

## ORIGINAL RESEARCH

# Quality use of medicines in the rural ambulant elderly: a pilot study

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## ABSTRACT

**Introduction:** Australia has a rapidly ageing population, especially in rural areas, and strategies to address medicines and the elderly are particularly relevant. The aims of this 18 month study, therefore, were to: (1) determine the influence of a medication review on the quality of life of elderly ambulatory patients managed by a general practitioner; and (2) assess the impact of the medication review process on health outcomes such as medication-related hospital admissions in ambulant elderly patients actively managed by their GP.

**Methods:** The study was conducted within the area serviced by the rural Riverina Division of General Practice, New South Wales, Australia. Patients were identified by clinical audit, and recruited to the study if they met the inclusion criteria of being: older than 65 years, ambulant, living independently and on five or more medications. The study sample consisted of 402 participants (156 men, 38.8%; 246 women, 61.2%). Fifty-eight participants withdrew from the study for a variety of reasons. A two-group (intervention, control) pre- and post-intervention randomized study design was utilized. Quality of life was assessed using SF-36. The medication history and clinical details of the 202 study participants were reviewed by the project pharmacist and their GP. Medication changes were suggested to patients by their GP and follow-up SF36 and review of hospitalisation episodes were conducted after 6 months.

**Results:** 3382 medications were identified as being taken, an average of 8.4 medications per patient. After the initial medication review, the study pharmacist suggested an alteration in dose, form or frequency for 687 medications in the intervention group. The GPs recommended an alteration in 243 of patient medications. Of the entire study population (n = 402), only two participants' admission to hospital was specifically attributed to medication-related issues. There were no significant differences between the quality of life assessments for the combined groups; however, the intervention group recorded significantly higher scores in two of the nine dimensions measured: vitality (p 0.009) and mental health (p 0.0001), at the post-intervention assessment.



**Conclusion:** While the intervention did not reduce hospitalisation episodes and only led to a modest improvement in quality of life, the development of a mutually acceptable form of face-to-face pharmacist/GP medication review, identification of potentially serious adverse drug reactions, identification of previously unreported complementary medicine use, and enhanced GP awareness of the risks of polypharmacy were positive outcomes of the study.

**Key words:** elderly community-dwellers, general practice, medication review, medicines, pharmacist.

## Introduction

The Australian National Medicines Policy document<sup>1</sup>, asserts that all medicines should be used judiciously, appropriately, safely and efficaciously. Health practitioners' role in ensuring that this goal is achieved is viewed as critical. The roles of health practitioners are seen to include appropriate treatment choices, collaboration with other health professionals across discipline boundaries, and provision of accurate information about medicines<sup>1</sup>.

A recent report asserted that between the years 1996 and 2016 the number of people in Australia over the age of 65 years will increase by 59% which is equivalent to 1.3 million individuals<sup>2</sup>. In small rural communities in New South Wales (NSW) the age group >65 years is over-represented relative to the State, and this disparity is increasing over time<sup>3</sup>. The Federal Government has supported a rapid growth in the number of new health services to rural areas (350 in 2002-2003). In particular, the growth in MultiPurpose Services, Regional health services (especially podiatry, palliative care and allied health) and programs directed to the viability of rural practices have particular benefits for the elderly<sup>4</sup>. Because Australia has a rapidly ageing population, strategies to address medicines and the elderly are particularly relevant. In addition, because the majority of research to date has concentrated on the institutionalised elderly, little is known of the ambulant, community-dwelling elderly. Strategies to investigate the quality use of medicines, that would be achievable in most communities across Australia, would include a clinical audit by GPs, medication reviews by pharmacists and evaluation

of hospital admission records. These strategies were employed in this project.

### *Aims*

1. To determine the influence of a medication review on the quality of life of elderly ambulatory patients taking five or more medications, managed by a GP.
2. To assess the impact of the medication review process on health outcomes, such as medication-related hospital admissions, in such ambulant elderly patients actively managed by their GP.

## Methods

The study was a pre- and post-intervention randomised control trial, principally designed to address the two aims. Additional data on complementary medicine use in the study population was also collected.

### *Study site*

The study was conducted within the area serviced by the Riverina Division of General Practice, NSW, Australia. The Division is situated in rural NSW, with a population of 118 005 serviced by 92 GPs. Eight GPs participated in the study and worked in a regional city (Wagga Wagga) and three smaller rural towns (no remote areas). Based on Census data, the area consisting of the Riverina Division had a similar population structure to that of the State with 12.8% of the population aged over 65 years.



## *Study population and recruitment*

At the surgeries of participating GPs, surgery staff distributed a brief screening checklist and consent form to all patients aged 65 years and over. Those who consented and who were identified as meeting the requirements of the inclusion criteria, were recruited by their GP.

Inclusion criteria:

- Aged more than 65 years
- Ambulant, living independently
- Able to offer informed consent
- Five or more regular medications
- And one or more of the following:
  - Anticholinergic medication
  - Anticonvulsant medication
  - Antipsychotic medication
  - Narcotic medication
  - Benzodiazepines
  - Medications with a narrow therapeutic index
  - More than 12 doses per day
  - More than six diagnoses
  - Low body weight (BMI <22)

Exclusion criteria:

- Significant dementia
- Insufficient English language to be able to complete the assessments
- Unable to self-medicate

## *Study design*

A two-group (intervention and control) pre- and post-intervention randomized study design was utilized. The sample size of 402 participants (156 men, 38.8%; 246 women 61.2%) was determined by the power required to 'pick a difference', as found in comparable studies in the literature. Due to the sequential recruitment, the duration of the study was 18 months. Statistical analysis used ranked

multiple analysis of covariance. Randomisation was achieved by the GP allocating eligible patients alternately to the intervention or control groups.

**Intervention:** Quality of life (SF-36) measures were administered on both control and study participants pre-intervention. The pharmacist reviewed the study participants' medication profiles and presented his recommendations to the relevant GP at a case conference. Agreed interventions were presented/suggested to each patient by their GP at a recall appointment. By mutual agreement, medication changes were then implemented. Six months after this, a repeat SF-36 was administered and a record taken of the participant's medication profile. For the control group, a repeat SF-36 was administered 6 months after the initial measure.

Hospitalisation episodes were determined retrospectively by asking patients to recall the number of episodes at the 6 month follow up. The cause of each episode was determined by the GP by: review of the patients file, hospital discharge summary and the patient's own recollection of events. On many occasions the GP was the doctor responsible for their in-patient care.

## *Roles*

The major roles of participating GPs were to:

- Identify and recruit patients to the study.
- Facilitate collection of clinical data by the project nurse.
- Case conference with the project pharmacist to consider issues and recommendations identified during the domiciliary medication review.
- Recommend and alter medication (arising from the review process) in consultation with the patient.

The major roles of the project nurse included:

- Document and collect relevant clinical and socio-demographic information.



- Administer the quality of life measure the SF-36.
- Forward clinical information to the project pharmacist.
- Re-administer the quality of life measure 6 months after case conference.

The major roles of the project pharmacist included:

- Complete a medication review with respect to medications and therapeutic devices.
- Document recommendations arising from the medication review.
- Discuss the recommendations (and any options) with the GP.

### *Quality of life measure*

After a review of the literature, the SF-36 Health Survey was selected as the measure of the impact of the intervention on quality of life. While the SF-36 did not prove to be a particularly sensitive measure, it was, however, the best and most widely used measure of quality of life identified in the literature for this population. The advantages of using the SF-36 were identified as: its widespread use throughout the Western world; its performance equal to or better than comparable measures, such as the Sickness Impact Profile; and its modest respondent burden<sup>5,6</sup>.

### *Ethics*

Ethical Approval was obtained from the Greater Murray Health Human Ethics Committee.

## Results

### *Sociodemographics*

The study sample consisted of 402 participants, of whom 38.8% ( $n = 156$ ) were male and 61.2% ( $n = 246$ ) were female. The age range was 66 to 102 years of age with mean ( $\pm$  SD) of  $77.7 \pm 6.6$  years. There was no statistically

significant difference in the mean ( $\pm$  SEM) age of males and females ( $78.2 \pm 6.9$ ;  $77.4 \pm 6.4$ ).

The majority of study participants lived with their spouse (52.2%,  $n = 210$ ), although a substantial proportion lived alone (39.1%,  $n = 157$ ). The remainder lived with other family members. This parallels the results for marital status where 211 (52.5%) declared that they were married, 130 (32.3%) that they were widowed and 24 (6%) either divorced or single.

With respect to smoking, 7% of participants were current smokers, 47% had never smoked and 33% had ceased smoking. By contrast, 43.3% of participants currently consumed alcohol, 38.3% never consumed alcohol and 4.7% had ceased consuming alcohol.

**Withdrawals from the project:** 58 participants withdrew from the study for a variety of reasons, including: death, spousal disapproval and moving from their home; 30 (14.3%) of these were from the intervention group and 28 (14.5%) were from the control group. The difference was not statistically significant.

**Patient diagnoses:** Patients diagnoses spanned 538 categories, with the majority recording multiple diagnoses.

### *Medications*

**Medications taken:** A record of medications being taken by control and study patients in the study identified 3382 medications. This represents an average of 8.4 medications per patient.

*Complementary therapies* Use of at least one complementary therapy was declared by 60% of patients. The majority were not recorded on the GP's medication record pre-intervention. A total of 164 products were identified, with most patients recording use of multiple products. The most common items were: vitamin C (12.8%), multivitamins (7.6%), vitamin E (6.3%), B-group vitamins (5.4%), calcium (5.2%), garlic and



combination products (4.0%), cod liver oil (2.7%), zinc (2.7%), folate (2.4%), and ginko biloba (2.2%).

**Medication review (intervention group):** The medication history and clinical details of 202 study participants were reviewed by the project pharmacist.

After an initial medication review, the study pharmacist met with the GP and suggested an alteration in medication dose, form or frequency for 687 of these medications. The GP then recalled the patient and recommended an alteration in 243 patient medications.

The seven most commonly recommended interventions are as follows: cessation of long half-life benzodiazepines; changing prednisone to prednisolone; evaluation of NSAIDs and a diuretic; discontinuation or evaluation of aspirin in asthmatic patients; evaluation of diuretics in diabetic patients; reduction of high-dose thiazide diuretics.

## ***Hospitalisations***

During the course of the study, most participants recorded no episodes of hospitalization (74.9%,  $n = 287$ ), however some did recall up to three admissions (one admission 20.6%,  $n = 83$ ; two admissions 2%,  $n = 8$ ; three admissions 1.2%,  $n = 5$ ). Of the entire study population ( $n = 402$ ), only two participants' admission to hospital was specifically attributed to medication-related issues. There was no significant difference in hospitalisation rates between control and intervention groups.

## ***Quality of life measures***

The SF-36 was completed and each sub-scale score calculated, initially and 6 months after the review, in both study and intervention groups.

There were no significant differences between the overall quality of life scores for the combined groups at first and second assessment. However, when considered separately, the intervention group did record significantly higher scores

in two of the dimensions measured: vitality ( $p < 0.009$ ), and mental health ( $p < 0.0001$ ), at the post-intervention assessment.

## **Discussion**

This study was intended to assess the utility of explicit risk criteria developed from the literature to reduce medication-related impediments to better quality of life, and to reduce hospital admission rates among ambulant community-residing elders in rural Australia. A number of potentially impacting medications were identified after review by the study pharmacist. The pharmacist was required to document any potential issues and recommendations for discussion at a case conference with the GP. This documentation was notable because most clinical interventions made by pharmacists in the course of their normal practice are communicated by telephone or facsimile. This form of face-to-face interaction was viewed positively by both parties, but would only be sustainable if dedicated funding was provided for both the GP and pharmacist's time.

A number of GPs expressed the belief and expectation that the drug-drug interactions function of the prescription writing programs would have ensured that their patients medications were optimal. While these comments have some validity, it must be appreciated that most, if not all, such programs do not detect drug-disease state interactions, such as the concomitant use of aspirin in asthmatic patients, nor do they detect psychoactive medications requiring a 'wash-out' period such as Zyban (bupropion) being added to established Aurorix (moclobemide) therapy.

When quality of life was assessed after the intervention, the study group recorded higher scores on two areas: vitality and mental health. This may reflect alterations in patients' medications; however, it may also reflect additional interaction with the GP, participation in the study, or other change in circumstances which were not assessed during the pilot study (eg pet ownership and increased opportunities to socialise). Changes to the medication regimen could have impacted on vitality and mental health





by either more appropriate prescribing (eg positive effect of antidepressants) or a reduction in inappropriate prescribing (eg reduction in the negative effects of long-acting benzodiazepines). Participation in the study entailed active recruitment and intervention by the patients' own GP. A perception of heightened interest in their wellbeing by their GP may have contributed to an improvement in the participants' mental health and vitality and, as such, may have been a confounding factor.

The impact of the intervention on medication-related hospitalisation rates was not statistically significant, with only two patients' hospital admission being attributed to this factor. This may have resulted because the at-risk criteria were inadequate, or medication-related causes may not have been identified as a cause or contributing factor to the hospitalisation.

This pilot project identified a number of areas into which further research could be directed. Importantly, the need of the ambulant elderly for support from allied health professionals, such as occupational therapists, needs to be established. The study nurse detected a number of patients for whom some form of physical therapy/aid, and/or social intervention may have been indicated. Such interventions could have a large impact on quality of life

## Conclusion

The study did not demonstrate a significant reduction in hospitalisation rates but did show a modest, but significant, improvement in two out of the nine domains of quality of life measured. It did, however, develop an effective and mutually acceptable form of face-to-face pharmacist-general

practitioner medication review, it identified potentially serious adverse drug reactions and drug-drug interactions, identified previously unreported complementary medicine use (and potential interactions with patients' prescribed medications) and enhanced GP awareness of the risks of polypharmacy and interactions between prescribed and complementary medicines. Reassuringly, this intervention did not demonstrate adverse outcomes on quality of life or hospitalisation rates over the study period.

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