Resource 2

Analysis of Australian Secondary Fracture Prevention Programs using Ganda's classification system

The systematic review of models of care for the secondary prevention of osteoporotic fractures by Ganda and colleagues provides a useful framework for classification of Secondary Fracture Prevention (SFP) Programs[1]. Models are classified as Type A to D, with Type A being the most intensive and Type D the least intensive. The main objectives of a SFP Program are to **identify** fracture patients, conduct **investigations** to diagnose osteoporosis and assess future fracture risk and, where appropriate, **initiate** osteoporosis treatment.

This resource considers Type A (3 i) models, Type B (2 i) models, Type C (1 i) models and Type D 'Zero' i models, which have the following characteristics:

- **Type A models:** Identifies, investigates and initiates treatment, where appropriate, for fragility fracture patients.
- **Type B models:** Identifies and investigates but leaves the initiation of treatment to the primary care provider.
- **Type C models:** Fracture patients receive education about osteoporosis and receive lifestyle advice including falls prevention. A key feature of this model is that the patient is recommended to seek further assessment because they are at increased risk of osteoporosis and repeat fractures, and the primary care provider is alerted that his/her patient has suffered a fracture and that further assessment is needed. This model does not undertake BMD testing or assessment of need for osteoporosis treatment.
- **Type D models:** Only provides osteoporosis education to the fracture patient. Type D models do not educate or alert the primary care provider.

The Australian and New Zealand Bone and Mineral Society (ANZBMS) recommends Type A models as the most effective model of care which should be the model implemented across Australia. However, we recognise that Type B models also represent a significant improvement in post fracture care. In addition, a Type B model can relatively easily be expanded to a Type A model within the same infrastructure. The SFP Program will employ dedicated personnel, often a nurse practitioner (NP) or a registered nurse (RN), to coordinate the fracture patient's care. The NP can provide all 3 i's* whereas the RN can only provide the first 2 (leaving the initiation of treatment to the primary care provider). The SFP Program coordinator(s) will work to pre-agreed protocols within the particular institution, with input from a physician with expertise in osteoporosis.

Descriptions of service models and key clinical outcomes follow for Type A to Type D models from Australia. For published studies of models which included a control/usual care group, the descriptions adhere to a standard format:

- The control/usual care group is described first, the intervention group(s) is/are described second.
- For the intervention group, the process for identification is described first, then investigation and, finally, initiation.
- Results for the various groups evaluated are tabulated for comparison in a standardised format.

Type A (3i) SFP Programs

Concord Repatriation General Hospital, Sydney

Post-fracture osteoporosis care was evaluated in a prospective controlled study for non-frail patients presenting with fragility fractures to this large tertiary referral centre in Sydney[2]. Care differed between the intervention and control groups as follows:

- **Control group:** Fracture patients who chose to decline the consultation freely offered by the program, in favour of follow-up with their primary care physician, were considered as the control group for statistical comparison. These patients were informed of the risks associated with minimal trauma fractures and their primary care physician (PCP) was informed of the fracture via the regular discharge summary. However, the PCP was not recommended to undertake further assessment. No data on BMD testing, biochemistry or imaging is available for this group. This is a **Type D (Zero i) model**.
- **Intervention group:** Patients aged 45 years and older who presented to Concord Repatriation General Hospital (CRGH) with a non-vertebral fracture were screened to establish whether the fracture had resulted from minimal trauma. This program did not manage frail patients who received care from an Orthogeriatrics Service at the same hospital. The program was delivered by an advanced trainee (i.e. a physician in his/her 4th-6th year of post-graduate training). Fracture patients underwent a standardised series of assessments and investigations, including:
  - Comprehensive clinical risk factor assessment
  - BMD testing at the hip and lumbar spine
  - Thoracolumbar spine radiographs (lateral and AP views)
  - Blood and urine tests

  Patients diagnosed with osteoporosis received education about their condition, the risks and benefits of treatment and the need for long-term adherence and persistence with medication. The majority of those treated received specific osteoporosis pharmacotherapy (either anti-resorptives or anabolics) in combination with vitamin D and calcium as clinically indicated. Patients were reviewed at 3 and 6 months, and annually thereafter. This is a **Type A (3i) model**.

The proportion of patients who received specific osteoporosis treatment following their fracture, and the proportion who suffered a refracture during 4 years follow-up are shown in table 1. Notably, more than 95% of patients in the intervention group remained on their initial treatment throughout the study period. Data on adherence rates for the control group were not available on account of the study design.

Table 1. Osteoporosis treatment after fracture and refracture rates at 4 years

Outcome	Control group Zero i model (%)	Intervention group 3i model (%)
Osteoporosis treatment	32.5	80.5
Refracture	19.7	4.1[a]

a. P<0.01 versus control group

The prospective controlled trial informed a formal cost-effectiveness analysis of the CRGH SFP Program[3]. The modelling was based upon the actual investigations used in the trial and their costs according to the Australian Medicare Benefits Schedule at the time. Key findings included:

- A mean improvement in discounted quality-adjusted life expectancy per patient of 0.089 QALY gained.
- Partial offset of the higher costs of the MTFL service by a decrease in subsequent fractures, which lead to an overall discounted cost increase of AU$1,486 per patient over the 10-year simulation period.
- The incremental costs per QALY gained (incremental cost-effectiveness ratio - ICER) were AU$17,291, which is well below the Australian accepted maximum willingness to pay for one QALY gained of AU$50,000.

A randomised controlled trial was conducted to evaluate compliance and persistence to oral bisphosphonate therapy[4]. The study sought to determine whether follow-up by the SFP Program over a 2 year period was superior to follow-up by the PCP, after initiation of treatment by the SFP Program. After initiation of oral bisphosphonate therapy by the SFP Program, patients were randomised to either 6 monthly follow-up by the SFP Program or referral to their PCP with a single visit to the SFP Program at 2 years. Compliance and persistence with treatment were measured using pharmaceutical claims data, and were defined as follows:

- **Compliance:** The extent to which patients act in accordance with the prescribed interval and dose of a treatment. Compliance at 2 years was measured by calculating the medication possession ratio (MPR), i.e. the ratio of the number of days a patient is in possession of a medication over the observation period, with maximum possible value being 1.
- **Persistence:** The cumulative time from initiation to eventual discontinuation of therapy. Persistence was defined as the number of days a patients was in possession of a medication to the first gap of therapy of >90 days after completion of the previous refill. A patient was considered persistent if there were no gaps in therapy of >90 days.

The results for the intention-to-treat analysis are shown in table 2.

Table 2. Intention-to-treat analysis of compliance and persistence with bisphosphonates at 2 years

Outcome	PCP follow-up for 2 years	SFP Program follow-up for 2 years
Compliant patients	47%	49%[a]
Medication possession ratio (MPR) at 2 years	0.79	0.78[b]
Persistence at 2 years	61%	64%[c]

a. P=0.85 versus PCP follow-up for 2 years
b. P=0.68 versus PCP follow-up for 2 years (Mann-Whitney U test)
c. P=0.75 versus PCP follow-up for 2 years (chi-squared test)

The authors concluded that compliance and persistence remained high for patients initiated on oral bisphosphonate treatment by an SFP Program, regardless of whether follow-up over a 2 year period was delivered by the SFP Program or local PCPs. This study highlights that early post-fracture intervention by an SFP Program is the key role of such services. This group also evaluated predictors of re-fracture amongst patients managed by the SFP Program[5]. Poor compliance with therapy, the presence of multiple co-morbidities, treatment with corticosteroids, low hip BMD and low body weight were all associated with increased risk of re-fracture.

Royal Prince Alfred Hospital, Sydney

The First Fracture Project (FFP) was established at this major public teaching hospital in Sydney in 2003[6]. A dedicated Osteoporosis Nurse (ON) was appointed to coordinate and facilitate secondary preventive care after initial educational and awareness raising programmes failed to change outcomes for patients presenting with fragility fractures. The FFP has not been evaluated in a study with a control/usual care group. The processes the FFP used to deliver care are as follows:

- **Identification:** The ON attends fracture clinics daily to interview patients aged over 50 years who have suffered a minimal trauma fracture. Patients are educated about diet, exercise, risk factor reduction and falls prevention.
- **Investigation:** The ON organises BMD testing, lateral spine X-ray, measurement of thyroid-stimulating hormone, vitamin D, parathyroid hormone and testosterone in men, and coeliac serology.
- **Initiation:** Patients with low bone mass (osteopenia or osteoporosis) are reviewed by a medical practitioner. Appropriate therapy is instituted and a letter is sent to inform the PCP that this has been done. A follow-up telephone call to the patient is made one month later to encourage compliance with treatment and to identify any issues. Bone density and vitamin D measurements are offered at the 12 month stage and communicated to the PCP. A summary recommendation letter is provided to the PCP of patients that decline or are unable to attend the review with the medical practitioner. This is a **Type A (3i) model**.

During the first 2½ years of the FFP, 655 fragility fracture patients with low bone mass, who were previously untreated for osteoporosis, received appropriate intervention. Whilst a formal cost-effectiveness evaluation was not conducted, the following information relating to cost implications of the FFP were reported:

- The cost to Medicare Australia for the FFP work-up was $423 per patient
- The FFP component of the Osteoporosis Nurse salary costs $40,000 per year
- The cost savings achieved by prevention of 1 hip fracture equates to 6 months salary of the Osteoporosis Nurse

Compliance with recommendations from the FFP appears to be high. Of the 90% of individuals that returned for the 12 month follow-up assessments, 95% of those recommended bisphosphonate therapy continued to take the medication. In 2013, this group published an analysis of logistical problems encountered and outcomes achieved for a cohort of fracture patients managed during one year of operations from July 2008 to June 2009[7].

Royal Melbourne Hospital

Development of a SFP Program at this major teaching hospital for tertiary health care occurred in three stages. From November 2008 to January 2009, an audit of secondary fracture prevention was undertaken for patients aged 50 years and over who had presented to orthopaedic fracture clinics[8]. This can be considered as a historical control group. In the following two years, two models of differing intensity were implemented to address the care gap identified by the baseline audit:

- **Intervention group 1:** Immediately after the baseline audit was completed, a simple orthopaedic policy was developed with relevant clinicians. The policy advised orthopaedic doctors to do the following:
  - Perform BMD testing
  - Measure serum 25-hydroxyvitamin D [25(OH)D] and calcium
  - Order renal function tests
  - Provision of dietary advice or supplementation for patients with inadequate calcium intake or low 25(OH)D (i.e. <50 nmol/L)
  - Send a letter to the PCP to recommend consideration of specific osteoporosis pharmacotherapy

  This is a **Type C (1i) model**.
- **Intervention group 2:** In April 2010, a SFP Program was established. A part-time nurse coordinator (0.3 FTE appointment) identified patients aged over 50 years who presented with a minimal trauma fracture who did not require hospitalisation. The nurse was responsible for the following tasks:
  - Identification of eligible patients at orthopaedic fracture clinics
  - Provision of a letter to the patient to explain the SFP Program
  - Order tests including DXA scan and blood tests (renal function tests [RFTs], liver function, calcium, thyroid function, serum protein electrophoresis, 25(OH)D, complete blood examination

  Patients were then referred to an endocrinologist (0.1 FTE appointment) for an osteoporosis assessment. Where warranted, osteoporosis treatment was initiated in accordance with NHMRC guidelines and patient preferences. A follow-up appointment was organised at 3 months after the initial assessment to assess medication tolerance and adherence, whereupon the patients was discharged to the care of their PCP. All patients' PCPs received comprehensive documentation pertaining to the care delivered by the SFP Program. This is a **Type A (3i) model**.

The results for the interventions as compared to the historical control group are shown in table 3.

Table 3. BMD testing and osteoporosis treatment

Outcome	Historical control group (%)	Intervention group 1 1i model (%)	Intervention group 2 3i model (%)
BMD Testing	2	28[a]	100
Osteoporosis treatment	6	10[b]	61

a. P<0.001 versus historical control group
b. P=0.504 versus historical control group

Forty four percent and 40% of patients managed by the SFP Program met the DXA criteria for osteoporosis and osteopenia, respectively.

Royal Newcastle and John Hunter Hospital

In 2007, a multidisciplinary SFP Program was established at this large tertiary referral hospital in New South Wales[9]. The SFP Program was subsequently evaluated in a prospective controlled study[10]. Care differed between the intervention and control groups as follows:

- **Control group:** Fracture patients who chose not to attend the SFP Program clinic were considered as the control group for statistical comparison. A letter was sent to these patients and their PCP suggesting investigation and treatment of bone fragility. This is a **Type C (1i) model**.
- **Intervention group:** Patients aged 50 years and older who presented to the Royal Newcastle and John Hunter Hospital were identified by a designated fracture prevention nurse (FPN) through the electronic Emergency Department (ED) reporting and review system. The SFP Program is delivered by the FPN and a rheumatologist who organise the following investigations:
  - Comprehensive clinical risk factor assessment
  - BMD testing
  - Blood tests
  - Falls risk is assessed and referral to a falls prevention clinic if indicated

  Patients receive education regarding osteoporosis with special emphasis on calcium and vitamin D intake, exercise and falls risk. Patients are initiated on specific osteoporosis pharmacotherapy of are reviewed on a second visit to discuss osteoporosis medications. The FPN undertakes telephone follow-up at 3, 6 and 12 months after clinic attendance to discuss compliance, diet and exercise, and falls risk. This is a **Type A (3i) model**.

Patients in both groups were surveyed between 12 and 40 months (mean 24 months) after their initial fracture. The proportion of patients who received specific osteoporosis treatment following their fracture, and the proportion who suffered a refracture during 2 years follow-up are shown in table 4.

Table 4. Osteoporosis treatment after fracture and refracture rates at 2 years

Outcome	Control group 1i model (%)	Intervention group 3i model (%)
Osteoporosis treatment	34.1	66.8[a]
Refracture	16.4	5.1[b]

a. P<0.001 versus control group
b. P<0.001 versus control group

St. Vincent's Hospital, Sydney

Development of a SFP Program at this major teaching hospital in Sydney occurred in two stages. From 2002 to 2003 two different information-based interventions were implemented with the aim of improving post-fracture osteoporosis care[11]. Participants who had not been investigated or treated for osteoporosis 3 months after their fracture had occurred were randomised to a letter group or a letter plus BMD group. Six months after randomisation, a standardised telephone interview was performed on all participants. Subsequently, from 2004 to 2006, a SFP Program was established to

address the persistent post-fracture care gap[12]. Care differed between these three intervention groups as follows:

- **Intervention group 1:** A personalised version of a letter was addressed to the patient, which noted the patient's risk factors for osteoporosis and recommended follow-up with the PCP. This is a **Type D (Zero i) model**.
- **Intervention group 2:** This group received the same letter as above and an offer of a free BMD test. The BMD test results were sent with a covering letter which suggested follow-up with their PCP. This is a **Type C (1i) model**.
- **Intervention group 3:** This group underwent comprehensive clinical risk factor assessment, including information about previous osteoporosis treatment. Face-to-face interaction with a medical registrar provided education about osteoporosis and consideration of potential lifestyle modifications. Bone density and blood tests were organised, the results being given to the patient by telephone. Patients with low BMD were invited to attend the Bone and Calcium Clinic to discuss anti-resorptive therapy. Treatment recommendations were given to the patient and sent by letter to their PCP. This is a **Type A (3i) model**.

The results for the three interventions are shown in table 5.

Table 5. BMD testing and osteoporosis treatment

Outcome	Intervention group 1 Zero i model (%)	Intervention group 2 1i model (%)	Intervention group 3 3i model (%)
BMD Testing	7	38[a]	83[b]
Osteoporosis treatment	7	5	36[c]

a. P=0.001 versus letter group
b. Of the 74% of patients who had not had a prior DXA scan
c. Of the 79% of patients who had not previously been treated with an anti-resorptive agent

Type C (1i) SFP Programs

Sir Charles Gairdner Hospital, Perth

Development of a SFP Program at this large, tertiary public hospital occurred in two stages. Between 2003 and 2005, an audit of secondary fracture prevention was undertaken for patients aged 50 years and over who had presented to orthopaedic fracture clinics with a probable minimal trauma fracture. This was part of a national survey that included 200 patients discharged from Sir Charles Gairdner Hospital (SCGH)[13]. This can be considered as a historical control group. Between 2007 and 2008, a multimodal strategy to improve secondary preventive care was developed and implemented[14]. The strategy had the following components:

- A member of the Care Coordination Team reviewed patients discharged from the Emergency Department (ED) with a fragility fracture.
- Patients were given a patient information leaflet and a single-page local consensus guideline.
- Patients were offered the options of review by the PCP or at the Fragile Bone Clinic (FBC).

- Patients referred to the FBC were contacted by a fracture liaison nurse within 2 weeks of referral, provided with further education on osteoporosis and encouraged to attend the FBC or visit their PCP for a review of osteoporosis risk.

This is a **Type C (1i) model**. The results for the intervention group as compared to the historical control group are shown in table 6.

Table 6. BMD testing and osteoporosis treatment

Outcome	Historical control group (%)	Intervention group 1i model (%)
BMD Testing	3	45[a]
Osteoporosis treatment	6	30[b]

a. P<0.05 versus historical control group
b. P<0.05 versus historical control group

The authors concluded that while the multimodal intervention had significantly improved rates of BMD testing and osteoporosis treatment, implementation of a Type A (3i) model SFP Program akin to that implemented in St. Michael's Hospital, Toronto would likely improve care further[15].

Type D (Zero i) Programs

The Coffs Fracture Card Project, New South Wales

The impact of a low-cost public health campaign combined with provision of a 'Fracture Card' to patients presenting with a minimal trauma fracture to Coffs Harbour Health Campus (CHHC) was evaluated[16]. The two components of the intervention were as follows:

- **Public health campaign:** This included:
  - Full-page advertisements in a local newspaper 4 times per year
  - Four educational meetings held with local health care professionals
- **Fracture Card:** The card was given to the patient with the recommendation to take to their PCP. The Card recommended that the PCP undertake 4 tasks:
  - Refer the patient for a BMD scan
  - Check 25(OH)D level aiming for a level of >60 nmol/L
  - Initiate a Pharmaceutical Benefits Scheme (PBS) subsidised osteoporosis treatment for which the fracture patient qualified
  - Advise about falls prevention

This is a **Type D (Zero i) model**. The initiative began in June 2010. The impact was evaluated by 'before and after' analysis of the number of 25(OH)D assays ordered, BMD scans conducted and the number of PBS-subsidised prescriptions for osteoporosis dispensed in Coffs Harbour. The results shown in table 7 overleaf compare the outcomes for the period July 2009 to June 2010, designated the historical control group, with the period July 2010 to June 2012, during which the intervention was delivered.

Table 7. Vitamin D assays, BMD testing and osteoporosis treatment

Outcome (per month)	**Historical control group (SD[a])**	**Intervention group Zero i model (SD[a])**
25(OH)D Assays	329 (±15)	568 (±21)[b]
BMD Testing	192 (±14)	296 (±12)[c]
Osteoporosis treatment	176 (±3.8)	180 (±3.5)[d]

a. Standard deviation
b. P<0.001 versus historical control group
c. P<0.001 versus historical control group
d. P>0.05 versus historical control group

These findings led to the establishment of a SFP Program in accordance with the New South Wales Agency for Clinical Innovation Model of Care[17].

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