Impact of a pharmacist-prepared interim residential care medication administration chart on gaps in continuity of medication management after discharge from hospital to residential care: a prospective pre- and post-intervention study (MedGap Study)

Rohan A Elliott,1,2 Tim Tran,1 Simone E Taylor,1 Penelope A Harvey,3 Mary K Belfrage,4 Rhonda J Jennings,3 Jennifer L Marriott2

ABSTRACT

Objectives: To test the impact of a hospital pharmacist-prepared interim residential care medication administration chart (IRCMAC) on medication administration errors and use of locum medical services after discharge from hospital to residential care.

Design: Prospective pre-intervention and post-intervention study.

Setting: One major acute care hospital and one subacute aged-care hospital; 128 residential care facilities (RCF) in Victoria, Australia.

Participants: 428 patients (median age 84 years, IQR 79–88) discharged to a RCF from an inpatient ward over two 12-week periods.

Intervention: Seven-day IRCMAC auto-populated with patient and medication data from the hospitals’ pharmacy dispensing software, completed and signed by a hospital pharmacist and sent with the patient to the RCF.

Primary and secondary outcome measures: Primary end points were the proportion of patients with one or more missed or significantly delayed (>50% of prescribed dose interval) medication doses, and the proportion of patients whose RCF medication chart was written by a locum doctor, in the 24 h after discharge. Secondary end points included RCF staff and general practitioners’ opinions about the IRCMAC.

Results: The number of patients who experienced one or more missed or delayed doses fell from 37/202 (18.3%) to 6/226 (2.7%) (difference in percentages 15.6%, 95% CI 9.5% to 21.9%, p<0.001). The number of patients whose RCF medication chart was written by a locum doctor fell from 66/202 (32.7%) to 25/226 (11.1%) (difference in percentages 21.6%, 95% CI 13.5% to 29.7%, p<0.001). For 189/226 (83.6%) discharges, RCF staff reported that the IRCMAC improved continuity of care, and primary care doctors reported that it reduced pressure on them to attend RCFs at short notice.

Conclusions: A hospital pharmacist-prepared IRCMAC significantly reduced medication errors and
**ARTICLE SUMMARY**

**Strengths and limitations of this study**
- This is the first study to evaluate the impact of a hospital-provided IRCMAC on medication errors or use of locum medical services. Strengths were that the two study groups were well matched in terms of demographics, ward type, number of medications and number of RCFs.
- The main limitations were the use of a pre-intervention and post-intervention study design and data collection via RCF staff telephone interview. However, quantitative data on medication errors and use of locum services were validated by strongly positive feedback from RCF staff and doctors and widespread uptake and ongoing use of the IRCMAC.

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**INTRODUCTION**

Continuity of medication management is often compromised when patients are discharged from hospitals to residential care facilities (RCF) such as ‘nursing homes’ and ‘care homes’.1–8 Missed, delayed or incorrect medication administration is common.

Patients discharged to RCFs have complex and intensive medication needs.1 An Australian study reported that patients discharged to RCFs were prescribed an average of 11 medications of which seven were new or had been modified during hospitalisation.2 The median time between arrival at the RCF and the first scheduled medication dose was 3 h and ‘when required’ (prn) medications were sometimes needed sooner.2

In a study conducted in the USA, most patients transferred to a RCF had one or more medication doses missed; on average, 3.4 medications per patient were omitted or delayed for an average of 12.5 h.2 In another US study, medication discrepancies related to transfers to and from hospitals and RCFs resulted in adverse drug events in 20% patients.7 In an analysis of medication incidents that resulted in patient harm in Canadian long-term care facilities, patient transfer was identified as a common factor.8

Australian studies report that up to 23% of patients experience delays or errors in medication administration after discharge from hospital to a RCF.2 3 9 A key reason is difficulty accessing primary care doctors (general practitioners (GPs)) at short notice to write or update RCF medication charts.2 3 10

Delays in obtaining an up-to-date medication chart can range from a few hours up to several days.2 10 11 In the absence of an up-to-date medication chart, RCF staff may withhold medications, administer them without a current medication chart or revert to pre-hospitalisation medication regimens.2 11 The clinical significance of delays or errors in medication administration depends on the clinical status of the patient, the nature of the medications involved and the length of the delay. In some cases, no adverse event occurs. However, delays in access to medications for symptom control (eg, analgesics and medications for terminal care) can adversely impact on quality of life, and delays or errors with regularly scheduled medications (eg, anti-epileptics and antibiotics) may have serious consequences.11 Unplanned hospital readmissions have been reported as a result of failure to receive prescribed medications after transfer to a RCF.11 When the patient’s GP is unable to attend, a locum medical service may be called to write the RCF medication chart; however, this does not eliminate missed doses and errors, and it adds significantly to the cost of care.2

When GPs (or locums) write RCF medication charts, they often do not have access to accurate discharge medication information.2 3 9 12 Medication changes made in hospital are frequently not explained in medical discharge summaries, and discrepancies between discharge summaries and discharge prescriptions occur in up to 80% of cases.2 9 12–15

Some Australian hospitals have attempted to improve continuity of medication management by providing 5- or 7-day interim residential care medication administration charts (IRCMACs) on discharge. These charts enable medications to be safely administered upon arrival at the RCF, without the need for urgent GP or locum attendance. They enable the GP to attend the RCF and review the patient at a clinically appropriate time, a few days after discharge, rather than on the day of hospital discharge. Use of IRCMACs is not widespread, and where they have been used, there has been no evaluation of their impact on medication administration or use of locum medical services. Most Australian hospitals do not use electronic prescribing systems and, based on anecdotal experience, expecting hospital doctors to prepare handwritten interim medication charts at the point of discharge is not a reliable, safe or sustainable method for providing IRCMACs. This is because it relies on hospital doctors remembering to write the chart, it introduces risk of discrepancies between the IRCMAC and the discharge prescription(s) and it adds to hospital doctors’ workload.

For this study, a novel method for preparing IRCMACs was developed. IRCMACs were generated via hospital pharmacy dispensing software during the processing of discharge prescriptions, with auto-population of the chart with patient, prescriber and medication data (name, strength and directions). This occurred after the discharge prescription had been reviewed by a pharmacist (including reconciliation with pre-admission medications and inpatient medication charts) and errors corrected. This method was chosen to avoid the need for manual transcription, minimise additional workload and ensure the IRCMAC and discharge medications were concordant. An additional novel aspect, designed to address gaps in provision of discharge medication...
information, was inclusion of the ‘change status’ for each medication (unchanged, new or dose changed, with date and reason for change if known to the pharmacist), a list of medications ceased (with the date and reason, if known) and time of last dose given in hospital for each medication. These details were manually added by the pharmacist.

The aim of this study was to evaluate the impact of the hospital pharmacist-prepared IRCMAC on continuity of medication administration and use of locum medical services following discharge to RCFs.

METHODS

A prospective pre-intervention and post-intervention study was undertaken at a 400-bed acute care hospital and an 80-bed subacute aged care (geriatric assessment and rehabilitation) hospital within a major metropolitan public health service in Melbourne, Australia, over two 12-week periods (January to April and September to November 2009). A detailed analysis of the baseline (pre-intervention) data has been previously published; this paper compares post-implementation data with that baseline data. The study was approved by the Austin Health and Monash University Human Research Ethics Committees.

Patients were eligible for inclusion if they were discharged to a RCF following an overnight stay on an inpatient ward. Exclusion criteria were discharge under the Transition Care Programme (a hospital-managed short-term residential care programme) or returning to an RCF with no medication changes made in hospital.

During the pre-intervention (control) period, no IRCMAC was provided. The hospitals’ discharge policy included provision of at least 7 days supply of all prescribed medications for patients discharged to a new RCF or new and changed medications for patients returning to a RCF, dispensed in original packaging. A photocopy of the discharge prescription(s) was provided in the bag of medications.

During the post-intervention period, a 7-day IRCMAC was prepared by a hospital pharmacist. The IRCMAC and a photocopy of the discharge prescription(s) were placed in a transparent red plastic sleeve along with instructions for using the IRCMAC. The red sleeve was placed in a clear plastic bag with the discharge medications and transported with the patient. The pharmacist telephoned the RCF prior to discharge to notify them that an IRCMAC would be provided. No other discharge procedures were changed.

Prior to implementation of the IRCMAC, stakeholders including hospital and RCF staff, GPs and regulatory, professional and accreditation organisations were consulted (appendix 1). They provided input into the design of the IRCMAC and procedures for its preparation and use. All pharmacists involved in hospital discharge management received training in IRCMAC preparation. A standard operating procedure for use of the IRCMAC at RCFs was mailed to all RCFs that accepted patients from the health service during the pre-intervention study period.

Data collection

Data collection methods have been described in detail previously. Briefly, a structured telephone interview was conducted with a RCF staff member responsible for managing the patient’s medications using a pre-piloted questionnaire. Interviews were conducted approximately 24 h after discharge. In the post-intervention period, for logistical reasons, interviews were not conducted on weekends; therefore, interviews for Friday and Saturday discharges occurred 48–72 h after discharge. Data collected included time of arrival at the RCF, whether the RCF medication chart had been written/updated in time for the first dose of regularly scheduled medication, who wrote/updated the chart (if written) and whether any doses had been missed or delayed since the resident arrived (and if so, the medication name and length of delay). In the post-intervention period, additional questions were asked, including whether an IRCMAC was received, whether it was used to record medication administration and whether the RCF staff member felt that the IRCMAC improved the medication transfer process. Also in the post-intervention period, a second structured telephone interview was performed on day 8 post-discharge if the patient had not had their RCF medication chart written/updated at the time of the initial interview (to determine who wrote/updated the RCF medication chart and whether the IRCMAC avoided or merely delayed locum doctor attendance).

To assess GP satisfaction with the IRCMAC, a four-item questionnaire was mailed to the GPs of patients who had been provided with an IRCMAC during the last 4 weeks of the post-intervention period, along with a pre-addressed reply-paid envelope. There was no follow-up of non-responders.

Primary end points were the proportion of patients who experienced one or more missed or significantly delayed medication doses, and the proportion of patients whose RCF medication chart was written/updated by a locum doctor, in the 24 h after discharge. Missed or significantly delayed doses were defined as regularly scheduled medication dose completely omitted, regularly scheduled medication dose delayed by more than 50% of the prescribed dose interval or ‘when required’ (prn) medication delayed by any length of time if it was required by the patient.

Secondary end points were the proportion of patients for whom a ‘workaround’ was used by RCF staff to avoid a delayed or missed dose when an updated medication chart was not available and RCF staff and GP satisfaction. A ‘workaround’ was defined as any action taken by RCF staff that was not usual practice for medication administration at the RCF (eg, using a copy of a hospital inpatient medication chart or administering medications without a medication chart).

The minimum sample size required was 112 patients per group, based on a predicted reduction in the
incidence of missed or delayed doses from 25% to 10% (power 80%, level of significance 0.05, two sided). Statistical analysis was performed using SPSS V.19.0 (IBM SPSS Statistics). The χ² test was used to compare categorical data and Mann–Whitney U test for all other (non-parametric) data.

RESULTS

Of 593 patients discharged to a RCF, 428 met the inclusion criteria and had a post-discharge RCF staff interview completed (figure 1).

There were no significant differences between the pre-intervention and post-intervention groups in terms of age, gender, length of hospital stay, number of medications, level of residential care or time from discharge to first scheduled dose (table 1). The distribution of patients across RCFs was similar in the two study periods, with a median of two patients discharged to each RCF in both periods (figure 1).

In the pre-intervention period, 75 medications for 37 (18.3%) patients had one or more doses missed or significantly delayed within 24 h of discharge from hospital. Following implementation of the IRCMAC, nine medications for six (2.7%) patients were missed or delayed (difference in percentages 15.6%, 95% CI 9.5% to 21.9%, p<0.001). Missed doses accounted for most medication administration errors: 70 (93%) pre-intervention and 9 (100%) post-intervention.

The number of RCF medication charts written or updated by a locum medical service within 24 h of discharge declined following implementation of the IRCMAC, from 66 (32.7%) to 25 (11.1%) (difference in percentages 21.6%, 95% CI 13.5% to 29.7%, p<0.001). Day 8 telephone interviews identified only one additional patient whose RCF medication chart was subsequently written/updated by a locum medical service.

One hundred and seventy-five (77.4%) patients in the post-intervention period did not have their RCF long-term medication chart written/updated by a GP or locum service in time for their first scheduled dose. In 147 (84%) of these cases, the RCF received and used the IRCMAC, 20 (11%) received but did not use the IRCMAC and eight (5%) did not receive the IRCMAC. The number of patients for whom a ‘work-around’ was used to avoid a missed or delayed dose fell following implementation of the IRCMAC, from 90 (44.6%) to 22 (9.7%) (p<0.001).

For 189 (83.6%) discharges, the interviewed RCF staff member reported that the IRCMAC improved continuity of medication management, and in 139 (61.5%) cases, the information about medication changes was useful. Questionnaires were sent to 84 GPs. Four were returned as the GP was no longer managing the resident’s care and 35 were completed (response rate 43.8%). Thirty-one (88.6%) GPs reported that provision of an IRCMAC reduced urgency to attend the RCF after patients were discharged.
discharged from the hospital, 35 (100%) said they were comfortable with a hospital-provided IRCMAC being used at the RCF for up to 7 days until they reviewed the patient, 34 (97.1%) reported that ‘Change status’ and ‘Medications ceased’ sections on the IRCMAC were helpful, and 35 (100%) agreed that provision of an IRCMAC should be standard practice for all patients discharged from hospital to a RCF. Examples of comments from RCF staff and GPs are provided in table 2, categorised by theme.

**DISCUSSION**

This is the first study to evaluate a hospital-provided IRCMAC for patients discharged to residential care. It demonstrated that a 7-day IRCMAC prepared by hospital pharmacists (linked with review and processing of

<table>
<thead>
<tr>
<th>Theme</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Reduction in need for urgent</td>
<td>“Avoided us needing to call locum” [Nurse]</td>
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<tr>
<td>medical practitioner attendance</td>
<td>“Beautiful, perfect, gives time to organise doctor” [Nurse]</td>
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<td></td>
<td>“So good. Saves getting locum, saves getting a phone order” [Nurse]</td>
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<td>“Very good, can’t get doctor always. Could accept patients (from hospital) later now. Normally only before 1 pm” [Nurse Manager]</td>
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<td>“This is a great help in arranging an easy move from hospital to residential care facility and helps take the pressure off the first few days—thank you” [GP]</td>
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<td>Clarity of information</td>
<td>“Brilliant, able to read, very easy to read” [Nurse]</td>
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<td>“The typed nature of these charts helps a lot — some hand written discharge medication lists in the past have been illegible” [GP]</td>
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<td>Usefulness of information</td>
<td>“Change status alerted nurse of new medications” [Nurse]</td>
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<td>“Did not need to check when last dose was given” [Nurse]</td>
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<tr>
<td>Reduction in medication</td>
<td>“Wouldn’t have been able to administer medications (without it)” [Nurse]</td>
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<td>administration errors</td>
<td>“… Usually cannot administer from script so this allowed for signing” [Nurse]</td>
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<td>Lack of familiarity with IRCMAC</td>
<td>“… didn’t realise it could be used til the day after” [Nurse]</td>
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<td>(RCF staff who received but did not use</td>
<td>“Unfamiliar with the chart though fantastic idea” [Nurse]</td>
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<td>the IRCMAC)</td>
<td>“Would have been helpful if staff familiar” [Nurse]</td>
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<tr>
<td>Other</td>
<td>“Interim chart is very useful. Would be useful if done for every patient discharged to residential facilities on a regular basis” [GP]</td>
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<td>“(I) think this is the best idea ever” [GP]</td>
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*Australian Government-approved and subsidised residential aged care place for a person who needs a high level of assistance with activities of daily living and 24-h nursing care.

†Australian Government-approved and subsidised residential aged care place for a person who needs a lower level of personal and nursing care.

‡RCF providing non-government subsidised personal and/or nursing care (eg, Supported Residential Service).
discharge prescriptions) improved continuity of medication administration, reduced pressure on the GP workforce and reduced the need for locum medical services to write RCF medication charts. It also led to a reduction in potentially unsafe medication administration ‘workarounds’ used by RCF staff.

Clinical outcomes were not assessed, but case reports and anecdotal evidence indicate that ‘workarounds’ and missed doses sometimes result in adverse outcomes. Of the 75 missed and delayed medications in the pre-intervention period, a moderate or high risk of adverse outcome was considered by a multidisciplinary expert panel to be likely in 49 (65.3%) cases.

Reduced reliance on locum doctors to write medication charts after hospital discharge also has potential to improve patient safety because the locum would be unfamiliar with the patient and may not be the most appropriate person to write the long-term care medication chart (which may be used for up to 6 months). The IRCMAC enabled GPs to review their patients (and write long-term care medication charts) at a clinically appropriate time, a few days after discharge, rather than on the day of hospital discharge (when the patient should not require a clinical review).

The duration of the IRCMAC was limited to 7 days to ensure that post-discharge medical review could not be excessively delayed, while also providing flexibility for GPs in the scheduling of their visit to the RCF (during stakeholder consultation, some GPs reported that they usually attend the RCF for routine patient care activities on a set day each week). If the patient is stable and the GP’s usual day of attendance is 7 days away, a 7-day chart avoids the need for the GP to make an extra visit and/or the need for locum attendance. If the patient is clinically unstable, the GP can attend sooner.

We did not assess whether there was a change in the time from hospital discharge to first GP visit. Anecdotal we noted that the chart was usually used for <7 days. While there is a potential risk that the IRMCAC may delay GP review of an unstable patient, the risk may be smaller with the IRCMAC than without the IRCMAC. This is because without the IRCMAC, a locum medical service is often called to write a long-term care medication chart on the day of discharge, and this chart will last for up to 6 months; therefore, the patient’s GP can delay their attendance for much longer than 7 days.

Another benefit of reducing reliance on locum medical services is that it reduces healthcare costs. If the results of this study were replicated across all hospitals in Australia (based on 2001–2002 discharge data and the minimum Medicare Australia locum medical consultation rebate in 2010 ($A126), savings to the Australian Government in excess of $A2.1 million annually could be realised. Avoidance of adverse medication events may lead to further cost savings. The IRCMAC could also lead to efficiency gains within the RCF and GP workforce; telephone interviews and satisfaction surveys suggested that the IRCMAC resulted in considerable (though unquantified) time savings for RCF staff and GPs. Countering these savings would be costs incurred by hospitals to deliver the IRMCAC, but in our experience, these are significantly less than the likely savings (approximately 10 Australian dollars per IRMCAC for labour and consumables, excluding software and set-up costs, in a setting in which pharmacists were already conducting admission and discharge medication reconciliation and entering discharge medication data into dispensing software; greater labour costs for IRMCAC provision would be incurred if these tasks needed to be introduced).

Although RCF medication charts are traditionally written by medical practitioners, the IRMCAC used in this study was able to be legally prepared and signed by the pharmacist because in the RCF setting, the chart was an administration record, not a prescription, and therefore did not need the signature of a medical practitioner. Preparing the IRMCAC in this way provided a number of advantages. It ensured that IRMCAC production occurred after the discharge prescription had been reviewed and reconciled by a pharmacist and errors corrected, and it enabled auto-population of the chart from the pharmacy dispensing software. This ensured a high level of concordance between the IRMCAC and the discharge prescription. An audit of a random selection of 76 IRMCACs prepared during this study revealed a medication discrepancy rate of 9/870 (1.0%). Although there are no studies that have assessed accuracy of handwritten IRMCACs, medication transcription error rates on handwritten inpatient orders and discharge summaries range from 12% to 56%.

For 11% of patients, the RCF received an IRMCAC but did not use it. In some cases, this was because a doctor attended in time to write a new RCF medication chart. In other cases, it was because the RCF had a policy requiring all admissions to be reviewed/admitted by a medical practitioner or stating that all medication administration charts must be written by a medical practitioner. Sometimes RCF staff did not use the chart because they were unfamiliar with it (Table 2).

In our study, the hospital supplied medications on discharge along with the IRMCAC. In settings in which the hospital does not supply discharge medications, the IRMCAC may be less effective but would still be expected to provide some benefits. It may reduce pressure on the GP workforce and use of locum medical services. And because the IRMCAC provides RCF staff with clarity as to what the intended discharge regimen is, if pre-admission medications are available at the RCF, with an IRMCAC, they can be given correctly, without delay. For new or changed medications, whether the IRMCAC would be effective will depend on how the medications are supplied—if delays in medication supply and/or delivery occur then missed doses may still occur until the medications become available, but if the medications are
supplied on time (within 1–6 h of discharge), the IRCMAC could facilitate timely and accurate administration.

There were some limitations with our study methodology. Data on missed and delayed doses were obtained by telephone interview, introducing risk of underreporting and recall bias. However, as described elsewhere, we piloted several methods of data collection, and telephone interview 24 h after discharge was judged to be the most reliable and practical. Any underreporting and recall bias is likely to have been similar during the pre-intervention and post-intervention periods. While transfer-related medication administration errors may continue for several days after discharge, our methodology did not enable us to assess what proportion of errors persisted beyond 24 h after discharge. Use of a pre-intervention and post-intervention study design meant that the interviewer could not be blinded to group allocation and that factors other than the IRCMAC could have contributed to the reduction in medication administration errors and locum medical service attendances over time. However, the strongly positive feedback from GPs and RCF staff regarding the impact of the IRCMAC suggests that it was the primary cause of observed improvements and because the problems addressed by the IRCMAC have been long standing, it is unlikely that over the space of a few months, they would decline significantly without specific intervention. Furthermore, the participating hospitals have continued to provide IRCMACs since this study finished and (unsolicited) positive feedback continues to be received. Several RCFs have indicated that they are now happy to accept patients on weekends or after hours, provided they receive the IRCMAC, whereas previously they would not. A major locus medication service in the area has indicated that since the IRCMAC was introduced, they infrequently receive calls to write medication charts following hospital discharge. Data were collected from RCFs within approximately 24 h for all discharges in the pre-intervention period, but up to 48–72 h in the post-intervention period for Friday and Saturday discharges (24 h for all others). It is possible that the longer time between discharge and interview in the post-intervention period may have increased the risk of recall bias. However, Saturday discharges were rare (5/296), and it was our experience that delaying interviews for Friday discharges until Monday was advantageous because the interview was more likely to involve a RCF staff member who was present on Friday, when the patient arrived. Therefore, this minor difference in methodology was unlikely to have resulted in underestimation of error prevalence.

In conclusion, implementation of a hospital pharmacist-prepared IRCMAC led to significant improvements in continuity of medication administration and reduced reliance on locum medical services to write medication charts after discharge from hospital to RCFs. As a result of this study, hospital pharmacist-prepared IRCMACs have been implemented in several Australian hospitals, and a national IRCMAC and guidelines addressing continuity of medication management on transfer from hospital to RCF are planned. Although health systems vary between countries, problems with continuity of medication management on discharge from hospital to residential care have been reported internationally, so the findings of this study may be widely applicable.

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Contributors RAE, SET and PAH conceived the study and developed the methodology with input from all investigators. RAE wrote the study protocol and managed the study. TT collected the data. RAE and TT conducted the data analysis with input from SET, PAH and JLM. RAE wrote the manuscript. All investigators reviewed and contributed to the manuscript.

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Competing interests None.

Ethics approval Austin Health Human Research Ethics Committee and Monash University Human Research Ethics Committee.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Access to the study data may be provided by the authors to other researchers upon request.

REFERENCES
Medication management after discharge from hospital to residential care


APPENDIX 1

Stakeholders consulted during development of the IRCMAC

Australian government and professional bodies:
- Aged Care Standards & Accreditation Agency
- Australian Nursing Federation
- North East Valley Division of General Practice
- Northern Division of General Practice
- Nurses Board of Victoria
- Pharmacy Board of Australia
- Victorian Department of Health—Aged Care Branch
- Victorian Department of Health—Ambulatory & Continuing Care Programs Branch
- Victorian Department of Health—Drugs and Poisons Unit
- Victorian Department of Health—Quality Use of Medicines Programme

Individual health professionals and aged care staff:
- Community pharmacists (n=4)
- Hospital pharmacists (n=6)
- Hospital doctors (n=3)
- Hospital aged care liaison nurse (n=1)
- RCN staff (directors of nursing, care coordinators, division 1 & 2 registered nurses, personal care assistants) (n=34)
- GPs (n=6)


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# STROBE Statement—Checklist of items that should be included in reports of cohort studies

<table>
<thead>
<tr>
<th>Item</th>
<th>No</th>
<th>Recommendation</th>
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| **Title and abstract** | 1 | (a) Indicate the study’s design with a commonly used term in the title or the abstract  
(b) Provide in the abstract an informative and balanced summary of what was done and what was found |
| **Introduction** | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses |
| **Methods** | | |
| Study design | 4 | Present key elements of study design early in the paper |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection |
| Participants | 6 | (a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up  
(b) For matched studies, give matching criteria and number of exposed and unexposed |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable |
| Data sources/measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group |
| Bias | 9 | Describe any efforts to address potential sources of bias |
| Study size | 10 | Explain how the study size was arrived at |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why |
| Statistical methods | 12 | (a) Describe all statistical methods, including those used to control for confounding  
(b) Describe any methods used to examine subgroups and interactions  
(c) Explain how missing data were addressed  
(d) If applicable, explain how loss to follow-up was addressed  
(e) Describe any sensitivity analyses |
| **Results** | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed  
(b) Give reasons for non-participation at each stage  
(c) Consider use of a flow diagram |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders  
(b) Indicate number of participants with missing data for each variable of interest  
(c) Summarise follow-up time (eg, average and total amount) |
| Outcome data | 15* | Report numbers of outcome events or summary measures over time |
| Main results | 16 | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included |
(b) Report category boundaries when continuous variables were categorized  
(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period  

| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | NA |

**Discussion**

| Key results | 18 | Summarise key results with reference to study objectives | ✓ |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | ✓ |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | ✓ |

**Other information**

| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | ✓ |

*Give information separately for exposed and unexposed groups.*