Treatment for osteoporosis in Australian residential aged care facilities: consensus recommendations for fracture prevention

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here are about two million Australians over 70 years of age and the number is set to double within the next 20 years.¹ According to the federal Department of Health and Ageing statistics, a 70-year-old person today has a 36% chance of needing high-level residential care in his or her lifetime.² There are about 187 000 residents in 2938 residential aged care facilities (RACFs) across Australia. The average age of residents is 83 years, with an average length of stay of just under 3 years.²

Once older people enter an RACF, several changes occur in their care, including the opportunity to maximise adherence to medication regimens.^{3,4}

Osteoporosis treatment is a particularly challenging area in RACFs. Most residents are at high risk of suffering a fracture,⁵ but only a minority receive treatment according to their level of risk.⁶⁻⁸ The Consensus Conference on Treatment of Osteoporosis in RACFs in Australia (Consensus Conference), held in Sydney in July 2009, aimed to deal with some problems of treatment of older residents with osteoporosis in RACFs (Box 1). In this statement, we summarise the most relevant evidence on osteoporosis treatment in older people living in RACFs, graded according to its National Health and Medical Research Council (NHMRC) level of

1 Process of position statement development

Aim: To develop recommendations for the clinical management of osteoporosis in residential aged care facilities (FRACFs)

Source: At the Consensus Conference on Treatment of Osteoporosis in RACFs in Australia, experts in the fields of osteoporosis treatment, geriatric medicine and rehabilitation (n = 8) acted as moderators of small groups of participants and spoke at the plenary sessions. Geriatricians and general practitioners practising at the residential aged care level (n = 50) from all over Australia participated in the workshops and plenary sessions. The event was endorsed by the Australian and New Zealand Bone and Mineral Society and Osteoporosis Australia.

Method: A review of peer-reviewed journals was conducted using MEDLINE (1966–20 July 2009). Relevant articles were identified using combinations of the subject headings "osteoporosis", "nursing homes", "residential care", "long term care", "fractures", "fracture prevention", "calcium", "vitamin D", "bisphosphonates", "strontium ranelate", "teriparatide", "hip protectors", "falls" and "falls prevention".

Levels of evidence: Articles retrieved were graded according to their level of evidence (based on the National Health and Medical Research Council [NHMRC] levels of evidence [I, II, III (including III-1, III-2, III-3), and IV]). When an NHMRC level of evidence for a clinically relevant aspect of fracture and falls prevention in the residential aged care setting was lacking, recommendations were based on consensus expert opinion (designated evidence level V).

Final recommendations: Comments from all participants (experts and other participants) on the draft position statement were received and considered. Final clinical recommendations were prepared by the small groups and approved at the final plenary session.

ABSTRACT

- Older people living in residential aged care facilities (RACFs) are at considerably higher risk of suffering fractures than older people living in the community.
- When admitted to RACFs, patients should be assessed for fracture risk to ensure early implementation of effective fracture prevention measures.
- Routine or regular determination of calcium and phosphate serum levels in institutionalised older people is not indicated. Opinion is divided about the value of routine measurements of serum concentrations of 25-hydroxyvitamin D, parathyroid hormone and bone turnover markers.
- The non-pharmacological approach to fracture prevention includes multifactorial programs of falls prevention and the use of hip protectors.
- Vitamin D supplementation is recommended for all patients in RACFs. Dietary calcium intake should be optimised (1200– 1500 mg per day is recommended) and supplementation offered to those with inadequate intake. The decision to prescribe calcium supplements should be guided by patients' tolerance, whether or not they have a history of kidney stones, and emerging data about its cardiovascular safety.
- Bisphosphonates are the first-choice pharmacological agents for fracture prevention in older persons at high risk. Intravenous administration is as efficient as oral and has the significant advantage of better adherence.
- Use of strontium ranelate has not been tested on people in RACFs, but evidence in the "old-old" (those aged 75 years and older) suggests it could be a therapeutic option for fracture prevention in this setting.
- In general, teriparatide should not be considered as a firstline treatment for fracture prevention, particularly for people in RACFs.

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evidence and relevance.⁹ We hope that our summary will be an important guide for Australian physicians in their decision making.

Residential aged care facilities in Australia

The typical profile of an institutionalised older person in Australia includes chronic diseases, multiple medications, cognitive disorders, vision and hearing impairment, poor muscle strength, high risk of urinary and faecal incontinence, high risk of falls, and low bone mineral density (BMD).^{10,11} The institutional aged care system in Australia includes two levels of care: hostels and nursing homes.

In general, nursing home residents are heavily dependent on nursing staff to assist with their activities of daily living, whereas residents in hostels have support staff available but are unsupervised for substantial periods.¹⁰ For their medical care, residents in hostels can, because of their relative independence, see their usual general practitioners on a regular basis. In contrast, nursing home residents are usually assessed and treated by GPs who visit them at variable intervals.

Risk factors for fractures

Eighty-five per cent of nursing home residents worldwide are reported to have osteoporosis.¹² About 40% of all hip fractures occur in this population.^{13,14} Therefore, identification of at-risk institutionalised older people should be actively pursued. Although the risk factors for fractures in non-institutionalised populations are well known,¹⁵⁻¹⁸ the risk factors for people in RACFs remain less studied. In their recent study, Chen and colleagues reported the results of the Fracture Risk Epidemiology in the Frail Elderly (FREE) study.¹⁰ This prospective cohort study was designed to evaluate risk factors for falls and fractures in a population of 1894 older people (1433 women and 461 men) recruited from 52 nursing homes and 30 hostels in the Northern Sydney Central Coast Area Health Service. It was found that risk factors for people in RACFs differed from those for communitydwelling older people. Bringing together the results reported by Chen et al¹⁰ and other recent evidence¹⁹⁻²¹ on risk assessment for osteoporosis in RACFs, we summarised a new risk profile for hip fractures in people in RACFs (Box 2).

Assessing fracture risk

Two risk assessment tools are available to facilitate the identification of fracture risk in community-dwelling individuals. The FRAX²² and the Garvan²³ fracture risk assessment tools have become pivotal in closing the gap in care for people with osteoporosis. However, these tools have been validated in predominantly community-dwelling populations; their applicability to residents of RACFs, who have a different risk profile to community populations, remains unknown.

In their analysis of the FREE study data, Chen et al developed and validated²⁴ an algorithm to identify fracture risk in nursing home residents. This algorithm, which is available online,²⁵ integrates easily assessed clinical factors to predict the risk of fractures in the general population and is a promising tool for use in RACFs.

Routine or regular determination of calcium and phosphate serum concentrations in institutionalised older people is not indicated. Opinion is divided about the value of routine measurements of serum concentrations of 25-hydroxyvitamin D (25[OH]D), parathyroid hormone and bone turnover markers.

Fracture prevention

Despite the high risk of fracture in institutionalised older people, osteoporosis treatment rates in RACFs remain markedly low.^{26,27} Some of the potential causes for this treatment gap include limited access to diagnostic methods to identify fractures and quantify BMD; lack of knowledge about evidence-based interventions for osteoporosis in RACFs; assumptions about patients' length of stay and survival; and family and patients' concerns about polypharmacy and potential side effects.⁸ Nevertheless, hip fractures in institutionalised older adults are an important cause of morbidity

General population (evidence level I) Low bone strength (as assessed by dual energy x-ray absorptiometry or ultrasound) Female^{*} Older age* Maternal history of fracture History of previous fractures* Being tall at age 25 years Previous hyperthyroidism **Diabetes** mellitus Psychotropic medication use Greater caffeine use Postural instability* Institutionalised older persons (in addition to previous list) (evidence level III-2) Hostels Nursing homes Male* Male* Low serum vitamin D* Low serum vitamin D* Bowel or bladder incontinence* Bowel or bladder incontinence* Cognitive impairment* Cognitive impairment* Poor balance* Use of anxiolytics* Ambulatory* High serum phosphate* * Higher hazard ratio in institutionalised older persons v community-dwelling individuals. Adapted from Chen et al.¹⁰

2 Risk factors for osteoporotic fractures

and mortality that could be prevented with an appropriate evidence-based approach to treatment. $^{12}\,$

Several initiatives have been tested to improve physicians' awareness of the importance of identifying and treating osteoporosis. A recent randomised trial to improve fracture prevention in nursing home residents showed that audit feedback and education interventions are ineffective in improving fracture prevention.²⁷ In contrast, a practice redesign project was implemented in nursing homes in Arkansas, which included increasing physician awareness on preventing ageism, understanding polypharmacy and an eight-point post-fall assessment.²⁸ The use of a similar structured multidisciplinary approach, which includes pharmacological as well as non-pharmacological interventions, could be very useful in the Australian context, where access to prescriptions for osteoporosis is highly regulated and based on evidence of cost-effectiveness.

Fracture prevention interventions

Non-pharmacological

Falls prevention in nursing homes

As falls risk is an important determinant of fractures in institutionalised older people, there is agreement that all residents of RACFs should be screened for falls risk. Recently, researchers evaluated two models for screening falls risk in nursing homes.²⁹ They concluded that these two screening models were useful for identifying older people living in RACFs who were at increased

- 3 Falls prevention in residential aged care facilities recommendations
- On admission, new residents should be screened for falls risk using an evidence-based tool with clear links to interventions (level III-2).
- Risk assessment should be repeated every 6 months or in the event of a fall (level III-2).
- Evidence of screening and delivery of evidence-based falls prevention strategies should be included in residential aged care facilities' accreditation processes (level V).
- Medication should be reviewed annually by a pharmacist in association with the general practitioner to identify medicationrelated problems and ensure appropriate prescribing (level II).
- Psychotropic medications should specifically be reviewed in relation to falls risk. Use of benzodiazepines should be actively avoided in older people (level II).
- Education of residents and staff is required about alternative methods to enhance sleep quality (eg, day-time activity, avoiding day-time naps, non-pharmacological aids to sleep) (level II).
- Use of cholecalciferol with calcium should be considered for all residents (level II).
- Multifactorial comprehensive assessment linked to tailored intervention should be routine practice (level II).
- Exercise as part of a multifactorial intervention is recommended. Exercise must challenge balance and be undertaken at least twice weekly; carers should be encouraged to assist (level I).
- Environmental assessment, to make the interaction of residents with their environment safe, should be part of a multifactorial intervention (level I).
- Hip protectors should be part of a multifactorial intervention and targeted at people likely to be able to use them appropriately (level I).
- Use of physical, mechanical and chemical restraint is not recommended as a falls prevention strategy (level II).

risk of falls. The screening models, summarised in Box 3, are easy to administer and contain items for which data are routinely collected in RACFs in Australia.

Furthermore, a pharmacist in association with the GP should perform a medication review annually to identify potential or actual medication-related problems and support appropriate prescribing. This medication review should be particularly focused on the use of benzodiazepines and psychotropic medications.³⁰⁻³²

Other interventions to prevent falls have been multifactorial in nature and have addressed risk factors pertaining to the individual (eg, strength and balance training) as well as their ability to safely interact with their environment.³³ A recent Cochrane metaanalysis³⁴ reported that multifactorial interventions reduce falls and risk of falling in hospitals and may do so in nursing care facilities. The authors confirm the evidence supporting the correction of vitamin D deficiency³⁵ as an effective intervention to prevent falls in institutionalised older populations. However, in contrast to previous evidence showing that group exercise has an effect on falls prevention,³⁶ the authors of the Cochrane review conclude that exercise in subacute hospital settings appears effective but its effectiveness in nursing care facilities remains uncertain.

Hip protectors

Studies of the efficacy of hip protectors to prevent hip fractures in residents of RACFs have reported conflicting results, possibly due

to potential bias from clustered randomisation designs and modest adherence to the intervention.³⁷⁻³⁹ A multicentre, randomised controlled trial in 37 nursing homes,⁴⁰ which included 1042 residents, was unable to detect a protective effect against the risk of hip fracture despite good adherence to the protocol. In contrast, a Bayesian meta-analysis of four trials on the effect of hip protectors on fracture risk reported that hip protectors decrease the risk of hip fracture in elderly nursing home residents.³⁸

Pharmacological

Pharmacological treatment of osteoporosis based on BMD assessment has been found to be cost-effective in community populations and nursing home residents aged 85 years and older.^{41,42} Nevertheless, considering the particular characteristics of this population, and the difficulties of performing BMD assessment in RACF residents, physicians decide what treatment is appropriate after consultation with the patients, their families and the members of the multidisciplinary team, and after assessing the harm–benefit ratio of pharmacological interventions. The Consensus Conference concluded that, at the very least, those residents with a history of prior low-trauma fracture should be offered treatment with currently available agents.

Given the proven benefit for fracture prevention of most medications used for osteoporosis, their low risk of interactions with other medications and their relatively low incidence of adverse effects, osteoporosis medications should not be considered as "inappropriate prescriptions" in RACFs.⁴³ However, despite strong evidence supporting the use of osteoporosis medications in RACFs (Box 4), their use remains extremely low.⁴⁵

In general, selection of the most appropriate osteoporosis medication for the patient should include consideration of their likely potential benefit (the potential benefit for bed-bound individuals would be limited given the low risk); optimal dose frequency and route of administration; potential side effects and patient tolerance; adherence and compliance problems; cost-effectiveness; and ability to prevent fractures early.¹² In this statement, we summarise the evidence on the effectiveness of osteoporosis medications revised and discussed at the Consensus Conference. Although scarce, the relevant evidence, based on data about residents of RACFs, is provided. In addition, evidence obtained in similar populations (non-institutionalised "old-old" [75 years and older] and frail older persons) is discussed and summarised because of its relevance and potential benefit for the institutionalised population.

Calcium and vitamin D supplementation

There is evidence that vitamin D supplementation benefits most RACF residents.⁴⁶ Benefits include prevention of falls and fractures.^{47,48} Cholecalciferol (vitamin D₃) should be administered at a dose of 800 IU/day or higher.^{12,42,43} This is relatively inexpensive and achieves serum 25(OH)D concentrations >50 nmol/L in most subjects, so can be implemented without baseline or follow-up measurement of serum 25(OH)D concentrations, which can be relatively expensive. Recent studies suggest that high intermittent doses of vitamin D may be more effective in correcting deficiency than small regular doses; increase fracture and falls prevention;⁴⁹ and might achieve higher compliance,^{49,50} which is a major limitation of this therapy.⁵¹ In addition, access to sunshine for nursing home residents improves vitamin D status.⁵⁰ See Box 5 for recommendations.

A recent position statement on calcium and bone health⁵² concluded that adequate vitamin D status was essential for active

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4 Pharmacological prevention of fractures in residents of aged care facilities v community-dwelling older persons (adapted from Duque et al⁴⁴)

Agent	Dose	Evidence in institutionalised older persons	RRR in hip fracture in general population
Primary prevention			
Cholecalciferol	800 IU/day	Yes (fracture prevention) (level I)	0.12–0.29
Alendronate	10 mg/day	Yes (improves BMD only) (level II)	0.45–0.51
Risedronate	5mg/day	No	0.30-0.40
Zoledronate	5mg/year	No	0.41
Teriparatide	40µg/day	No	0.25
Strontium ranelate	2g/day	No	0.19
Secondary prevention			
Risedronate	5mg/day	No	0.26
Zoledronate	5mg/year	No	0.3
Strontium ranelate	2g/day	No	0.36

calcium absorption in the gut. In adults with a baseline calcium intake of 500–900 mg/day, increasing or supplementing this intake by a further 500–1000 mg/day has a beneficial effect on BMD.⁵² However, recent evidence suggesting supplementation may increase the risk of myocardial infarction indicates the need for caution.⁵³ Resolving the problem of whether or not benefits outweigh risks will determine the appropriateness of supplemental non-dietary calcium in fracture prevention. The use of high doses of vitamin D, either oral or parenteral, has not been approved for falls and fracture prevention in Australia. Based on the evidence suggesting that high doses achieve earlier correction of serum levels of vitamin D and could improve patients' compliance,⁵⁴ use of higher doses of vitamin D should become an alternative for people in RACFs in the near future.

Bisphosphonates

Bisphosphonates are the most commonly used medications for fracture prevention in the general population. However, the evidence supporting the use of bisphosphonates in institutionalised older persons is limited to just one randomised controlled study, which showed that alendronate improves BMD in nursing home residents.⁵⁵ Moreover, the optimal frequency and route of administration of bisphosphonates to minimise adverse events and maximise benefits in the RACF population need to be defined.¹² Considering the limited evidence available on the use of bisphosphonates in RACFs, the Consensus Conference reviewed, as have recent reports, ^{12,56,57} the evidence on the effectiveness of bisphosphonates on fracture prevention in the closest type of populations — the old-old and the frail older population.^{12,56,57} A summary of the evidence is provided in Box 6.

A particular limitation of using oral bisphosphonates for people in RACFs is that adherence could be affected by the administrative

5 Vitamin D and calcium supplementation in residential aged care facilities — recommendations

Vitamin D

- Supplementation should be universal (level V).
- Baseline and follow-up monitoring is not supported because of cost (level III-2).
- Optimal serum 25-hydroxyvitamin D concentration is > 50 nmol/L (level I).
- Dose equivalent to vitamin D 1000 IU/day (25µg/day) is necessary to achieve optimal serum 25-hydroxyvitamin D concentration (level I).
- Acceptability to the patient is likely to be higher with monthly dosing (level III-2).
- Sunlight exposure should be encouraged (level III-2).

Calcium

- General endorsement of calcium supplementation for all patients is not appropriate (level III-2).
- Long-term compliance with taking calcium is very poor (level I).
- Antifracture efficacy of calcium supplements is marginal (level I).
- Calcium supplements may increase the rate of hip fractures (level II).
- Calcium supplementation alone may increase the risk of myocardial infarction (level II).
- Increased dietary calcium should be encouraged in place of calcium supplements (level III-2).

burden on both nursing staff and patients caused by complex directions; patients with cognitive impairment; and a high prevalence of swallowing problems among residents.⁵⁸ In this setting, intravenous bisphosphonates could become a useful alternative because of the lack of gastrointestinal side effects, prolonged dose intervals (1 year) and 100% adherence over 12 months at least.⁵⁹

The number of potential side effects associated with bisphosphonates is a common concern of physicians when deciding on an osteoporosis treatment.⁵ Osteonecrosis of the jaw (ONJ) and atrial fibrillation are the potential side effects of most concern as they occur early after treatment has been initiated.⁵⁸ Although there are no reports on the prevalence of ONJ in nursing home patients treated with either oral or intravenous bisphosphonates, a recent task force of the American Society for Bone and Mineral Research⁶⁰ concluded that the risk of ONJ associated with oral bisphosphonate therapy for osteoporosis was low and that routine pretreatment dental assessment should only be performed in patients at high risk (cancer patients receiving intravenous bisphosphonates) and is not a cost-benefit option for all patients treated for osteoporosis. Finally, a recent systematic review and metaanalysis⁶¹ concluded that, while there are some data linking bisphosphonates to serious atrial fibrillation, heterogeneity of the existing evidence and a paucity of information on some of the agents precluded any definitive conclusions on the exact nature of the risk.

Other treatments

One anabolic treatment (teriparatide) and one other treatment (strontium ranelate) are available for fracture prevention in Australia (Box 7). A systematic review⁵⁶ on the efficacy and safety of pharmacological agents in managing osteoporosis in the old-old concluded that there was good evidence for the benefit of current

6 Use of bisphosphonates for fracture prevention in residential aged care facilities — recommendations

Primary prevention — patients without fractures¹⁰

- Prescribe calcium and vitamin D, and use multifactorial falls prevention strategy (level I).
- Strongly consider oral or intravenous bisphosphonates in those at high risk of fracture (level I).
- Recommend assessment of bone mineral density in patients at risk of osteoporosis before they move to a residential aged care facility (level III-2).

Secondary prevention — patients with fractures¹⁰

- Prescribe calcium and vitamin D, and use multifactorial falls prevention strategy (level I).
- Recognise that oral and intravenous bisphosphonate therapies are equally effective (level I).
- Recognise practical problems preventing successful uptake of oral bisphosphonates, including swallowing impairment; upper gastrointestinal side effects; patients' non-compliance; and probability of incorrect oral dosing because of practical administration difficulties.
- Recommend education of nursing staff by pharmacists on oral bisphosphonates dosing (level III-2).
- Consider intravenous administration of bisphosphonates as an effective way of overcoming dosing and compliance problems associated with oral administration (level V).
- Check serum levels of 25-hydroxyvitamin D and calcium, and the estimated glomerular filtration rate before using intravenous bisphosphonates (level II).

Fracture in residents taking bisphosphonates

- Consider using teriparatide if fracture occurs in a patient after 12 months of bisphosphonate therapy with a bone mineral density tscore < -3 and a history of at least one other fracture (level II).
- Consider strontium ranelate as an alternative treatment (level V).

Side effects of bisphosphonate therapy

- Oral bisphosphonates should not be used in patients with dysphagia or disordered swallowing (level I).
- Acute-phase reaction after intravenous bisphosphonates can be managed with prophylactic paracetamol therapy (level II).
- Osteonecrosis of the jaw is rare (between 1 in 10000 and 1 in 100000); good dental care is recommended.
- Atrial fibrillation is not thought to be significantly related to bisphosphonate use.
- Atypical femoral fractures are unlikely to be of concern in this group with the short total duration of bisphosphonate therapy.
- Treatment with oral or intravenous bisphosphonates should be reviewed after 5 years.

treatments in reducing vertebral fractures, but that data were limited for non-vertebral and hip fracture reduction. Strontium ranelate is the only agent to date that has demonstrated a reduction in non-vertebral and hip fracture in a high-risk elderly female population, but no studies have assessed the effect of strontium ranelate in an RACF population.

The anabolic medication teriparatide, recently approved in Australia, is administered subcutaneously once daily. Although no studies have assessed the effect of teriparatide on an RACF population, several problems, including the nursing time needed to administer the drug and its high cost, may limit its use in this

7 Other pharmacological treatment for fracture prevention in residential aged care facilities — recommendations

- Strontium ranelate can be considered as an alternative first-line treatment (level I).
- Strontium ranelate can also be considered for patients with possible bisphosphonate "failure" or intolerance (level II).
- Strontium ranelate should not be prescribed with other osteoporosis treatments except calcium and vitamin D (level V).
- Teriparatide should not be considered a first-line treatment and should only be considered in special circumstances (level V).

population.⁶² In general, teriparatide should not be considered as a first-line treatment for fracture prevention, and even less so in the RACF population.

Prevention of falls and fractures in older persons living in RACFs should include risk identification, fracture and BMD documentation, non-pharmacological and pharmacological interventions, staff education and participation of patients and families in treatment decisions. In addition, research in the field of falls and fracture prevention in RACFs should be encouraged.

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