Statement of Dr Juanita Westbury

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Date: 29 April 2019

1. This statement made by me accurately sets out the evidence that I am prepared to give to the Royal Commission into Aged Care Quality and Safety. This statement is true and correct to the best of my knowledge and belief.

2. The views I express in this statement are my own based on my education, training and experience. They are not intended to represent any views of my employer.

Professional background:

3. I am currently employed as a Senior Lecturer in Dementia Care at the Wicking Dementia Research & Education Centre at the University of Tasmania and have been in this role since 1/7/2015. I am a Registered Pharmacist specialising in aged care. I qualified with a Bachelor of Pharmacy degree in Sydney in 1985, completed a Graduate Diploma in Community Practice Pharmacy in South Australia in 1997, a Master of Science (Distinction) in Staffordshire, England in 2002 and graduated with a Doctor of Philosophy from the University of Tasmania in 2011.

4. After completing my degree, I worked as a RAAF military pharmacist from 1985-1991. Upon discharge I worked as a community pharmacist in England, Scotland and Adelaide from 1991-2000. I became accredited to perform medication reviews in South Australia in 1997 and worked in three Adelaide ACHs as a consultant pharmacist until 2000. I then moved to the U.K. and worked in community pharmacy and as a Primary Care Pharmacist for the Central Cheshire Primary Care Trust. In this role I supported prescribing in 5 GP practices, provided medication review services for a large aged care home and was also the Lead for Older People. My U.K. Masters' thesis research involved decision making in older people. When I returned to Australia, I commenced a PhD researching psychotropic medication use in Residential Aged Care Facilities (RACFs), also known as ACHs (ACHs). The main part of the thesis was designing, implementing and evaluating an intervention program; Reducing Use of Sedatives (RedUSe), aimed to reduce the use of psychotropic medication in this setting. In 2009 I was appointed as a Lecturer in Pharmacy at the University of Tasmania. I also became re-accredited to perform medication reviews in 2012 through the U.S.A Board of Pharmacy Specialties. From 2013-2017 I led and managed the expansion of the RedUSe program to 150 ACHs in all 6 Australian States and the A.C.T. From 2014 to 2015 I was a NHMRC 'Translating Research Into Practice' (TRIP) Fellow.
5. Regarding professional appointments, I have been a non-legal member of the Guardianship and Administrative Board of Tasmania since 2013. In 2017 I was invited to join the Cognitive Impairment Advisory Group of the Australian Commission on Safety and Quality in Health Care (ACSQHC). I presently serve as the Chair of the Tasmanian Branch of the Australian Association of Gerontology.

6. Prior to working at the University of Tasmania I worked for Full Life Edwards’ Pharmacy, Kingston, Tasmania as a Community Pharmacist.

**Background to my PhD and subsequent research on aged care psychotropic use:**

7. The main objective of my PhD was to determine if aged care psychotropic use could be reduced via a customised intervention. Before this could be achieved, background research was conducted in three stages. First, a detailed evaluation of psychotropic use was undertaken in 40 Tasmanian ACHs during 2006. Previous studies had shown a high use of psychotropics in Tasmanian ACHs. This trend was also evident in this study, with an average of 42% of residents taking daily doses of benzodiazepines and 20% of residents taking daily antipsychotics (Westbury et al, 2009). As professional guidelines recommend psychotropics are reviewed regularly, with dose reductions attempted, the measure was repeated 12 months later to evaluate the extent of alteration. We found over 60% of psychotropic medications and doses were unchanged from year to year; a finding which strongly signifies limited review (Westbury et al, 2010a).

a. The second stage of the thesis sought to gain a greater understanding of the reasons underlying psychotropic use. A qualitative approach involving analysis of semi-structured interviews with health practitioners and relatives was chosen to answer key questions; including why these medications are widely used and who influences their initiation and review? This study not only provided valuable insight but also strongly informed the strategies of the intervention. It became evident that many health practitioners had limited knowledge about psychotropics and the risks associated with their use, and that reviews were conducted infrequently, if at all. Of all health practitioners, aged care staff were the most influential when these medications were initiated. Because of these findings, the key strategies of the intervention were primarily targeted at staff and designed to offer feedback on psychotropic use to each home, provide education about these agents and associated risks, provide and promote professional guidelines and encourage regular review and dose reduction.

b. The third and final stage involved a large controlled trial run in 25 ACHs in the two major cities of Tasmania called the ‘Reducing Use of Sedatives’ (RedUSe) program. RedUSe was funded $149,500 by the Department of Health and Ageing in 2007. Thirteen Hobart ACHs were recruited as intervention homes, with 12 Launceston homes acting as the control group. RedUSe was run over 6-months from 2008 to 2009. A series of quality improvement strategies were provided to intervention homes, including two dedicated psychotropic audits, nurse education and an interdisciplinary sedative review process. At the end of the program, the use of benzodiazepines was significantly reduced in intervention homes (32% to 27%).
whereas a small increase was found in control homes. Likewise, antipsychotic use was reduced in intervention homes when compared to control (20% to 18.5%). The proportion of psychotropic dose reductions in intervention homes was double that of control homes. Extensive evaluation was conducted, including a series of focus groups with staff and pharmacists (Westbury et al, 2010b, Westbury, 2011).

8. In 2012 I led a small qualitative study entitled 'Promoting interdisciplinary evidence-based management of behavioural and psychological symptoms of dementia (BPSD) in RACFs'. A series of focus groups with staff (n=24) and community pharmacists (n=8) working in 3 ACHs were conducted to scope attitudes towards non-pharmacological management of mental health and interdisciplinary practice. Although all participants revealed an wide knowledge of non-pharmacological strategies, they felt there were inadequate resources to apply them. Despite negative attitudes towards pharmacological management, most staff were uncertain what drugs were psychotropics or whether they were effective and safe. Pharmacists did not query high doses or extended duration of use. Most participants were not sure about the role of relatives, particularly regarding consent. Nurses rarely consulted pharmacists about behaviour and both groups were unsure whose role it was to review psychotropic medication.

9. In 2013 the University of Tasmania was awarded $3M from the Dementia and Aged Care Service (DACS) fund for a national expansion of the RedUSe program to 150 ACHs. There was a strong demand from homes to participate in RedUSe after two Australian peak aged care organisations, Leading Age Services Australia (LASA) and Aged and Community Services Australia (ACSA), promoted the program in online newsletters, resulting in over 300 expression of interest for 100 available places.

a. During the 6-month RedUSe program, each home’s psychotropic use was audited at baseline, 3 and 6 months. The audit results were then presented to aged care staff during two educational sessions. Following this, all residents taking sedatives (N.B. antipsychotics and benzodiazepines) were reviewed in an interdisciplinary process involving a pharmacist, a champion nurse and the resident’s GP. Figure 1 below illustrates the main strategies:
b. As part of RedUSe, an interactive training session for staff was designed to challenge positive beliefs around psychotropic use. Training was also delivered on their risks and benefits, and concise guidelines provided. A 'champion nurse' role was created for an expert peer to promote and model 'good practice' and to become an integral member of the interdisciplinary team. GPs were also informed. The education provided to the aged care sector was substantial, with over 2500 nursing staff and carers attending sessions. Using a validated quiz, significant improvement was found in psychotropic knowledge of all levels of nursing and care staff attending the training. Participants particularly valued the opportunity to discuss the use of medications of their residents and many wanted to learn more about medications and their side effects, along with non-pharmacological approaches.

c. Overall, a significant reduction was found in antipsychotic and benzodiazepine use. A 13% relative reduction was observed in the use of antipsychotics from baseline to 6-months (22% to 19% of residents). The reduction in benzodiazepine use was higher; at 21% (22% to 17%). The reduction was sustained: Over 80% of antipsychotics and 90% of benzodiazepines reduced at 3-months, remained reduced when residents were re-checked at 6-months (Westbury et al, 2018).

d. Out of 150 ACHs involved, two-thirds (66%), reduced both antipsychotic and benzodiazepine prescribing rates. A total of 115 homes (77%) reduced their antipsychotic use, with 127 (85%) reducing benzodiazepine use. Substitution to other psychotropics or higher 'pm' (as required) use of these agents, did not occur.

e. Importantly, there were no significant increases in behavioural symptoms in residents who reduced psychotropic use. In fact, antipsychotic reducers saw small improvements in some behaviours, specifically agitation. Reducing benzodiazepine use was shown to increase the residents' ability to perform activities of daily living. A health economic analysis was not possible due to the funding rules. However, based on data from a clinical impact study, with assumptions of implementation /operation costs and extrapolated nationally, the RedUSe program is expected to provide overall cost savings in the order of $3.9m per annum, primarily driven through reduced hospitalisations in residents who had psychotropics reduced and savings from reduced antipsychotic use (Westbury et al, 2017).


Key quality and safety issues in residential aged care relating to medication use:

10. For the past three years, the most common issue raised in complaints about residential aged care relate to medication administration and management, with the proportion increasing from 11% to 16% from 2016 to 2018. (Reports available at: https://www.agedcarecomplaints.gov.au/internet/accc/publishing.nsf/Content/annual-report)

a. In my opinion many aged care staff are not qualified to administer medication, nor is there adequate or consistent training in appropriate use. Many staff are not even aware what medication they are administering, let alone their adverse effects or appropriate monitoring. Professional guidelines to assist staff with medication are not used. In general, the current Accreditation Standards relating to medication use are inconsistently followed. This will worsen with the new Standards as there is a complete absence of detail on what is, or is not, good clinical practice.

b. Overall, ‘Guidelines’ are not used by many prescribers in aged care to base decisions about agents to prescribe, doses and duration of use; leading to widespread use of unlicensed agents, inappropriate doses and extended duration of use, and a lack of monitoring for effectiveness, adverse effects and drug interactions. Education provided to health practitioners about old age mental health, especially the management of changed behaviour in dementia, is limited.

c. The public purse is effectively subsidising the unlicensed use of antipsychotics in residents of aged care as prescribers have free range to prescribe these agents under current streamlined authority arrangements. Older agents are able to be prescribed without restriction. Although indications and durations for newer antipsychotics are clearly stipulated in the Pharmaceutical Benefits Scheme (PBS) and the Therapeutic Goods Administration (TGA) their prescribing is not audited.

d. Pharmacists are funded to provide professional services to ACHs as part of the Community Pharmacy Agreement however service provision has eroded markedly over the past 5 years. In 2014, Residential Medication Management Review (RMMR) services were capped from annual provision to once every two years. Capping has resulted in independent accredited pharmacists to leave the aged care sector and the promotion of companies that provide bulk-review services within a short time frame. Currently there exists a wide range of interpretations of what adequately constitutes a RMMR. For example, some providers may use only a drug-drug interaction check as the sole content of a report or, conversely, reporting is comprehensive, encompassing all relevant issues. Although detailed reporting criteria have been published the quality of RMMRs is not audited.

e. The ‘Quality Use of Medicine’ (QUM) program, again part of the Community Pharmacy Agreement, was specifically designed to provide quality improvement strategies to aged care such as staff training, psychotropic audits and improve medication management in each home. Yet, like with RMMRs, the QUM service provision quality is not audited, pharmacists are not trained to provide these services and recipients are able to receive QUM funding for activities such as stocking the medication cupboard or attending a meeting once every three months.
The use of 'restrictive' medications in residential aged care settings:

11. The most common types of medications used in residential aged care setting that may have the effect of restricting an individual's behaviour or free movement are known as psychotropics. 'Psychotropic' medications are 'capable of affecting the mind, emotions, and behaviour, and are used to treat mental illnesses' (Farlex, 2012). The three main psychotropic classes used in Australian residential aged care are antidepressants (e.g. citalopram, mirtazapine, sertraline), anxiolytics/hypnotics, predominantly benzodiazepines (e.g. diazepam, temazepam, oxazepam), and antipsychotics (e.g. risperidone, olanzapine, quetiapine). Other psychotropic agents include anticonvulsants. (Psychotropic Expert Groups, 2013).

12. Psychotropics capable of restricting an individual's behaviour or free movement possess sedating properties. The two main classes of psychotropics used to sedate are antipsychotics and benzodiazepines; however, other agents, including antidepressants and anticonvulsants, can possess sedative properties and may be prescribed to restrict an individual's behaviour or movement. They slow down thinking, functioning, movement, lessen agitation and reduce anxiety. These medications can cause confusion and impair communication, particularly in residents with existing cognitive impairment such as dementia.

a. Antipsychotics were developed for use in schizophrenia. In general, there are two types: Older 'first generation antipsychotics' (haloperidol, chlorpromazine) and newer 'second generation antipsychotics' (e.g. risperidone, olanzapine, quetiapine). This distinction originally related to the increased rate of movement disorders in the older agents, however, the newer agents have serious metabolic adverse effects (Psychotropic Expert Groups, 2013). In Australia, only one antipsychotic, risperidone, is both licensed by the TGA and PBS subsidised, for use in Alzheimer's disease (not vascular or Lewy Body dementia), for severe agitation and psychosis when non-drug treatments have failed, and only then, for a maximum of 12 weeks (Australian Government, 2019). When taken by people with dementia, antipsychotics increase the risk of stroke, death from any cause, heart arrhythmias, falls, pneumonia and cause metabolic and movement disorders (RANZCP, 2016). This risk appears to be at least as great or greater for first generation antipsychotics (Psychotropic Expert Groups, 2013). For this reason, the Royal Australian and New Zealand College of Psychiatrists (RANZCP) endorse that 'the first-line approach to management of behavioural and psychological symptoms in dementia is a person-centred, psychosocial, multidisciplinary treatment plan.' Reasons for antipsychotic use in dementia include: severe agitation and aggression associated with risk of harm; delusions and hallucinations (RANZCP, 2016).

b. Benzodiazepines are indicated short-term 'for anxiety and insomnia after non-drug approaches are trialled' (RACGP, 2015). They are often prescribed to treat 'changed behaviour' in people with dementia, despite limited evidence (Loi et al., 2015). Due to side effects of drowsiness, language and cognitive impairment, and falls they are considered to offer more risks than benefits in older people (Glass et al., 2005). Falls in ACHs are associated with substantial mortality; over a third of...
residents with a hip fracture will die within 6 months, and among those who survive 6 months, 28% will become totally disabled (Neuman et al., 2014). Long-term benzodiazepine users often become tolerant to their effects meaning that higher doses are needed to relieve symptoms. The RACGP now recommends that people with anxiety should be treated initially with psychological therapies, then with antidepressants if anxiety symptoms do not resolve with ‘benzodiazepines used as a short-term measure only and chronic use avoided.’ In insomnia, although benzodiazepines show improvements in sleep, ‘the magnitude of effect is small, and the benefits of these drugs may not justify the increased risk’. If benzodiazepines are used for insomnia, 'treatment should be short-term (i.e. less than 4 weeks) at the lowest possible dose (RACGP, 2015). In people with dementia with severe anxiety and agitation, guidance suggests ‘oxazepam 7.5mg up to 3 times a day for no longer than two weeks’ (Psychotropic Expert Groups, 2013).

c. Certain antidepressants such as mirtazapine and tricyclic antidepressants (e.g. amitriptyline) can be prescribed for their sedating properties, especially in residents whose agitation is significant at night time. The most common adverse effects of mirtazapine include daytime drowsiness, increased appetite, weight gain, and dry mouth. Tricyclic antidepressants are not recommended for dementia patients for several reasons, including confusion, constipation, dry mouth and cardiac issues. Notably, all antidepressants confer a higher falls risk in older people.

d. Anticonvulsant drugs are used to prevent seizures in epilepsy. They are also used for symptoms of aggression and agitation in people with dementia. Of these, sodium valproate is the most widely utilized; however, a Cochrane review failed to demonstrate efficacy (Lonergan et al., 2009). Carbamazepine has shown some effect in reducing aggression but has many side effects including falls, skin rashes, low sodium levels and blood disorders (Psychotropic Expert Groups, 2013).
Prevalence of psychotropic use in Australian ACHs:

13. For several decades, high prevalence rates and inappropriate ACH use of psychotropic medication have been reported, particularly for antipsychotics and benzodiazepines. The first major Australian study of psychotropic use was conducted in 46 Sydney ACHs during 1993 by Prof John Snowdon. The rates of regular antipsychotic (27%) and benzodiazepine (35%) use were ‘among the highest reported in the world’ (Snowdon, 1995). This study attracted considerable media attention, resulting in the establishment of the ‘NSW Ministerial Taskforce into Psychotropic Medication Use in Aged care’ during which concerns were raised regarding high rates of combination psychotropics, excessive dosages and extended duration of use (NSW Ministerial Taskforce, 1997).

a. Comprehensive data on overall aged care psychotropic use in Australia is limited. Most studies focus on antipsychotic use and measure prevalence through varying methods, usually obtaining data from medication charts or medication reviews. There is also variation in the location, resident case mix and number of homes in each study. Respecting these limitations, the rate of antipsychotic use in Australian homes over the past 20 years ranges from 13 to 42% of residents (See Fig 2) (Westaway et al., 2018).

b. The first national prevalence study conducted in Australian residential aged care was published this year using baseline data from the RedUSe expansion. This study examined psychotropic use in a large sample of 139 homes across 6 States and the A.C.T in 2014-2015, involving over 11,500 residents (Westbury et al, 2019). Specifically, 22% of residents were taking antipsychotics, 41% antidepressants and 22% benzodiazepines on a regular basis, largely daily. The most commonly prescribed antidepressant was the sedating agent mirtazapine at 12% of residents, with tricyclic antidepressants taken by 4%. Sodium valproate and carbamazepine anticonvulsants were taken by 5% and 1% of residents, respectively.

Figure 2: Antipsychotic prevalence in Australian Homes (Westaway et al., 2018)
c. The use of multiple psychotropics was common, with a quarter of all residents (23%) taking two or more agents daily, concomitantly. Notably, 30% of those residents taking a daily antipsychotic dose were also taking benzodiazepines daily.

d. A high prevalence of ‘prn’ or ‘as needed’ charting was also observed. Eleven percent of all residents were prescribed ‘prn’ antipsychotics and almost a third of all residents (31%) were charted for ‘prn’ benzodiazepines, with anxiolytic ‘prn’ prescribing (e.g. oxazepam) at 18% higher than hypnotic (i.e. temazepam) ‘prn’ prescribing (16%). Nearly half of residents prescribed daily doses of benzodiazepines were also prescribed these agents on a ‘prn’ or ‘top-up’ basis. Similarly, 29% of regular antipsychotic users were also charted for additional ‘prn’ doses when needed.

e. With both regular and ‘prn’ charting considered, more than half of residents (54%) were prescribed antipsychotics and/or benzodiazepines (Westbury et al, 2019).


Appropriateness of psychotropic use in Australian ACHs:

14. In terms of duration of use, several Australian studies highlight that most aged care residents are prescribed psychotropics for longer periods than recommended:

a. When antipsychotics are prescribed for agitation, aggression and/or psychosis in dementia, professional guidelines recommend they be reviewed within 3 months, and the dose reduced and stopped when possible (RANZCP, 2016; Psychotropic Expert Groups, 2013). The average duration of antipsychotic use in a 2017 study across 24 homes in N.S.W was 416 days (Pont et al., 2017). In baseline data for the ‘Halting Antipsychotic use in Long-Term care’ (HALT) intervention in 23 NSW ACHs, residents were prescribed an antipsychotic for an average duration of 2.1 years and with an unchanged dose for 1.2 years (Brodaty et al., 2018).

b. RACGP guidelines for benzodiazepine use suggest that these drugs are not used for longer than 4 weeks (RACGP, 2015). There is limited data on benzodiazepine utilisation in Australian ACHs. When we compared the dosages of benzodiazepines in the same group of residents of ACHs in 2006 and then again, 12 months later, in 2007, we found that nearly two-thirds of residents taking benzodiazepines were taking the same agent, at the same dose. Less than a quarter of all residents had their dose reduced as recommended (Westbury et al., 2010).

c. Regarding specific dosages of psychotropics prescribed, mean antipsychotic doses aligned with current recommended doses for older people with dementia. However, the average doses of benzodiazepines prescribed to residents exceeded maximum
recommended geriatric doses. Doses of sedating antidepressants and anticonvulsants were in accordance with recommendations (Westbury et al. 2019).

15. Another aspect of psychotropic prescribing is marked variation in usage between different homes. To illustrate, the proportion of residents in each home taking antipsychotics in our sample of 150 homes ranged from 6 to 44\% (Fig 3). Concerningly, over a quarter of the residents in a third of our total sample \((n = 53)\) were taking antipsychotic medication every day. It should be stressed that homes specialising in changed behaviour or severe mental illness were excluded from our study. What is striking is that some homes were able to operate with minimal antipsychotic use, whereas other homes were giving these medications to over 40\% of their residents.

![Percentage of residents taking regularly charted antipsychotics](image)

Figure 3: Variation in antipsychotic rates of use between ACHs. N.B. Each vertical pink line represents a separate home.

16. As alluded to previously, review of psychotropic medication in Australian homes tends to occur infrequently. A 2014 study tracked psychotropic review in 17 NSW ACHs over a 6-month period, reporting that fewer than half of residents were reviewed over this period. Of those residents taking psychotropic medication that had reviews, less than 8\% had their doses reduced or ceased over this timeframe. Residents were more likely to have a dose increase than reduction (Yang et al, 2014). The overall review rate would be even lower now as funding for pharmacist-provided medication reviews was capped from once a year to once every two years shortly after this study was conducted.

17. High rates of sustained antipsychotic and benzodiazepine use in ACHs strongly suggest an absence of awareness or non-adherence to guidelines. Further, the marked variation in psychotropic prescribing also indicates inconsistency in practice. In general, antipsychotic and benzodiazepine medications are prescribed too often and for too long to aged care residents. Less is known about antidepressant and anticonvulsant utilisation in Australian ACHs.
Alternatives to psychotropic use in Australian ACHs:

18. For common old age mental health conditions (mild-moderate depression, anxiety, insomnia and ‘changed behaviour’ in residents with dementia) there is some evidence to support using psychotropic medication; however, for most older people their effectiveness is modest, and they can cause severe adverse effects such as falls, pneumonia, and stroke (RANZCP, 2016; Glass et al., 2005). Given this unfavourable risk/benefit ratio, guidelines now recommend that psychotropics are trialled only when symptoms cause distress or confer risk of harm, and then after detailed assessment and when non-pharmacological approaches fail (RACGP, 2015; RANZCP, 2016).

a. As a pharmacist I am an expert in medication and strive to ensure its quality use. Other health practitioners, especially those specifically trained in old age mental health (i.e. from old age mental health services or the Dementia Behavioural Management Advisory Service (DBMAS)), have training and experience in alternative strategies to psychotropic use and would be better placed to talk to this. In summary, good practice management of old age mental health symptoms, including changed behaviours in people with dementia, involves targeting the symptom and detailed mapping of it, and working collaboratively with family, carers and staff at the ACHs to establish the background, needs and wishes of the resident. Such an approach is often referred to as ‘person-centred care’. Detailed guidance is available within the DCRC/DBMAS 2012 publication, ‘Behaviour Management: A Guide to Good Practice’ which is available at: https://www.dementia.com.au/hotattachment/947e82e7-841f-49ed-bb8b-4348b446b0f1/Behaviour-Management-A-Guide-to-Good-Practice-5.aspx. All current Australian guidelines advocate that detailed assessment of people with dementia and changed behaviour is conducted to seek and address potential causes and contributors, and that non-pharmacological strategies are trialled before psychotropics are used.

b. Behavioural and psychological symptoms are wide ranging and will respond to different non-pharmacological approaches. These include modifying communication, distraction techniques, providing meaningful activities matched to the resident’s abilities and preferences, and altering the environment so it is more or
less stimulating. One of the most effective approaches is providing one-to-one care. It needs to be stressed that non-pharmacological strategies are an essential for person-centred care and should be continued when psychotropics are administered.


**Aged care staff psychotropic medication knowledge:**

19. In my experience aged care staff have very limited knowledge about psychotropic medication. When I first started researching psychotropic use I was concerned by basic questions staff were asking. As examples; they were checking whether oxazepam should be prescribed instead of risperidone to calm an agitated resident? (there is no evidence supporting the use of routine oxazepam for BPSD). They were also surprised that benzodiazepines cause falls (they are the leading cause of falls!). They queried if mirtazapine was best for sleep (it is an antidepressant). In general, staff know more about the practical aspects of psychotropics such as the reasons they are used for than recommended durations of use and the adverse effects to look out for.

a. As part of my qualitative research I asked staff what guidelines they referred to when they used psychotropic medication. None of the twenty nurses interviewed could name a guideline. Several said they checked doses occasionally in the ‘MIMs’, a pocket-sized manufacturer listing of Australian licensed medications. Relevantly, guidelines for use are not incorporated within the MIMs.

b. As part of my doctorate I developed and validated a dedicated ‘Older Age Psychotropic’ (OAP) quiz in 2008; a simple 10-item quiz. For the subsequent RedUSe expansion, the quiz was revised to incorporate new guidelines and a ‘don’t-know’ option included to discourage guessing. The main rationale of the OAP quiz was to test staff knowledge before and after educational sessions. At the same time the quiz proved effective at identifying the key deficits in staff knowledge and informed educational content of the staff training (Brown & Westbury, 2016). The OAP quiz was completed by 1273 staff from 2014-2015 at the start of all RedUSe training. Fig 4 shows staff baseline knowledge before the training sessions. Only 4 out of 10 questions were answered correctly by more than half of participants. Questions about indications, or reasons for use, were more likely to be answered correctly than those about guidelines or side effects. Registered nurses received significantly higher scores than enrolled nurses or carers. Likewise, enrolled nurses performed significantly better on the quiz than carers.


As part of my Doctorate and subsequent post-doctoral study I conducted a large body of research to understand the key influences underlying psychotropic prescribing. After interviewing nurses, doctors, directors of care, pharmacists and relatives I found that the drivers affecting use are complex and multi-factorial. Of all groups impacting prescribing, nursing and care staff are the most influential. Ultimately, aged care staff are front-line. They provide direct personal care to residents, observe changes in health status, directly deal with changed behaviour and psychological symptoms when they occur and observe their impact on other staff, residents and relatives. Many staff believe that these medications are more beneficial than research suggests. They often stated that they felt psychotropics improved residents' quality of life and that they were needed to ‘calm and comfort’ them. Staff also expressed the view that they were required to improve the quality of care that other residents experienced and that relatives often asked them to ‘do something’ about behavioural symptoms such as calling out. Further, aged care staff were often not aware of side effects associated with use, often attributing adverse effects of falling, drowsiness or movement effects as related to ‘getting old’. There was marked reluctance shown by staff to alter agents or doses due to the possibility that behavioural or psychological symptoms would worsen or reappear.

a. In one-to one interviews GPs said they were asked to prescribe these medications by nursing staff. None could recall being asked for them by relatives. Most GPs assumed that assessment and trials of non-drug strategies had occurred before being asked to prescribe. They often felt that if they used low doses side effects would be minimised and would often justify use by stating they only prescribed ‘a small amount’. Comprehensive assessment of a resident’s symptoms by GPs as recommended by professional guidelines occurred infrequently. Review of psychotropic agents did not occur routinely, if at all.

b. Although pharmacists are funded by the Federal government to review medications of residents in ACHs they reported resistance from GPs and staff to suggestions to reduce psychotropic use. Many said that other prescribing was much easier to influence.

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Figure 4: Baseline knowledge of care staff taking the OAP quiz (Westbury et al, 2017).
c. Relatives often reported that the only time they were knew about medications being started was when they noticed them listed on a pharmacy bill. Consent to start, or alter, existing psychotropic medication was rarely sought from ‘persons responsible’ despite the legal obligation to do so (Westbury, 2011).

21. Similar themes have emerged in international research. Walsh et al. (2017) conducted a systematic review of international studies determining factors influencing antipsychotic use in people with dementia. Of 18 studies meeting inclusion criteria from inception to July 2016 reasons for prescribing antipsychotics included:

a. Understaffing and insufficient time to engage with residents, for thorough assessment and to perform non-drug strategies;
b. Staff inability to deal with the severity of behaviour of residents;
c. Lack of training on non-drug ways to manage ‘changed behaviour’, leading to pressure on prescribers from staff to initiate antipsychotics;
d. Inadequate knowledge of prescribers and staff on the risks and benefits;
e. Poor communication within healthcare teams and with families;
f. Uncertainty regarding roles and responsibilities in relation to antipsychotic prescribing, and

g. Fear of behaviour recurrence if medication was altered (Walsh et al., 2017).


Regulatory provisions and guidelines for psychotropic medications in ACHs:

22. Psychotropic medications, like all potentially dangerous drugs and chemicals, are restricted to enable their safe and effective use. ‘Scheduling’ is the legal process used to achieve this. Scheduling is in legal terms a State matter, but all States now adhere closely, or entirely, to the Poisons Standard, which is administered by the Department of Health. In general, the higher the schedule number, the more access is restricted. Most psychotropic drugs are Schedule 4 which means that they must be prescribed by a registered prescriber, predominantly a GP or less often, a nurse practitioner.

23. Standards for medication management in aged care are currently covered by the Accreditation standards, specifically Standard 2.7: Managing Medications Safely and Correctly. These standards set out the requirements relating to safe and effective use of medications in aged care. They are supported by a Department of Health publication, the ’2012 Principles for Medication Management in Residential Aged Care Facilities’ which are intended to assist homes to develop, implement, and evaluate locally specific policies and procedures, support those involved in assisting residents, and support residents in the medication management process. Concerningly, the new Standards to apply from July 2019, do not clearly spell out what is expected of ACHs with regards to
medication management. There is limited mention of restraint in the new standards despite calls from professional and advocacy bodies to do so. The term 'restrictive practices' is referred to briefly in standard 3 and broadly encompass physical, psychological, environmental and chemical restraint. At present, the only direct stipulation relating to restraint is in Standard 8: that the organisation demonstrates a clinical governance framework, including minimising the use of restraint.

tional-web.pdf). In April 2019 this publication was re-promoted by the Department of Health without updating despite new Standards and regulations for restraint coming into force from July 2019, and changes to pharmacist-provided RMMRs. The publication provides background about the use of psychotropics as chemical restraint and strongly endorses appropriate assessment, consent and the use of non-pharmacological strategies before psychotropics are initiated. Throughout my research I interviewed 20 aged care staff in depth and conducted focus groups with 8 directors of nursing and 24 other aged care staff (n= 52 staff in total). Not a single participant referred to this publication when asked about their use of guidelines. To my knowledge it is not referred to or commonly used in practice.

b. A more general reference book to guide ACH clinical care is the 'Silver book' or 'Medical care of older persons in residential aged care facilities (4th edition)' (RACGP, 2006). This publication was published 13 years ago by the RACGP. There are many professional guidelines and advice sources to guide prescribers and pharmacists on appropriate psychotropic use. During the RedUSe study the Therapeutic Guidelines, published by a consortium of Victorian professional organisations and intended to guide the prescribing decisions of GPs, was referred to by pharmacists (Psychotropic Expert groups, 2013). There is also the Australian Medication Handbook - Aged Care Companion which is updated regularly (AMH Aged Care companion, 2018). In 2015, the RACGP published a lengthy guideline on benzodiazepine use for GPs, and in 2016 the RANZCP released a professional guideline on antipsychotic use for BPSD (RACGP, 2015; RANZCP, 2016).

c. Despite the publications listed above, only one of five GPs interviewed could identify a guideline or information source they referred to when prescribing. This was a leaflet about antipsychotic use in people with dementia from NPSMedicineWise.

Factors that should be considered before psychotropic medication is prescribed:

24. All professional and government endorsed guidelines, including as the recently re-endorsed 'Supporting a Restraint-Free Environment in Residential Aged Care' stress that a comprehensive assessment by the prescriber and healthcare team be conducted before psychotropics are prescribed. This assessment should seek possible causes and contributors to behavioural and psychological symptoms (e.g. pain, infection, sensory impairments and medication). Triggers for symptoms should also be sought. Relatives and people who know the resident well should be contacted to establish the needs and preferences of the residents with regards to their care and day to day activities. These people may also have information about what may trigger certain behaviours and advise on ways to assist the resident. Usually, one symptom is targeted and documented in the resident's care plan, as well mapping on how often the behaviour occurs and its severity. In this way antecedents can be sought, and other staff informed about the target behaviour and suggested management.

a. Another important factor to consider is the resident's current medication and co-morbidities (other illnesses) before psychotropics are prescribed. For example, most antipsychotics should not be given in people with Lewy Body Dementia or Parkinson's disease because to do so will increase movement disorder symptoms. Antipsychotics should be also used under specialist supervision in people with hypertension, diabetes or other cardiovascular risk factors due to an increased likelihood of stroke. Likewise, benzodiazepines should be used cautiously given their risk of over-sedation, increased falls risk, and paradoxical agitation (Psychotropic Expert Groups, 2013).

b. Minimising the total number of psychotropics prescribed is essential to reduce the risk of an adverse event. Many people in aged care are prescribed multiple agents with sedating properties. A large Swedish database study of over a million patient records of older people reported that the overall number of psychotropics was associated with an increased risk of falls, hospitalization and death. Among persons with dementia (n = 58,984), a dose-response relationship was found between number of psychotropics and risk of death (Johnnell et al, 2017).

c. Before psychotropics are prescribed, all professional guidelines stress the importance of obtaining informed consent from the resident, or in the event they lack capacity, from the 'person responsible', usually a close relative, enduring guardian or Public Guardian. Legal requirements vary from state to state. 'Informed consent' means the prescriber or ACH clinical nurse advising the resident, or their legal representative, of the benefits to be expected with psychotropic use, adverse effects and risks that taking the medication may confer, and the plan for review.

d. In my qualitative interviews, most relatives said that the first they knew of these medications was when they queried the pharmacy bill (Westbury, 2011). In practice, I came across one Tasmanian ACH that had a dedicated form to be signed by the resident or their legal representative before psychotropic medication was started. I believe such practice and documentation is rare.
Review of psychotropic medication that may have the effect of restricting an individual's behaviour or free movement:

25. Low starting doses of psychotropic medication should be used in older people, with doses increased slowly. To start, there should be at least weekly review of the target behaviour and potential adverse effects. The goal of treatment is to use the lowest effective dose for the shortest period (Psychotropic Expert Groups, 2013).

a. The professional guidelines for antipsychotic use to treat BPSD stress that these medications are reviewed within 3 months and the dose reduced and ceased where possible (Psychotropic Expert Group, 2013; RANZCP, 2016).

b. In general, benzodiazepines should be used on an intermittent basis for severe agitation or anxiety. If required for anxiety and/or insomnia in older people, these agents should be used for a maximum of 2-4 weeks, with the dose reduced and ceased where possible (Psychotropic Expert Groups, 2013; RACGP, 2015).

c. Sedating antidepressants should only be used in people with diagnosed clinical depression not exclusively for insomnia or agitation at night. Review for effectiveness as an antidepressant is recommended after 6-8 weeks (Psychotropic Expert Groups, 2013).

d. Other psychotropics are not indicated for use in BPSD. Off-license use for behavioural and psychological symptoms should be initiated by specialist medical practitioners (i.e. old age psychiatrist, geriatrician). Review of all psychotropics should be conducted on a 3-monthly basis (Psychotropic Expert Group, 2013).

26. It is the duty of care of a community pharmacist to query any medication that exceeds maximum recommended dosage or may result in a major drug interaction. Accredited pharmacists conducting RMMRs have access to medical case notes so are able to comment on duration of treatment and recommend dose reduction in accordance with guidelines.


'Chemical Restraint':

27. The Government publication 'Supporting a Restraint Free Environment in Residential Aged Care' defines chemical restraint as 'the control of a resident's behaviour through the intentional use of medication'. Chemical restraint 'is when no medically identified condition is being treated and includes the use of medicines when part of the intended pharmacological effect of the medicine is to sedate the person for convenience or for disciplinary purposes' (Australian Government, 2012).

a. It is difficult to clearly explain what constitutes 'chemically restraining' a resident. I have had several directors of care homes categorically state that chemical restraint is never used and has never been used in their home. When queried about their high rates and extended duration of psychotropic use they claim that all these drugs are prescribed for mental illness, or to residents with the medical condition of dementia; thus, all use is justified.

b. In my opinion, the focus should not be on whether a medication is being used to 'restrain' a resident. It is very easy to excuse use by stating that the resident is diagnosed with a medical condition or mental illness. Instead, the focus should be whether psychotropic medication prescribed for any resident is used appropriately. That is, in accordance with professional or government guidelines and publications.

c. A consistent recommendation in all professional and government publications is that informed consent of the resident, or their legal representative, is obtained before initiating or altering psychotropic medication (Australian Government, 2012; Psychotropic Expert Groups, 2013; RACGP, 2015 RANZCP, 2016).


Suggested measures to ensure appropriate psychotropic use in aged care homes:

28. Inappropriate psychotropic use in ACHs has been highlighted as an issue in aged care for several decades. Psychotropic use is a complex problem and, as such, requires a combination of complex multi-strategic, interdisciplinary and regulatory approaches. Involving aged care staff in all strategies, especially the review process, and fostering an 'evidence-based prescribing culture' within each home is key. There are several systematic reviews of interventions addressing inappropriate psychotropic use in aged care. Most conclude that multiple co-ordinated strategies are required to reduce use and that inter-disciplinary collaboration between health practitioners is crucial for success (Harrison et al, 2019, Thompson-Coon et al, 2015, Westaway et al, 2018). The following strategies are recommended:
a. Many homes are not aware of their own psychotropic use. Although this data is readily available from pharmacy packing programs and more recently, from PBS data, homes find it difficult to interpret this information. Quality indicators of antipsychotic use are used in the U.S.A and Canada to benchmark each home's use. However, Quality Indicators for psychotropic use should not be confined to a single agent. To do so often results in prescription of substitute sedating medication. Measures of antipsychotic and benzodiazepine use (regular and prn) are required quarterly and should be benchmarked against local and target rates of use. Rates of dose reduction/cessation also require auditing.

b. Quality evidence-based educational programs on psychotropic use are required for aged care staff, prescribers and pharmacists. Such education needs to be evaluated for effectiveness (e.g. through validated knowledge tools). Ideally, these programs should be delivered face to face in the care home to foster interactive discussion, with all staff and health practitioners encouraged to attend. Education needs to be re-enforced by practical guidelines. Practical training and support are also required for staff on non-pharmacological strategies. The Federal Government recently announced that clinical pharmacists will be employed by the Aged Care Quality and Safety Commission (ACQSC) to conduct staff training on psychotropic use although specific detail on the program or its reach has not been provided. The ACQSC has been offered the use of all RedUSe educational material.

c. Targeted interdisciplinary review of residents taking psychotropic medication needs to be performed on a 3-monthly basis as recommended. Teams require a registered nurse, GP and accredited pharmacist. At present, RMMRs do not involve nursing staff. Given the substantial influence staff exert when psychotropic medication is initiated it is vital they inform and support all prescribing decisions particularly review. Staff also interact with residents so are ideally placed to monitor the impact of any alteration to psychotropic medication.

d. We often received feedback that a strength of the RedUSe program was that it offered a structured process for review. Strategies were conducted in a systematic fashion within a distinct timeline (i.e. audit, then education & feedback, followed by review). Roles of the nurse, pharmacist and prescriber with regards to psychotropic review were also clearly defined. Each home was part of a group of 8 - 15 homes under the mentorship of a trained pharmacist. This pharmacist conducted training for the designated champion nurse and for the QUM pharmacist to deliver the staff training. Similar mentorship may be required in aged care homes to ensure evidence-based psychotropic use.

e. The RedUSe program provided substantial evidence that a pharmacist-led program, incorporating quality improvement strategies and review, can significantly reduce the rate of psychotropic use and promote their review in aged care. Pharmacist-led medication review and quality use of medicines strategies have been funded and endorsed as part of Australian aged care policy since 1997. However, funding for these services is tied directly to funding arrangements for retail community pharmacy. The Federal Government negotiates payments for these aged care
professional services directly with the Pharmacy Guild, an organisation solely comprised of retail pharmacy owners. This funding arrangement has seen a marked deterioration in service provision over the past decade. It is not in pharmacy owners’ interest to have funding diverted from their own businesses for these services, many which are provided by independent pharmacists or bulk providers. Funding for professional pharmacy services in aged care needs to be clearly separated from that provided to retail community pharmacy for dispensing and local pharmacy programs. Accredited pharmacists with additional qualifications require a provider number and MBS item numbers to be funded to perform medication reviews and QUM services. To ensure these professional services are consistent with professional standards, regular auditing should be conducted through an independent body such as the ACQSC.

f. Finally, the current regulation and PBS availability of psychotropic medication needs to be tightened. Excessive rates of psychotropic use, along with continued evidence of multiple agent use, extensive ‘prn’ charting, excessive durations of use and the lack of monitoring and review provides strong evidence that current regulation offers no disincentive to inappropriate psychotropic use. Unrestricted access to these medications via the PBS through current streamlined authorities or listings on the general schedule further compounds the problem.


The Quality of Care Amendment (Minimising the Use of Restraints) Principles 2019:

29. Tough regulations on the use of restraint in residential aged care were promised by Minister Ken Wyatt in January 2019. Accordingly, new principles were released on 2 April 2019. The principles introduce two new provider responsibilities which regulate the use of restraint. The responsibilities differ according to whether the restraint is considered ‘physical’ or ‘chemical’. N.B. Physical restraint is now defined as any restraint other than chemical restraint or the use of medication prescribed for mental or physical illness. This means that environmental restraint and aversive treatment practices specifically referred to in the Government’s own recently promoted restraint publication are now considered to be physical restraint (Australian Government, 2012).

30. The new principles define chemical restraint as ‘involving the use of medication for influencing a person’s behaviour as opposed to a medication prescribed to treat mental or physical illness or physical condition’. The latest 2018 AIHW publication for residential aged care reports that over 85% of residents have mental illness. In addition, over 53% of residents have dementia; a diagnosed physical condition (AIHW, 2018). Thus, using this definition, there would be minimal ‘chemical restraint’ in Australian residential aged care.
a. The provider responsibilities for physical restraint are strong. This form of restraint (i.e. any restraint practice aside from chemical restraint) can only be used after an assessment that the resident poses a risk of harm by an approved health practitioner with day to day knowledge of the resident; that alternatives have been trialled, the least restrictive restraint is used, and legal informed consent is obtained (unless under an emergency). In the event physical restraint is used the provider must ensure that the care plan documentation includes the behaviours managed, alternatives used, reasons for restraint; that the restraint is used for the minimum time required; and that the resident is monitored, and the restraint reviewed regularly for need.

b. The provider responsibilities for chemical restraint are significantly weaker. According to the new principles the prescriber just needs to assess the resident. However, there is no stipulation that someone with day to day knowledge of the resident is involved. In the event chemical restraint is used the provider must ensure that the care plan documentation includes the behaviours managed, alternatives used (if any), reasons for restraint (if known) and that the resident is monitored, and information is provided to the prescriber regarding the restraint.

c. Most concerning, for chemical restraint to be used, there is no requirement for alternatives to be trialled, that the least restrictive option be used, nor that informed consent is required. There is no mention that the resident needs to pose a risk of harm before chemical restraint is used. The only stipulation is that the resident, in the prescriber’s opinion, requires restraint. Although physical restraint should be time-limited, there is no requirement for chemical restraint to be time-limited. Similarly, there is no stipulation that chemical restraint be reviewed regularly.

31. In my opinion, these regulations will make chemical restraint, or the inappropriate use of psychotropic medication, a much easier and preferable option than physical restraint. In addition, the new principles directly contradict professional guidance and their own government publication advice around the use of chemical restraint with regards to appropriate assessment, the need for non-pharmacological strategies to be trialled before use, time-limited durations of use and most importantly, obtaining legal informed consent before use (Australian Government, 2012; Psychotropic Expert Groups, 2013; RACGP, 2015; RANZCP, 2016).


Comment on the Coronial Findings in the case of the death of the Late Margaret Elizabeth Barton:

32. The case of Margaret Barton made distressing reading. Her medical history included advanced Alzheimer's disease; osteoarthritis; osteopenia (poor bone density with an history of fractures); hypertension and coronary heart disease. At the time of death, Mrs Barton had been given citalopram (antidepressant), olanzapine (antipsychotic), temazepam (benzodiazepine), paracetamol (analgesic), hydromorphone (narcotic analgesic), oxycodone (narcotic analgesic), metoclopramide (anti-emetic-vomiting), irbesartan (antihypertensive), buprenorphine (narcotic analgesic) and scopolamine (antihistamine/palliative care – to reduce secretions).

a. The day after admission to respite her GP prescribed 'prn' oxazepam 7.5-15mg twice a day for agitation. There is no mention of detailed assessment, trial of non-pharmacological strategies or obtaining informed consent.

b. The psychotropic therapeutic guidelines state to relieve symptoms of severe anxiety and agitation ‘oxazepam 7.5mg be given 1 to 3 times daily for no longer than 2 weeks as they exacerbate cognitive impairment and increase the risk of falls and associated injuries in older people’. Mrs Barton; however, was given a 15mg tablet (double recommended dose) over the next 2 weeks. The GP then changed the ‘prn’ order over to regular 15mg dosing three times a day (45mg total). The daily dose was double the maximum recommended and the duration of use well exceeded.

c. It is very apparent that despite extensive (excessive) oxazepam use, reports of her spitting, hitting and agitated behaviour continued. Benzodiazepines were not effective to abate her changed behaviour.

d. Falls occurred shortly after oxazepam was dosed the second and third time each day. Although the link between benzodiazepine use and falls is well established, regular high benzodiazepine dosing continued to occur despite Mrs Barton being categorised as a high falls risk. Although her oxazepam dose was reduced to 30mg/day the dose and duration of use still exceeded that recommended.

e. On 17th Feb Mrs Barton was diagnosed with queried delirium, yet the high dosing of benzodiazepines continued. The Therapeutic Guidelines state: It is impossible to emphasise enough how often delirium is due to drugs and that most patients recover without specific treatment once the drugs are withdrawn.

f. For an unexplained reason Mrs Barton was resumed on oxazepam 15mg three times a day (45mg total). She experienced 7 falls over the ensuing week. ‘Prn’ oxazepam dosing was also added over the next few weeks. On 2nd March she was administered a total of 5 x 15mg tablets (75mg); exceeding the maximum recommended ‘Therapeutic Guidance’ daily dosage of 22.5mg more than three-fold.

g. The omission of regular pain medication in her initial medication list speaks to poor assessment given Mrs Barton’s history of arthritis and fractures. Untreated pain, especially that related to possible untreated fractures, would have contributed to her agitation and behaviours, including hitting and spitting.
33. In my view, the prescribing and monitoring practice demonstrated in this case are haphazard and careless and not based on any available therapeutic guidance. I cannot understand why extensive doses of benzodiazepines were administered to an older person with osteopenia and a history of fractures? Why they were prescribed on a regular basis for agitated behaviours associated with dementia and continued for someone categorised as a ‘high falls risk’? There appeared to be limited assessment or review for treatment effect or adverse effects. When delirium was queried as a possible cause for agitation her psychotropic medication regime was continued despite clear recommendations to cease these medications in the event of delirium. It was clear benzodiazepines were not working in any case to alleviate her behaviours. Finally, I cannot understand, given Mrs Barton’s recent admission to the home, the complexity of this case and her lengthy medication list, why no pharmacist provided RMMR service was conducted?

34. Although this case is on the extreme side it demonstrates the overall lack of assessment, poor documentation and monitoring practice, extended use of multiple psychotropic agents, lack of knowledge about adverse effects and guidelines for psychotropic use in health practitioners, prescribers and aged care staff. Despite the complex nature of Mrs Barton’s case, cardiovascular risk factors and extensive risk of falls there was no consultation sought with an old age psychiatrist. It also points to a lack of provision of, or willingness to access, professional pharmacist and/or specialist advice.

35. To the best of my knowledge, no change to practice, Professional Guidance or recommendations occurred because of this Coronial Finding.