into Australian residential aged care facilities. The results will provide policymakers with recommendations relevant to further implementation of this model.

Trial registration: ACTRN12620000430932. Registered on 1 April 2020 with ANZCTR

* Correspondence: sam.kosari@canberra.edu.au
[1]Discipline of Pharmacy, Faculty of Health, University of Canberra, Bruce, ACT, Australia
Full list of author information is available at the end of the article

Appendix 1. Protocol paper *cont.*

Keywords: Residential aged care facility, Aged care, Care home, Quality use of medicines, Elderly, Potentially inappropriate medicine, Pharmacists, Cluster randomised controlled trial

Background

Older adults residing in residential aged care facilities (RACFs) generally have complex co-morbidities and are prescribed a large number of different medications [1]. Studies have reported that, on average, RACF residents take between 9 and 11 regular medications [2–4]. Polypharmacy increases the risk of medication-related problems and adverse drug events, including hospitalisations, placing a significant burden on residents and economic cost on the health care system [5–7]. Australian studies have shown that almost all RACF residents have at least one medication-related problem [4, 8–11] and between 30% and 73% of residents are prescribed at least one potentially inappropriate medication (PIM) [4, 12–18]. According to a recent meta-analysis of 33 international studies, the use of PIM is significantly associated with an increased risk of hospitalisation in the older population, and the risk was higher in those who took more than one PIM [19]. Additionally, PIMs are associated with other potential adverse outcomes in older indivisuals, including fall, fracture, cognitive decline, delirium, stroke and cardiovascular events [20, 21].

Among PIMs, sedatives, antipsychotics and drugs with anticholinergic properties are particularly associated with greater risk of harm. A large Australian cohort study among 11,368 residents found that 61% were taking psychotropic medications, with the majority of these agents having sedative properties that can contribute to falls or confusion [22]. The over-use of psychotropic medications has been recently highlighted in the interim report of the Australian Royal Commission into Aged Care Quality and Safety [23]. Australian studies have reported that over 20% of RACF residents were taking antipsychotics regularly [22, 24], and the duration of antipsychotic use was longer than recommended [25–27]. Prolonged use of antipsychotics in older people is linked with increased risk of hospitalisation, hip fracture, peneumonia, stroke and death [28, 29]. Another large Australian study [30] of 17,000 RACF residents reported that 46% were taking drugs with moderate to strong anticholinergic effects; these drugs can contribute to cognitive and functional decline, delirium, worsening dementia, and increased mortality in older people [31].

Additionally, over-prescribing, using medicines longer than recommended, and drug interactions affect medication safety in aged care residents. The Australian 2018 Aged Care National Antimicrobial Prescribing Survey reported that 10% of residents were taking an antibiotic on the day of the survey, and about two thirds of these prescriptions were lacking relevant documentation of sign and symptoms to justify the need for antibiotic use [32]. Another large Australian study reported that more than 50% of residents were prescribed proton pump inhibitors with a median duration of use of 360 days in the year, while the recommended duration of use is 8 weeks [27]. Over-prescribing can also lead to unwanted drug interactions; a retrospective study of aged care resident's medication records showed that 16% of residents were at high risk of drug-induced QT prolongation and potential arrhythmia due to polypharmacy [33]. Overall, many published studies highlight the need to improve medication management in RACFs. It is an area where pharmacists, doctors and nurses can work together, ensuring improved medication safety and quality use of medicines for residents [34].

Amongst the factors affecting medication safety and quality use of medicines in RACFs, lack of accessibility to pharmacists and doctors, and poor interdisciplinary collaboration were highlighted in a recent systematic review of international studies [35]. Consistent with these findings, the Australian Medical Association highlighted the "extremely urgent" need to increase the number of health care professionals in RACFs [36]. General practitioners (GPs), nurses and pharmacists are the key health professionals involved in the prescribing, administration and supply of medicines. Since these health professionals are generally not co-located, there are significant limitations in access, communication [37] and coordination of medication management processes [1] for aged care residents.

In Australia, there are two government-funded pharmacist-led services in place that aim to improve medication management in RACFs: (i) residential medication management review (RMMR) program [38] and (ii) quality use of medicine (QUM) service [39]. The RMMR for RACF residents has been in place since 1997 [37] and is similar to "clinical medication reviews" in the UK, "comprehensive medication reviews" in the USA and "MedsCheck LTC" in Canada [40–42]. The RMMR program enables GPs to refer RACF residents to accredited pharmacists to receive a medication review every 24 months or when there is a clinical need [43]. Although the RMMR service has been shown to be an effective strategy to identify and resolve medication-related problems and improve quality use of medicines for RACF residents [2], the service has logistical limitations. These include physical separation of community pharmacies, RMMR pharmacists and RACFs which leads

to lack of timely access to pharmacist services when residents need them most [37]. Additionally, access to clinical pharmacists to conduct RMMRs for RACF residents is limited to periodic visits to the facility. Consequently, pharmacists performing RMMRs may not have a thorough understanding of the resident and may not be familiar with the facility staff and organisational structure, resulting in limited effectiveness of their activities within RACFs [44]. Other limitations of RMMR include limited involvement of pharmacists in the implementation and follow-up of recommendations and inconsistency in the level of collaboration between the health professionals in the RMMR processes [45]. QUM services are funded by the Commonwealth Department of Health for pharmacists to visit RACFS and conduct education to improve practices and procedures related to medication use. QUM services are intended to improve the medication management at the RACF level (e.g. through audits and staff education) [39, 46]; however, there has been little research to explore the effectiveness of this service [37].

Integrating an on-site pharmacist as part of the RACF health care team may address the gap in provision of medication management practices, policies and processes. On-site pharmacists, in collaboration with nurses, GPs, specialists, community pharmacists, residents and families will conduct medication management activities to improve the quality use of medicines at the facility [47–50]. This new model can improve communication among the healthcare team and enhance resident and family's involvement in medication management decisions for individuals [48], leading to improved person-centred care. At the facility level, the on-site pharmacist can develop and enhance RACF policies and procedures for overall medication management [44]. These system improvement activities include reviewing and enhancing medication ordering, storage and administration processes, as well as conducting staff education, providing medication information, responding to medication utilisation reports, developing clinical referral pathways and contributing to staff and resident influenza vaccination.

A proposed model of integrated on-site pharmacist services into the RACF health care team was examined in a pilot study which was conducted by the lead author [47–51]. The conceptual foundation of the new model was to improve multi-disciplinary care, communication and collaboration in RACF's healthcare team to enhance medication management [47, 48]. The findings of the pilot study indicated that the integration of a pharmacist into a RACF was feasible and acceptable to RACF staff, residents and GPs and resulted in improved medication administration and clinical documentation [47], increased provision of education for nursing and carer staff to promote the quality use of medicines and prevent medication administration errors [48], and enhanced staff influenza vaccination rates [49]. The positive findings of the pilot study informed the allocation of program funds from the Australian Department of Health to implement and evaluate this model in RACFs in the Australian Capital Territory (ACT).

The aim of this larger study is therefore to conduct a cluster randomised controlled trial (RCT) to evaluate if integrating pharmacists into RACFs, improves medication management in RACFs in the ACT, Australia. Objectives of the study include determining if this new integrated model (i) improves appropriateness of prescribing for RACF residents, as determined by the use of PIMs according to 2019 Beers Criteria [52], (ii) reduces RACF residents' Emergency Department (ED) presentations and hospital admissions, (iii) improves other quality use of medicine indicators at the resident and facility levels, and (iv) is cost-effective.

Methods

Study design

This is a cluster RCT in RACFs in the ACT, Australia, with RACFs as the unit of randomisation. Participating RACFs will be randomised into either an intervention or control group. RACFs in the intervention group, in addition to 'usual care', will each employ an on-site pharmacist as member of the healthcare team. RACFs in the control group will continue 'usual care' that includes receiving government funded RMMR and QUM services from visiting pharmacists. Intervention and control groups will be recruited and randomised in staggered groups which will run in parallel.

Participants

RACFs

All RACFs in the ACT that are nationally accredited facilities will be invited to participate in the trial. RACFs that have less than 20 beds will be excluded. There are a total number of 1978 RACF beds in facilities in the ACT, and the ACT had a population of 431,000 in 2020 [53].

Residents

Permanent residents of included RACFs will be included in the study unless they specifically request their data not to be included in the trial. Respite (non-permanent) residents will be excluded.

Pharmacists

Qualified pharmacists will be recruited through open expressions of interest sent to pharmacy professional groups and associations. The selection criteria for pharmacists include having registration with the Australian

Appendix 1. Protocol paper *cont.*

Health Practitioner Regulation Agency, accreditation to conduct medication reviews by the Australian Association of Consultant Pharmacy or equivalent hospital or geriatric clinical pharmacy experience, and accreditation to conduct vaccination. A list of eligible pharmacists will be provided to the intervention RACFs, who will employ pharmacists as per their organisational policy. Salaries for pharmacists will be funded by the research grant; however, they will be directly employed by RACFs as RACF staff members.

Recruitment process

All RACFs in the ACT, Australia, that meet the inclusion criteria will be invited to participate in this study. After being provided information on the nature of the study and data required, each RACF will agree to participate through a signed contract. Recruitment will be staggered over a period of 6 months or until the sample size achieved. The recruitment and study timelines are shown in Fig. 1.

Randomisation and blinding

Randomisation will be at the facility level. RACFs will be randomised into either intervention or control group through computer-generated allocation by an independent researcher external to the research team. Randomisation will be stratified by size of facility. Due to the nature of the intervention, the trial participants will not be blinded.

Intervention and model of care

RACFs in the intervention arm will have a pharmacist employed by their organisation as part of their health care team for 2 to 2.5 days a week for 12 months. Intervention pharmacists can work in up to 2 RACFs. Pharmacists will report to RACF managers. They will conduct resident and facility level activities that are within their current scope of practice as a health professional registered with Australian Health Professional Registered Agency.

The intervention (model of care) was informed by the findings from the pilot study [47–51] and discussion with RACF managers, GPs, pharmacists and a consumer representative who participated in the pilot. Components of this model of care are informed by integration of pharmacists into non-dispensing primacy care roles [37, 54]. Components and how they differ from usual care are presented in Table 1.

Pharmacist activities in intervention RACFs include the following:

- Performing medication reviews in collaboration with residents, families, prescribers and nurses
- Identifying residents at high risk of medication-related harm and hospitalisation, and prioritising interventions to address them
- Medication reconciliation and review at transition of care
- Participating in case conferences with GPs, palliative care team, families and residents
- Reviewing and optimising medication administration rounds
- Updating and improving resident records including clinical and care information
- Answering medication-related queries from residents, families and staff
- Conducting regular clinical audits to identify medication-related problems
- Educating residents, families and RACF staff about medication-related issues
- Improving the RACF's medication management policies and procedures
- Participating in relevant RACF committees and meetings including Medication Advisory Committee, Quality and Safety meetings, Falls Review Committee, and Medication Incidents Review Committee
- Improving influenza vaccination rates of staff and residents

Pharmacists in intervention sites will not be permitted to conduct RMMR or QUM services. RACFs will receive these services from existing providers as a part of usual care.

Pharmacist training and support

Pharmacists will participate in mandatory training before commencing in RACFs, including an initial full-day overview of clinical pharmacy practice in the aged care setting, followed by a session focused on the pharmacist's role in RACFs and the trial design and processes. Pharmacists will be provided with clinical and geriatric pharmacy resources including content on deprescribing, psychotropics, pain management, principles of medication review in aged care, Beers Criteria [52] and wound management.

The study team will meet face to face with pharmacists monthly to discuss potential problems and address questions. Furthermore, pharmacists will be invited to participate in quarterly meetings held by the study team to discuss study activities. An online Microsoft Teams will link on-site pharmacists to each other to facilitate a community of learning to discuss issues they are experiencing.

Outcomes

All outcome measures will be collected from both intervention and control RACFs and compared as below.

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			
TIMEPOINT**	**-t_1**	**0**	**t_1 baseline data collection**	**t_2 0 month Intervention starts**	**t_3 12 month Intervention ends**	**t_4 post data collection**
ENROLMENT						
Eligibility screen	X					
Contract and RACF consent	X					
Allocation		X				
INTERVENTIONS						
RACFs in the intervention group will receive an on-site pharmacist added to their healthcare team				←	→	
Assessments:						
Prevalence of potentially inappropriate medications prescribed			X		X	
Rate of Emergency Department presentation and hospital admission per resident				←	→	
Prevalence and dose of prescribed psychotropics			X		X	
Anticholinergic Cognitive Burden Score of prescribed medicines			X		X	
Rate of staff influenza vaccination					X	
Number of resident falls				←	→	
Time taken to conduct medication rounds			X		X	
Appropriateness of medicine dose form modification			X		X	
Appropriateness of residents' clinical documentation			X		X	
Number of medication-related incidents				←	→	
Cost-consequence & cost-effectiveness analysis						X

Fig. 1 Study timeline

Appendix 1. Protocol paper *cont.*

Table 1 Key components and comparison between existing and proposed model

Key component	Existing model	Proposed model
Governance and service structure	RMMR & QUM activities are conducted by independent pharmacist (who are contractors) on visitational basis.	Pharmacist is employed by the RACF and is incorporated into RACFs care team. Pharmacist works within RACFs clinical governance structures.
Multi-disciplinary care (including resident and family)	Pharmacist is not incorporated into the RACF care team. They visit RACF at semi-regular intervals, provide medication advice to GPs through RMMRs and provide quality improvement projects.	Pharmacist is incorporated into the RACF care team and has contact with residents, families, GPs and prescribers, nurses and care staff. The pharmacist is available on-site at RACFs and involves residents and families into decision-making processes to improve medication management.
Reciprocal interdependence	Pharmacist provides medication review as an add-on service to assist GPs with quality of prescribing. However, they are not incorporated into the RACF care teams.	Multi-disciplinary team members, including pharmacists, nurses, carers, GPs and prescribers, community pharmacists, residents and families engage in shared decision making and work together to achieve goals.
Communication	Pharmacist communicates medication-related issues about individual residents to the GPs, usually through RMMR. GPs communicate medication changes to RACF nurses.	Pharmacist communicates and coordinates medication-related issues directly with GPs, nurses, carers, residents, community pharmacy and hospital.
Collaboration	Pharmacist usually collaborates with GPs to conduct RMMR.	Pharmacist closely collaborates on a regular basis with nurses, aged care staff and management, GPs and other prescribers, visiting pharmacists, community pharmacy, residents, families and hospital.
Sharing and access to information	Pharmacist has limited access to residents' clinical records, which may include laboratory reports, while GPs and nurses have full access to clinical records.	All team members, including the pharmacist, will have full access to residents' records, current medication lists, information about allergies, lab results, notes, procedures, and hospital discharge summaries.
Coordinated care/outcomes	Pharmacist provides once-off advice and opinion to GPs in RMMRs (including 2 follow-ups) but are not involved in implementing medication management changes or ongoing monitoring.	Residents' treatment goals and outcomes are coordinated within the team of nurses, carers, pharmacist, GPs and other service providers. Pharmacist is involved in providing advice to GPs, prescribers and the RACF care team, and in implementing residents care plans and goals of care. Pharmacist also contributes to improving RACF medication management policies and procedures.

Primary outcome

- Change in proportion of residents who are prescribed at least one PIM (from baseline to 12 months) according to the 2019 Beers Criteria [52]

Secondary outcomes

- Rate of unplanned ED presentations and hospital admissions per resident collected from RACF records over 12 months
- Polypharmacy—number of regular medications
- Change in proportion of residents who are prescribed at least one psychotropic medicine (defined as antipsychotics and benzodiazepines), excluding those residents with major psychiatric diseases or epilepsy (from baseline to 12 months)
- Change in dose of psychotropic medicines (measured as chlorpromazine or diazepam equivalent daily dose [55] (from baseline to 12 months)
- Change in residents' Anticholinergic Cognitive Burden Score (ACB) [56] (from baseline to 12 months)
- Rate of staff influenza vaccination measured at the end of influenza season, from RACF records
- Fall rate per resident, as documented from RACF fall records over 12 months
- Change in time spent on medication administration rounds per RACF, through observing randomly selected medication rounds [47] (from baseline to 12 months)
- Change in appropriateness of medicine dose form modification per RACF, through observing randomly selected medication rounds [47] (from baseline to 12 months)

- Change in proportion of residents who have drug allergies or adverse drug reactions documented in their RACF records (from baseline to 12 months)
- Number of medication-related incidents over 12 months
- Cost-consequence and cost-effectiveness of the intervention over 12 months

Data collection

Data will be collected at RACF, resident and pharmacist levels throughout the 12-month trial period. RACFs' characteristics (number of beds, number of permanent residents, resident profile and number of staff) will be collected through surveys with RACF managers. De-identified residents' data for outcome measures will be collected by the research team visiting the facilities at baseline, each month and at 12 months. Randomly selected medication rounds will be observed to determine the time spent on medication rounds and assess the appropriateness of dose form modifications using the method described earlier [47]. In case of potential logistical limitations in light of COVID-19 and any future restriction of access to RACFs, RACF staff will collect the required data. On-site pharmacists in the intervention group will self-report their daily activities through an online diary using QUALTRICS. Details of data collection items and timing are listed in Table 2.

Sample size

It was estimated that a conventional RCT with randomisation of individuals would be able to detect a reduction from 60 to 40% of residents having at least one PIM [14], with a minimum of 106 residents in each arm (total of 212 residents in both arms) with a significance level of 5%, a power of 80% on equal allocation and a response rate of 85%. By adjusting for the loss of power due to clustering, with an intra-cluster correlation coefficient of 0.05 and a cluster size of 93 residents per RACF, the estimated sample size is (1 + [(93–1) x 0.05] =5.6 x 106) or 594 residents in each arm (1188 in both arms), equating to a minimum of 13 sites. The sample size was calculated using G*Power 3.1.9.4 [57].

Table 2 Data collection details

Data	Data collection
Facility level data	
Number of permanent residents, proportion of residents with dementia, and proportion receiving the highest level of government funding	Baseline and at 12 months
Number of RACF registered nurses rostered during day/night/weekend	Baseline and at 12 months
Care staff turn-over reported by RACFs	Baseline
Total number of beds and bed occupancy rate	Baseline
Resident turn over	Monthly
Number of medication-related incidents	Monthly
Number of resident falls	Monthly
Time taken to conduct medication rounds	Baseline and at 12 months
% of staff/residents received influenza vaccination	At one time point
% of residents that have drug allergy and adverse drug reactions documented	Baseline and at 12 months
Number of GPs visiting residents in facility	Baseline
RACF managers perceived top 5 reasons for unplanned hospitalisations of residents in previous 12 months, and possible solutions for reducing these	Baseline
Resident level data	
Age and gender	Baseline
Date of admission and discharge and reason for discharge from the facility	Baseline and monthly
Diagnosis	Baseline and at 12 months
Number and list of regular and PRN medications including dosages	Baseline and at 12 months
Emergency Department visit/transfer*	Baseline and monthly
Hospital admissions* and length of hospital stay as determined by RACF residents' records	Baseline and monthly
Reason for Emergency Department visit/admission to hospital - as determined by RACF residents' records	Baseline and monthly
Intervention pharmacist activity data	
Daily activities and time taken to conduct each activity	Daily

*Outpatient appointments & scheduled procedures will not be included in hospital admission/emergency department visit data

Appendix 1. Protocol paper *cont.*

The estimated prevalence of PIM in RACFs at baseline (60%) was based on previous studies in which the prevalence of PIM in Australian RACF residents were reported as 73% in 2018 [16], 49% in 2014 [14] and 56% in 2012 [58].

Data management

Data will be collected from RACFs, by research staff. RACF staff will facilitate the collection of data from RACF digital and paper records. Collection of data will be onto a university laptop which is password-protected. Resident's identifying details (e.g. names and date of birth) will be deleted prior to analysis. Residents will be given a unique study identifier to link data that will be stored in a secure place at the RACF. Data will be entered onto a central database developed with Microsoft Access and stored on the University of Canberra secure and password-protected data storage system. Access to the database will be by the key members of the research team with unique usernames and passwords. The servers are protected by firewalls and are maintained according to best practice. After the completion of the study, the database will remain on the university storage system for 5 years, as per National Health and Medical Research Council (NHMRC) guidelines.

Statistical analysis

Descriptive statistics will be used to summarise and compare the data at the RACF level in each group at baseline and at the end of the trial, including primary and secondary outcomes as well as additional potential confounder variables (such as demographic profile, duration of residency, presence of dementia, Charlson comorbidity index [59] and number of medical conditions).

Bivariate analyses for group comparisons will use either t tests or ANOVA for data that are normally distributed, Mann-Whitney U and Kruskall-Wallis tests for data that are not normally distributed, or chi-square-based analysis for categorical outcome data. For within group comparisons, paired t tests and repeated measures ANOVAs will be used; if variables are not normally distributed, the Wilcoxon signed-ranks and Freedman tests will be used, while the McNemar test will be used for changes in proportions.

To determine the effect of the intervention on the outcome measures and the changes over time (between-within group effects), multilevel modelling methods, which take into consideration the hierarchical structure of the data (including clustering within RACF and repeated measurement occasions) will be applied. These modelling methods will include mixed-effects generalised linear models (Logistic and Poisson regression models) for binary and count outcomes as well as mixed-effects linear models for continuous outcomes assumed to have a normal distribution, or otherwise transformed to meet the assumption.

Analysis will be weighted by cluster size as required. Interactions and adjusting for demographic characteristics and other potential covariates will be included when deemed necessary. Residents who enter, die or move from RACFs after baseline data collection will have only one data point and will be included in the analysis. When data are missing at random, patterns of missing data will be evaluated, and potential predictors of missing responses will be investigated. Methodological attempts to fill in missing data will be extensively explored and applied as appropriate. These include single imputation approaches (such as regression imputation and nearest neighbours or hot-deck imputation) and multiple imputation approaches. Analysis will be conducted using either SPSS version 26 or STATA version 16. Significance level will be set at the usual 5% alpha-level (two-tailed where applicable). All estimated effects will be reported along with their 95% confidence intervals.

Since the sample size and power calculation have been devised based on the primary outcome and hypothesis, the level of adjustment and number of potential covariates to adjust for may be limited by the sample size and the response rate. Posterior power calculations will be performed based on available sample size and the secondary outcomes.

Economic evaluation

A within trial cost consequence followed by a cost-effectiveness analysis will be conducted. The cost consequence analysis will explore the incremental impact (compared to the control arm) of the intervention on the disparate secondary outcomes, providing more information to decision makers in addition to a having a focus on the primary outcome. For the cost-effectiveness analysis, effectiveness will be measured in terms of the primary outcome—avoided PIM (reduction of the number of residents who take at least one PIM). A public health sector perspective will be used. All resource use will be valued in 2020/21 Australian dollars without discounting. Total costs for the intervention and control groups will be calculated, as well as average costs per participant, incorporating any additional costs relating to the delivery of the intervention (e.g. additional training, time that a GP spends on reviewing pharmacist recommendations). Resource use captured during the trial will include health service utilisation by each participant (ED visits, hospital admissions, ambulance transfer during the 12 months of control/intervention period; and medications used at baseline and at 12 months). Analogous multilevel modelling described above (controlling for differences in characteristics of participants and RACF clusters) will be used to estimate average cost per

participant for both intervention and control groups. An incremental cost-effectiveness ratio (ICER) will be computed by comparing the costs and outcomes of the intervention and control groups. Results will be expressed as incremental cost per incremental reduction in the proportion of residents taking at least one PIM. Mean estimates will be used, and confidence values and sensitivity analysis will indicate the robustness and validity of the results and test any assumptions used. Uncertainty around the ICER will be explored using cost-effectiveness acceptability curves.

Fidelity assessment

Fidelity in intervention sites will be assessed using Hasson's Conceptual Framework [60], that assesses adherence against content, coverage, frequency and duration domains at the cluster level. First, 100% of pharmacist diaries in each intervention RACF will be assessed and cumulative number and proportion of activities will be calculated. Second, a random sample of 10% of resident's medications reviews conducted by intervention pharmacists will be assessed by an experienced pharmacist to determine the appropriateness of medication reviews. Third, interviews with RACF managers, staff and pharmacists will further explore adherence to the trial activities. Intervention RACFs will be given a fidelity rating of high/medium/low based on the assessment.

Trial management

The trial is overseen by the trial management group comprising chief investigators and the senior programme manager. The trial is advised by the governance committee organised by the funder, the ACT Primary Health Network (PHN) and comprises representative from RACFs, Pharmaceutical Society of Australian, Pharmacy Guild of Australia, Calvary hospital, a GP and a consumer representative. Potential protocol modifications by the trial management group will be communicated to the governance committee and human research ethics committees.

Safety evaluation and reporting

RACFs are required to have clinical governance processes and complaints procedures in place. Criteria for monitoring the trial are informed by Stallard [61], whereby adverse events will be monitored and the trial ceased if there is evidence of harm. All adverse events will be entered into an *Adverse Event Log* and reported to external clinical consultants to determine whether or not they are considered causally related to study. For every adverse event, researchers and external consultants will provide an assessment of the severity, causal relationship to the study, outcomes and seriousness of the event, and document all actions and inform the Human Research Ethics Committee. In light of the COVID-19 pandemic, the research team will follow all RACF's safety protocols and guidelines when they visit RACFs to ensure the safety of the residents and RACF staff.

Discussion

The initial pilot study [47–51] confirmed the feasibility of the model, and no adverse events were identified. This is the first cluster RCT to our knowledge that investigates the effectiveness of integrating pharmacists in RACFs on improving medication management. The primary outcome is the appropriateness of prescribing that in a broader sense may represent an ideal for care [62]. Inappropriate prescribing has become an important public health concern worldwide [63] and is also prevalent in Australian RACFs [14, 16, 58]. In this trial, appropriateness of prescribing is measured using explicit Beers Criteria [52] which can be readily applied to a large sample of study participants with a high level of reliability and reproducibility [63]. Secondary outcomes include measures such as hospital admission and ED visit that are important from the public health, aged care industry and resident perspectives.

Medication management for older residents in RACFs is sub-optimal [4]. International evidence has demonstrated that pharmacist-led interventions in RACFs improve the quality use of medicines; however, the majority of these interventions were conducted by visiting pharmacists on once-off or limited visitation basis [34, 64]. There is a need for sustainable interventions to enable system level improvement in medication management practices in RACFs.

The study is using a staggered approach to the recruitment and intervention. Due to the impact of the recent COVID-19 pandemic on RACF's workforce and operations, this staggering will provide the facilities with time to prepare and adapt to recent policy and procedural changes. These changes may impact on the study outcomes; for example, there may be changes in the number of regular healthcare staff in RACFs or residents may receive fewer GP and other visiting healthcare professional visits and this may impact the level of collaboration with pharmacists. Potential restrictions in visiting RACFs due to COVID-19 pandemic may affect the data collection processes. On-site pharmacists participating in this study will have accreditation to conduct medication review; however, they may be at different level of experience and skills, which may impact the quality of pharmacist activities in some RACFs. This will be further explored by assessing the fidelity of interventions that determines whether the intervention was conducted as planned across the intervention RACFs and includes an audit on the appropriateness of pharmacists' medication reviews. Participating RACFs will be all within ACT

which is a metropolitan area in Australia; thus, the findings may not be generalisable to RACFs located in rural and remote areas.

A number of limitations should be noted. PIMs are a proxy measure for appropriateness of prescribing, which represents an ideal level of care and is reliable in predicting adverse events [62]. The study does not include measurements of resident focused indicators such as Quality of Life, noting the difficulties in seeing changes in elderly frail population. The reporting of secondary outcomes is based on facility records, which may be under reported.

The study provides important information on clinical and economical outcomes of the model where on-site pharmacists are integrated into RACFs' health care team to improve medication management. The results will provide policymakers with recommendations relevant to the potential further implementation of this model.

Trial status

The study is being conducted according to the trial protocol version 3 revised on April 7, 2020. Recruitment began on Oct 28, 2019, and is anticipated to be completed by July 1, 2020.

Abbreviations

RACF: Residential aged care facility; PIM: Potentially inappropriate medication; RMMR: Residential medication management review; GP: General practitioner; QUM: Quality use of medicines; RCT: Randomised controlled trial; ED: Emergency department; ICER: Incremental cost-effectiveness ratio; NHMRC: National Health and Medical Research Council

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Authors' contributions

All authors contributed to the design of the study and writing of the manuscript. All authors confirm their eligibility as authors and involvement in this study. The authors read and approved the final manuscript.

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The study is funded by the ACT PHN through the Australian Government's PHN Program. The funder is given opportunity to provide feedback but does not have ultimate authority over the study design, data collection and management, analysis, and interpretation of data, writing of the report, and the decision to submit the report for publication.

Availability of data and materials

The trial dataset will not be made publicly available. Only investigators have access to the trial dataset.

Declarations

Ethics approval and consent to participate

The trial is approved by the University of Canberra (HERC:2007), ACT Health (2019/ETH13453) and Calvary Public Hospital Bruce Human Research Ethics Committees (30-2019). The study will be conducted in compliance with NHMRC guidelines [65], the World Medical Declaration of Helsinki [66] and all amendments. The trial was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) (ACTRN: ACTRN12620000430932) on April 1, 2020.

Consent to participate will be gained at the facility level, rather than the resident level, given the impracticalities of gaining informed consent from a large population (estimated > 1500 people), many of whom are likely to have cognitive impairment; there is a low risk to participants and actions will be taken to protect of participant of privacy. Residents are able to opt out of having their data included in the study, and the process on how to do this is provided to residents and families. This consent process follows Australian NHMRC guidelines [65] and is consistent with comparable studies conducted in Australia [67, 68].

Consent for publication

No individual identifiable person's data is included in this manuscript or will be included in the future publications of the main trial results. Study findings will present aggregated resident data and will not include personal identifying details. A summary of study findings will be made available to participants.

Competing interests

SK and MN are pharmacists who provide clinical consulting services to some RACFs in the ACT. Other authors have no competing interests.

Author details

[1]Discipline of Pharmacy, Faculty of Health, University of Canberra, Bruce, ACT, Australia. [2]Health Research Institute, Faculty of Health, University of Canberra, Bruce, ACT, Australia. [3]School of Pharmacy and Pharmacology, University of Tasmania, Hobart, TAS, Australia. [4]Department of Health Services Research and Policy, Research School of Population Health, Australian National University, Acton, ACT, Australia. [5]School of Pharmacy, University of East Anglia, Norwich, UK.

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Publisher's Note

APPENDIX 2. DATA COLLECTION TYPES AND TIMEPOINTS

Details of data collection timepoints for facility, resident and pharmacist are presented below.

Data		Time of data collection
Facility level data	Number of beds	At baseline
	Number of permanent residents	At baseline
	Number of residents with a diagnosis of dementia	At baseline
	Number of residents receiving the highest level of funding through the Aged Care Funding Instrument	At baseline
	Number of GPs visiting residents in facility	At baseline
	RACF managers top 5 reasons for unplanned hospitalisations	At baseline
	% of staff/residents receiving influenza vaccination	At 12 months
	Time taken to conduct medications rounds	At baseline and 12 months
Resident level data*	Resident's date of admission, date of discharge, and reason for discharge	At baseline and monthly
	Resident's age, gender, languages spoken and Aboriginal and Torres Strait Islander status	At baseline and monthly
	Diagnoses	At baseline and 12 months
	Number and list of regular and PRN medications including dosages	At baseline and 12 months
	Documentation of allergies and adverse drug reactions	At baseline and 12 months
	Number of medication-related incidents	Monthly
	Number of falls	Monthly
	Date and reason for ambulance visit or transfer, Emergency Department or unplanned hospital visit, GRACE visit	Monthly
Pharmacist activities	Daily activities and time taken to conduct each activity	Daily
Service model evaluation — pharmacists, RACF staff, health care professionals, residents and families	Integration and collaboration — pharmacists, prescribers, health care professionals and RACF staff	Survey
	Collaboration — residents and families	Survey
Education survey — pharmacists	Age	Survey
	Gender	Survey
	Qualifications	Survey
	No. of years working as a registered pharmacist	Survey
Implementation package — RACF managers	Age	Interview with RACF manager
	Gender	Interview with RACF manager
	Role	Interview with RACF manager
	No. of years of experience in role	Interview with RACF managers
	No. of years working in current facility	Interview with RACF managers
Evaluation of fidelity	Assessment of medication reviews	10% of medication reviews randomly assessed

Note: * Permanent residents data will be included for analysis.

APPENDIX 3. PHARMACIST'S ACTIVITY SURVEY

Faculty of Health

UNIVERSITY OF CANBERRA
AUSTRALIA'S CAPITAL UNIVERSITY

Main Page

This form is submitted to the UC research team

Please type in the name of the aged care facility

Date (dd/mm/yyyy)

Email address

What activity would you like to record?

- ◯ Medication Management Review
- ◯ Clinical Audit
- ◯ Communication
- ◯ Education
- ◯ Quality Improvement
- ◯ Vaccination
- ◯ Administrative tasks

- ◯ Other
- ◯ Case studies

Note: If you have any support or training needs in conducting any activity, please do not hesitate to forward your concerns or feedback to the support email (**racfstudy@canberra.edu.au**)

Medication Management

Medication Review

Conduct regular Medication Review for residents and record the outcomes in this form (when recommendations were discussed and decided the prescribes). Follow deprescribing guidelines and make recommendations accordingly to reduce patients' harm with a focus on limiting **potentially inappropriate medications** using Beers criteria (e.g. PPIs, NSAIDs, and TCAs) , psychotropics (antipsychotics and benzodiazepines) and anticholinergic burden.

Please make sure that you have kept the hard copy paper version of the full medication review notes in your folder.

Tools you may find helpful

Beers Criteria for potentially inappropriate medications (refer to table 2, table 3 and table 5)

https://geriatrictoolkit.missouri.edu/drug/Beers-Criteria-AGS-2019.pdf

Deprescribing guidelines:

PPIs
http://www.cpsedu.com.au/uploads/Documents/Deprescribing%202016%20Version/11.%20PROTON%20PUMP%20INHIBITO
Deprescribing algorithm for PPI
https://www.open-pharmacy-research.ca/wp-content/uploads/ppi-deprescribing-algorithm-cc.pdf

Antipsychotics for BPSD
http://www.cpsedu.com.au/uploads/Documents/Deprescribing%202016%20Version/4.%20ANTIPSYCHOTICS%20V3.pdf
Deprescribing algorithm for antipsychotics
https://deprescribing.org/wp-content/uploads/2018/08/AP-deprescribing-algorithm-2018-English.pdf

Benzodiazepines
http://www.cpsedu.com.au/uploads/Documents/Deprescribing%202016%20Version/5.%20BENZODIAZEPINES%20V3.pdf
Deprescribing algorithm for benzodiazepines

https://deprescribing.org/wp-content/uploads/2019/03/deprescribing_algorithms2019_BZRA_vf-locked.pdf

Appendix 3. Pharmacist's activity survey *cont.*

TCAs
http://www.nswtag.org.au/wp-content/uploads/2018/06/1.4-Deprescribing-Guide-for-Tricyclic-Antidepressants-TCAs.pdf

NSAIDs
http://www.cpsedu.com.au/uploads/Documents/Deprescribing%202016%20Version/9.%20NSAIDs%20V3.pdf

Anticholinergic Burden

https://www.veteransmates.net.au/VeteransMATES/documents/module_materials/M39_TherBrief.pdf

ACB scale calculator

http://www.acbcalc.com/

Please select resident type

- ◯ Existing Resident
- ◯ New admission
- ◯ Post discharge from hospital

For resident's having a medication review-Is this the first time this resident is having a Medication Review?

- ◯ Yes
- ◯ No
- ◯ I don't know

Please select type of activity (tick all that apply)

- ☐ Medication Review
- ☐ Medication Reconcilation

How many potentially inappropriate medication(s) (PIMs according to Beers criteria) did you identify and discuss/communicate with the prescriber (e.g. GP)?

Please type the number of outcomes accepted by the prescriber in regards to the above PIM(s)

0 Medication(s) deprescribed

0 Alternative medication(s) recommended and accepted

0 Decrease in dose recommended and accepted

How many other recommendation(s) (not related to PIMs) did you discuss/communicate with the prescriber?

Out of the above recommendation(s) (not related to PIM), please type the number of outcomes accepted by the prescriber

0 Medication(s) deprescribed

0 Alternative medication(s) recommended and accepted

0 Decrease in dose recommended and accepted

0 Increase in dose recommended and accepted

0 Change(s) in dosage form and accepted

Please type the name and strength of medication(s) deprescribed (if any)

Appendix 3. Pharmacist's activity survey *cont.*

Write list and strength of medicines

Was My Health Record used for this activity?

- ◯ Yes - accessed or retrieved data from My Health Record
- ◯ Yes - updated resident's My Health Record
- ◯ No

What would be the potential clinical outcome for the resident if this intervention was not made (based on your judgement)?

- ☐ Potentially prevented a hospitalization
- ☐ Potentially prevented a minor adverse drug reaction
- ☐ I don't know
- ☐ None

Is this resident receiving palliative care treatment?

- ◯ Yes
- ◯ No

To whom did you communicate to complete this activity? (tick all that apply)

- ☐ GP
- ☐ Staff at GP reception
- ☐ Specialist
- ☐ Nurse Practitioner
- ☐ Resident
- ☐ Resident's family

- [ ] Community Pharmacy
- [ ] Hospital
- [ ] RACF staff
- [ ] Other

How did you communicate with the above person?

- [ ] In person
- [ ] Fax
- [ ] Phone
- [ ] Emails
- [ ] Text message
- [ ] Written communication (i.e. progress notes, communication book)
- [ ] Other

Time spent on this activity (in minutes)

Clinical Audit

Clinical Audit / Chart Review

A clinical audit activity is when the pharmacist purposefully identifies residents with certain medications of concern in a systematic way in order to prioritize medication reviews. This can be achieved through conducting chart reviews to identify residents at risk (e.g. taking specific medications or combinations).

The focus on audits should be on deprescribing residents with potentially inappropriate medications. Examples include inappropriate high dose PPIs, antipsychotics, benzodiazepines, NSAIDs, TCAs and etc according to Beers criteria.

Appendix 3. Pharmacist's activity survey *cont.*

Please note this activity involves identification of patients at risk only. Examples include when you spend time doing chart reviews for a large number of residents and shortlist a few with specific medications/medical condition and develop action plan to attend those (do not record individual medication review detail here, record recommendations made for each resident in the 'Medications Management" activity section).

Select type of clinical audit?

- ◯ Antipsychotics for BPSD
- ◯ Benzodiazepines (including Z-drugs)
- ◯ PPIs
- ◯ NSAIDs
- ◯ TCAs
- ◯ Opioids (e.g. for residents who have had a fall or fracture in the past - see Beers Criteria 2019)
- ◯ Other PIMs listed on Beers Criteria
- ◯ Other

Number of residents identified at risk in this audit

Briefly describe the activity (if applicable)

Time spent on this activity (in minutes)

Communication

Communication

This activity involves communication or interaction between pharmacist and other personnel which cannot be classified under any other activity. Counselling of residents or attending to medication-related queries are examples of communication or interaction that can be listed here.
The data will assist the research team to identify the communication pattern between the pharmacist and clients.

Is this a case conference?

- ○ Yes
- ○ No

Who was the communication with? (tick all that apply)

- ☐ GP (including Drs rounds)
- ☐ Staff at GP reception
- ☐ Specialist
- ☐ Nurse Practitioner
- ☐ Resident
- ☐ Resident's family
- ☐ Community Pharmacy
- ☐ Hospital
- ☐ RACF staff
- ☐ UC Research Team
- ☐ Drug Company
- ☐ Other

Appendix 3. Pharmacist's activity survey *cont.*

How did you communicate with the above person?

- ◯ In person
- ◯ Fax
- ◯ Phone
- ◯ Emails
- ◯ Text message
- ◯ Written communication (i.e. progress notes, communication book)
- ◯ Other

Please briefly describe this activity

Time spent on this activity (in minutes)

Vaccination

Vaccination

This section is used to record flu (and other) vaccinations conducted by pharmacist in RACF.

Please make sure that you have kept the consent form in your folder.

Number of residents vaccinated

Number of staff vaccinated

Please briefly describe any additional information about this activity

Time spent on this activity (in minutes)

Administration

Administrative tasks

This section is used to record administrative tasks (such as attending different meetings about various topics). If you specifically take action

Administrative tasks

This section is used to record administrative tasks (such as attending different meetings about various topics, report preparation, documentation but this category does not quality improvement activities. If your activity contains a combination of administrative task and quality improvement activity, record each components under separate categories).

Select activity

◯ Meeting - Meeting/preparation with RACF staff to discuss any facility related issues, including participating in relevant policy committees such as Medication Advisory Committee, Falls Committee, Quality and Safety Committee (note that actions to review and change RACF policies and procedures must be recorded under quality improvement).

Appendix 3. Pharmacist's activity survey *cont.*

- ◯ Administrative tasks - such as any documentation (e.g. updating allergies or adverse drug reactions ADRs in residents charts)
- ◯ Filling this online pharmacist diary
- ◯ Meeting with the study team or participating in the online discussion blog
- ◯ S8 count, recording, destruction
- ◯ Other

Please briefly describe this activity

Time spent on this activity (in minutes)

Education block

Education

This section is used to record any educational activities conducted by the pharmacist such as in-service talks, group or individual training sessions for residents/staff, or self-learning sessions (on specific topics you feel you need to up-skill yourself). Other examples include accompanying a new staff on medication rounds or other activities to provide supervision and or education.

Who are you providing education to? (tick all that apply)

- ☐ Resident or family education (group or individual)
- ☐ General practitioner
- ☐ RACF RN/EN staff
- ☐ RACF Carer staff

- [ ] RACF Allied Health staff
- [ ] RACF Executive staff
- [ ] Self - education (inc. CPD on a specific topic)
- [ ] Other

Please provide some details of the activity

Time spent on this activity (in minutes)

Quality improvement

Quality Improvement

This sections is used to record a) any activity the pharmacist performs to improve or review medication-related processes or procedures and b) ward stock management (also known as IMPREST).
Refer to the Pharmacist Toolkit under 'Procedures and Policies to Improve Quality Use of Medications' to find examples of how pharmacists can contribute to RACF policies and procedures.

What was the quality improvement activity

- ○ Ward stock related
- ○ Medication rounds related
- ○ Schedule 8 related
- ○ Reviewing RACF policies and procedures & attending relevant meeting
- ○ Writing policies and procedures
- ○ Implementing policies and procedures
- ○ Other

Appendix 3. Pharmacist's activity survey *cont.*

Please briefly describe this activity

Time spent on this activity (in minutes)

Other activity

Any other Activity
Record any activity that cannot be classified under any other category. This includes COVID related activities (If COVID related, write COVID: in the below box and provide a brief explanation about the actions taken).

Please describe this activity

Time spent on this activity (in minutes)

Case studies

Please provide interesting and challenging case studies that provide insights into your role as an on-site pharmacist - include good news stories as well as difficult stories. Please do not provide names. Examples can include:

- *when you made a change in policies and procedures and it was well or badly received*

- *when you identified or did not identify a medication-related problem that had an impact on resident's health and well-being*
- *when your collaboration made a positive or negative impact to a resident, staff or health professional*
- *when you established new systems or changed communication with community pharmacy or GPs/prescribers*

APPENDIX 4. EVALUATION SURVEYS

Appendix 4.1 Collaboration survey

This survey explores the interprofessional collaboration between the on-site pharmacist and managers, prescribers and RACF nursing staff.

This survey will ask you about your background and to think back **[to the first three months — for time point 1; over the last six months — for time point 2]** and your relationship and interactions with the on-site pharmacist during this time. The survey will take approximately **5–10 minutes** to complete.

Your participation is voluntary. There are no financial incentives provided to participate in this study. You can choose not to participate at any time without penalty or disadvantage.

Your information will be treated confidentially. All responses will be compiled, de-identified, analysed and reported on as a group. No data published will identify individuals or general practices participating in the research. The results from this study will be presented and published in a scientific journal.

Ethical consideration. The study has been approved by the Human Research Ethics Committee of the University of Canberra in accordance with the guidelines of the Ethics Committee and the NHMRC. All potential participants can discuss their participation in this study with the Chief Investigator by calling **02 6201 2158** or e-mailing **sam.kosari@canberra.edu.au**. If any participant would like to speak with an Officer of the University not involved in the study, you may contact the Research Ethics & Integrity Advisor on **02 6206 3916** and quote the project number 2007.

- ○ Yes. I confirm that I agree to participate in this survey.

Instructions

This survey contains 2 parts. Please select the answer that applies for you. Wherever you are asked to write the answer, please write it in the provided box.

Part 1 — Demographic details

1. What is your age? (tick box with age ranges)
2. What is your gender? (tick box)
3. What is your current role? (tick box)
4. How many years have you worked with or in this facility? (tick box)
5. How many years of experience do you have working with or in residential aged care in any role? (tick box)
6. How many years of experience do you have in your profession? (tick box)
7. What qualifications do you hold? (text box)

Part 2

Please consider your interactions with the on-site pharmacist over time and select from the options below.

Responses measured on a 7-point Likert scale (1=Very Strongly Disagree, 2=Strongly Disagree, 3=Disagree, 4=Neither Agree or Disagree, 5=Agree, 6=Strongly Agree, 7=Very Strongly Agree — N/A included as appropriate

1. When providing resident care which relates to medications, I need this on-site pharmacist as much as this on-site pharmacist needs me
2. This on-site pharmacist is credible
3. My interactions with this on-site pharmacist are characterised by open communication of both parties
4. I can count on this on-site pharmacist to do what he/she says
5. This on-site pharmacist depends on me as much as I depend on him/her when providing resident care which relates to medications
6. This on-site pharmacist and I are mutually dependent on each other when providing resident care which relates to medications
7. This on-site pharmacist and I negotiate to come to agreement on our activities in managing resident care which relates to medications
8. I will work with this on-site pharmacist to overcome disagreements on his/her role in managing resident care which relates to medications
9. I intend to keep working together with this on-site pharmacist
10. I trust this on-site pharmacist's medication expertise
11. Communication between this on-site pharmacist and myself is two-way
12. This on-site pharmacist has spent time trying to learn about how he/she can help me provide better resident care in relation to medications
13. This on-site pharmacist has provided information to me that is about a specific resident
14. This on-site pharmacist has shown an interest in helping me improve my practice in relation to medications
15. I have provided information to the on-site pharmacist that is about a specific resident
16. I have contacted the on-site pharmacist about specific medication queries

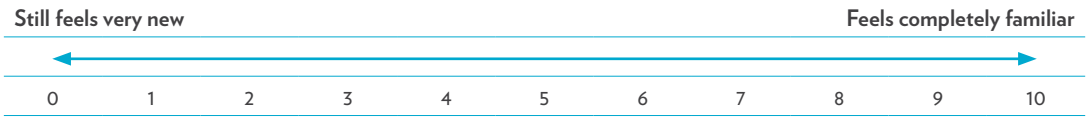
Appendix 4.2 Integration survey

Part 1 — Demographic details

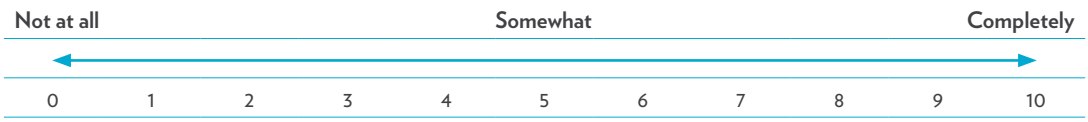
1. What is your age? (tick box with age ranges)
2. What is your gender? (tick box — F, M, Other, Prefer not to say)
3. What is your current role? (tick box — on-site pharmacist, RACF staff member, other, please specify...)
4. How many years have you worked with or in this facility? (tick box)
5. How many years of experience do you have working with or in residential aged care? (tick box)
6. What qualifications do you hold? (open ended)
7. Please select from the list below:
   - ○ I am involved in managing the on-site pharmacist
   - ○ I am involved in working with the on-site pharmacist
   - ○ Other, please specify: _____

Please take the time to decide which answer best suites your experience for each statement and circle the applicable number.

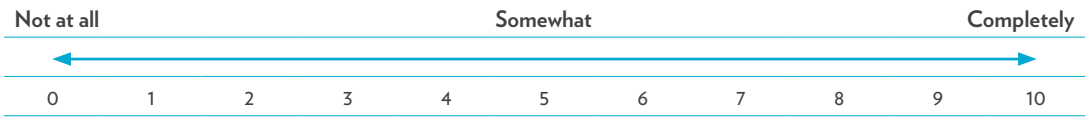
1. How familiar does it feel to have the on-site pharmacist at the facility?



2. Do you feel that working with the on-site pharmacist is currently a normal part of your work?



3. Do you feel that having the on-site pharmacist will become a normal part of your work?



For each statement please select an answer that best suits your experience using Option A. If the statement is not relevant to you, please select an answer from Option B.

Question	Option A					Option B		
	Strongly agree	Agree	Neither Agree nor Disagree	Disagree	Strongly disagree	Not relevant in my role	Not relevant at this stage	Not relevant to the on-site pharmacist in aged care trial
1. I can see how having the on-site pharmacist at the facility differs from not having an on-site pharmacist at the facility	○	○	○	○	○	○	○	○
2. Staff at the facility have a shared understanding of the on-site pharmacist's purpose at the facility	○	○	○	○	○	○	○	○
3. I understand how the on-site pharmacist affects the nature of my own work	○	○	○	○	○	○	○	○
4. I can see the potential value of having the on-site pharmacist for my work	○	○	○	○	○	○	○	○
5. There are specific people who support the on-site pharmacist activities	○	○	○	○	○	○	○	○
6. I believe that participating in activities with the on-site pharmacist on medication management is a legitimate part of my role	○	○	○	○	○	○	○	○
7. I am open to working with the on-site pharmacist	○	○	○	○	○	○	○	○
8. I will continue to support the on-site pharmacist working at the facility	○	○	○	○	○	○	○	○
9. I can easily integrate working with the on-site pharmacist into my existing work	○	○	○	○	○	○	○	○
10. The on-site pharmacist disrupts existing relationships	○	○	○	○	○	○	○	○
11. I have confidence in other people's ability to work with the on-site pharmacist	○	○	○	○	○	○	○	○
12. Sufficient training is provided to enable aged care staff to work with the on-site pharmacist	○	○	○	○	○	○	○	○
13. Management adequately supports the on-site pharmacist	○	○	○	○	○	○	○	○
14. I am aware of reports about the impact of the on-site pharmacist	○	○	○	○	○	○	○	○
15. Aged care staff agree that having the on-site pharmacist is worthwhile	○	○	○	○	○	○	○	○
16. I value the impact that the on-site pharmacist has had on my work in relation to medication management	○	○	○	○	○	○	○	○
17. Feedback about the activities undertaken by the on-site pharmacist can be used to improve medication management practice in the future	○	○	○	○	○	○	○	○

APPENDIX 5. INTERVIEW GUIDES

Appendix 5.1 Interview guide for residents or family members — evaluation of the service model

1. Could you please tell me how long you/your family member have been living at this residential aged care facility?
2. Could you please describe any previous interactions you have had with a pharmacist before the on-site pharmacist started working at this facility?
3. Could you please describe what contact you/your family member have had with the on-site pharmacist?
4. How would you describe your/your family member's contact with the on-site pharmacist (prompt from resident/family member survey)?
5. When it comes to medicines, what role do you feel residents/family members should have?
6. Do you think there is a need for on-site pharmacists in residential aged care homes?
7. Is there anything else you would like to share with me about your/your family member's experience with the on-site pharmacist?

Appendix 5.2 Interview guide for on-site pharmacists — evaluation of the service model

Role and responsibilities

1. Could you please briefly describe the on-site pharmacist role and responsibilities?

Implementation fidelity

2. Could you please describe the types of activities you undertake in this role?

On-site pharmacist experience

3. Could you tell me a little bit about your experience of being an on-site pharmacist at a RACF?
   - What was easy about being the on-site pharmacist at the facility?
   - What was difficult about being the on-site pharmacist at the facility?
   - What are the disadvantages and advantages of being the on-site pharmacist at the facility?

Collaboration — RACF care team member, prescribers, others

4. Could you please tell me about your relationship with a RACF care team member?
5. Could you please tell me about your relationship with a prescriber?
6. Could you please tell me a little bit about how you interact with other allied health professionals and others (e.g. GRACE and PEACE team members)?

Support and impact

7. What support have you received from the RACF so that you could contribute at the facility?
8. Could you tell me about any changes that have occurred at the facility since you commenced?

Final section

9. For the final section of the interview, I would now like to ask you about:
   - What works well?
   - What does not work well?
   - What could be improved?
10. Is there anything else you would like to share with me about your experience as an on-site pharmacist?

Appendix 5.3 Interview guide for RACF care team — evaluation of the service model

Role and responsibilities

1. Could you please briefly describe your current role and responsibilities?
2. From your perspective, what is the purpose of the on-site pharmacist?

Implementation fidelity

3. Could you please describe the types of activities the on-site pharmacist undertook?

Collaboration

4. Could you please describe your relationship with the on-site pharmacist?

Support and impact

5. What supports were put in place so that the on-site pharmacist could contribute at the facility?
6. Could you tell me about any changes that have occurred at the facility since the on-site pharmacist commenced?

Final section

7. For the final section of the interview, I would now like to ask you about:
    - What works well?
    - What does not work well?
    - What could be improved?
8. What are your thoughts on having on-site pharmacists at other facilities?
9. Is there anything else you would like to share with me about your experience working with the on-site pharmacist?

Appendix 5.4 Interview guide for prescribers including GPs — evaluation of the service model

Roles and responsibilities

1. Could you please tell me a little bit about your role providing care to residents at this facility?
2. From your perspective, what is the purpose of the on-site pharmacist role?

Collaboration

3. Could you please tell me about your relationship with the on-site pharmacist?

Impact

4. Could you tell me about any changes that have occurred at the facility since the on-site pharmacist commenced?

Final section

5. For the final section of the interview, I would now like to ask you about:
   - What works well?
   - What does not work well?
   - What could be improved?
6. What are your thoughts on having on-site pharmacists at other facilities?
7. Is there anything else you would like to share with me about your experience working with the on-site pharmacist?

Appendix 5.5 Interview guide for allied health professionals — evaluation of the service model

Roles and responsibilities

1. Could you please tell me a little bit about your role providing care to residents at this facility?
2. From your perspective, what is the purpose of the on-site pharmacist?

Collaboration

3. Could you please tell me about your relationship with the on-site pharmacist?

Impact

4. Could you tell me about any changes that have occurred at the facility since the on-site pharmacist commenced?

Final section

5. For the final section of the interview, I would now like to ask you about:
   - What works well?
   - What does not work well?
   - What could be improved?
6. What are your thoughts on having on-site pharmacists at other facilities?
7. Is there anything else you would like to share with me about your experience working with the on-site pharmacist?

Appendix 5.6 Interview guide for RACF managers — implementation materials

Thank you for participating in this interview. The purpose of this interview is to ask about your experience with the RACF on-site pharmacist education and resources that includes the following components:

- Study folder
- Face-to-face, Zoom and telephone meetings with the study team

1. What were your expectations of the study folder/meetings with study team?
2. Did the study folder/meetings with study team assist you in:
   - Understanding how the on-site pharmacist can help with improving the medication management in your RACF?
   - Embedding the pharmacist in your care team and clinical governance processes?
   - Utilize the pharmacist in your team to improve meds management in your facility?
3. How did they achieve or not achieve this?
4. What information, support and resources would further assist you with integrating the on-site pharmacist in your RACF team

Demographic questions

If you feel comfortable, can you please tell us your age and gender?

Current role.....

No. of years working in this role.....

No. of years working in this facility.....

APPENDIX 6. BASELINE PAPER

Journal of *Clinical Medicine*

MDPI

Article

Quality Use of Medicines Indicators and Associated Factors in Residential Aged Care Facilities: Baseline Findings from the Pharmacists in RACF Study in Australia

Ibrahim Haider [1,2,*], Sam Kosari [1], Mark Naunton [1], Theo Niyonsenga [2], Gregory M. Peterson [1,3], Jane Koerner [2] and Rachel Davey [2]

[1] Discipline of Pharmacy, Faculty of Health, University of Canberra, Bruce, ACT 2617, Australia
[2] Health Research Institute, Faculty of Health, University of Canberra, Bruce, ACT 2617, Australia
[3] School of Pharmacy and Pharmacology, University of Tasmania, Hobart, TAS 7005, Australia
* Correspondence: ibrahim.haider@canberra.edu.au

Abstract: Prescribing potentially inappropriate medications (PIMs), including antipsychotics and benzodiazepines, has been used as an indicator of the quality use of medicines in residential aged care facilities (RACFs). PIMs are associated with an increased risk of falls and hospitalisations in the elderly. The purpose of this study is to assess the extent of prescribing of PIMs in RACFs at baseline in the Pharmacists in residential aged care facilities (PiRACF) study and examine the association of resident and system factors with the number of PIMs. A cross-sectional analysis of 1368 participants from 15 Australian RACFs was performed to detect PIMs using the American Geriatrics Society 2019 Beers® criteria. Most residents (68.1%) were taking at least one regular PIM; 16.9% were taking regular antipsychotics and 11.1% were taking regular benzodiazepines. Long-term proton pump inhibitors were the most frequent class of PIMs. History of falls and higher Charlson Comorbidity Index were associated with an increased number of prescribed PIMs, while dementia diagnosis and older age (85 years or more) were associated with decreased number of PIMs (p-value <0.05). Residents in facilities with lower nurse-to-resident ratios were more likely to have an increased number of PIMs (p value = 0.001). This study indicates that potentially inappropriate prescribing is common in RACFs and interventions to target residents at highest risk are needed.

Keywords: potentially inappropriate medications; elderly; quality use of medicines; Beers Criteria; prescribing; residential aged care facilities; factors associated with PIM prescribing

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1. Introduction

People living in residential aged care facilities (RACFs) are at high risk of medication-related harm due to age-associated physiological decline in pharmacokinetic and pharmacodynamic properties [1]. These changes are further complicated by multiple medications, comorbidities, and potential drug–drug and drug–disease interactions [2–4].

Quality use of medicines (QUM) refers to the optimal use of medications to maximise the benefit of treatment and limit any medication-related harm [5]. No standardised set of QUM indicators has been widely adopted in RACFs, but prescribing of potentially inappropriate medications (PIMs) [6–9], antipsychotics [10–15], benzodiazepines [16–18], and highly anticholinergic medications [19] have all been used as markers for QUM. A PIM refers to a medication for which the risk of adverse events outweighs the clinical benefit [20]. There are different validated tools used to identify PIMs in the elderly, with the most commonly used being the Beers® criteria, developed by the American Geriatrics Society, which is based on systematic reviews of evidence and expert consensus [21]. The presence of PIMs has been associated with significant adverse events, hospitalisations, and death among older people [6–9]. A recent meta-analysis of 33 studies revealed a statistically significant association between hospitalisation and PIMs [7]. Another meta-analysis of

21 studies found PIMs to be associated with increased odds of hospital admissions and emergency department visits [22]. Amongst PIMs, the use of antipsychotics has been associated with increased risk of hospitalisation, stroke, and death [10,11]. The use of benzodiazepines has also been linked to adverse clinical outcomes, such as falls, increased risk of pneumonia, and dementia [16–18].

Recent studies examining residents' exposure to PIMs in the Australian RACF setting have reported high prevalence of PIM prescribing, ranging from 44% to 81% of residents exposed to PIMs [23–28]. In international studies, a systematic review found a prevalence ranging from 18.5% to 82.6% [29]. Many pharmacist-led interventions have been trialled in RACFs to improve QUM. Common approaches have included medication reviews and educational programs, with most showing a lack of association between interventions and reduced adverse drug events (ADEs) [30,31]. A recent systematic review examining pharmacist-led interventions concluded that targeted and tailored interventions are required to improve QUM in RACF settings [30]. Another systematic review emphasised the importance of targeting interventions to those residents who are most at risk of exposure to medications that potentially may cause harm [31].

Several resident and clinical factors have been associated with the increased odds of PIMs in RACFs, including polypharmacy, younger age, and certain medical conditions, such as diabetes and depression [4,29,32]. However, the association of system level factors, such as facility size and staffing arrangements, with the presence of PIMs has been explored less [32]. Associations between facility size and PIMs prevalence have been mixed. A study investigated medication appropriateness in aged care residents using Beers® criteria and found that larger aged care facilities had increased PIMs use [33], while another study showed a smaller RACF size was linked with increased PIMs use [34]. A study explored the association of skilled staff with the use of PIMs, and found that a lower registered nurse (RN) to resident ratio was a predictor of increased PIMs use [33]. A better understanding of PIMs use and associated resident, system and clinical factors may help develop targeted interventions aimed at residents and RACFs most affected by increased number of PIMs.

The objective of this study was to investigate the prevalence of PIMs prescribing and other relevant QUM indicators in RACFs, including the use of antipsychotics and benzodiazepines, utilising baseline data from the PiRACF study. Moreover, we aimed to identify resident, clinical, and system-level factors associated with the use of PIMs.

2. Materials and Methods

This study was a cross-sectional analysis of the baseline data from the 15 RACFs particiaptaing in the PiRACF study [35]. The PiRACF study is a cluster randomised controlled trial to evaluate the effectiveness of on-site pharmacists integrated into RACFs care teams to improve medication management. Only residents who are permanent residents of the RACF and over the age of 65 years were included in the study. Data collected included demographic details of residents, medical diagnoses, and medication schedules. A Microsoft Access® (version 16; Microsoft Inc, Seattle, WA, USA) database was designed to capture and store data. Residents' medications were entered according to the Anatomical Therapeutic Chemical (ATC) classification system [36]. Residents' data, such as demographics, medications, and medical conditions, were collected at baseline. Other data related to the RACFs, such as number of beds, number of residents, and number of RNs, were collected through surveys completed by the RACF managers.

2.1. Data Analysis and Identification of QUM Indicators

Resident's medications were examined for PIMs using the Beers® 2019 criteria [21]. The Beers® criteria were slightly modified to fit the Australian setting by including medications from the same classes that are available in Australia; this approach was employed in a previous similar Australian study [28]. Use of antipsychotics and benzodiazepines were also analysed. Residents on an antipsychotic with a documented history of major

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psychiatric illness (schizophrenia and bipolar disorder) have been excluded, as well as residents taking a benzodiazepine and having a history of epilepsy.

2.2. Selection of Factors

The selection of factors to test for association with PIMs use was based on a literature review and discussions amongst the study team. Resident's factors included age, sex, Aboriginal and Torres Strait Islander status, length of stay in the facility, and speaking a language other than English. Clinical factors included total number of medications (polypharmacy), number of chronic medical conditions, Charlson Comorbidity Index (CCI) [37], presence of dementia, and history of falls as per RACF records. System factors included each facility's bed capacity and RN-to-resident ratio.

Polypharmacy has been associated with numerous negative consequences in the elderly population, such as increased risk of ADEs, drug-to-drug interactions, and cognitive decline [38]. Total number of medications include regular and as pro re nata or PRN (as required use) medications as charted in the RACFs records. The number of medical conditions can also be a risk factor influencing polypharmacy and the number of PIMs [39]. RN-to-resident ratio has been used as a measure of RN staffing [33], which may affect overall quality of care and QUM in RACFs. RN-to-resident ratio was calculated based on the number of registered nurses that work each week divided by the number of residents, as reported by the facility. This was categorised into three categories for analysis, namely, RN-to-residents ratio 1:7 or higher, RN-to-residents ratio between 1:8 to 1:11, and RN-to-residents ratio of 1:12 or lower.

2.3. Statistical Analysis

Data were exported from the Microsoft Access® database into SPSS (version 27.0; IBM Corp. Armonk, NY, USA) for statistical analysis. Descriptive statistics included the mean, median and standard deviation for numeric variables and proportion for categorical variables.

The key PIM outcome variable (number of PIMs prescribed for each patient) is a discrete count outcome and therefore regression modelling approaches appropriate for count data were used. To account for the overdispersion that characterise count outcome data, a negative binomial regression was performed, instead of the usual Poisson regression. First, a bivariate analysis was conducted to examine the association between PIM outcome and each covariate. Second, covariates for which an association with the PIM outcome was found in the bivariate model at the level of significance of p-value < 0.1 were included as candidates for the final multivariable model. The model also controlled for sex and number of medications. Multicollinearity was tested using the variance inflation factor (VIF). Covariates for which VIF < 6 were kept in the model. For the final model, the level of significance was set at 5%. Any observed result with associated probability value less than 5% (p-value < 0.05) was considered statistically significant for all analyses.

3. Results

A total of 1357 residents from the 15 participating RACFs were included. The median age was 86 years, 65.1% were female, and 13.3% spoke a language other than English. The median total number of medications used by each resident was 12. The median CCI score was 2, and 53% of residents from the cohort had a diagnosis of dementia. The demographics and clinical characteristics of residents are summarised in Table 1.

Table 1. Characteristics of residents.

Variable	N	(%)
Age (years)		
65–74	159	11.7
75–84	424	31.2
85 or more	774	57.0
Sex		
Male	478	34.9
Female	890	65.1
Aboriginal and Torres Strait Islander status		
Yes	6	0.4
No	1362	99.6
Preferred language		
English	1186	86.7
Other	182	13.3
Number of medications		
Less than 5	131	9.6
5–9	331	22.8
10 or more	922	67.4
Charlson comorbidity index (CCI)		
0	178	13.0
1	394	28.8
2	299	21.9
3 or more	497	36.3
Length of stay (years)		
Less than 3	911	66.6
3–6	335	24.5
7–12	83	6.1
13 or more	26	1.9
History of falls		
Yes	1090	79.7
No	278	20.3
Dementia diagnosis		
Yes	725	53.0
No	643	47.0
Nursing home bed capacity		
Less than 50	17	1.2
50–100	703	51.4
101–200	648	47.4
Registered Nurse (RN)-to-resident ratio		
1:7 or higher	407	29.8
1:8–1:11	557	40.7
1: 12 or lower	404	29.5

Most residents (75.5%) were prescribed at least one PIM, as identified by the Beers Criteria© (Table 2). At least one PIM was charted as regular in 68.1% of the residents, while 34.7% of residents had at least one PIM charted as pro re nata or PRN (as required use). Over 20% of all residents were taking at least one antipsychotic (20.2%) or benzodiazepine/benzodiazepine-like medication (20.9%).

Appendix 6. Baseline paper *cont.*

Table 2. Prevalence of QUM indicators.

Prevalence	Total (N = 1368) (%) *	Regular Use	PRN Use
Residents with at least one instance of Potentially Inappropriate Medication (PIM)	1033 (75.5%)	932 (68.1%)	476 (34.7%)
Residents with at least one antipsychotic medication **	275 (20.2%)	230 (16.9%)	99 (7.3%)
Residents with at least one benzodiazepine or benzodiazepine-like medication ***	286 (20.9%)	151 (11.1%)	184 (13.5%)

* The total is not the sum of regular and PRN as sometimes residents were on both simultaneously. ** Residents with a history of major psychiatric illness (schizophrenia and bipolar disorder) have been excluded. *** Residents with a history of epilepsy have been excluded.

The most common class of medications implicated as PIMs was proton pump inhibitors, comprising 21% of total PIMs, followed by opioids (17.3%). Benzodiazepines and antipsychotics comprised of 27.2% of the total number of PIMs identified (Table 3).

Table 3. Most commonly prescribed Potentially Inappropriate Medications (PIMs).

Top 10 Most Common PIMs by Drug Class	Total Number of PIMs N = 2734	(%) *
Proton Pump Inhibitors **	**573**	**21**
Pantoprazole	267	9.9
Esomeprazole	140	5.1
Rabeprazole	85	3.1
Opioids ***	**472**	**17.3**
Oxycodone	180	6.6
Buprenorphine	96	3.5
Hydromorphone	58	2.1
Benzodiazepines	**373**	**13.6**
Midazolam	123	4.5
Temazepam	99	3.6
Lorazepam	79	2.9
Antipsychotics	**373**	**13.6**
Risperidone	134	4.9
Quetiapine	96	3.5
Olanzapine	74	2.7
Gastrointestinal	**177**	**6.4**
Metoclopramide	165	6
Prochlorperazine	12	0.43
Cardiovascular	**91**	**3.3**
Digoxin	76	2.8
Amiodarone	10	0.4
Diltiazem	2	0.1
Antiepileptics	**87**	**3.2**
Pregabalin	56	2.0
Levetiracetam	11	0.4
Phenytoin	6	0.2
Corticosteroids	**72**	**2.6**
Prednisolone	46	1.7
Fludrocortisone	7	0.3
Hydrocortisone	7	0.3

Table 3. *Cont.*

Top 10 Most Common PIMs by Drug Class	Total Number of PIMs N = 2734	(%) *
Endocrine	**51**	**1.9**
Gliclazide	49	1.7
Glipizide	1	0.0
Testosterone	1	0.0
Antidepressants	**51**	**1.9**
Amitriptyline	23	0.8
Paroxetine	15	0.5
Nortriptyline	7	0.3

* The percentage of the total number of PIMs (regular and PRN). ** Only proton pump inhibitors with continuous use of 8 weeks or more were included, as indicated by the Beers Criteria©. *** Only opioids for residents with history of falls or fractures as indicated by the Beers Criteria©.

In the final multivariable model (Table 4), five factors showed statistically significant associations with the number of PIMs, namely, age, CCI, history of falls, diagnosis of dementia and RN-to-resident ratio.

Table 4. Factors associated with potential inappropriate medications in bivariate and Multivariable model.

Variable	Bivariate Analysis			Multivariable Analysis	
	N	RR (95% CI)	*p* Value *	RR (95% CI)	*p* Value
Age (years)			**0.016**		**0.007**
65–74	159	1.00		1.00	
75–84	424	1.022 (0.817–1.277)	0.745	0.971 (0.773–1.219)	0.798
Equal or over 85 years	774	0.837 (0.739–0.944)	0.004	0.784 (0.629–0.976)	0.029
Sex			0.235		0.181
Female (0)	890	1.00		1.00	
Male (1)	478	0.946 (0.823–1.086)	0.235	0.906 (0.783–1.047)	0.181
Aboriginal and Torres Strait Islander status			0.515		
No	1362	1.00			
Yes	6	1.370 (0.530–3.540)	0.515		
Preferred Language			0.420		
English	1186	1.00			
Other	182	0.923 (0.758–1.122)	0.420		
Number of medications			0.387		0.655
Fewer than 5	131	1.00		1.00	
5–9	311	1.124 (0.957–1.320)	0.29	1.075 (0.823–1.403)	0.596
10 or more	922	1.176 (1.017–1.360)	0.154	1.113 (0.875–1.416)	0.381
Charlson comorbidity index (CCI)			**0.010**		**0.021**
0	178	1.00		1.00	0.635
1	394	0.864 (0.755–0.990)	0.035	0.944 (0.744–1.198)	0.722
2	299	0.972 (0.846–1.117)	0.687	1.046 (0.817–1.339)	0.080
3 or more	497	1.149 (1.014–1.303)	0.030	1.222 (0.976–1.530)	
Number of conditions (subgroups)			0.545		
Fewer than 5	84	1.00			
5–9	358	1.124 (0.957–1.320)	0.154		
10 or more	922	1.176 (1.017–1.360)	0.029		

Appendix 6. Baseline paper *cont.*

Table 4. *Cont.*

Variable	Bivariate Analysis			Multivariable Analysis	
	N	RR (95% CI)	*p* Value *	RR (95% CI)	*p* Value
Length of stay			0.276		
2 years or less	911	1.00			
3–6	335	1.125 (1.034–1.225)	0.006		
7–12	83	1.120 (0.974–1.287)	0.113		
Over than 13 years	26	1.415 (1.105–1.813)	0.006		
History of falls			**0.001**		**0.000**
No	1090	1.00		1	
Yes	278	1.448 (1.325–1.582)	0.001	1.445 (1.231–1.696)	0.000
Dementia diagnosis			**0.021**		**0.031**
No	643	1.00		1.00	
Yes	725	0.854 (0.790–0.924)	0.001	0.854 (0.740–0.986)	0.031
Nursing home bed capacity			0.509		
Fewer than 50 beds	17	1.00			
50–100	703	0.729 (0.536–0.991)	0.044		
101–200	648	0.750 (0.552–0.1021)	0.067		
Registered Nurse (RN) to resident ratio			**0.001**		**0.001**
1:7 or higher	404	1.00		1.00	0.060
1:8–1:11	557	1.382 (1.177–1.623)	0.001	1.377 (1.1168–1.623)	0.000
1: 12 or lower	407	1.162 (0.976–1.384)	0.092	1.188 (0.993–1.422)	

* Highlighted in bold if *p*-value of overall factor is <0.05.

Residents with higher CCI score, history of falls, or those who live in facilities with a low RN-to-residents ratio (1:8 or lower) were associated with increased number of PIMs. Residents with a CCI of 3 or more were 1.2 times more likely to have higher PIMs compared to residents with lower CCI scores. Residents with a history of falls were 1.4 times more likely to have more PIMs. Residents with lower RN to resident's ratio were likely to have an increased number of PIMs.

Older age (>85) and dementia diagnosis were associated with lower number of PIMs. Additionally, residents with dementia were less likely to have PIMs. Amongst all the factors, the strongest association with increased number of PIMs, was history of falls followed by RN-to-resident ratio.

4. Discussion

This study examined key QUM indicators in RACFs, including the prevalence rates of PIMs, and prescribing of antipsychotics and benzodiazepines. The study reported the most frequent classes of PIMs prescribed in RACFs and explored the associations between PIM use and various resident and RACF system-level factors. The proportion of residents with one or more PIMs according to the Beers criteria® was 75.5%. The study found a positive association between prescribing PIMs and certain resident factors such as having a history of falls and an increased CCI, while a negative association was found with the presence of dementia diagnosis. The only system factor that was found to be associated with PIMs use was the RN-to-resident ratio, where a lower ratio of RN-to-resident (understaffing) was associated with increased number of PIM prescribing.

The proportion of residents taking at least one regular PIM was 68.1%, with 34% taking at least one PRN PIM. This is consistent with the higher end of the range reported in previous Australian studies [23–28]. A systematic review of 21 studies showed a median of 45.5% of residents were prescribed at least one PIM [29]. Internationally, the prevalence of PIMs in RACFs varied depending on what criteria was used and the regions studies were conducted. The prevalence of PIMs was reported higher in Europe than in North

America [4]. Interestingly previous studies in Australian RACFs setting have not reported a breakdown of regular and PRN PIMs of residents. This is important as one recent study examined the frequency of administration of PRN relative to regular medications in 8 RACFs found PRN administrations over a 7-day period comprised less than 1% of all administrations [40]. This shows the contribution of PRN medications in RACFs is likely to be small and more attention should be focused on reducing regular PIMs which is evidently high as shown in this study.

The prevalence of residents prescribed regular antipsychotics and regular benzodiazepines in this study was 16.9% and 11.1%, respectively. Antipsychotics are commonly prescribed in RACFs to treat behavioural and psychological symptoms of dementia [41], but their use has been associated with increased risk of falls, stroke and death [42]. The use of benzodiazepines is also commonly used for insomnia, anxiety, and agitation but similarly their use has been associated with falls, increased rates of pneumonia, and increased risk of dementia [16–18]. Previous studies have reported higher prevalence of regular antipsychotic for residents in residential aged care settings. Westaway et al., reviewed sixteen studies between 2000 and 2017 and found 13% to 42% of residents, with an average of 26% of residents were prescribed an antipsychotic in RACFs [43]. A study in 2018 found regular benzodiazepines were prescribed in 22.2% of residents [44]. In contrast, our study showed a notable reduction in the use of benzodiazepines and antipsychotics. There has been increased awareness about the use of chemical restraint among RACF residents. One of catalysts for this was the Australian Royal Commission's enquiry into Aged Care Quality and Safety which emphasized high prevalence of psychotropic use for behavioural and psychological symptoms of dementia in their interim report [45]. This also may be explained by the multiple public health campaigns and interventions aimed at reducing the use of antipsychotics and benzodiazepines in RACFs such as the Reducing the Use of Sedatives (RedUSe) project and the Halting Antipsychotic use in Long Term care (HALT) study as well as the introduction of the NPS Medicinewise dementia education program in Australia [44,46,47].

The most frequently used class of PIMs found in this study was proton pump inhibitors (PPIs), exceeding the use of antipsychotics and benzodiazepines. The long-term use of PPIs has been linked with increased rates of Clostridium difficile infections, pneumonia, fractures, hypomagnesemia and both acute and chronic kidney disease [48,49]. Increasing levels of long-term PPI use over the past two decades have been well documented in Australian studies, partially attributed to changing prescribing patterns [49,50]. This increase is also shown in similar international studies [51,52]. While the use of PPIs is often justified, such as its use in conjunction with NSAIDs or anticoagulants, there are signs of non-evidence-based use of PPIs. A study of RACFs residents in the US found almost half of residents used PPIs for non-evidence-based indications [53]. Due to the safety concerns of long-term PPI use, there may be a need to tailor interventions to review and adjust the duration of PPI when appropriate. Pharmacists may be able to play a key role in assisting medical practitioners to optimise PPI use by implementing regular audits and assessing the need for continuation of PPIs on regular basis in RACF residents.

History of falls was associated with risk of PIMs. This may be explained by residents' use of antipsychotics, benzodiazepines and hypnotics which have been linked with increased number of falls [54,55]. An association was found between PIMs prescribing and a higher CCI in this cohort. CCI predicts the ten-year mortality for a patient who may have a range of comorbid conditions, however, this association was small however and needs to be interpreted with caution.

This study also found the use of PIMs was inversely associated with the presence of dementia diagnosis. Other studies also found inverse relationship with dementia and PIMs use [56–58], while most other studies did not find an association between dementia and PIMs use [33,59,60]. The association between use of PIMs and dementia diagnosis is conflicting and needs further research to determine which medications are more likely to be associated with dementia diagnosis. The inverse association with dementia may be ex-

plained by medical practitioners' and pharmacists' focus on deprescribing in residents with dementia due to changes in goals of therapy as well as avoiding inappropriate medication that may exacerbate the deterioration of residents' conditions

A lower RN-to-resident ratio was associated with a higher number of PIMs in this cohort. This finding is consistent with a previous study which found that residents in facilities staffed with fewer RNs relative to the number of residents were at twice the risk of receiving PIMs [33]. A low RN-to-resident ratio maybe a proxy for other quality related factors on the facility level, therefore further investigation is required to better understand the nature of the association between RACF staffing and quality of prescribing. Lower quality of care in RACFs has partly been attributed to inadequate level of nurse staffing [61]. Additionally, a recent review of factors influencing medication safety found that a higher skilled staff number played an important role in preventing medication errors [62]. The shortage of RNs in RACFs has been raised as a concern given its potential impact on delivering quality care, including medication use in RACFs [63,64]. Currently, there is no standard requirement to employ RNs per specific number of residents in RACFs. Due to the complex nature of medication management, the availability of more highly trained staff such as RNs or pharmacists may help reduce medication-related problems, but further evidence is needed [65].

This study shows there is a high level of PIMs use amongst residents of RACFs in Australia. There needs to be a concerted effort to conduct high quality studies examining novel interventions to improve QUM and target those residents most at risk. Implementing integrated pharmacist services in RACFs may help in this endeavour. An example in Australia is the pharmacist in residential aged care facilities study (the PiRACF study) which is a cluster randomised trial that aims to evaluate the effectiveness of embedding a pharmacist within the multidisciplinary team in the aged care facility to improve quality use of medicines [35].

There are some limitations to our study. This is a cross-sectional study; therefore, only the association between examined factors and PIMs can be determined, and there was no scope to assess causality. An implicit limitation of the Beers Criteria is to not take individual's circumstances into account; therefore, PIM use may be clinically appropriate in some residents. Additionally, all recruited RACFs were from the Australian Capital Territory in Australia and, therefore, generalisability to other regions may be limited.

5. Conclusions

Despite recent efforts to improve QUM in RACFs, the extent of PIMs prescribing remains high, with more than two-thirds of residents exposed to at least one regularly used PIM. Long-term PPI use was the most frequent class of PIMs found in this study while a notable reduction in regularly prescribed antipsychotics and benzodiazepines was found compared to previous studies, pointing to a possible change in prescribing patterns. History of falls, younger age and increased CCI scores for residents were found to be associated with an increased number of prescribed PIMs, while facilities with a lower RN-to-resident ratio were also associated with an increased use of PIMs. This study points to a need to further explore factors that might be associated with inappropriate prescribing and tailor interventions targeting those residents most at risk.

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Institutional Review Board Statement: This study was conducted in accordance with the Declaration of Helsinki. Ethics approval to conduct the study was obtained from: The University of Canberra Human Research Ethics Committee Approval Number 2007 on 5 November 2019; Calvary Public Hospital Bruce Human Research Ethics Committee Approval 30-2019 on 11 May 2020; and, ACT

Health Human Research Ethics Committee Approval Number 2020.ETH.00164 on 2 November 2020. The trial was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12620000430932 on 1 April 2020.

Informed Consent Statement: Consent to participate in the study was gained at the facility level, rather than the resident level, given the impracticalities of gaining informed consent from a large sample, many of whom are likely to have cognitive impairment; there is a low risk to participants and actions will be taken to protect of participant of privacy. Residents are able to opt out of having their data included in the study, and the process on how to do this is provided to residents and families. This consent process follows Australian NHMRC guidelines [66] and is consistent with comparable studies conducted in Australia [67,68]. Study findings present aggregated resident data and do not include personal identifying details.

Data Availability Statement: The study dataset will not be made publicly available. Only investigators have access to the trial dataset.

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APPENDIX 7. RE-AIM EVALUATION FRAMEWORK OUTCOMES

The RE-AIM evaluation implementation framework was used to report on essential program elements.

Evaluation question	Outcomes	Source of data	Indicator
Reach — The number, proportion, and representativeness of individuals/ organisations who participate in the service model	• Improved medications management for residents	• RACF resident records • RACF resident medication charts • Pharmacists' activity diaries	• What is the number and proportion of RACF residents who participate in the service model? • Number and proportion of residents who received a medication review by the pharmacist • Number of RACFs receiving funds to employ a pharmacist • Number and pharmacists employed to deliver the model
Effectiveness — The effectiveness or efficacy of the service model on outcome measures and economic outcomes Does the service model improve QUM for residents in RACFs?	• Reduction in PIM for residents • Reduction in anti-psychotic medications • Reduction in benzodiazepines	• RACF resident records • RACF resident medication charts • Evaluation of primary and secondary outcomes	• After 12 months of enrolling in the program there has been a 2% reduction from baseline in the number of anti-psychotic medications prescribed in those RACFS with higher prevalence of use of anti-psychotics (>20%) • 12 month — 2% reduction from baseline in chemical restraints as defined by use of anti-psychotics and benzodiazepine in those RACFs with high prevalence of chemical restraints (>20%)
	• Cost-effectiveness analysis	• Number and cost of PIMs • Number and cost of ED and hospital visits • Cost of training and employing the on-site pharmacists • Medication round timing • Cost of medicines	• Direct cost consequences of employing an on-site pharmacist will be reported
Effectiveness — The effectiveness or efficacy of the service model on outcome measures and economic outcomes. Does the service model reduce ED visits and hospitalisations?	• Reduction in ED visits and unplanned hospitalisations	• RACF resident data • Data linkage from ACT Health (and Calvary Healthcare pending Human Ethics approval)	• 12 month — overall 4% reduction in hospital presentation as defined by the composite number of hospital admission/readmission/ ED visit, determined by available RACF data such as residents leave days

Evaluation question	Outcomes	Source of data	Indicator
Effectiveness — The effectiveness or efficacy of the service model on outcome measures and economic outcomes Does the service model improve RACFs policies and procedures for medication management	• Increase in quality improvement activities	• Pharmacist activity diaries	• 12 month — at least 6 quality improvement activities undertaken by each employed pharmacist in each RACF
Effectiveness — The effectiveness or efficacy of the service model on outcome measures and economic outcomes Does the service model facilitate service integration?	• Evidence of increased and improved collaboration between on-site pharmacists and residents and families, RACF care staff and managers, GPs and prescribers (including Specialist Palliative Care team, specialists, gerontologists), and health professionals (including community pharmacists, hospital pharmacists, physiotherapists, occupational therapists, and dietitians) including utilisation of My Health Records and other digital health innovations	• Survey with residents and families • Survey with on-site pharmacists, RACF care staff and managers) • Survey with GPs and prescribers, and health professionals (PPCI index) • Qualitative interviews with on-site pharmacists, RACF care staff and managers, GPs and prescribers, and health professionals.	• Qualitative interviews with key stakeholders conducted by 12-months, to assess interprofessional interaction with pharmacist and other key health care professionals • Qualitative interviews with on-site pharmacists and RACF care staff and managers
Adoption — The number, proportion, and representativeness of take up of the service model by target staff, settings, or institutions. What is the number, proportion, and representativeness of pharmacists and RACFs who participate in the new service model	• Proportion of medication review recommendations made by the pharmacist which are accepted by the prescriber • The number of RACFs which drop out of the study	• Pharmacist diaries	–
Implementation — The implementation to the service model's fidelity to the various elements. This includes consistency of delivery as intended What was the level of adherence to the new service model?	• Assessing level of adherence to the service model • Assessing consistency of delivery of the service model across different RACFs • Assessing the extent to which service model is adapted or modified over time	• Pharmacist activity diaries • Medication reviews • Qualitative interviews with pharmacists and RACF care staff and managers, GPs and prescribers, and health professionals	• 100% of pharmacist diaries assessed and cumulative number/ proportion of activities calculated • Random sample of 10% of medication reviews checked to determine appropriateness of medication reviews
Were the training materials useful?	• Assessing the usefulness of training materials	• Qualitative interviews with pharmacists and RACF care staff and managers, GPs and prescribers, and health professionals	

Appendix 7. RE-AIM evaluation framework outcomes *cont.*

Evaluation question	Outcomes	Source of data	Indicator
What governance mechanisms did RACFs put in place and were these useful?	• Assessing the characteristics and usefulness of governance mechanisms RACFs put in place to include pharmacists in the care team	• Qualitative interviews with pharmacists and RACF care staff and managers, GPs and prescribers, and health professionals	–
Maintenance — The extent to which the service model becomes institutionalized or part of routine organisational practices and policies Is the new service model sustainable?	• Assessing sustainability and willingness of RACFs to continue with funding the on-site after the study ends • Assessing acceptability of implementation	• Qualitative interviews with pharmacists and RACF care staff and managers, GPs and prescribers, and health professionals • RACF resident medication charts • Evaluation of primary and secondary outcomes	• As part of final evaluation report and program report
	Cost-effectiveness analysis	• Number and cost of PIMs • Number and cost of ED and hospital visits • Cost of training and employing the on-site pharmacists • Medication round timing • Cost of medicines	–

APPENDIX 8. PROGRAM LOGIC

Program logic was developed to identify the study inputs, activities, and short-term, medium-term, and long-term outcomes. The table below summarises the key components of the logic.

Resources/ inputs	Activities	Study Outputs	Short-term Outcomes (within the scope of the study)	Medium-term Outcomes (within the scope of the study)	Long-term outcomes (beyond the scope of the study)
• Funding • Staff (on-site pharmacists) • Training for on-site pharmacists (provided by the research team) • On-going support for on-site pharmacists (provided by the research team)	• Pharmacists join the multidisciplinary care team at RACFs with RACF care staff, nurses and other health professional or teams (GPs, Specialist Palliative Care team, specialists, geriatricians, nurse practitioners, community pharmacists, hospital pharmacists, physiotherapists, occupational therapists, and dietitians) • Pharmacists conduct clinical audits to identify those residents at risk of hospitalisation or medication related harm • Pharmacists review residents' medications on admission, at transition of care and ongoing • Conduct person centered care in collaboration with residents and families, RACF care staff and manager, GPs and prescribers (Specialist Palliative Care team, specialists, geriatricians, nurse practitioners) and health professionals (community pharmacists, hospital pharmacists, physiotherapists, occupational therapists, and dietitians) • Pharmacists coordinate medication-related issues at transition of care • Pharmacists provide one-on-one and group training in medication administration to RACF staff • Pharmacists respond to resident, family and RACF staff about medication related enquiries • Pharmacists review RACF medication related policies & procedures and conduct quality improvement activities • Pharmacists promote influenza vaccination through education and follow up	• Number of RACFs with on-site pharmacist in their care team • Number of RACF care staff and health professionals work together with pharmacists on improving residents' care • Number of RACF residents who receive a medication review • Level of collaboration between on-site pharmacists and residents and families • Level of interdisciplinary collaboration between on-site pharmacists and RACF care staff and manager • Level of interdisciplinary collaboration between GPs and prescribers, and health professionals • Number of one-on-one and group education sessions with residents, families, RACF care staff and managers • Number of medications and anti-psychotic medicines deprescribed • Number of RACF policies reviewed • Number of influenza vaccinations conducted and vaccination related education sessions and follow ups conducted with RACFs residents and staff	• Increase screening and identification of residents at high risk of having PIM • Increase the number of medication reviews for residents at transition of care (after a visit to ED, hospital discharge or diagnosis with a new condition) • Increase the number of resident, family and staff education sessions around medication management • Increase communication and information exchange between the on-site pharmacist, RACF care team, hospital pharmacist, community pharmacist, GPs and prescribers, and health professionals, regarding residents' and facility's medication management • Regular review of RACF policies and procedures around medication management • Increase resident and staff influenza vaccination rates	• Reduce the number of PIM • Improve medication management and optimise prescribing • Reduce ED presentations and hospital admissions • Improve RACF policies and procedures • Improve RACF staff knowledge about medication management • Enhance collaboration between on-site pharmacists and the RACF care team, GPs and prescribers, and health professionals • Demonstrate cost-effectiveness of the intervention: cost-savings from primary and secondary care utilisation • Reduce transition of care medication errors e.g. duplication and omission • Reduce medication errors	• Improve health outcomes for RACF residents • Improve RACF operational efficiencies • Reduce GP, community pharmacy and RACF care staff workload • Improve RACF staff satisfaction with the new service model • Prevent influenza related adverse health outcomes for residents and staff • Sustainability of the service model over time and roll out

APPENDIX 9. ONLINE TRAINING VIDEOS

UNIVERSITY OF CANBERRA

DISTINCTIVE BY DESIGN

Integrating Pharmacists in Residential Aged Care Facilities to improve the quality use of medicines study - Training

Name:

Pharmacists in general practice and aged care - Training Videos			
Activity/Task	Length of Training	Completed	Date Completed
Training Video - Part 1	1hr:35min	Yes ☐ No ☐	
Training Video - Part 2	1hr:53min	Yes ☐ No ☐	
Training Video - Part 3	1hr:25min	Yes ☐ No ☐	
Aged Care Modules			
Activity/Task	Length of Training	Completed	Date Completed
Beers Criteria	17:30min	Yes ☐ No ☐	
Psychotropic and anticholinergic deprescribing	21:52min	Yes ☐ No ☐	
Pain management: opioids	17:43min	Yes ☐ No ☐	
Renal function and medication adjustment	15:06min	Yes ☐ No ☐	

Aged Care Modules			
Activity/Task	Length of Training	Completed	Date Completed
Cardiovascular disorders in the elderly	37:35min	Yes ☐ No ☐	
Depression, anxiety and sleep in the elderly	31:50min	Yes ☐ No ☐	
Diabetes and osteoporosis in the elderly	34:08min	Yes ☐ No ☐	
Gastrointestinal disorders in the elderly	28:31min	Yes ☐ No ☐	
Parkinson's disease in the elderly	27:20min	Yes ☐ No ☐	
Respiratory and pneumonia	26:28min	Yes ☐ No ☐	
Medication and the urinary tract - urinary tract infections in the elderly	37:01min	Yes ☐ No ☐	
Common wounds in aged care - Impacts of the medications	26:59min	Yes ☐ No ☐	

https://my.psa.org.au/s/training-plan/a110o000008r2P9/its-time-pharmacists-in-general-practice-and-aged-care-act

APPENDIX 10. ECONOMIC EVALUATION REPORT

Australian National University

Cost-effectiveness and cost-consequences analyses of integrating pharmacists in residential aged care facilities to improve the quality use of medicines

A trial-based economic evaluation of the PiRACF study

Draft Report

Contact Details:
Dr Syarifah Liza Munira
Department of Health Services Research and Policy
National Centre for Epidemiology and Population Health
College of Health and Medicine
Liza.Munira@anu.edu.au

Professor Emily Lancsar
Head, Department of Health Services Research and Policy
National Centre for Epidemiology and Population Health
College of Health and Medicine
Emily. Lancsar@anu.edu.au

The Australian National University
Canberra ACT 2600 Australia
www.anu.edu.au

CRICOS Provider No. 00120C

Appendix 10. Economic evaluation report *cont.*

Contents

Appendix 10. Economic evaluation report *cont.*

Key findings

- The average cost to the health care provider of integrating an on-site pharmacist in RACFs in this trial was $56,286.18 per RACF per year, with an average cost of $622.58 per facility bed per year.
- No statistically significant difference was identified across the two arms of the trial in the use of other health care resources. Therefore, the economic analysis does not apply any cost offsets against the costs of integrating pharmacists into RACFs.
    - Although there is potential for a reduction in time spent by RACF staff on medication management in RACFs with an integrated pharmacist, the sample of RACFs in the trial that provided data for this parameter was very small (three RACFs in each arm), which meant that detection of a statistical difference in this factor was improbable.
    - Despite the comprehensive collection of data concerning the attendance of residents to emergency departments and hospitalisation admissions over a year (e.g., due to falls, medication incidents, etc.), a statistically significant difference in the use of these resources was not observed in this trial.
- As there was no statistically significant difference in: i) ED visits; ii) hospital admissions; iii) medication incidents; iv) average number of falls per facility bed; v) average number of deaths per facility bed; vi) RACF staff time-use; and vii) proportion of residents with complete ADR, it is not clear that a reduction in the number of residents prescribed at least one regular PIM translates to an improvement in these important outcomes.
- The trial demonstrated a statistically significant 9.1% reduction in the primary endpoint of the proportion of residents prescribed at least one PIM with a regular administration schedule.
- The incremental cost effectiveness ratio (ICER) of integrating an on-site pharmacist at a residential aged care facility (RACF) was $6,842 per resident avoiding the use of a potentially inappropriate medicine (PIM) with a regular administration schedule.
- Although the ICER estimated and reported above is based on the primary outcome of the Pharmacist Integrated in Residential Aged Care Facility (PiRACF) trial, the ICER is difficult to interpret in the absence of knowing what the impact of avoiding administration of at least one PIM regularly means to a resident. Interpretation is further complicated by the absence of a cost effectiveness threshold in relation to a resident avoiding use of a regular PIM. As such, it is difficult to determine if this ICER of $6,842 per PIM avoided can be considered cost effective or good value from an economic point of view. It is recommended that future studies include rigorous capture of time spent on medication management by RACF staff and that they elicit the impact of avoiding the regular use of a PIM on patient outcomes such as quality of life. From such data, quality adjusted life years (QALYs) can be calculated and whether integrating an on-site pharmacist in RACFs can be considered cost effective more readily determined.
- A limitation of this trial is that it involved a small sample of RACFs in a single, geographically small, territory of Australia which potentially means that the results from the trial may not be generalisable to larger states in Australia or to other countries.

Introduction

Background and Objective

Diseases and disabilities increase with advancing age. Functional impairment, combined with chronic conditions, can result in an increased need for medical services and long-term care in older adults (1). Therefore, it is no surprise that the increased need to treat and manage chronic illnesses and conditions makes the elderly the highest consumers of medicines (2, 3).

The elderly often have multiple morbidities, which can require multiple medications (polypharmacy). Polypharmacy can increase the risk of harm to patients, as there can be an increased risk of adverse drug reactions (ADRs) and drug interactions(4). The increased potential for harm can result in poor clinical outcomes for patients (e.g., falls, cognitive impairment) that may require medical care and/or emergency care and/or hospital admission and/or premature mortality(5-8). The requirement for medical resources to manage iatrogenic conditions can result in significant burden and economic cost for the health care system (9-11).

The Pharmaceutical Society of Australia (2020) reports that over 95% of residents in aged care facilities have experienced problems with their medicines, with some 6% of residents administered at least one potentially hazardous medication combination (12). Previous studies have reported that up to 61% of older patients in hospital settings develop ADRs and nearly half of these are preventable (13). Therefore, ensuring the appropriate use of medications, especially avoiding potentially inappropriate medications (PIMs), in older adults is imperative.

In 2020, the Pharmacist Integrated in Residential Aged Care Facility (PiRACF) trial was conducted by a team at the University of Canberra to examine the impact of a novel model of interdisciplinary care of medication management in residential aged care facilities (RACFs) in improving the appropriateness of mediation use in RACFs. This model employs an on-site pharmacist working alongside the RACF staff in delivering medication management in RACFs.

Integrating an on-site pharmacist as part of the health care team of an aged care facility may address the gap in safe medication management practices, policies, and processes. For this trial, we conducted an economic evaluation comparing a scenario where pharmacists are integrated on-site into RACFs to improve medication management in RACFs compared to usual care. Usual care included government-funded services from community pharmacists, such as the Residential Medication Management Review (RMMR) and the Quality Use of Medicines (QUM) program (14, 15).

The Australian National University (ANU)[1] was engaged by the PiRACF team to perform an economic evaluation based on the results from the PiRACF trial. The primary objective of the economic evaluation was to conduct a cost-effectiveness analysis comparing integrating an on-site pharmacist to improve the appropriateness of prescribing for RACF residents versus usual care with effectiveness measured in terms of the primary outcome from the clinical trial. The appropriateness of prescribing was assessed by measuring the extent of use of PIMs, defined in accordance with the 2019 Beers Criteria (16). A secondary objective was to present a cost-consequences analysis considering a disparate range of secondary outcomes, to provide decision makers with greater information on potential benefits of the intervention beyond the primary outcome assessed in the trial. The secondary outcomes considered include: (i) change in RACF residents' visits to an emergency department (ED) and hospital admissions; and (ii) change in other quality use of medicine indicators at the resident and facility levels.

[1] The ANU research team members include Syarifah Liza Munira, Ellie Aali, Helen Mason, Liliana Bulfone and Emily Lancsar

Appendix 10. Economic evaluation report *cont.*

Methods

We conducted a cost-effectiveness analysis and cost consequences analyses from a public health sector perspective based on outcomes from the PiRACF trial, a cluster randomised controlled trial (cRCT). The cRCT compared the integration of pharmacists into RACFs versus usual care over a 1-year time horizon. The intervention delivered in this study is described below and in more detail elsewhere (17). The Consolidated Health Economic Evaluation Reporting Standards Statement (CHEERS) statement was used in the design and reporting of the results of this research (Appendix 1) (18).

Ethics approval was granted by the University of Canberra (HERC:2007), ACT Health (2019/ETH13453) and Calvary Public Hospital Bruce Human Research Ethics Committees (30-2019). The trial was registered in the Australian and New Zealand Clinical Trials Registry (ANZCTR) and was given the registration number ACTRN 12620000430932.

Study design and participants

Twenty of a total of 26 residential aged care facilities (RACF) in the Australian Capital Territory (ACT) (19) were invited to participate in the cRCT. RACFs were eligible if they were a nationally accredited facility based in the ACT, had over 20 beds and were not dementia-specific facilities. Of the 20 RACFs invited to participate, 15 facilities participated in the trial.

Randomisation was at the facility level, where computer-generated allocation to intervention or control arms were conducted by an independent researcher external to the clinical trial research team. Of the 15 RACFs, eight were allocated to the control arm and seven to the intervention arm. It was not possible to blind residents, RACF staff or pharmacists to allocations; however, the outcome assessor was blinded to the facility names.

All residents above 65 years old within the seven recruited RACFs received the intervention unless they specifically requested for their data not to be included in the trial. Respite (non-permanent) residents were also excluded. A total of 1668 residents (771 in the intervention and 897 in the control) were included in the trial.

Usual care

The existing model of care included government-funded services from community pharmacists who were not incorporated into the RACF care team and provide medication management on a visitation basis. They visited RACF at regular intervals and provided medication advice as an add-on service to assist general practitioners (GPs) with quality of prescribing. Under the existing model, pharmacists had limited access to residents' clinical records and were not involved in implementing medication management changes or ongoing monitoring. Any medication changes were communicated to RACF staff through GPs.

Intervention

RACFs in the intervention arm received an on-site pharmacist for 12 months at 0.4 full-time equivalent (FTE) or 0.5 FTE (2 or 2.5 days per week, respectively), depending on the RACF size. Those with more than 104.9 residents[2] were allocated a pharmacist at the 0.5 FTE level. At the RACFs, pharmacists were responsible for the medication management of residents, previously managed by RACF staff under usual care. Delivery of the intervention and data collection took place between March 2020 and January 2022.

[2] The average number of beds per facility for all facilities in the ACT at the start of the study were 104.9 residents. Facilities below that number were allocated a pharmacist for 0.4 FTE, those above were allocated a pharmacist for 0.5 FTE.

The on-site pharmacists received training, which included an initial full-day overview of clinical pharmacy practice in the aged care setting, followed by a session focused on the pharmacist's role in RACFs and the trial design and processes. Pharmacists were also provided with clinical and geriatric pharmacy resources including content on deprescribing, psychotropics, pain management, principles of medication review in aged care, Beers Criteria (16) and wound management.

Economic evaluation

Overview

A within-trial cost-effectiveness analysis followed by a cost consequences analysis was performed. For the cost-effectiveness analysis, effectiveness was measured in terms of the primary outcome of the trial, reduction in the proportion of residents prescribed regular use of PIMs. The cost consequences analysis explored the incremental impact of the intervention (compared to the control arm) based on the various secondary outcomes, to provide decision makers with greater clarity on potential benefits of the intervention beyond the primary outcome assessed in the trial.

We developed an unpublished health economic analysis plan prior to the cRCT data collection. The cRCT study provided data on health care utilisation, changes in PIM prescription, and other quality use of medicine indicators such as falls and medication incidents, over one year. The cost effectiveness and cost-consequence analyses were conducted from a public health sector perspective. Costing of health care services assumed that all RACF residents have universal health care coverage for health care services given that all residents were Australian residents with access to Medicare.

Health outcomes

Patient-relevant outcomes such as the incidence of ED visits, hospitalisations and falls are more clinically meaningful outcome than the rate of reduction in prescribing regular PIMs. However, the change in the prevalence of appropriate prescribing was considered to be a more direct and immediate outcome following pharmacist intervention.

Several secondary outcomes were also assessed through the trial: i) medication-related incidents; ii) change in ED visits; iii) change in incidence of hospital admissions; and iv) change in clinical quality indicators at the resident level. The clinical quality indicators included:

- Proportion of residents prescribed at least one regular antipsychotic or benzodiazepine;
- Prevalence of prescription of at least one psychotropic medicine (defined as antipsychotics and benzodiazepines);
- Average daily dose of psychotropic medicines (measured in chlorpromazine or diazepam equivalent doses);
- Residents' anticholinergic burden score (ACB);
- Proportion of residents with documentation of drug allergies or adverse drug reactions;
- Number of residents with falls over 12 months; and
- Total (and percentage of) all-cause deaths per RACF.

Utilisation and cost estimates

We followed the standard approach of identifying resources used, quantifying and then valuing the resources used by applying unit prices to the quantities used. A time-use survey was sent to RACF managers in both intervention and control sites to measure the costs associated with time use of RACF staff for the same set of activities performed by the on-site pharmacists. Unit

Appendix 10. Economic evaluation report *cont.*

costs were obtained from national sources, such as Fair Work Ombudsman (21, 22), and the ACT public sector nursing and midwifery enterprise agreement (23).

Each intervention site was assigned an on-site pharmacist. Pharmacists' activities were self-reported through a Qualtrics online diary. The activities recorded include: (i) medication review; (ii) clinical audit; (iii) communication; (iv) vaccination; (v) administrative tasks; (vi) education; (vii) quality improvement; and (viii) other activities. Vaccination activities were later excluded given the COVID-19 pandemic situation shifting the task from GPs to RACF staff, which may not be applicable in following years.

Total costs for the intervention and control groups were calculated. These were used to calculate average costs per facility bed (over one year). Intervention costs included time use of on-site pharmacists and RACF staff in managing medications. The RACF staff included facility and care managers, nursing staff (including registered nurses, nursing assistants, enrolled nurses, directors of nursing, clinical nurse consultants), and care staff. For the purpose of the analysis, only costs that would be involved in the actual delivery of the intervention were included. Therefore, sunk costs of training on-site pharmacists (video material and 3 hours per session training) and costs associated with orientation of the intervention (2-hour orientation and resource material) were not included. The cost of an on-site pharmacist was estimated at $50 per hour plus 30% on-cost for 12 months. The cost per full FTE of a pharmacist was estimated at $ $127,097.83. After removing costs related to vaccination tasks, costs per on-site pharmacist were divided by the number of beds per facility to produce the average cost per facility bed (over one year).

Resource use captured during the trial included utilisation of health services by each resident. The use of health services included capture of ED visits, hospital admissions, ambulance services, and a nursing triage assistance provided by the Geriatric Rapid Acute Care Evaluation (GRACE) team (24). Data on use of primary care physicians use were not collected and are therefore not included in the analysis. Medicine-related data were limited to number of PIMs prescription, and secondary outcomes on PIM-related indicators (i.e., number of antipsychotic or benzodiazepine prescription, ACB score, number of regular medications, ADR documentation, and mean dosage of chlorpromazine- and diazepam-equivalent medication). Although it was intended that overall utilisation of medications would be assessed, such utilisation was not able to be measured due to the inconsistency of recording prescription data at the facility level. Incomplete and inaccurate data (i.e., incorrect drug name, missing dosage form, missing strength, incorrect frequency of administration, etc) and inconsistent data entry methods across facilities precluded assessment of overall medication costs. The unit costs of health care services and intervention costs were valued in 2021 Australian dollars and are summarised in Table 1. A discount rate was not applied given the 12-month time horizon examined by the trial.

A variety of data sources were used to capture the health care resources used. Indication of PIMs prescription, and clinical quality indicators (GRACE callouts, falls, medication incidents, and deaths) were based on RACF records. The primary outcome (change in PIMs) and secondary outcomes that were non-medicine related such as hospitalisations, ED visits, GRACE callouts, medication incidents, falls and deaths were collected for the duration of the study, while the medicine-related outcomes such as the clinical quality indicators above were collected at both baseline and endpoint.

The primary outcome (change in proportion of residents prescribed at least one regular PIM) was calculated for residents with exposure to the intervention or comparator for the full year of the trial. Other medication-related outcomes (i.e., proportion of residents prescribed at least one regular antipsychotic or benzodiazepine, number of regular medications, ACB scores) were estimated by the clinical trial team.

Hospitalisation admissions were included if preceded by an ED visit to indicate an unplanned admission, and a 30-day timeframe between ED visits and hospitalisations was applied.

ED visits and hospital admissions were ascertained using ACT Health records, which classify encounters at hospitals under the Australian Refined Diagnosis Related Groups (AR-DRGs) classification system. These health services were valued using the cost weights by AR-DRG as estimated by the National Hospital Cost Data Collection (NHCDC) (25, 26). Information on GRACE team assistance and ambulance services were provided by the ACT Ambulance Services (ACTAS). The unit cost for ambulance services are available on the ACTAS website (27). GRACE ambulatory care assessments were valued at a standard consult (15 minutes) for a Clinical Nurse Coordinator (CNC) (28).

Appendix 10. Economic evaluation report *cont.*

Table 1: Unit costs in AUD (2021/2022)

Item	Cost used ($)	Unit	Reference source
RACF staff			
Registered nurse (RN) [a]	36.04	Hour	(29)
Enrolled nurse (EN) [a]	28.07	Hour	(29)
Assistant in nursing (AIN) [a]	25.90	Hour	(29)
Deputy Director of Nursing (DDON) [b]	39.00	Hour	(29)
Clinical Nurse Coordinator (CNC)	34.58	Hour	(29)
Nurse Practitioner	45.69	Hour	(29)
Care staff	28.15	Hour	(29)
Facility Manager	66.67	Hour	Market rate [c]
Care Manager	59.16	Hour	Market rate [c]
Physio	41.03	Hour	Market rate [c]
Leisure	28.98	Hour	Market rate [c]
Chaplain	43.45	Hour	Market rate [c]
GRACE service	16.46	Visit	GRACE CNC [d]
Ambulance costs			
Treatment and transport	1000	Visit	ACTAS [e]
Treatment only (no transport)	693	Visit	ACTAS [e]
Transport only (no treatment)	1000	Visit	ACTAS [e]
No treatment/transport [f]	140	Visit	ACTAS [e]
Emergency Department costs [g]			
Departure status – 1	1,143.95	Visit	(25)
Departure status – 2	625.54	Visit	(25)
Departure status – 3	1,853.30	Visit	(25)
Departure status – 4	181.86	Visit	(25)
Departure status – 5	562.68	Visit	(25)
Departure status – 6	1,814.78	Visit	(25)
Departure status – 7	345.88	Visit	(25)
Departure status – 8	435.68	Visit	(25)
Hospitalisation costs	Admission-specific (DRG cost)	Visit	(25)

Notes: [a] hourly rates calculated as average over all relevant pay-scales and contract type (permanent, part-time, casual and agency). Agency rates were estimated by reducing the 25% overhead for casual type employees and adding an agency overhead of 45% (30). [b] DDOM equivalent to RN level 4 (31) [c] Market rate quoted from: https://au.talent.com/salary. [d] Estimated at a standard consultation duration (15 minutes) [e] ACTAS rates as of August 2021. [f] Although ambulance callouts which did not require treatment/transport are not charged, we estimated the cost of the travel time to be an average of $140 per callout (taking the per km charge of $14 and assuming a 10km ride). [g] Departure status values by registration status: 1) Admitted to this hospital; 2) Non-admitted - Left without being admitted; 3) 3Non-admitted - referred to another hospital; 4) Did not wait to be attended; 5) Left at own risk after being attended; 6) Died in emergency department; 7) Dead on arrival; and 8) Registered, left without being attended

Cost effectiveness analysis

For the cost-effectiveness analysis, effectiveness was measured in terms of the primary outcome of the trial, reduction in the proportion of residents prescribed regular use of PIMs. Costs to the health care system included the cost of the integration of an on-site pharmacist in RACF, RACF staff time-spent on delivering medication management, as well as other health care services such as ambulance services, GRACE services, ED visits and hospitalisation admissions.

An incremental cost-effectiveness ratio (ICER) was computed by comparing the incremental costs and incremental outcomes of the intervention and control groups. Results were expressed as incremental cost per resident avoiding use of at least one regular PIM. Mean estimates were used, and confidence intervals and sensitivity analysis indicating the robustness and validity of the results were also used. To address the uncertainty in the data from the missing values of RACF staff time use, a sensitivity analysis was conducted using a complete case analysis (32, 33) for the missing RACF staff time-spent data.

Cost consequence analysis

A cost-consequence analysis (CCA), based on a public health perspective, was used to provide more information on the incremental impact (compared to the control arm) of the intervention on the disparate secondary outcomes.

The CCA was complemented by a balance sheet containing a descriptive comparison based on the CCA to provide a more representative reflection of the impact of an on-site pharmacist on quality use of medicine in RACFs.

Statistical analysis

Data were entered into Microsoft Excel and analysis undertaken using Stata (Version 17) and Python version 3. Average total counts and costs were calculated by facility bed in each group. The analysis included all residents and staff member for whom we had information collected during the clinical trial. The primary outcome (change in proportion of residents prescribed at least one regular PIM) only included residents with exposure to the intervention or comparator for the full year of the trial. All outcomes were checked for missing values, normality, and outliers.

The secondary outcomes presented in the CCA for medicine-related variables were generated by the clinical trial team using generalised linear mixed models (GLMMs) to compare between intervention and control groups at baseline and endpoint.

A limitation of this study is that data relating to time-spent on medication management by RACF staff was missing for nine (60%) of the fifteen RACFs. Thus, conclusions regarding comparative costs of RACF staff time spent on medication management should be considered speculative. These missing values were considered to be missing at random and imputed using a multiple imputation technique (34), using a Poisson regression distribution. The imputation procedure included predictors from the known covariates (35), such as intervention/control status (categorical), total number of beds of the RACF (discreet), not-for-profit (categorical) and standalone (categorical) status of the RACF, and whether or not the RACF has a dementia ward (categorical).

Medication management costs were analysed at the facility level, while other health services costs were analysed at the resident level. Costs and outcomes are presented as means (over one year) and standard deviation (SD) per facility bed. Two-sample t-test were conducted to examine the alternative hypothesis of statistical significant difference, and confidence

Appendix 10. Economic evaluation report *cont.*

intervals were calculated around the difference in means (intervention and control). A 5% alpha-level was taken to indicate statistical significance.

Results

A total number of 1668 residents were included in the study over a 12-month period. We identified a subgroup of residents with exposure to the intervention or comparator for the full year of the trial for assessment of change in proportion of residents prescribed administration of PIMs on a regular basis. The mean age of all the residents was 86.8 (SD: 7.90). The baseline characteristics for all residents in both arms were similar with respect to age and Aboriginal & Torres Strait Islander (ATS&I) status (Table 2).

A potential limitation of the trial is that, despite randomisation of RACFs, as shown in Table 2, there were some imbalances in resident characteristics across the intervention and control groups. A greater proportion of residents in the control arm reported English as a second language and a higher proportion of residents in the intervention arm had a dementia diagnosis at baseline. No adjustments for such differences were applied in analysis of results.

Table 2: Baseline characteristics – all residents included in the trial

Variable	All residents		
	Intervention (PiRACF)	Control (Usual Care)	P value
Total Residents	771	897	
Number of resident-beds per facility (mean, SD)	103.4 (50.36)	107 (54.59)	0.89
Age, years (mean, SD)	87.14 (8.26)	85 (8.31)	0.18
Gender, n (%)			0.00
Male	250 (32.47)	348 (38.79)	
Female	520 (67.53)	549 (61.20)	
Secondary language, n (%)	88 (14.24) (N=618)	136 (20.21) (N=673)	0.00
Identifies as Aboriginal and/or Torres Strait Islander, n (%)	3 (0.39)	4 (0.48)	0.79
Dementia diagnosis, n (%)	313 (58.18)	365 (49.93)	0.00

Note: Percentages represent the proportion of residents with characteristics from among residents for whom there were available data. SD=standard deviation

The number of beds in RACF interventions ranged between 53 and 207 beds, while RACF control sites ranged between 21 and 176 beds (Figure 1).

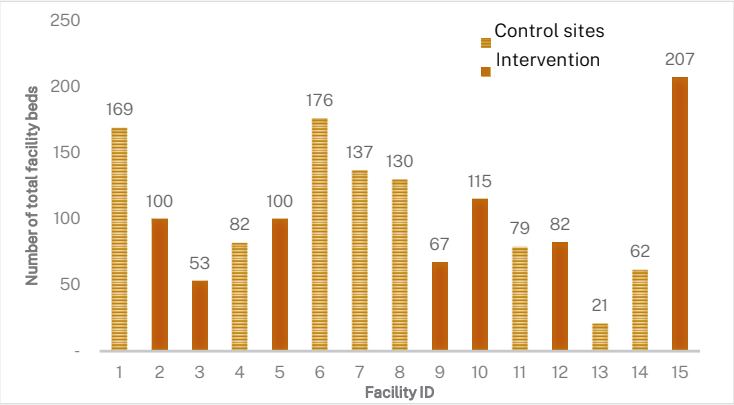

Figure 1. Number of facility beds in facilities 1-15.

The RACFs in the two arms of the trial were comparable in terms of average number of resident beds and staff-bed ratio (Table 3).

None of the RACFs in the intervention arm were operated on a for-profit basis whereas 3 of the 8 RACFs in the intervention arm were operated on such a basis.

Table 3: Baseline characteristics – RACFs

Variable	Intervention (PiRACF)	Control (Usual Care)	P value
Number of RACF facilities	7	8	
Average number of resident-year (SD)	85 (23.2)	87 (43.1)	0.924
Average number of resident beds (SD)	103 (46.62)	107 (51.06)	0.89
Staff : Beds ratio (SD)	0.86 (0.31)	0.74 (0.38)	0.49
Number of not-for-profit facilities	7	5	
Number of stand-alone facilities	0	4	

Note: SD=standard deviation

Appendix 10. Economic evaluation report *cont.*

Effectiveness

Table 4 shows the primary outcome, which is the change from baseline in proportion of residents prescribed at least one regular PIM. The change from baseline in intervention sites (a 9.7% reduction) was greater than in control sites (0.6% reduction) resulting in a 9.1% incremental effect between the intervention and control groups.

Table 4: Primary outcome for PiRACF compared to usual care over 12 months

Item	Intervention (PiRACF)			Control (Usual care)			Difference in changes [95% CI] (Intervention – Control)
	Baseline	Endpoint	Change [95% CI]	Baseline	Endpoint	Change [95% CI]	
Proportion (%) of residents prescribed at least one regular PIM (SD)	69.5 (46.12)	59.8 (49.09)	-9.7 [2.92 – 16.39]	65.7 (47.52)	65.1 (47.71)	-0.6 [-5.26 – 6.45]	-9.1 [6.04 – 12.10]

Notes: calculations were based on residents with full exposure to the intervention or comparator for the full year of the trial.

Costs of intervention and health care service use

Utilisation of health care service resources is reported in Table 5. On average (over one year), the on-site pharmacists spent 10.03 (± 3.40) hours per facility bed undertaking medication management tasks. Time spent by RACF staff in undertaking the same medication management tasks on average per facility bed (over one year) in intervention sites was 48.26 hours (95% CI: -116.15; 19.63, P=0.14) less compared to control sites. The difference between the intervention and control arms in terms of time spent by RACF staff on medication management was not statistically significant. No statistically significant differences were found between the intervention and control groups for use of ambulance services, GRACE services, ED visits and hospital admissions (Table 5).

Table 5: Health service utilisation (average per facility bed over 1 year) – all residents

Resource item	Intervention (PiRACF)	Control (Usual Care)	Difference [95% CI] (Intervention – Control)
Intervention – medication management			
On-site pharmacists* (hours)	10.03 (3.40)	N/A	10.03 [6.88 – 13.17]
RACF staff (hours)	64.50 (13.10)	112.77 (81.18)	-48.26 [-116.15 – 19.63]
Ambulance service (attendances)	0.69 (0.37) (N=474)	0.52 (0.13) (N=424)	0.17 [-0.17 – 0.50]
GRACE service (attendances)	1.20 (0.74) (N=806)	0.92 (0.92) (N=850)	0.28 [-0.63 – 1.20]
ED visits (attendances)	0.67 (0.29) (N=435)	0.53 (0.11) (N=431)	0.14 [-0.12 – 0.41]
Hospitalisation admissions (episodes)	0.50 (0.20) (N=336)	0.46 (0.10) (N=369)	0.046 [-0.15 – 0.24]

All data are reported as mean (SD) per facility bed (over one year). * 5% alpha-level.

In this trial, the average cost to the health care provider of integrating an on-site pharmacist in a RACF was $56,286.16 per annum, which equated to an average cost per resident of $622.58. No statistically significant difference was identified across the two arms of the trial in the use of other health care resources. Although there is potential for a reduction in time spent by RACF staff on medication management in RACFs with an integrated pharmacist, the sample of RACFs in the trial that provided data for this parameter was very small (three RACFs in each arm), which meant that detection of a statistical difference in this factor was improbable. Despite the comprehensive collection of data concerning the attendance of residents to emergency departments and hospitalisation admissions over a year (e.g., due to falls, medication incidents, etc.), a statistically significant difference in the use of these resources was not observed in this trial. Therefore, the economic analysis does not apply any cost offsets against the costs of integrating pharmacists into RACFs. The incremental average cost of resources per facility bed over one year was therefore $622.58, which corresponds to the cost of integrating a pharmacist in a RACF (Table 6).

Table 6: Cost of resources (considering those that were significantly different between the two arms of the trial) (per facility bed over one year,)

Resource item	Cost per facility bed*		Difference [95% CI] (Intervention – Control)
	Intervention (PiRACF)	Control (Usual Care)	
On-site pharmacist (SD)	$622.58 (209.92)		$622.58 [428.44 – 816.72]

Notes: *Costs are reported as mean (SD) per facility bed over one year, in 2021 Australian dollars. 95% CI for between group differences are shown within brackets.
There was no statistically significant difference in the utilization of other health care services including: RACF staff time, ambulance services, GRACE services, hospitalisations and ED visits, therefore costs across the two arms for these resources are expected to be equivalent and cancel each other out. They were therefore not included in the analysis shown.

Cost-effectiveness analysis

The incremental cost effectiveness ratio of integrating on-site pharmacists in RACFs was $6,842 per resident avoiding the use of a PIM with a regular administration schedule. Results of the cost–effectiveness analysis is presented in Table 7.

Table 7: Incremental cost-effectiveness analysis for PiRACF compared to usual care over 12 months

	Total costs	Total effect (% prescribed ≥ 1 regular PIM)
Intervention (PiRACF)	$622.58	-9.7%
Control (Usual Care)	0	-0.6%
Increments	$622.58	-9.1%
ICER	$6,842 per resident avoiding the use of a PIM with a regular administration schedule	

Notes: costs are in 2021 Australian dollars. Effects are presented as absolute change between proportions.

Appendix 10. Economic evaluation report *cont.*

Cost consequence analysis

Table 8 and Table 9 summarise the secondary outcomes. There was no statistically significant difference in non-medicine outcomes such as ED visits, hospital admissions, medication incidents, falls and deaths. Secondary outcomes for the intervention group were poorer for non-medicine related variables except for average number of deaths (Table 8), and were better for medicines-related variables except for number of regular medicines per resident and diazepam-equivalent daily dose per resident (Table 9). The medicine-related outcomes did not show a statistically significant difference. However, when an adjusted model was fit to the data, using relative risk ratio and gamma distributed logistic regression as per communication with the clinical trial team, results for mean ACB scale scores and chlorpromazine equivalent daily dose per resident showed a statistically significant difference (p=0.008 and p=0.018, respectively).

Table 8: Summary of consequences: Non-medicine related outcomes in intervention and control facilities (reported in units of average per facility-bed over one year)

Item	Intervention (PiRACF)	Control (Usual Care)	Differences (95% CI) (Intervention – Control)
ED visits (SD)	0.67 (0.29) (N=435)	0.53 (0.11) (N=431)	0.14 [-0.12 - 0.41]
Hospital admissions (SD)	0.50 (0.20) (N=336)	0.46 (0.10) (N=369)	0.05 [-0.15 – 0.24]
Medication incidents (SD)	1.42 (1.86) (N=731)	0.85 (1.21) (N=756)	0.57 [-1.24 – 2.37]
Falls (SD)	2.74 (1.29) (N=1715)	2.08 (1.14) (N=1749)	0.66 [-0.69 – 2.01]
Deaths (SD)	0.20 (0.06) (N=129)	0.22 (0.06) (N=183)	-0.01 [-0.08 - 0.06]

Table 9: Summary of consequences– Medicine related outcomes in control and intervention facilities

Item	Intervention (95% CI)			Control (95% CI)			Difference in changes
	Baseline (N=541)	Endpoint (N=620)	Change	Baseline (N=734)	Endpoint (N=681)	Change	
Proportion (%) of residents prescribed at least one regular antipsychotic or benzodiazepine (SD)	24.6 (43.1)	18.4 (38.8)	-6.2 [-10.94 – 1.46]	25.1 (43.4)	23.8 (42.6)	-1.3 [-5.78 - 3.18]	-4.9 [-12.55 – 2.75]
Mean ACB Scale Score	1.21 (1.66)	0.94 (1.49)	-0.27 [-0.45 - -0.09]	1.21 (1.80)	1.14 (1.66)	-0.07 [-0.25 – 0.11]	-0.2 [-0.45 – 0.05] ◊
Number of regular medicines per resident	10.00 (4.72)	9.64 (4.49)	-0.36 [-0.89 – 0.17]	9.85 (4.93)	9.11 (4.35)	-0.73 [-1.23 - -0.25]	0.37 [-0.35 – 1.09]
Chlorpromazine equivalent daily dose per resident, in mg	12.46 (41.64)	8.64 (32.32)	-3.82 [-8.03 – 0.39]	15.42 (49.89)	15.18 (52.51)	-0.25 [-5.58 – 5.10]	-3.57 [-10.37 – 3.23] ◊
Diazepam equivalent daily dose per resident, in mg	0.77 (2.76)	0.43 (1.73)	-0.34 [-0.60 - -0.08]	0.84 (2.49)	0.48 (1.89)	-0.36 [-0.59 - -0.13]	0.02 [-0.33 – 0.37]
Proportion (%) with complete ADR documentation	95.6 (20.6)	98.2 (13.2)	2.6 [0.63 – 4.57]	97.4 (15.9)	99.1 (9.4)	1.7 [0.32 - 3.08]	0.90 [-2.04 – 3.84]

Note: Proportions presented as % and continuous variables as means. ACB=Anticholinergic Burden, ADR = Adverse Drug Reaction, mg=milligram, PIM = Potentially Inappropriate Medication. ◊ results showed a p value < 0.05 when an adjusted model was fit to the data as per communication with the clinical trial team.

Appendix 10. Economic evaluation report *cont.*

The average cost to the health care provider of integrating an on-site pharmacist in RACFs in this trial was $56,286.18 per RACF per year. A balance sheet comparing the incremental impact of the intervention compared to the control arm, across the disparate secondary outcomes is presented in Table 10.

Table 10: Cost consequence analysis balance sheet of on-site pharmacists in RACFs

In favour of intervention (PiRACF)	In favour of usual care
• Resident's ACB Scale score • Chlorpromazine equivalent daily dose per resident (mg)	
Neither in favour of nor against intervention	
• Number of regular medicines per resident • Proportion (%) of residents prescribed at least one regular antipsychotic or benzodiazepine • Diazepam equivalent daily dose per resident (mg) • ED visits • Hospital admissions • Medication incident reports • Average number of falls per facility bed • Average number of deaths per facility bed • RACF staff time-use • Proportion with complete ADR	

Note: Outcomes in favour of intervention were based on whether the change between baseline and endpoint were statistically significantly better in intervention than in the control group, and vice versa. Outcomes neither in favour of nor against PiRACF are those with no statistically significant difference between intervention and control groups.

Sensitivity analysis

A sensitivity analysis was performed based on the subset of residents who had data both at baseline and at the one-year endpoint to ensure that the conclusions of the analyses presented with the results above are robust. The mean age of the subgroup was 86.7 (SD: 7.96). Baseline characteristics for the subgroup in both arms were similar with respect to gender and Aboriginal and/or Torres Strait Islander status (Table 11). The imbalances observed in the total population (in proportion reporting English as a second language and proportion with a dementia diagnosis) were also observed in the subgroup. Consistent with the analyses shown in the results section, the sensitivity analysis also showed that no statistically significant differences were found between the intervention and control groups for use of ambulance services, GRACE services, ED visits and hospital admissions for the subgroup of residents exposed to the intervention or control for the full year of the trial (Table 12), which indicates that the conclusions based on the results presented in the results section above are robust.

Table 11: Baseline characteristics – subset of residents with full exposure of the trial

Variable	Residents with full exposure of the trial		
	Intervention (PiRACF)	Control (Usual Care)	P value
Residents	383	507	
Age, years (mean, SD)	87.4 (7.41)	86.16 (8.32)	0.02
Gender, n (%)			0.21
Male	115 (30.02)	172 (33.93)	
Female	268 (69.97)	335 (66.07)	
Secondary language, n (%)	61 (15.92) (N=383)	101 (20.12) (N=502)	0.00
Identifies as Aboriginal and/or Torres Strait Islander, n (%)	2(0.53)	3 (0.61)	0.87
Dementia diagnosis, n (%)	214 (55.87)	248 (48.92)	0.04

Note: Percentages represent the proportion of residents with characteristics from among residents for whom there were available data. SD=standard deviation

Table 12: Health service utilisation (average per facility-bed over one year) in the subgroup of residents with full exposure of the trial

Resource item	Intervention (PiRACF)	Control (Usual Care)	Difference [95% CI] (Intervention – Control)
Ambulance service	0.29 (0.12) (N=200)	0.29 (0.09) (N=217)	-0.00 [-0.13 – 0.12]
GRACE service	0.66 (0.47) (N=462)	0.58 (0.57) (N=514)	0.08 [-0.49 – 0.66]
ED visits	0.32 (0.15) (N=211)	0.30 (0.08) (N=235)	0.01 [-0.13 – 0.16]
Hospitalisation admissions	0.25 (0.10) (N=170)	0.26 (0.08) (N=202)	-0.016 [-0.15 – 0.24]

All data are reported as mean (SD) per facility bed (over one year). * 5% alpha-level.

As discussed, only six facilities (three in each of the facilities) provided data on time that RACF staff spent on medication management activities. Missing data for the other nine facilities was imputed using a multiple imputation methodology. A sensitivity analysis that considers a complete case analysis (i.e., based directly on data from the six facilities with complete RACF staff time-use data) was conducted. The results showed that the time RACF staff spent on medication management activities on average per facility-bed (over one year) across the two arms of the trial was not statistically significant (Table 13). This is consistent with the findings presented in the results section (Table 5).

Table 13: Complete case analysis – RACF staff time-use in undertaking the same medication management tasks as the on-site pharmacists (reported in average hours per facility-bed over one year)

RACF staff time-use	Intervention (PiRACF)	Control (Usual Care)	Difference [95% CI] (Intervention – Control)
Base case (multiple imputation method)	64.50 (13.10)	112.77 (81.18)	-48.26 [-116.15 – 19.63]
Sensitivity analysis (complete case analysis, N=6)	54.37 (12.35)	108.32 (75.69)	-53.96 [-227.94 – 120.05]

We also performed a sensitivity analysis around the upper and lower 95% confidence limits of the change in % of residents prescribed at least one PIM and found that the ICER ranged between $5,145 to $10,307 per residents avoiding the use of a regular PIM (Table 14).

Table 14: Sensitivity analysis – ICER per resident avoiding the use of a regular PIM – applying upper and lower bound of primary outcome

	Change in % of residents prescribed at least one PIM			ICER – Upper bound	ICER – Lower bound
	Base case	Upper bound	Lower bound		
Sensitivity analysis - ICER	9.1%	12.1%	6.0%	$5,145	$10,307

Discussion

We evaluated the economic implication of integrating a pharmacist to the RACF team using costs and effectiveness data from RACF facilities and their residents enrolled in the PiRACF cluster randomised controlled trial. Our results demonstrated that the ICER associated with integrating an on-site pharmacist at a residential aged care facility (RACF) was $6,842 per residents avoiding prescribed administration of at least one PIM on a regular basis. Although there is the potential for some cost offsets against the costs of the pharmacist integration by savings in time RACF staff spend on medication management tasks, the difference between intervention and control groups was not statistically significant in this trial.

Our results also showed that while there was evidence of a statistically significant reduction in regular PIM prescription, there was no evidence for the difference in clinical outcomes of RACF residents. That is, the observed reduction in PIMs prescribed on a regular basis did not translate into statistically significant improvements in health care resource utilisation. Indeed, this finding reflects the ambiguity that exists in the literature with respect to implications of PIMs. For example, two prospective cohort studies have reported that PIMs were associated with increased health care usage, increased ADRs, and diminished quality of life (4, 36); whereas a systematic review reported the size magnitude of these effects to be inconclusive (5).

Our observation that integrating pharmacists to RACFs costed $6,842 per resident avoiding the use of a PIM can be considered alongside the findings reported by Gillespie et al (2017)(37). The cost-effectiveness analysis conducted alongside a cRCT reported by Gillespie et al (2017) estimated that the cost of a multifaceted intervention in primary care was €1,269 (equivalent to

$2,380.52 in 2021 Australian dollars[3]) [95 % CI, −1400–6302] per prescription of a PIM avoided (37). Compared with usual care (control), the intervention which included a pharmacist review and educational material was associated with a cost of €407 (equivalent to $763.49 in 2021 Australian dollars[3]) [95 % CI, −357–1170) and reduction in PIMs of 0.379 [95% CI, 0.092–0.666]. Results from the PiRACF trial and the results reported by Gillespie et al (2017) are not directly comparable because the same metrics were not used as the denominator in the calculation of the ICER – whereas the denominator in the ICER reported by Gillespie et al (2017) was number of prescriptions for PIMs, the denominator (and primary outcome assessed) in the PiRACF trial was proportion of residents with at least one prescription of a PIM with a regular dosing schedule. However, both studies found that pharmacist interventions result in increased but also demonstrated a general reduction in prescription of PIMs.

Results from the PiRACF trial contrast with results of other economic evaluation studies that reported findings in cost per QALY gained (38-40). Several other studies showed that pharmacist review interventions (not necessarily integration of pharmacists in RACFs) dominated (i.e., were cost saving) compared to usual care (41, 42). A meta-analysis in 2019, that included 52 studies, showed that pharmacist-led services reduced the mean number of falls (-0.50; 95%CI: -0.79 to -0.21) among residents in nursing home. Mixed results were noted on the impact of pharmacists' services on mortality, hospitalisation and admission rates among residents. Modest cost savings were also noted due to a reduction in medication bills (43).

Although the ICER estimated and reported above is based on the primary outcome of the Pharmacist Integrated in Residential Aged Care Facility (PiRACF) trial, the ICER is difficult to interpret in the absence of knowing the impact of avoiding administration of at least one PIM regularly means for a resident. Interpretation is further complicated by the absence of a cost effectiveness threshold in relation to a resident avoiding use of a regular PIM. As such, it is difficult to determine if this ICER of $6,842 per PIM avoided can be considered cost effective or good value from an economic point of view. It is recommended that future studies include rigorous capture of time spent on medication management by RACF staff and that they elicit the impact of avoiding the regular use of a PIM on patient outcomes such as quality of life. From such data, quality adjusted life years (QALYs) can be calculated and whether integrating an on-site pharmacist in RACFs can be considered cost effective more readily determined.

Stakeholders with an interest the planning and delivery of medication management in RACFs may prefer to consider the impact on the secondary outcomes in addition to the primary outcome. The cost-consequence analysis displays the impact of the intervention on the disparate secondary outcomes which included non-medicine related outcomes such as hospital and ED presentations at the facility-bed level, and medicine-related indicators at the resident level. A summary of outcomes that were either in favour of the intervention or the usual care was provided in the CCA balance sheet.

Reporting the outcomes in a disaggregated fashion, including those where it might not be possible to quantify the scale of the effect, allows stakeholders to identify costs and benefits that they are likely to accrue and plan appropriately and, more importantly, put in place monitoring systems that can detect whether the benefits of an on-site pharmacist are being realized in practice. This disaggregated approach to evaluation might also provide information on how on-site pharmacists can contribute to meeting specific priorities or addressing inequalities within a population (e.g. reduction in avoidable hospitalisation and ED visits). On this basis, the CCA is expected to be an attractive form of evaluation in public health settings and resonate with a broader range of stakeholders (44).

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[3] Converted into 2021 Australian dollars using cost converter by Campbell and Cochrane Economics Methods Group (CCEMG) and the Evidence for Policy and Practice Information and Coordinating Centre (EPPI-Centre), https://eppi.ioe.ac.uk/costconversion/default.aspx.

Limitations

There are several limitations to consider when interpreting our results. First, we used an indicator of regular use of a PIM as a proxy for improved medication management for aged care facility residents. However, a change in proportion of residents on regular PIMs is unlikely to be as clinically important to policymakers as endpoints that clearly have an impact on residents' quality of life such as avoided hospitalisations, avoided falls, etc. An increase in residents not being prescribed regular PIMs may not always have a positive impact on a residents' quality of life. For example, if residents previously prescribed a PIM for regular administration (e.g., three times daily) and are switched to be prescribed the drug on an as needed basis such that residents may take more or less than is ideal for the resident. Nevertheless, several other studies have assessed the association between the reduction in regular prescribing of PIMs and quality use of medicines (45-48).

Given the ICER reported may be difficult to interpret as it requires an understanding of the impact of avoiding administration of at least one PIM regularly for a resident. Interpretation is further complicated by the absence of a cost effectiveness threshold in relation to a resident avoiding use of a regular PIM. As such, it is difficult to determine if an ICER of $6,842 per PIM avoided can be considered cost effective or good value from an economic point of view. From such data, quality adjusted life years (QALYs) can be calculated and whether integrating an on-site pharmacist in RACFs can be considered cost effective more readily determined. It is recommended that future studies include rigorous capture of time spent on medication management by RACF staff and that they elicit the impact of avoiding the regular use of a PIM on resident-relevant outcomes such as quality of life.

Second, our observations are limited to a 12-month time period; therefore the long-term cost-effectiveness of integrating pharmacists to RACFs remains unclear. In practice, it is possible that RACFs with on-site pharmacists would have ongoing assessments and improvements in PIMs prescription and other quality use of medication. By contrast, previous studies have shown that, in the absence of ongoing care and interdisciplinary support, quality use of medicine tended to remain suboptimal or continue to deteriorate over time in elderly patients with multiple morbidity conditions. Third, we based our economic analysis on 1668 residents with various exposure times of the trial (58% exposed for the full 12 months and 22.4% had less than 6 months exposure to the study). We believe that using an average based on facility beds, as done in this study, would provide a more stable estimate, given the fluctuations of resident numbers in RACFs over one year due to events such as discharge and deaths. Last, these are within-trial economic analyses where the wider generalisability may not be applicable in normal settings. For instance, the number of residents in one setting may not be sufficient to justify an on-site pharmacist and thus require consideration of the additional costs required to travel to multiple locations.

Conclusion

The economic analysis suggests that integrating an on-site pharmacist to RACFs was more costly but more effective in terms of improving quality use of medicine in RACFs compared to the control – at least when considering the deprescribing of regular PIMs over a 12-month time horizon. However, the economic evaluation did not show a statistically significant improvement in clinical outcomes of RACF residents who received additional care from an on-site pharmacist.

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Appendix 10. Economic evaluation report *cont.*

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Appendix 10. Economic evaluation report *cont.*

Appendix

The Consolidated Health Economic Evaluation Reporting Standards (CHEERS) checklist

Table 15: CHEERS 2022 Checklist (18)

Topic	No.	Item	Location where item is reported
Title and abstract			
Title	1	Identify the study as an economic evaluation and specify the interventions being compared.	Page 1
Abstract	2	Provide a structured summary that highlights context, key methods, results, and alternative analyses.	na
Introduction			
Background and objectives	3	Give the context for the study, the study question, and its practical relevance for decision making in policy or practice.	Page 6
Methods			
Health economic analysis plan	4	Indicate whether a health economic analysis plan was developed and where available.	Page 8
Study population	5	Describe characteristics of the study population (such as age range, demographics, socioeconomic, or clinical characteristics).	Page 7
Setting and location	6	Provide relevant contextual information that may influence findings.	Page 7
Comparators	7	Describe the interventions or strategies being compared and why chosen.	Page 6, 7
Perspective	8	State the perspective(s) adopted by the study and why chosen.	Page 7, 8, 12
Time horizon	9	State the time horizon for the study and why appropriate.	Page 7
Discount rate	10	Report the discount rate(s) and reason chosen.	Page 9
Selection of outcomes	11	Describe what outcomes were used as the measure(s) of benefit(s) and harm(s).	Page 8-9
Measurement of outcomes	12	Describe how outcomes used to capture benefit(s) and harm(s) were measured.	Page 8-10
Valuation of outcomes	13	Describe the population and methods used to measure and value outcomes.	Page 8-10
Measurement and valuation of resources and costs	14	Describe how costs were valued.	Page 10
Currency, price date, and conversion	15	Report the dates of the estimated resource quantities and unit costs, plus the currency and year of conversion.	Page 9
Rationale and description of model	16	If modelling is used, describe in detail and why used. Report if the model is publicly available and where it can be accessed.	na
Analytics and assumptions	17	Describe any methods for analysing or statistically transforming data, any extrapolation methods, and approaches for validating any model used.	na

Topic	No.	Item	Location where item is reported
Characterising heterogeneity	18	Describe any methods used for estimating how the results of the study vary for subgroups.	Page 12
Characterising distributional effects	19	Describe how impacts are distributed across different individuals or adjustments made to reflect priority populations.	Page 19-21
Characterising uncertainty	20	Describe methods to characterise any sources of uncertainty in the analysis.	Page 19-21
Approach to engagement with patients and others affected by the study	21	Describe any approaches to engage patients or service recipients, the general public, communities, or stakeholders (such as clinicians or payers) in the design of the study.	na
Results			
Study parameters	22	Report all analytic inputs (such as values, ranges, references) including uncertainty or distributional assumptions.	Page 13
Summary of main results	23	Report the mean values for the main categories of costs and outcomes of interest and summarise them in the most appropriate overall measure.	Page 13-14
Effect of uncertainty	24	Describe how uncertainty about analytic judgments, inputs, or projections affect findings. Report the effect of choice of discount rate and time horizon, if applicable.	Page 19-2
Effect of engagement with patients and others affected by the study	25	Report on any difference patient/service recipient, general public, community, or stakeholder involvement made to the approach or findings of the study	na
Discussion			
Study findings, limitations, generalisability, and current knowledge	26	Report key findings, limitations, ethical or equity considerations not captured, and how these could affect patients, policy, or practice.	Page 21-23
Other relevant information			
Source of funding	27	Describe how the study was funded and any role of the funder in the identification, design, conduct, and reporting of the analysis	na
Conflicts of interest	28	Report authors conflicts of interest according to journal or International Committee of Medical Journal Editors requirements.	na

APPENDIX 11. REVISED SERVICE MODEL DOCUMENTS

Appendix 11.1 Position description

The pharmacist will work under the general direction of the Residential Aged Care Facility (RACF), clinical or care manager and will collaborate with RACF staff, GPs and prescribers (nurse practitioners, geriatricians, and specialists), health care professionals, and community and hospital pharmacists.

Pharmacists will conduct activities within their scope of practice as a registered pharmacist and relevant to the clinical pharmacist role to improve the quality use of medicines and resident-centred care.

Duties

The pharmacist's duties will include:

- conducting clinical audits to identify residents most at risk of medication related problems and hospitalisations
- assessing and advising on resident's medication management
- liaising with residents, families and carers, RACF staff, GPs and prescribers (nurse practitioners, geriatricians, and other specialists), dietitians, speech pathologists, occupational therapists, and community and hospital pharmacists to coordinate medication-related issues
- participating in multidisciplinary case conferences
- improving resident's clinical documentation
- providing medication reconciliation at transition of care
- providing education to staff on medications management, including assessing medication administration competencies
- contributing to and improving medication management policies and procedures
- participating in relevant committees including Medication Advisory Committee
- reviewing and optimising medication rounds
- conducting and coordinating vaccinations.

Rate of pay — $50 per hour

Hours of work — 0.4 FTE 2 days a week /0.5 FTE 2.5 days a week (based on 7.5 hour working day)

Appendix 11.2 Pharmacist's activities and orientation checklist for RACFs and OSPs to use to integrate the pharmacist into the facility

This document outlines:

- the activities that on-site pharmacists conduct in residential aged care facilities
- a checklist of ways to integrate the pharmacist into the residential aged care facility.

Activities that on-site pharmacists conduct in residential aged care facilities

Medication reviews
Review medications, screen for PIMs, communicate with prescriber, follow up and keep notes, at these time points:
• Upon resident's admission to RACF
• After a resident returns from ED or hospital, after being prescribed new medication and after referral to palliative care
• At regular intervals
• When a resident is identified at a clinical meeting to have deteriorating health
• When a resident is referred to palliative care
• When a resident has a fall or experiences frequent falls
• When a medication causes adverse effects or symptoms
• If a resident, family member or carer requests a medication review
• When a speech pathologist identifies the need for medication dose form modification for a resident
Clinical audits
Conduct clinical audits to identify residents most at risk of medication related problems and hospitalisations, on the following classes of medications:
• PIMs
• Anticoagulants (due to falls risk, to ensure dose is adjusted according to renal function, for residents taking aspirin, and for other indications)
• Polypharmacy audit report (also to identify falls risk)
• PPI — in particular high dose PPI
• Antimicrobial audit (for reporting, to ensure there is supporting indication including pathology, to check dose and duration of treatment, to check renal function, NAPS survey benchmarking)
• PRN usage (e.g. past 4 months)
• Opioids
• Insulin administration
• Prolia audit (including timing, and supporting blood tests)
• Non-packed medication
• Medication storage
• Medication chart
• Expiry date audit
• Chart audits to ensure diagnoses and ADR are up to date
Medication round optimisation
Observe medication rounds and dose-form modification (crushing) to identify potential problems, and:
• Take action to address problem in a collaborative manner
• Provide education to staff
• Develop relevant procedures and checklists (such as trolley check)

Appendix 11.2. Pharmacist's activities and orientation checklist for RACFs and OSPs to use to integrate the pharmacist into the facility *cont.*

Activities that on-site pharmacists conduct in residential aged care facilities *cont.*

Education
Conduct ad-hoc and regular, planned education with group and individual RACF staff, residents and carers, for example:
• Insulin and diabetes management
• Psychotropics and chemical restraints
• S8 medicines, including legislation
• Inhaler and eye drop administration and storage
• Cytotoxic medications and handling
• Medication administration competencies
Educate residents on their medications and what they are for
Quality improvement
Review and improve medication management policies and procedures including:
• Update medication management policies and procedures
• Ensure S8 medicines are used, stored and disposed of according to legislation
• Attend and take an active role in MAC meetings
• Set up processes to review new admissions and transitions of care
• Ensure the on-site pharmacist is added to the clinical team email list
Other activities
Conduct other relevant medication management activities, including:
• Participate in case conferences with GPs
• Have on-site discussions with GPs/prescribers when medicines are changed
• Establish relationships with GPs — make an appointment to meet and be introduced to all GPs
• Assist with COVID vaccines, antiviral supply and education
• Liaise with hospital and community pharmacists
• Liaise with pharmaceutical manufacturers
• Assist RNs with S8 destruction

The following actions have been identified as ways that on-site pharmacists can embed themselves into clinical governance processes in the facility. An orientation checklist (see below) has been developed to facilitate this.

Upon commencement in RACFS, and in an ongoing way, the on-site pharmacist should:

- proactively build relationships with GPs and prescribers and outline their role by: attending Dr rounds or making a time to meet or talk with GP and prescribers
- attend and actively participate in MAC meetings
- attend clinical meetings (e.g. weekly) and follow up on residents with declining health or who have returned from ED or hospital
- proactively talk to RACF managers and staff about medication management activities that the on-site pharmacist can help with (e.g. announcements at staff and clinical meetings as well as emails)
- work closely with clinical care managers
- proactively build relationships with staff

These actions have been identified for RACF managers and staff to integrate the on-site pharmacist into the workflow in the facility:

- facilitate the on-site pharmacist to attend relevant committees (e.g. MAC, quality, falls, Antimicrobial Stewardship)
- invite the on-site pharmacist to attend clinical meetings and include them in clinical email lists and notifications
- give the on-site pharmacist a specific time to present on medicine management topics at clinical and staff meetings
- encourage staff to attend education sessions run by the on-site pharmacist
- give the on-site pharmacist space to contribute to resident newsletters to outline what they can assist with and how to contact them
- involve the on-site pharmacist in assessing staff medication competencies assessment and education
- involve pharmacists to review and address medication incidents and provide necessary education
- seek systematic ways to involve the on-site pharmacist in reviewing resident's medications at transitions of care, such as when a resident enters the facility, returns from ED or hospital, or commences palliative care

Appendix 11.2. Pharmacist's activities and orientation checklist for RACFs and OSPs to use to integrate the pharmacist into the facility *cont.*

RACF study orientation checklist

Upon commencement in RACFs, the on-site pharmacist and facility manager should go through this check-list to embed the pharmacist into the facility.

Checked	Item	Comments
☐	Ensure the on-site pharmacist completes the facility's induction processes	
☐	Identify who the on-site pharmacist's line manager is and discuss preferred communication processes e.g. weekly face to face meeting, email	
☐	Go through the pharmacist's activities (see pages 1 to 3) and identify priority activities for the facility	
☐	Introduce the on-site pharmacist to residents, families and carers: • Send the Introduction to residents, families and carers • Invite the on-site pharmacist to attend residents and families meetings • Invite the on-site pharmacist to contribute an article to the residents and families newsletter	
☐	Introduce the pharmacist to facility staff, including care managers, RNs, ENs, Care staff: • Introduce the on-site pharmacist to facility staff at clinical and staff meetings • Discuss the activities the on-site pharmacist will be conducting in the facility • Send the Introduction to RACF managers and facility staff template	
☐	Introduce the pharmacist to clinical staff and discuss how the on-site pharmacist can collaborate with them, including: • GPs • Geriatricians and specialists • Community/supply pharmacist • Nurse practitioners • Specialist palliative care team • GRACE team • Other relevant health care professionals such as dietitians, occupational therapists, speech pathologists, occupational therapists. • Provide the pharmacist with contact details for GPs • Introduce the pharmacist to GPs and prescribers when they visit the facility • Invite the on-site pharmacist to attend resident's Case Conferences • Send the Introduction to GPs, prescribers and health care professionals template	
☐	Invite the on-site pharmacist to attend and actively contribute to clinical governance at the facility, including: • Medication Advisory Committee • Relevant meetings including falls, medication incidents, and Quality and Safety, and Anti-Microbial Stewardship • Hand over and clinical meetings	

RACF study orientation checklist *cont.*

Checked	Item	Comments
☐	Involve the pharmacist in reviewing and improving medication management policies and procedures including: • ensuring relevant jurisdictional policies are followed • updating resident's clinical documentation including allergies, adverse drug reactions and diagnoses	
☐	• Invite the pharmacist to develop systems to review resident's medications at transitions of care such as when residents enter the facility, after an Emergency Department or hospital admission, when a resident has declining health, or admission to palliative care	
☐	• Identify priorities for regular individual and group education sessions around medication management for new and existing staff and encourage staff to attend these • Involve the pharmacist in assessing staff medication administration competencies	
☐	• Invite the pharmacist to observe medication administration rounds and advise on ways to improve efficiencies	
☐	• Discuss vaccination processes and how the pharmacist can conduct or contribute to improving these	
☐	Ensure the pharmacist has access to facility information systems, including: • resident records • medication charts • My Health Records • Email • access to a computer • eMIMS or similar resources	

Appendix 11.3 Introduction to residential aged care staff

Dear Residential aged care staff

Re: Integrating on-site pharmacists into Residential Aged Care

This facility is participating in a program to integrate on-site pharmacists into residential aged care. Registered pharmacists are employed to work with facility staff to improve resident centred care. On-site pharmacists work collaboratively with facility staff as well as residents, families, carers, GPs and health care professionals who are involved with resident's care.

On-site pharmacists will be registered and will work within their recognised scope of practice. They have undertaken training in the aged care clinical context, and will make recommendations using evidence-based tools to improve medicine management for residents.

Activities that pharmacists can assist staff with include:

- Conduct clinical audits to identify residents most at risk of medication related problems and hospitalisations
- Assessing and advising on resident's medication management
- Liaising with GPs and prescribers (nurse practitioners, geriatricians, and other specialists), dietitians, speech pathologists, occupational therapists, and community and hospital pharmacists to coordinate medication-related issues
- Participating in multidisciplinary case conferences
- Improving resident's clinical documentation
- Medication reconciliation at transition of care
- Providing education to staff on medications management, including assessing medication administration competencies
- Contributing to medication management policies and procedures
- Reviewing and optimising medication rounds
- Contributing to medication management policies and procedures
- Conducting and coordinating vaccinations

See Orientation document to assist you with integrating pharmacists into your facility.

The name of the on-site pharmacist is:

.....

Contact details are:

.....

Days and hours of work:

.....

Appendix 11.4 Introduction to GPs, prescribers (nurse practitioners, geriatricians and specialists), and health care professionals

Dear GPs, prescribers (nurse practitioners, geriatricians and specialists), and health care professionals

Re: Integrating on-site pharmacists into Residential Aged Care

This facility is participating in a program to integrate on-site pharmacists into residential aged care. Registered pharmacists are employed to work with facility staff to improve resident centred care. On-site pharmacists work collaboratively with facility staff as well as residents, families, carers, GPs and health care professionals who are involved with resident's care.

On-site pharmacists will be registered and will work within their recognised scope of practice. They have undertaken training in the aged care clinical context, and will make recommendations using evidence-based tools to improve medicine management for residents.

Activities that pharmacists can assist with:

- Conduct clinical audits to identify residents most at risk of medication related problems and hospitalisations
- Assessing and advising on resident's medication management
- Liaising with GPs and prescribers (nurse practitioners, geriatricians, and other specialists), dietitians, speech pathologists, occupational therapists, and community and hospital pharmacists to coordinate medication-related issues
- Participating in multidisciplinary case conferences
- Improving resident's clinical documentation
- Providing education to staff on medications management
- Contributing to medication management policies and procedures in facilities
- Conducting and coordinating vaccinations

The on-site pharmacist may contact you to discuss resident's medications management related issues. We invite you to work collaboratively with the on-site pharmacist.

The name of the on-site pharmacist is:

.....

Contact details are:

.....

Days and hours of work:

.....

Appendix 11.5 Introduction to residents, families, and carers

Dear Residents, families and carers

Re: Integrating on-site pharmacists into Residential Aged Care

This facility is participating in a program to integrate on-site pharmacists into residential aged care. Registered pharmacists are employed to work with facility staff in improving medication management and resident centred care. On-site pharmacists work collaboratively with residents, families, carers as well as facility staff, GPs and health care professionals who are involved with resident's care.

On-site pharmacists will be registered and will work within their recognised scope of practice. They have undertaken training in the aged care clinical context, and will make recommendations using evidence-based tools to improve medicine management for residents.

Residents, family members and carers may be invited to discuss medications with the on-site pharmacist. You are welcome to contact the on-site pharmacist and discuss any questions or queries you may have about your medications and how to take them.

The name of the on-site pharmacist is:

.....

Contact details are:

.....

Days and hours of work:

.....

NOTES

Canberra ACT 2601 Australia
T +61 2 6201 5111

canberra.edu.au