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Submission for the Inquiry into the Quality of Care Amendment (Minimising the Use of Restraints) Principles 2019 [F2019L00511] to be held 20/08/2019, Sydney.

This submission made by me accurately sets out the evidence that I am prepared to give to the Inquiry into the Quality of Care Amendment (Minimising the Use of Restraints) Principles 2019 [F2019L00511]. The views I express in this submission are my own based on my education, training and experience. They are not intended to represent any views of my employer.

Professional and Academic background:

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 and old age mental health research. I qualified with a Bachelor of Pharmacy degree in Sydney in 1985, completed a Graduate Diploma in South Australia in 1997, a Master of Science (Distinction) at Keele University in Staffordshire, England in 2002 and graduated with a Doctor of Philosophy from the University of Tasmania in 2011.

After completing my pharmacy degree, I was commissioned as a RAAF pharmaceutical officer 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 aged care homes as a pharmacist until 2000. I then moved to the U.K. and worked as a 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 nursing home and was also the Lead for Older People. My U.K. Masters' research thesis involved *decision making in older people*.

When I returned to Australia in 2006, I commenced a PhD researching psychotropic medication use in Aged Care Homes (ACHs). The main component was an intervention program*; Reducing Use of Sedatives (RedUSe),* aimed to reduce the use of psychotropic medication. The program involved audit and feedback, staff education and interdisciplinary psychotropic medication review.

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. In 2018, the RedUSe project was awarded 'the Mental Health Services' (theMHS) award for Education, training or workforce development.

Regarding professional appointments, I have been a non-legal member of the Guardianship and Administrative Board of Tasmania since 2013. From 2017-2019 I was invited to join the Cognitive Impairment Advisory Group of the Australian Commission on Safety and Quality in Health Care (ACSQHC). I am a board member of 'Capacity Australia' and I presently serve as the Chair of the Tasmanian Branch of the Australian Association of Gerontology.

Medications that chemically restrain

The medications that are used to chemically restrain usually belong to a group of drugs called psychotropics. The most common class used to sedate residents with dementia are antipsychotics but other agents, including benzodiazepines and antidepressants are also used. All sedating psychotropic drugs increase the rate of falls and pneumonia. It is well known antipsychotics increase the rate of stroke and death from all causes. The ironic thing is that they often don't work very well for symptoms like wandering and calling out, the behaviours they are often prescribed for.[1]

Quality of Care Amendment (Minimising the Use of Restraints) Principles 2019 [F2019L00511]

This year we have heard harrowing stories of restraint use in our aged care homes in both the media and the Royal Commission. One story, screened by the ABC in January 2019, showed powerful images of Trevor before and after admission to one of these homes.[2] These pictures of a man effectively comatose in a chair, prompted the then Aged Care Minister, the Hon Ken Wyatt, to announce that legislation to address the overuse of 'chemical restraint' would be drawn up in just a few weeks.[3] The legislation, in the form of the 'Minimising the Use of Restraints Principles', were actually released 10 weeks later and came into force July 2019.[4]

Question 1: Whether the restrictions in the instrument on the use of physical and chemical restraints by approved providers sufficiently protect the human rights of aged care consumers?

My expertise is in psychotropic use in aged care. Accordingly, I will speak to the practice of chemically restraining residents. Instead of sending a clear message that chemical restraint will not be tolerated, the new principles effectively endorse their use over physically restraint. Further, the principles support prescription without consent. So not only do the principles contravene basic human rights but puzzlingly contradict advice from other government and professional bodies.

<u>What do the new Restraint Principles say?</u>

The stated purpose of the new principles is to limit the use of chemical and physical restraint by providers of residential care. Restraint is clearly defined as '*any practice, device, or action that interferes with a consumer's ability to make a decision or which restricts their free movement*'.[4]

In the new principles, restraint is divided into two categories: physical and chemical. Chemical restraint involves '*the use of medication to influence a person's behaviour*'. Physical restraint is now broadly defined as all other restraint forms (e.g. belting a resident to a chair, bed rails, confinement).[4]

The principles state that 4 conditions must be satisfied before physical restraint is used:

- There must be a full assessment conducted and documented by a medical or nurse practitioner or registered nurse who has day-to-day knowledge of the resident.
- The provider must consider, trial and document alternatives to physical restraint.
- The provider should determine the total period for which the physical restraint will be used, including periods of release; and,
- The provider must ensure it has the informed consent of the resident, or their legal proxy.

The conditions that must be satisfied before chemical restraint is used are a lot less stringent:

- A medical or nurse practitioner must assess the resident as requiring restraint, they must also prescribe the medication and record this decision, and
- *If practicable*, the resident or their legal proxy must be informed about the chemical restraint.[4]

Unlike physical restraint, the prescriber of chemical restraint doesn't have to know or physically examine the resident. They could prescribe this type of medication by phone or by fax which is a common practice.[5] There is no stipulation that alternatives to medication are sought or the duration of use set. More concerningly, consent of the resident, or their legal proxy, is not required. The prescriber just needs to tell the resident, or their legal proxy, when chemical restraint has been used, *if practicable*.

At present, the new Restraint principles appear to be written primarily for the convenience of prescribers? Surely, their intent needs to be focused on protecting the rights and ensuring the dignity and quality of life of one of Australia's most vulnerable groups, older frail residents of residential aged care homes.

What's the problem?

The Australian Charter of Healthcare Rights clearly states that people have a basic right to be included in decisions and choices about their care.[6] Consent is the agreement for the health practitioner to provide a person with treatment, including medicines. 'Informed consent' means the prescriber has explained the available options, the expected benefits and any risks. The onus is also on the prescriber to ensure that this information is clearly understood.[7]

The fact that consent, let alone informed consent, is not required in the new principles sends a clear message that restraining someone using medication is something that should be solely decided by the prescriber, usually a doctor. The principles show a stunning disregard for the rights of older vulnerable residents and the relatives, friends or proxy that legally represent them if they lack the capacity to make decisions for themselves.

Question 2: how the regulation of the use of restraints in the instrument compares to the regulation of the use of restraints in comparable jurisdictions and sectors (i.e. state and territory jurisdictions, the disability sector and broader health care settings)?

I cannot speak to regulation or existing legislation but I am familiar with the Australian Government publications and professional guidance relating to chemical restraint use.

Excessive use of psychotropics in Australian aged care has been highlighted for decades, with a recent 2018 report from the Australian Commission of Safety and Quality in Health Care (ACSQHC) stressing that the use of antipsychotics remained too high. To address this, a key recommendation was to gain informed consent (from patient or legal proxy) on a structured consent form to be mandated for use in aged care homes.[8] This was overlooked when the new principles were drawn.

In 2016, the Australian & New Zealand College of Psychiatrists released Professional Practice Guideline 10 on antipsychotic use in dementia in 2016. They stress "*when prescription of a medication is being considered, informed consent is essential. Therefore, it is necessary that information about the risks and benefits of prescribing a medication to a person with dementia is conveyed to the person or their substitute decision maker, and that this is understood*".[1] This guideline recommendation is not applied in the new principles.

Finally, and most perplexingly, in the Federal Government's own publication, '*Decision-making tool: Supporting a Restraint Free Environment in Community aged care*'[9], strongly endorsed in the new Aged Care Standards, it is stated that the use of restraint should only be considered after exhausting all reasonable restraint free options and be informed by a comprehensive assessment of the client. Importantly, the reference recommends that *'consultation should take place with the client, their carers and/or their representative, the person's family or other close associates, the medical officer if necessary and other relevant health professionals prior to a decision to apply restraint'*.[9] The new restraint principles thus contradict the Department of Health's own publication on restraint.

Question 3: Whether it would be appropriate for the instrument to be amended to provide additional safeguards for the use of both physical and chemical restraints?

The new principles require substantial amendment to comply with basic Human rights. They also urgently require amendment to align with professional guidelines, the recommendations provided by the ACSQHC and their own Department of Health Restraint reference: '*Decision-making tool: Supporting a Restraint Free Environment in Community aged care*'[9]

Specifically, the following amendments should be made:

1. Informed consent should be sought from the patient or their legal proxy before any form of restraint is used.

2. A psychotropic medication, for the purposes of restraint, should only be prescribed after exhausting all reasonable restraint-free options and only after a full comprehensive assessment of the resident by a prescriber, in person, informed by a nurse who has day-to-day knowledge of the resident.

3. The decision and reasons for chemical restraint should be documented in the resident case notes by the prescriber, alongside a clearly described plan for monitoring for effect and side effects, a date for review, with the view to dose reduction/cessation when clinically appropriate.

4. Prescriptions for 'prn' psychotropic medication should be prescribed under the same stipulations. In addition, the maximum dose/times to be administered each day, and indications for administering the medication should be clearly documented.

Question 4: Whether the substitute decision making arrangements set out in the instrument sufficiently protect the rights of aged care consumers.

Regarding the regulations pertaining to chemical restraint, there is little consideration for the basic human rights of aged care consumers. At present, the restraint principles appear to be written to appease prescribers and not inconvenience them.

The new restraint principles, as currently written, effectively reflect current practice in which consent is rarely sought, let alone documented, when chemical restraint is prescribed. It is well acknowledged that psychotropic medication is currently overprescribed in Australian aged care.[10] These principles do nothing to improve this situation. In fact, the concern is that by making chemical restraint the easier, less onerous option, to control the behaviour of residents, use of psychotropic medication will increase even further.

References:

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2. Anne Connolly & John Stewart, ABC News. *Aged care home resident strapped to chair for total of 14 hours in one day*. https://www.abc.net.au/news/2019-01-16/elderly-dementia-patients-given-anti-psychotics-and-restrained/10621658

3. Hon. Ken Wyatt. Media release. '*Aged Care Restraint Regulation to Protect Senior Australians'* 17 January 2019 http://pandora.nla.gov.au/pan/159736/20190131-0041/www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2019-wyatt011.html

4. Australian Government. Federal Register of Legislature. *Quality of Care Amendment (Minimising the Use of Restraints) Principles 2019*. https://www.legislation.gov.au/Details/F2019L00511

5. Westbury J. (2011) *Roles for pharmacists in improving the quality use of psychotropic medicines in Residential Aged Care Facilities*. PhD thesis. University of Tasmania

6. NSQHS. *Healthcare rights and informed consent*. © Australian Commission on Safety and Quality in Health Care 2017. https://www.nationalstandards.safetyandquality.gov.au/2.-partnering-consumers/partnering-patients-their-own-care/healthcare-rights-and-informed-consent

7. HealthDirect. *Informed consent* https://www.healthdirect.gov.au/informed-consent

8. ACSQHC. *Australian Atlas of Healthcare Variation Series. Atlas 2018. Repeat analyses.* https://www.safetyandquality.gov.au/atlas/the-third-australian-atlas-of-healthcare-variation-2018/5-repeat-analyses-2/#2

9. Australian Government. Department of Health.(2012) '*Decision-making tool: Supporting a Restraint Free Environment in Residential Aged Care'* available at: https://agedcare.health.gov.au/sites/default/files/documents/09_2014/residential_aged_care_internals_fa3-web.pdf.

10. Westbury J, Gee P, Ling T et al. (2019) More Action needed: Psychotropic prescribing in Australian RACFs. *Australian and New Zealand Journal of Psychiatry*. 53(2):136-47.

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What are psychotropic medications?

Psychotropic medications are '*capable of affecting the mind, emotions, and behaviour, and are used to treat mental illnesses*' (Farlex, 2012). The three main classes of psychotropic medications prescribed are antidepressants, anxiolytic/hypnotics (mostly benzodiazepines to manage anxiety and insomnia) and antipsychotics. Other psychotropic classes include anticonvulsants. Some practitioners class anti-dementia medication and opioids as psychotropic medication.

Medication used to manage changed behaviour in dementia

People with dementia may at some point in their illness develop behavioural or psychological symptoms, also referred to as '*changed behaviours'*. These symptoms include apathy, anxiety, restlessness, sleep disturbance, aggressive behaviour, delusions or hallucinations. For most of these symptoms it is important to understand and address the underlying reasons why they occur.

It is essential to ensure that the person with dementia is physically healthy, comfortable and well cared for. Whenever possible, the person should be helped to lead an active life with interesting daily activities. Changed behaviour can result from unrelieved pain, infections, eyesight or hearing problems, medication side-effects and the environment; e.g. changes to routine. It is important to investigate and rectify these factors before using medication (Dementia Australia, 2016).

When should psychotropic medication be used?

It may be necessary at times to prescribe medication if the psychological and behavioural symptoms are severe, cause distress to the person with dementia, pose a significant risk of harm and have not responded to non-drug treatments. Various classes of medications may be of benefit in the treatment of changed behaviour (Royal Australian & New Zealand College of Psychiatry, 2016).

When psychotropic medications are needed, a start low, go slow strategy should be used and non-drug managements continued. A single agent should be trialled at a time, with efficacy and side-effects monitored. Since the natural history of changed behaviours is variable (symptoms may 'come and go' or suddenly resolve), it is recommended that psychotropic use is time-limited and reviewed for potential dose reduction or cessation at least 3-monthly (RANZCP, 2016).

The treatment of depression and/or anxiety is slightly different as these conditions can have a major impact on the person's functioning and quality of life. Mild cases often respond well to psychological treatments, but more severe persistent depression and/or anxiety should usually be treated with antidepressant medication (Dementia Australia, 2016).

Consent

When psychotropic medication is proposed, obtaining 'informed consent' is essential. Information about the risks and benefits of prescribing a medication to a person with dementia must be conveyed to the person or their substitute decision maker (also known as their legal proxy), and it is important to check that this information is understood. In an emergency, when the safety of the patient or significant others are at risk, a doctor can act in the best interests of a patient unable to provide valid consent to their own treatment. When psychotropics are prescribed in such circumstances, informed consent should be obtained as soon as practicable if treatment is to be continued (RANZCP, 2016).

References:

Australian Medicines Handbook (AMH) (2018) Australian Medicines Handbook Pty Ltd.

Dementia Australia (2016) Drugs used to relieve behavioural and psychological symptoms of dementia. Help Sheet Q&A 4

RANZCP (2016). Antipsychotic medications as a treatment of behavioural and psychological symptoms of dementia Professional Practice Guideline 10. August 2016.

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N.B. This sheet does not represent an endorsement of any medication

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Psychotropic medications used in Australia (2019)

This list includes the psychotropic medications available in Australia grouped according to class. The generic name is given first, followed by examples of brand names.

Antipsychotics

Antipsychotic medications are used mainly to treat psychotic disorders and relieve symptoms such as hallucinations, delusions or disordered thought. Reasons for antipsychotic use in people with dementia include severe agitation and aggression associated with risk of harm, delusions and hallucinations and pre-existing mental health conditions such as schizophrenia (RANZCP, 2016).

Amisulpride (Solian, Sulprix)
Aripiprazole (Abilify, Abyraz)
Chlorpromazine (Largactil)
Haloperidol (Serenace)
Olanzapine (Zyprexa, Lanzek, Zypine)
Paliperidone (Invega)
Periciazine (Neulactil)
Quetiapine (Seroquel, Delucon, Quetia)
Risperidone (Risperdal, Rispa, Rixadonel)
Trifluoperazine (Stelazine)
Ziprasidone (Zeldox)

Antidepressants

Antidepressants are used to relieve psychological and physical symptoms of depression, with the benefit of treatment increasing with severity. Less serious depression is not routinely treated with medication as psychological therapies alone may be effective. Psychotherapy often enhances the effectiveness of antidepressant therapy (Australian Medicines Handbook, 2018). Antidepressants are also prescribed to treat severe and persistent anxiety disorders. The role of antidepressants to treat depression in people with dementia is still uncertain (Dementia Australia, 2016).

Agomelatine (Valdoxan)
Amitriptyline (Endep)
Citalopram (Celapram, Talam, Cipramil)
Clomipramine (Anafranil)
Desvenlafaxine (Desfax, Pristiq)
Dothiepin (Dothep)
Doxepin (Sinequan, Deptran)
Duloxetine (Andepra, Drulox, Cymbalta)
Escitalopram (Cilopam, Lexam, Lexapro)
Fluoxetine (Zactin, Lovan, Prozac)
Fluvoxamine (Faverin, Luvox)
Imipramine (Tofranil)
Mirtazapine (Mirtazon, Avanza, Axit, Remeron)
Moclobemide (Aurorix, Amira)
Nortriptyline (Allegron)
Paroxetine (Paxtine, Aropax)
Reboxetine (Edronax)
Sertraline (Xydep, Eleva, Sertra, Zoloft)
Venlafaxine (Efexor, Elaxine, Enlafax)
Vortioxetine (Brintellix)

Anxiolytics (for anxiety) Hypnotics (for sleep)

Benzodiazepines may have a limited role in the short-term treatment of anxiety and restlessness. Long-term use is not recommended. All benzodiazepines and the newer Z-drugs can result in excessive sedation during the day and an increased risk of falls. People can also become tolerant to their effects. They are often best used intermittently, rather than regularly (Dementia Australia, 2016)

Alprazolam (Kalma, Alprax, Xanax)
Diazepam (Antenex, Valpam, Valium)
Lorazepam (Ativan)
Oxazepam (Alepam, Serepax, Murelax)
Nitrazepam (Alodorm, Mogadon)
Temazepam (Temtabs, Temaze, Normison)
Zolpidem (Stildem, Stilnox)
Zopiclone (Imrest, Imovane)

Anticonvulsants (also used to treat epilepsy)

Carbamazepine (Teril, Tegretol)
Sodium valproate (Valpro, Valprease, Epilim)

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