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RESEARCH ARTICLE

Pharmacotherapy of Persons with Dementia in Long-term Care in Australia: A Descriptive Audit of Central Nervous System Medications

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Abstract: ***Background*:** Neuropsychiatric symptoms of dementia are often treated through the prescription of one or more psychotropic medications. However, limited efficacy and potential harmful side-effects has resulted in efforts to reduce the use of psychotropic medication in this population, particularly for those living in long-term care.

***Objectives*:** This study sought to describe the pattern of central nervous system medication usage in older adults with dementia living in long-term care; assess the appropriateness of prescribing against Beers criteria; and detect potential drug interactions from co-administered medications.

***Methods*:** A retrospective descriptive audit of the medical records of n=415 residents, aged >60 years with a diagnosis of dementia, from 28 long-term care facilities in Queensland, Australia. Information extracted included the types and usage of regular and *Pro Re Nata* central nervous system medications.

***Results*:** Of those taking medication (n=317), 68% were prescribed at least one potentially inappropriate medication, and there was a significant positive correlation between the number of medications prescribed and the number of potentially inappropriate medications. Two-hundred potential interactions with variable severity were identified from 130 residents on ≥1 medication – 38% were potentially severe interactions, 46% were moderate.

***Conclusion*:** This medication audit raises concerns that prescription of medications may still be the first resort to treat behavioural and psychological symptoms of dementia. There is a need for effective and sustainable person-centred interventions that address barriers for appropriate prescribing practice, and involve the collaboration of all healthcare professionals to optimise prescribing and improve the quality of medicines in older people with dementia.

Keywords: Dementia, drug interactions, geriatrics, long-term care, medication, prescribing.

1. INTRODUCTION

Medications are an integral part of care for residents in long-term care (LTC) facilities, being used to treat a disease process, reduce or eliminate symptoms, and prevent a disease, or when there is no cure – as is the case of dementia – to promote maintenance of, or enhance, quality of life. People with dementia living in LTC are often frail, with multiple chronic and acute comorbidities that result in an average of 21 different medical problems that are frequently treated with medications [1]. Whilst medications can provide a positive role in the treatment of disease, they can also increase the risk of medication-related problems, particularly when there is a combination of medications, excessive dose, and limited monitoring of effects, and this can result in significant morbidity and mortality. Although the number of medication errors in Australian nursing homes is challenging to calculate, it is estimated that ~30% of unplanned geriatric admissions to acute hospitals are associated with adverse medication events, and at least 50% of them are potentially avoidable [2, 3].

Residents with dementia are prescribed, on average, 14.6 medications per person [4], and this has been shown to increase proportionally as the severity of cognitive impairment also increases [5]. Many of these medications may be con-

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sidered inappropriate [6], including medications used to restrain a person with dementia without their consent, which according to recent viewpoints has the potential to violate the Human Rights Act [7]. Consent for psychotropic medications via proxy is often low, with an Australian study finding that only 6.5% of residents with dementia, who lacked capacity to consent and were prescribed psychotropic medication, had proxy consent as needed to meet the Guardianship regulations [8]. In spite of such concerns, significant efforts have been made over the last five to ten years to reduce the use of psychotropic medication in this population [9-11]. Questions have been raised about medication used for the treatment of agitation, such as benzodiazepines and antipsychotics, which have shown limited efficacy, and do harm by increasing cognitive decline [10]. Further, whilst acetylcholinesterase inhibitors may offer people some improvement in the memory, function in daily activities, and behavioural and psychological symptoms of dementia (BPSD), such medications are effective for only a limited period of time, and this has added to the current debate about their use once people are institutionalised [12, 13].

Medication management in LTC facilities is managed by visiting health professionals. A quality of use of medicine (QUM) framework includes access to a Medication Advisory Committee, with the aim to support the safe and effective management and use of medicines. Beers and colleagues developed criteria to define the potentially inappropriate use of medication (PIM) in an LTC population [6]. Although developed for use in the US, Beers criteria are readily useable in Australia. It is imperative that the potential benefit and use of medications that affect brain functioning through pharmacological action on the central nervous system (CNS) is looked at in terms of benefits versus possible harmful effects. A review of medication patterns of residents with dementia living in LTC may help us to understand the impact of the medications, including their potential for harm. The current study sought to: 1) describe the pattern of CNS medication use in older adults with a diagnosis of dementia and living in LTC in Queensland, Australia; 2) assess the appropriateness of prescribing against Beers criteria [6]; and 3) detect potential drug interactions from the co-administered medications.

2. MATERIALS AND METHODS

2.1. Design

This retrospective descriptive audit was nested within a larger research project exploring the effect an interactive therapeutic robotic animal (viz., PARO) had on engagement, mood states, agitation, and psychotropic drug use in older people with dementia living in LTC [14] – Australian New Zealand Clinical Trials Registry (ACTRN12614000508673). Ethical approval was obtained from the University Human Ethics Committee (NRS/03/14/HREC) and respective care organisations. All participating residents provided personal or proxy written informed consent at the time of enrolment.

2.2. Setting and Sample

Residents were recruited from 28 LTC facilities operated by 20 care organisations in South-East Queensland, Australia. The facilities ranged in size (60 –167 beds) and age (2.5 – 49 years). Residents were eligible to participate if they had a documented diagnosis of dementia and were aged >60 years. Exclusion criteria included residents with: terminal illness; dual diagnosis of a serious or persistent mental illness; unremitting pain or distressing physical symptoms; and/or respite care admission.

2.3. Data Collection

Trained Research Assistants (RAs) collected the following data from participating residents at baseline of the larger project (within two-weeks of participant enrolment but prior to their participation in any intervention-related activities):

1. *Cognitive functioning* was assessed using The Rowland Universal Dementia Assessment Scale (RUDAS) [15]. The instrument covers the six domains of memory, visuospatial orientation, praxis, visuoconstructional drawing, judgement, and language. Total scores can range from 0 to 30, with lower scores indicative of greater cognitive impairment, and a score of ≤22 suggestive of possible impairment. RUDAS was used as it is unaffected by gender, education and non-English speakers' language.

The medical records of participating residents were also audited for details on the type and nature of diagnosed dementia.

2. *Agitation* was assessed using The Cohen-Mansfield Agitation Inventory – Short Form (CMAI-SF) [16]. Facility nursing staff rated – using a five-point scale ranging from "never" to "a few times an hour or continuous for half an hour or more" – how often the resident displayed 14 agitated behaviours in the previous two weeks. Total scores can range from 14 to 70, with higher scores indicative of greater agitation or behavioural disruption. The CMAI-SF is internationally established and recognised as reliable and valid for use with older people with dementia in LTC [17, 18].
3. *Medication* usage, both regular and *Pro Re Nata* (PRN) (*i.e*., as needed), and types were retrieved from resident medical records. Medications abstracted from the medical records were grouped by class according to the Monthly Index of Medical Specialties (MIMS) classification system [19].
4. *Demographic* data, extracted from medical records and discussions with residents/families/facility nursing staff, included: sex; age; health status; mobility status; sensory deficits; length of time at the facility; and information about the facility environment.

2.4. Data Analysis

Descriptive statistics were used to summarise resident demographic variables, with continuous data presented using means and standard deviations, and categorical data presented as numbers and percentages. Each medication dose was considered as one prescription event. Measures estimated included: total number of medications; number of

PRN medications; number of medications per resident; and percentage of each medication group prescribed of the total number of medications. The appropriateness of medication usage was compared against the 2015 modified version of Beers Criteria for Potentially Inappropriate Medication (PIM) use in older adults, including drugs to be avoided dependent or independent of a disease condition, and drugs to be used with caution lists [6]. The numbers of PIMs were calculated for each resident, and Spearman's rho correlation coefficient was used to assess the association between PIMs and the number of medications prescribed. For residents on more than one medication, MIMS DrugAlert, a reference-based interaction tool, was used to detect potential interactions between medications, and to provide a description of the severity level of each interaction [20]. A series of Spearman's rho correlations were undertaken to assess the association between residents' levels of agitation (CMAI-SF) and cognitive impairment (RUDAS), and prescribed antipsychotic and antidepressant medication. All data were analysed using SPSS version 22.0 (IBM Corp. Armonk, NY), with statistical significance set at $p<0.05$.

3. RESULTS

3.1. Sample Characteristics

A total of 415 residents from 28 LTC were included in the medication audit. Of these, three-quarters were female (n=314; 75.7%), with a mean age of 85 years (SD=7.76). All residents had a dementia diagnosis principally Alzheimer's disease (35.7%) or Vascular dementia (14.5%), when specified. Average RUDAS [15] scores were indicative of advanced cognitive impairment (7.32; SD=6.73), whilst average CMAI-Short Form [16] total scores completed by facility staff indicated infrequent agitation (scores equating to a frequency of 'less than once a week' – 30.07; SD=10.90). Three-quarters (76.4%) of residents were taking medications, with nearly half (48.0%) taking more than one CNS medication. The majority (84.1%) of residents had a sensory deficit – predominantly vision (82.8%) or hearing (54.2%) – and two-thirds had limited mobility (62.2%). Approximately 80% of residents had lived in their respective LTC for three years or less, and more residents lived in the secure dementia unit than the facility ward (56.9% versus 42.5% respectively) (Table **1**).

Table 1. Participant demographics.

Characteristic	*n*=415
Sex (female)	314 (75.66%)
Age (years)	84.97 (±7.76); 59-101
RUDAS (total score)	7.32 (±6.73); 0-27
CMAI-SF (total score)	30.07 (±10.90); 14-65
Diagnosis of dementia (yes):	415 (100%)
Alzheimer's disease	148 (35.66%)
Vascular dementia	60 (14.46%)
Dementia with Lewy bodies	6 (1.45%)
Fronto temporal lobar degeneration	6 (1.45%)
Alcohol-related dementia	3 (0.72%)
Unspecified	192 (46.27%)
Taking medication (yes):	317 (76.39%)
Taking ≥1CNS medication (yes)	199 (47.95%)
Mobility status:	
Mobile	147 (35.42%)
Mobile with aid	197 (47.47%)
Not mobile	61 (14.70%)
Sensory deficit (yes):	349 (84.10%)
Hearing[a]	189 (54.15%)
Vision[a]	289 (82.81%)
Olfaction[a]	6 (1.72%)
Touch/Pain/Tingling[a]	55 (15.76%)
Other[a]	16 (4.58%)
Time in facility (years):	
<1	146 (35.18%)
1-3	188 (45.30%)
4-6	61 (14.70%)
7-9	13 (3.13%)
≥10	6 (1.45%)
Facility care-type environment:	
Secure dementia unit	236 (56.87%)
Facility ward/unit	177 (42.65%)

Categorical data presented as n (%), continuous data are presented as mean (± standard deviation); range. Totals may not add up to n=415 or 100% due to rounding or missing data, or for items where more than one response could be provided, as indicated by [a]. RUDAS: The Rowland Universal Dementia Assessment Scale: A Multicultural Cognitive Assessment Scale; CMAI – SF: The Cohen-Mansfield Agitation Inventory – Short Form; CNS: Central Nervous System.

3.2. Medications Prescribed

A total of 665 medications were prescribed, of which 49 (7.3%) were PRN (Table **2**). Antidepressants were the most commonly prescribed CNS agent (28%), followed by antipsychotics (23.8%), and anxiolytics, hypnotics and analgesics (18.5%). The most commonly prescribed PRN medications were anxiolytics and hypnotics (57.1%), followed by analgesics (26.5%). The average number of medications prescribed per resident was two, although ranged from 1- 6 (Table **3**).

3.3. Appropriateness of Medications Prescribed

When Beers Criteria were applied independent of condition, 43.9% of the regular medications prescribed were identified as PIMs. These included first- and second-generation antipsychotics, benzodiazepines, and certain tricyclic antidepressants (TCAs), such as amitriptyline, doxepin and trimipramine, and the selective serotonin reuptake inhibitor (SSRI) paroxetine.

Table 2. PRN use.

Group	Medication	*n*	%
PRN antidepressants	Total group	1	2.04
	Escitalopram	1	100.00
PRN anxiolytics and hypnotics	Total group	28	57.14
	Lorazepam	1	3.57
	Clonazepam	0	0.00
	Midazolam	1	3.57
	Temazepam	12	42.86
	Diazepam	2	7.14
	Oxazepam	12	42.86
PRN antipsychotics	Total group	7	14.29
	Olanzapine	1	14.29
	Haloperidol	5	71.43
	Quetiapine	1	14.29
PRN analgesics	Total group	13	26.53
	Paracetamol-codeine	1	7.69
	Tramadole	1	7.69
	Oxycodone	7	53.84
	Morphine	4	30.77
Total PRN		49	7.37

PRN: Pro Re Nata.

Table 3. CNS medication use.

Group	Medication	*n*	%
Other CNS agents	Total group	40	6.49
	Donepezil	18	45.00
	Galantamine	11	27.50
	Memantine	8	20.00
	Rivastigmine	3	7.50
Antidepressants	Total group	173	28.08
TCAs:	Amitriptyline	4	2.31
	Doxepin	1	0.58
	Trimipramine	0	0.00
SSRIs:	Citalopram	25	14.45
	Escitalopram	21	12.14
	fluvoxamine	3	1.73
	Paroxetine	4	2.31
	Sertraline	31	17.92
Others:	Mirtazapine	46	26.59
	Duloxetine	6	3.47
	Venlafaxine	23	13.29
	Desvenlafaxine	9	5.20
Anxiolytics and hypnotics	Total group	114	18.50
	Temazepam	46	40.35
	Diazepam	11	9.65
	Oxazepam	56	49.12
	Lorazepam	0	0.00
	Flunitrazapam	1	0.88
Antipsychotics	Total group	147	23.86
	Olanzapine	15	10.20
	Haloperidol	8	5.44
	Quetiapine	18	12.24
	Chlorpromazine	1	0.68
	Risperidone	105	71.43
Antiemetics, antinauseants	Total group	1	0.16
	Prochlorperazine	1	0.16
Anticonvulsants	Total group	27	4.38
	Carbamazepine	2	7.40
	Sodium valproate	25	92.59
Analgesics	Total group	114	18.50
	Fentanyl	18	15.79
	Buprenorphine	66	57.89
	Paracetamol-codeine	1	0.88
	Tramadol	3	2.63
	Oxycodone	21	18.42
	Morphine	5	4.39
Total CNS		616	-

CNS: Central Nervous System; TCAs: Tricyclic Antidepressants; SSRIs: Selective Serotonin Reuptake Inhibitors.

Table 4. Beers Criteria.

Beers Criteria Application	*n*	%
PIMs condition independent (for regular medication)	271	43.99
PIMs condition dependent (for regular medication)	262	42.53
Medication use with caution (for regular medication)	285	46.27
Beers Criteria for PRN medications	7	14.29

PIMs: potential inappropriate medications; PRN: Pro Re Nata.

For condition dependent Beers Criteria, 42.5% of the regular medications were PIMs, including first- and second-generation antipsychotics and benzodiazepines. In addition, 46.2% of the included medications are recommended to be used with caution, including SSRIs, other TCAs, mirtazapine, carbamazepine and antipsychotics after failure of behavioural therapy. PRN antipsychotics (14.3%) were identified as condition dependent PIMs and, when possible, should be avoided (Table **4**).

Sixty-eight percent of residents on medications were prescribed at least one PIM, of which 29% were prescribed two or more PIMs. A significant, positive correlation was found between the number of medications prescribed and the number of PIMs ($r = 0.557$, $p < 0.01$).

3.4. Potential Drug-drug Interactions

A total of 200 potential interactions with variable severity were identified from 130 residents on more than one medication. Of these, 38% were potentially severe interactions, with the concurrent use of an antipsychotic and a hypnotic or an anxiolytic accounting for 64.4% of possible interactions that may cause respiratory depression, cardiac arrest, and death [20]. The co-administration of a hypnotic or an anxiolytic with the analgesic buprenorphine can lead to increased drug effects, such as sedation and decreased psychological performance [20], and this interaction accounted for 25% of the potentially severe events. Almost 6.5% of potentially severe interactions were between antipsychotics (quetiapine or haloperidol) and SSRI antidepressants – these can cause potentially life threatening polymorphic ventricular tachycardia [20]. Almost half of the potential interactions were of moderate severity. Twenty-six percent of these were for the concomitant use of the antipsychotic risperidone with SSRI antidepressants, which may lead to additive QT prolongation and serotonin syndrome effects [20] (Table **5**).

3.5. Prescribed Antipsychotic and Antidepressant Usage, and Levels of Agitation and Cognitive Impairment

A significant, positive correlation was found between residents' levels of agitation (CMAI-SF score) and prescribed antipsychotic usage ($r = 0.230$, $p < 0.0001$). Specifically, residents who were taking antipsychotic medication had significantly higher levels of agitation (Mean 33.4, SD=11.2) than residents not taking any antipsychotic medi-

Table 5. Drug-drug interactions [20].

Severity Level	*n*=200 (%)	Medication Classes	*n* (%)	Effect
Severe	76 (38.00)	Antipsychotic + anxiolytic or hypnotic (benzodiazepines)	49 (64.47)	Can cause respiratory depression, hypotension, ataxia arrhythmia, cardiac arrest and death
		Anxiolytic or hypnotic (benzodiazepines) + analgesic (buprenorphine)	19 (25.00)	Can lead to increased drug effects such as sedation and decreased psychological performance
		Antipsychotic (quetiapine, haloperidol)+SSRIs antidepressants	5 (6.58)	Can cause potentially life threatening torsade de pointes
Moderate	92 (46.00)	Antipsychotic (risperidone) + SSRIs antidepressants	24 (26.09)	May lead to additive QT prolongation or serotonin effects
		Anxiolytic or hypnotic (benzodiazepines) + analgesics (oxycodone, morphine, fentanyl)	20 (21.74)	Increase risk of sedation and respiratory depression
		SSRIs antidepressants + analgesics (fentanyl, oxycodone, tramadol)	13 (14.13)	May increase the risk of serotonin syndrome
		Anticonvulsants + antipsychotics (risperidone, quetiapine)	12 (13.04)	Carbamazepine may reduce antipsychotic effect
		Two analgesics buprenorphine + oxycodone or morphine	7 (7.61)	Valproate sodium can result in additive toxicity May precipitate withdrawal symptoms
Minor	28 (14.00)	Anxiolytic or hypnotic (benzodiazepines) + Antidepressant (mirtazapine)	22 (78.57)	May cause additive CNS depression
Caution	4 (2.00)	Antipsychotic (quetiapine) + antidepressant (mirtazapine)	4 (100.00)	May cause synergistic toxicity

SSRIs: Selective Serotonin Reuptake Inhibitor.

cation (Mean=28.3, SD=10.3). There was no association between levels of agitation and prescribed antidepressants (r = 0.069, p = 0.170), nor between residents' levels of cognitive impairment (RUDAS score) and prescribed antipsychotic (r = -0.071, p = 0.149) and antidepressant usage (r = 0.002, p = 0.968).

4. DISCUSSION

This paper provides a description of the pattern of CNS medication usage and the appropriateness of prescribing in older Australian LTC residents with dementia, according to Beers [6]. The paper also considers the potential for drug-drug interactions.

Despite medication guidelines calling for the reduction of psychotropic use in older people with dementia [6], this descriptive audit of persons with dementia living in LTC found that the majority of prescribed CNS medications were psychotropic medication, with two-thirds of residents prescribed at least one potentially inappropriate medication when assessed by Beers Criteria. This rate of inappropriate prescribing is higher than that found in previous Australian studies – perhaps owing to the prospective nature of our study – with 22% of inappropriate prescribing of benzodiazepines reported in war veterans identified in the Repatriation Pharmaceutical Benefit Scheme Claims database in 2005 [21], and 45% of inappropriate psychotropic use in nursing homes for the period 2006-2007 [22].

It is of concern that the quality of prescribing in this population does not appear to have changed, despite the clear recommendations against prescribing conventional and atypical psychotropic medication in older adults with dementia, with these agents known to cause serious adverse events such as stroke, death, cognitive decline, sedation, dizziness, and increase the risk of falls and fractures [23, 24]. Although antipsychotics were targeted in our study at residents with higher levels of agitation, our findings suggest that these medications had limited effect on BPSD, with proxy caregivers still rating agitation and behavioural disruption most frequently in those taking antipsychotics. The findings from a recent study undertaken in NSW, Australia, may heighten the need for a reduction in prescribing of antipsychotics in this population, as the study found no significant change in the behaviour of 75% of the 139 residents in LTC whose antipsychotic use was ceased at three, six, and 12 months [25].

Inappropriate prescribing can also result in inappropriate concomitant medications. As the number of prescribed medication increases, the possibility of drug-drug interactions and drug-disease interactions increases as well. In this study, an average of two (range 1-6) CNS medications were prescribed per resident. Some of the potential interactions from the co-prescribing of these CNS medications are serious enough to lead to hospitalisation, morbidity and mortality, and increases in health-related costs. For example, the co-administration of an antipsychotic and benzodiazepine can result in additive adverse effects and cause additive toxicity [20]. Another interaction that is common in practice, and is of particular concern, is the use of SSRIs with an opioid analgesic, particularly tramadol, as both medications have serotonergic effects that may increase the risk of serotonin syndrome and can result in mental, autonomic, and neuromuscular changes [26, 27]. All these interactions and hazardous consequences can be avoided if the involved medications are not concomitantly prescribed.

Although we have no data to confirm whether proxy consents were in place in this resident population, the question is raised as to whether the human rights of a person who is regularly restrained though psychotropic medication are being violated. An enquiry into the treatment of older people in the UK reported that inappropriate medication and use of restraint contravened the right not to be ill-treated, and can result in psychological harm [7]. An analysis of the prescribing situation through an ethical lens may help to reduce inappropriate medications being prescribed [28].

There are several factors that can influence inappropriate prescribing in LTC and these may make it difficult to change practice. First, it is difficult to change the prescribing habits of General Practitioners (GPs), especially if their mentoring and training are not evidenced-based [29]. Second, LTC facilities are attended by a number of GPs, and this has the potential for an inconsistent approach to the same problem and makes it very difficult to provide education [29].

Third, there is an absence of systems in LTC to identify and prevent PIMs, such as electronic prescribing or medical records, and computerised clinical decision support systems. When in place, these systems can have a significant improvement in reducing inappropriate prescribing [30]. A further challenge is also a poorly trained LTC workforce and, therefore, there are limited numbers of staff that can help GPs understand the impact of the medications prescribed. Staff education and pharmacist medication reviews have been shown to reduce the inappropriate use of psychotropic medications and need to be more regular within LTC [30, 31].

This medication audit raises concerns that prescription of medications may still be the first resort to treat BPSD, rather than a first-line approach to address residents' unmet needs through psychosocial interventions and cognitive therapy [32]. Although efficacy of psychosocial interventions is not strong, a recent systematic review reported that Person-Centred Care, communication training for staff, adapted dementia care mapping, and activities and music therapy are efficacious at reducing clinically significant agitation in care home residents, both immediately and up to 6-months [10]. It is imperative, therefore, that systems are in place to promote psychosocial interventions and reduce medications as a first resort.

There are several limitations to the current study. We only collected data on CNS medications and therefore this is a limitation to our reporting on drug interactions and inappropriate prescriptions. We did not measure the outcomes associated with the use of CNS medications, nor the consequences of the interactions – our aim was to explore medication patterns in LTC and to suggest potential solutions to optimise prescribing. Further, the duration of medication treatment was also not measured, meaning we are unable to assess the appropriateness of prescriptions in terms of the duration of treatment. Finally, the study was from one Aus-

tralian State (Queensland), and this may affect the generalisability of the results.

CONCLUSION

Inappropriate medication prescribing and potentially inappropriate drug combinations may increase morbidity, mortality, and healthcare cost. There is a need for effective and sustainable Person-Centred interventions that address barriers for appropriate prescribing practice and involve the collaboration of all healthcare professionals – physicians, nurses, and pharmacist – to optimise prescribing and improve the quality use of medicines in older people with dementia.

LIST OF ABBREVIATIONS

BPSD	=	Behavioural and Psychological Symptoms of Dementia
CMAI-SF	=	Cohen-Mansfield Agitation Inventory – Short Form
CNS	=	Central Nervous System
GP	=	General Practitioner
LTC	=	Long-Term Care
MIMS	=	Monthly Index of Medical Specialties
PIM	=	Potentially Inappropriate Medication
PRN	=	Pro Re Nata
QUM	=	Quality Use of Medicine
RA	=	Research Assistant
RUDAS	=	Rowland Universal Dementia Assessment Scale
TCA	=	Tricyclic Antidepressants
SSRI	=	Selective Serotonin Reuptake Inhibitor

CONFLICT OF INTEREST

Prof. Wendy Moyle was personally loaned equipment (five of the PARO) for the duration of the larger study by the developer, Dr. Takanori Shibata. Dr. Shibata provided no monetary support for the study, and had no role in any aspect of the study design, undertaking, analysis, and interpretation, or in the reporting of the findings and preparation of the manuscript. All other authors declare no financial, personal, or potential conflicts of interest.

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