



Osteoporosis and Fragility Fracture Risk Management

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Declarations

- I do private consultations at Claremont Hospital, Sheffield
- Received remuneration for speakership from pharmaceutical companies

I feel confident in managing osteoporosis and in preventing fragility fractures

1. Strongly disagree
2. Somewhat disagree
3. Neither agree or disagree
4. Somewhat agree
5. Strongly agree

Barnsley Health Economy

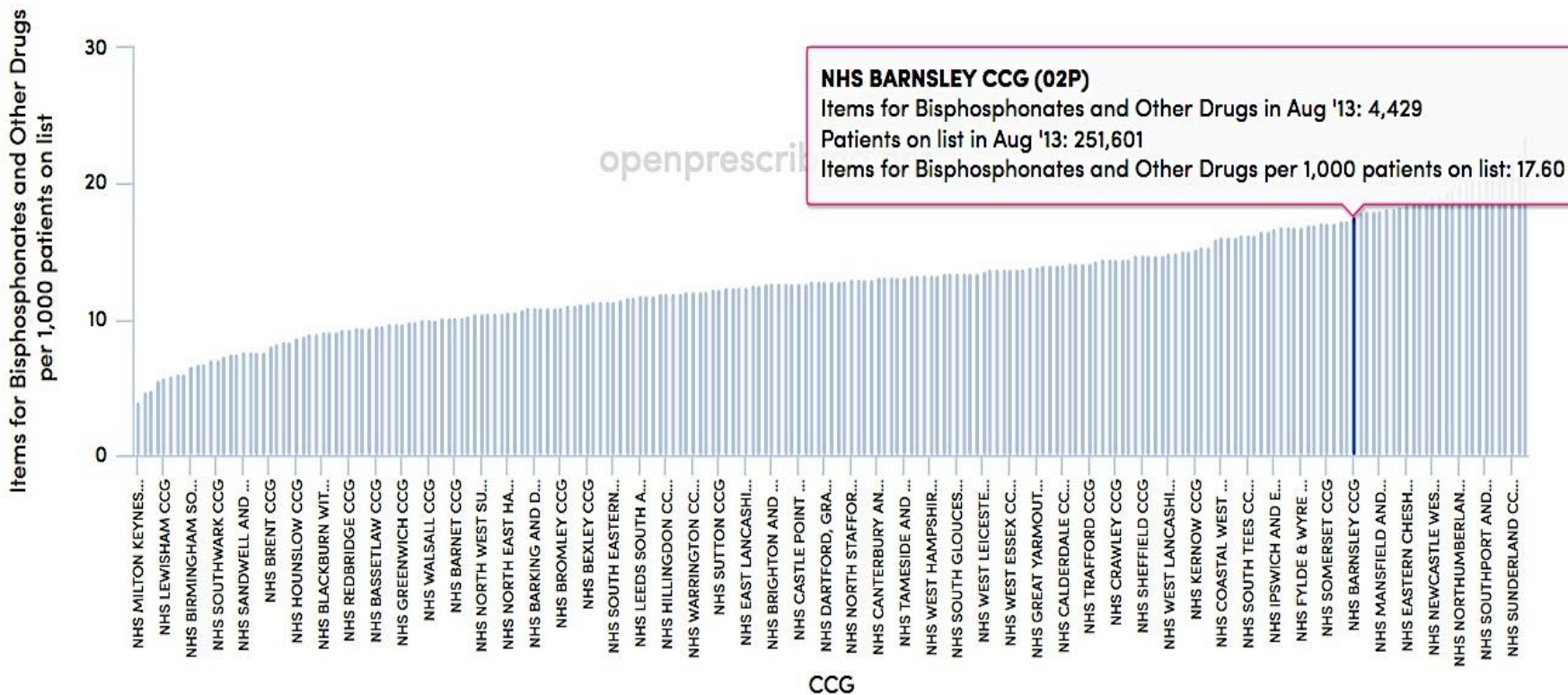
- Estimated population 2016 = 239,300
- Above age 50 years = 92,500
(above 75 = 19,500)

Average incidence of fractures in Barnsley (2015-16):

Hip fracture (inpatient)	Other fracture site (inpatient)	Other fracture site (outpatient)	Clinical vertebral	All
265	150	300	300	1015

Total cost of care 2015-16: £6.4 million (approx.)

Items for Bisphosphonates and Other Drugs vs patients on list by NHS BARNSELY CCG in Aug '13



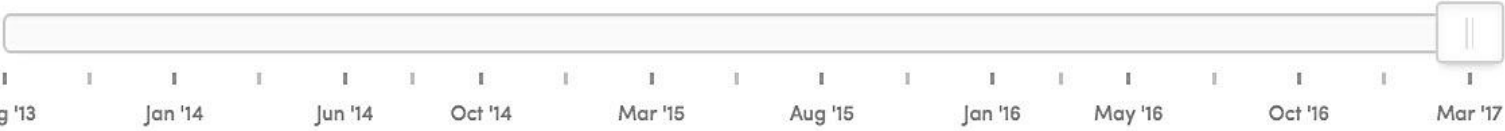
For clarity, practice graphs and maps only show standard GP practices, and exclude non-standard settings like prisons, out-of-hours services, etc.

Show vs other CCGs

Share ▾

Show over time

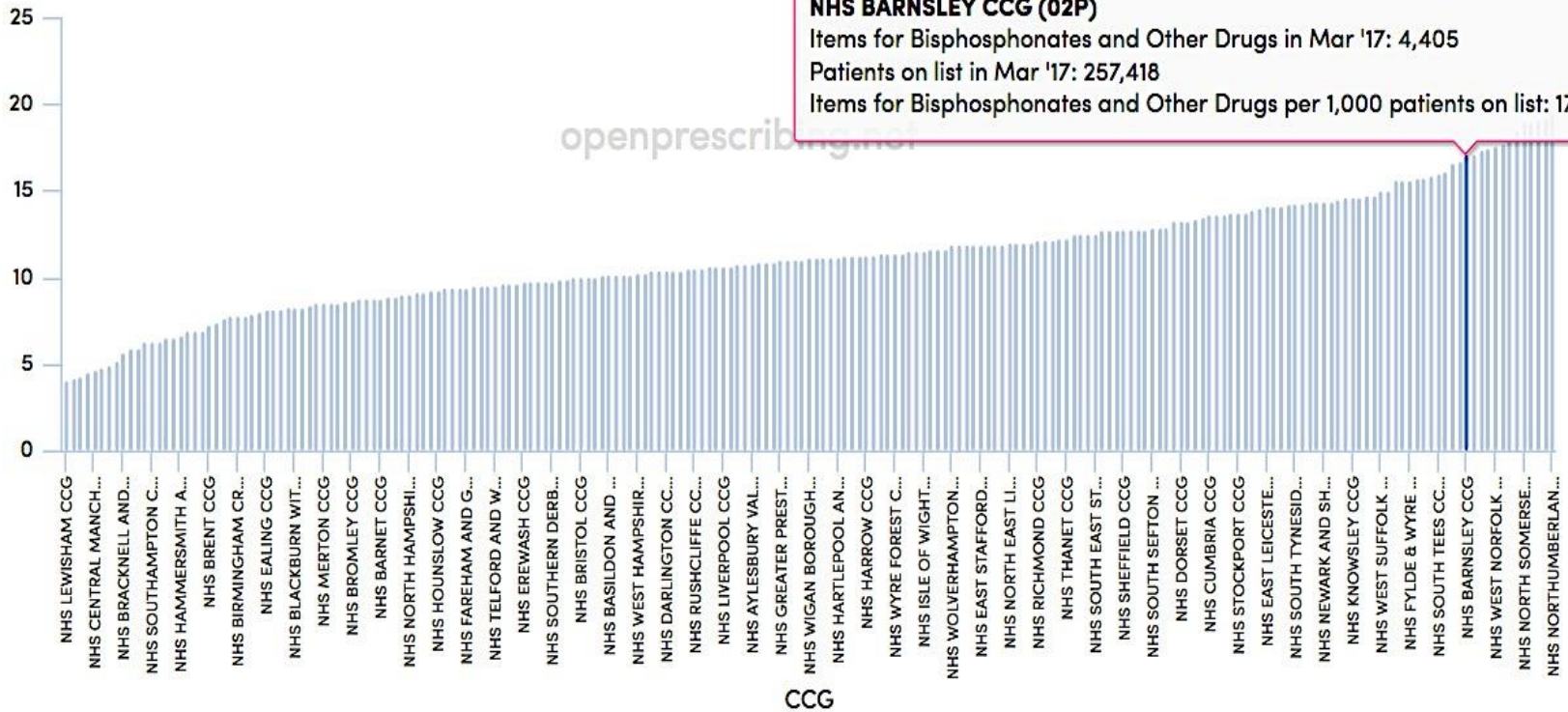
Show on map



spending **items**

Items for Bisphosphonates and Other Drugs vs patients on list by NHS BARNSELY CCG in Mar '17

Items for Bisphosphonates and Other Drugs per 1,000 patients on list



NHS BARNSELY CCG (02P)
 Items for Bisphosphonates and Other Drugs in Mar '17: 4,405
 Patients on list in Mar '17: 257,418
 Items for Bisphosphonates and Other Drugs per 1,000 patients on list: 17.11

For clarity, practice graphs and maps only show standard GP practices, and exclude non-standard settings like prisons, out-of-hours services, etc.

Built with Highcharts

Prevalence of PMO and Bisphosphonate prescription in top 5 practices in Barnsley (May 2017)

Practice	Total patients registered	Number of patients on oral BP	Approx. number of Female patients		Estimated prevalence of PMO		Estimated Percentage of PMO on BP
			above 50 + years age	above 75 + years age	above 50 + years age (14.6%)	above 75 + years age (43.6%)	
A	16809	276	3160	790	690	344	40%
B	13288	198	2498	624	546	272	36%
C	11963	136	2249	562	491	245	28%
D	11889	130	2235	559	489	244	27%
E	11719	160	2203	551	481	240	33%
F	11311	166	2127	531	464	231	36%

BP: Bisphosphonate – Alendronic acid, Risedronic acid, Ibandronic acid, Zoledronic acid

PMO: Post-menopausal osteoporosis

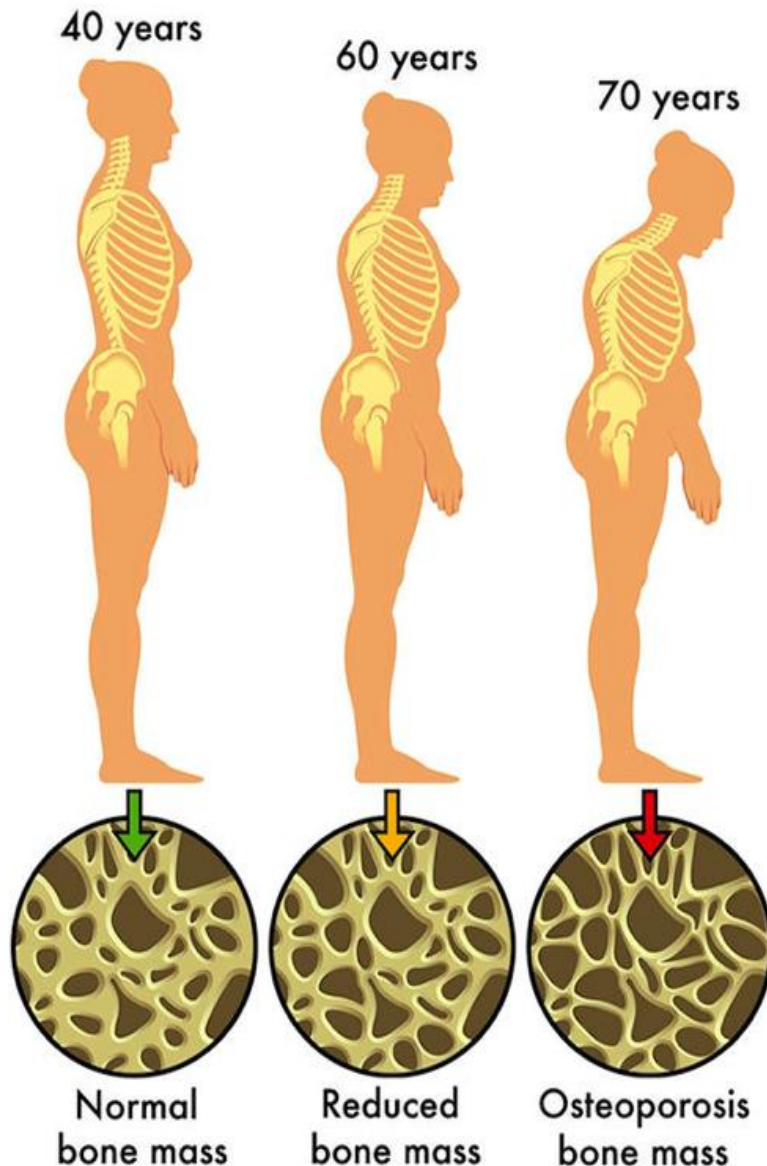
Case history

- 83 F. Had an unexplained fall at home and broke her right hip. Not sure about LOC.
- PMH – Left wrist fracture at age 65 after a fall
Known to suffer with hypertension.
- Drug history – Paracetamol, Ramipril,
Amitriptyline, Zopiclone

Risk of fragility fracture in women after age 50 in life time

1. 1 in 2
2. 1 in 3
3. 1 in 4
4. 1 in 5
5. 1 in 10

Definition and statistics



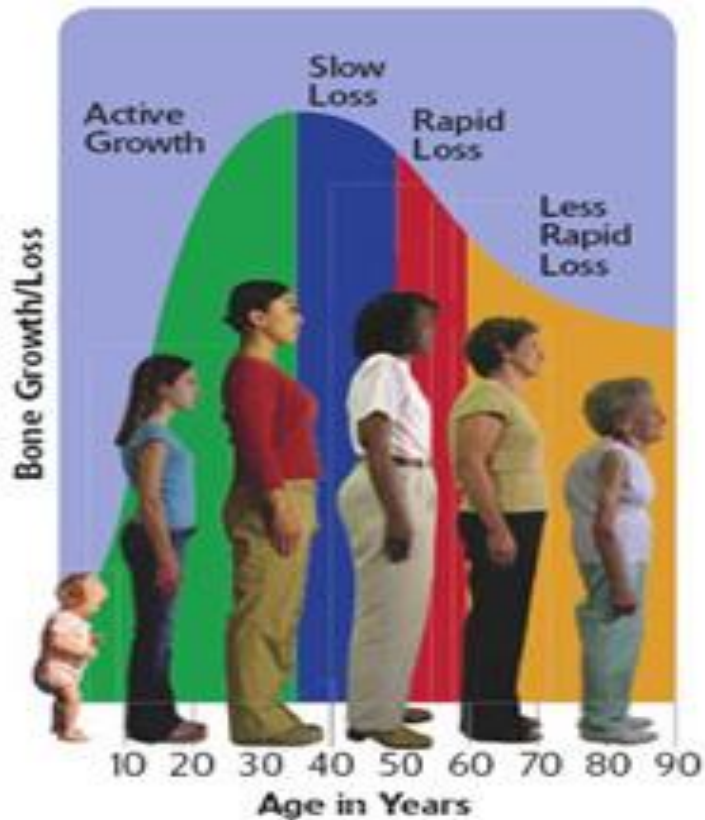
- Osteoporosis is a **progressive** systemic skeletal disease characterized by **low bone mass and microarchitectural deterioration** of bone tissue, with a consequent **increase in bone fragility and susceptibility to fracture**. (WHO 1994)
- Common sites of fragility fractures: Spine, distal radius, proximal humerus, proximal femur and pelvis.
- **95% of fractures occur due to fall**

Osteoporosis: definition and diagnosis

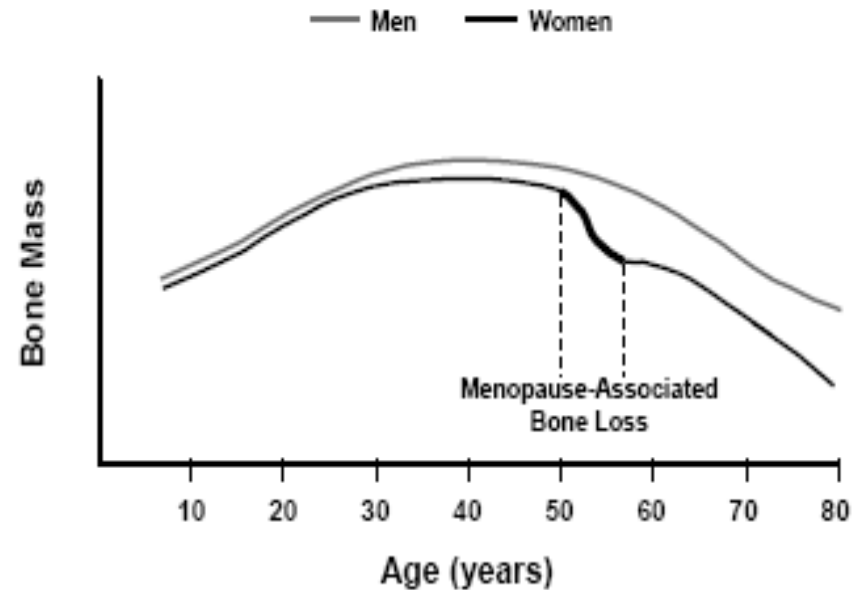
T Score	
>-1 SD	Normal
-1 to -2.5 SD	Low bone mass (osteopenia)
<-2.5 SD	Osteoporosis
<-2.5 SD plus one or more fractures	Severe or established osteoporosis

- The femoral neck is the preferred site because of its higher predictive value for fracture risk .
- The spine is not a suitable site because of the high prevalence of degenerative changes, which artefactually increase the BMD value; however, it is the preferred site for assessing response to treatment.

Bone Mass



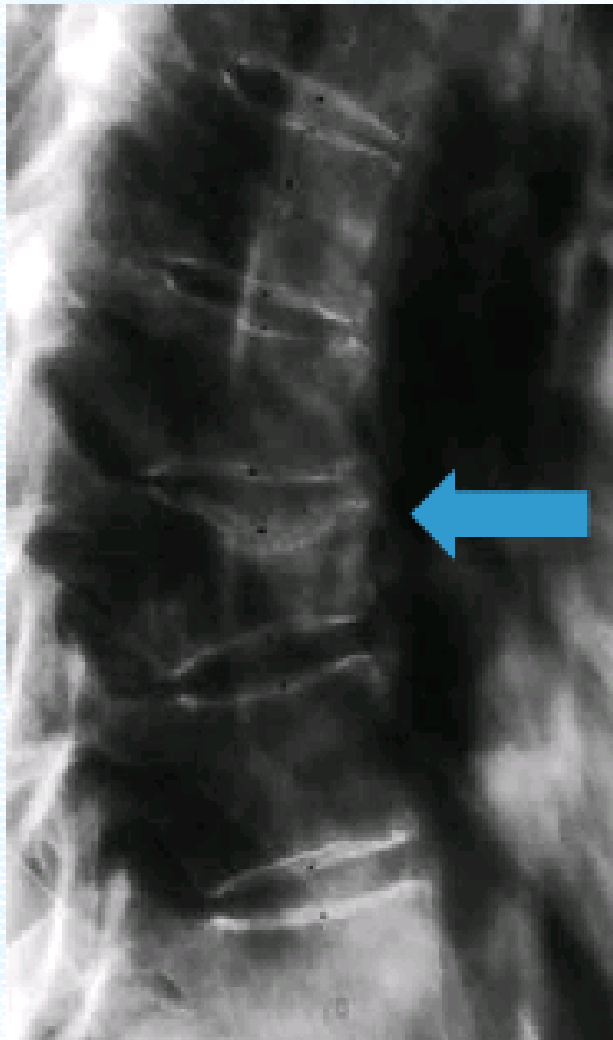
Bone Mass by Age and Sex



Adapted from Finkelstein JS. *Cecil Textbook of Medicine*. 21st ed. 1998;1388-73.
Riggs BL, Melton LJ III. *N Engl J Med*. 1988;314:1878-88.

Average female bone mineral density peaks at age 35, slow decline thereafter Density loss is accelerated post-menopausally

Vertebral fracture substantially increase the risk of new fragility fractures



- ▶ **Women with vertebral fractures have a 5-fold increased risk of a new vertebral fracture and a 2-fold increased risk of hip fracture**

Black et al., J Bone Miner Res 1999
Melton et al, Osteoporos Int 1999

- ▶ **One woman in five will suffer from another vertebral fracture within a year**

Lindsay et al., JAMA, 2001

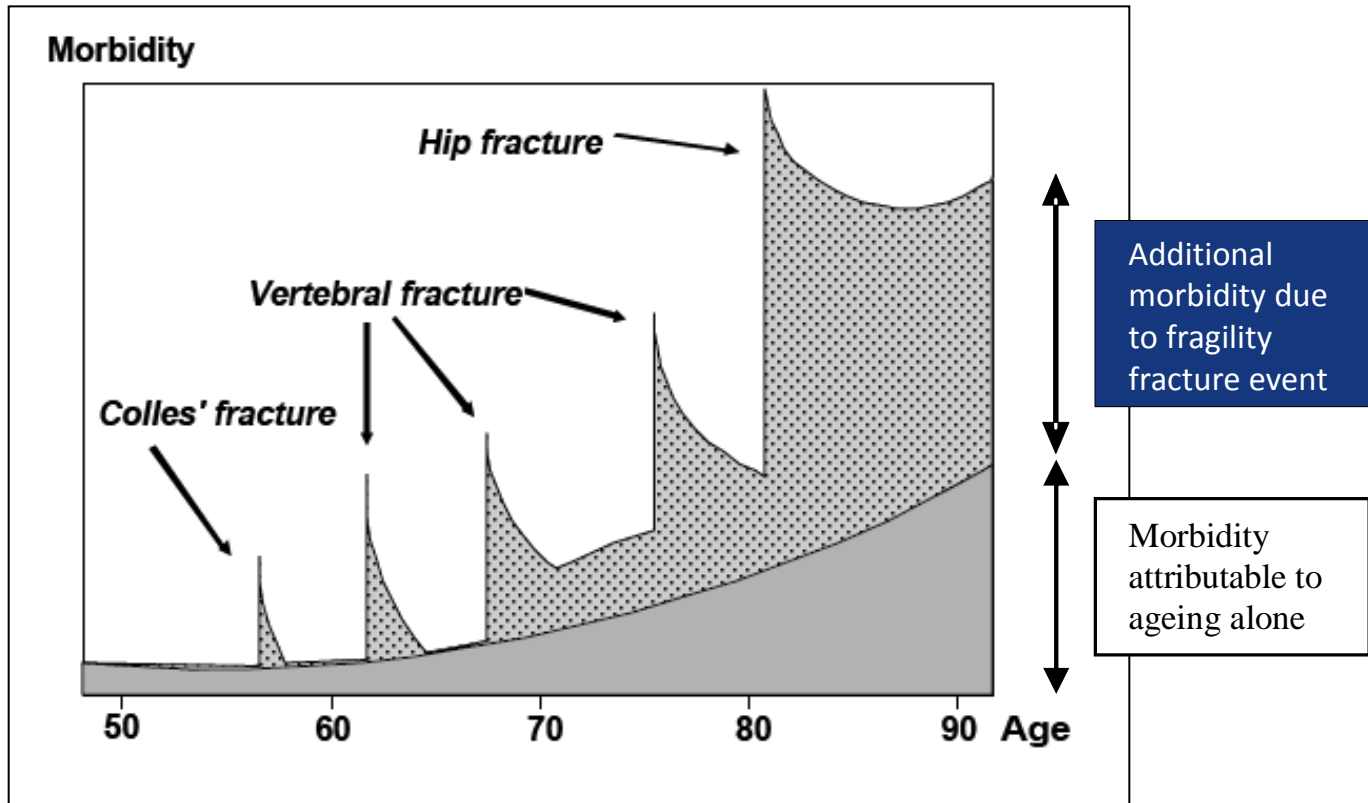
Hip fracture

265 hip fractures in Barnsley = 70% of total cost of care of fragility fracture (£4.4 million)

- 80% due to OP
- 95% due to fall
- 30% die within 12 months
- 50% of survivor gets discharged home and 50% to a care home
- 30% will achieve pre fracture independence
- 50% with chronic pain at 6 month

Fragility fracture through the life span

Osteoporosis + falls = fragility fractures



“Hip fracture is all too often the final destination of a 30 year journey fuelled by decreasing bone strength and increasing falls risk”²

1. J Endocrinol Invest 1999;30:583-588 Kanis JA & Johnell O

2. Osteoporosis Review. 2009;17(1):14-16 Mitchell PJ

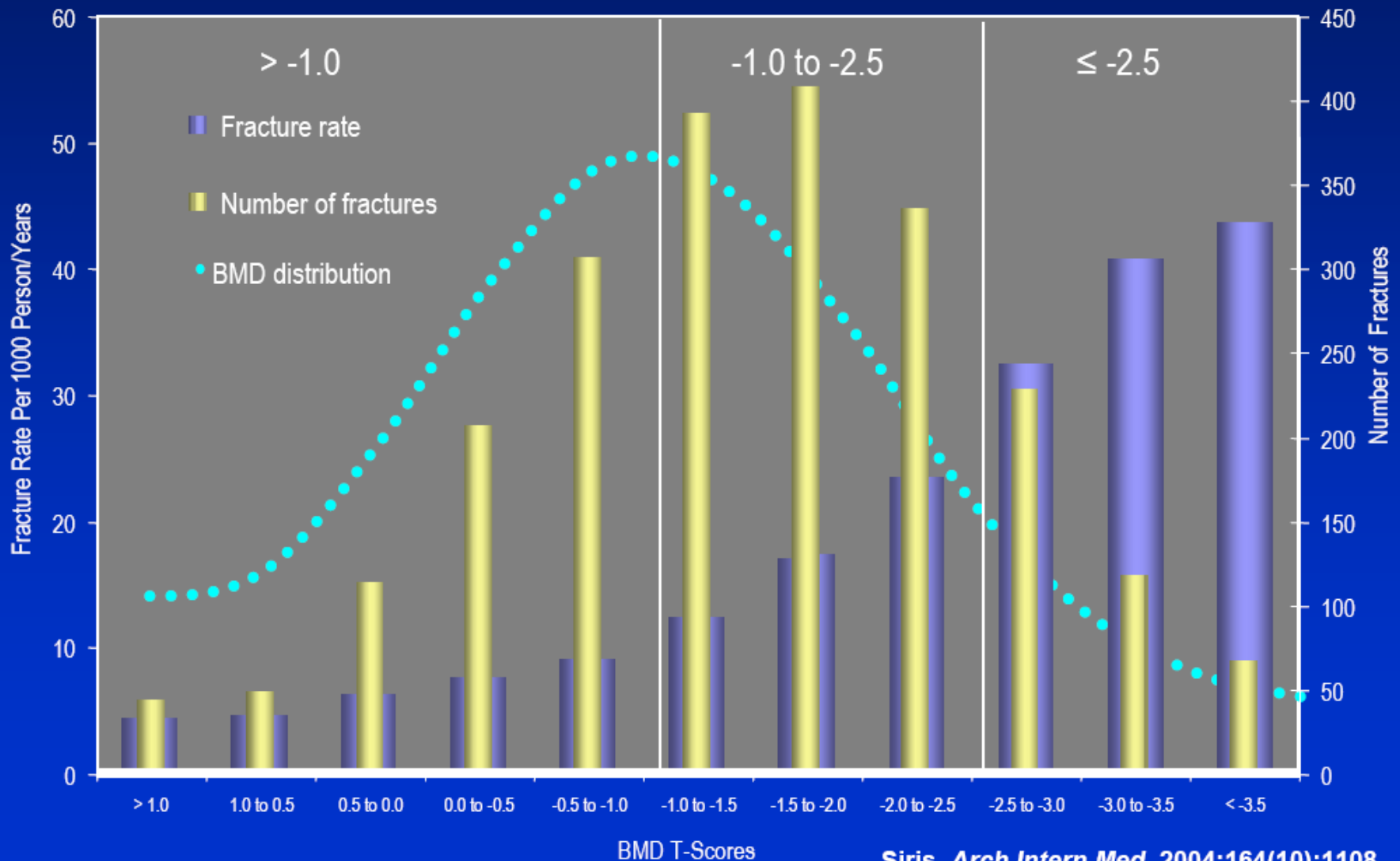
Current projections suggest that the number of hip fractures could increase by 65% in the next 20 years if secondary fracture prevention care does not improve.

National Osteoporosis Society. Effective secondary prevention of fragility fractures: clinical standards for fracture liaison services. Bath: NOS, 2015.

Fragility fracture can develop only when

1. Normal BMD (0- -1)
2. Osteopaenia (-1 to -2.5)
3. Osteoporosis (below -2.5)
4. All of the above

Fracture Rates, Population T-Score Distribution, and Number of Fractures in NORA



Case history

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- PMH – Left wrist fracture at age 65 after a fall
Known to suffer with hypertension.
- Drug history – Paracetamol, Ramipril,
Amitriptyline, Zopiclone

The problem

A fracture (any site) is associated with 2-3 times increase in future fracture risk

The opportunity

Appropriate targeting of treatment for osteoporosis halves future fracture risk (including risk of hip fracture)

What percentage of patients with non-hip fracture receive osteoporosis treatment?

1. 100%
2. 75%
3. 50%
4. 35%

National Audit Reports

- In 2013, 100% of patients with hip fracture received falls Ax and 100% of patients had osteoporosis assessment (Barnsley; NHFD 2015)
- 34% of patients with non-hip fractures received falls assessment and 33% received osteoporosis treatment (RCP 2013)

Fracture risk assessment

Fracture risk assessment

- The use of BMD alone to assess fracture risk has a **high specificity but low sensitivity**
- The performance characteristics of BMD assessment can be improved by the concurrent consideration of risk factors that operate independently of age and BMD.

Clinical Risk Factors for Fragility Fracture

- Non-modifiable
 - Age
 - Gender
 - Ethnicity
 - Previous fracture
 - Family history of hip fracture
 - Early menopause ≤ 45 years
- Co-existing diseases
- Modifiable
 - BMD
 - Alcohol
 - BMI <18.5
 - Smoking
 - Physical inactivity and falls
- Pharmacological risk factors

Other risk factors

- Endocrine: hypogonadism, untreated premature menopause; hyperthyroidism; hyperparathyroidism; hyperprolactinaemia; Cushing's disease; diabetes
- GIT: coeliac disease; inflammatory bowel disease; chronic liver disease; chronic pancreatitis; other causes of malabsorption
- Rheum: RA; other inflammatory arthropathies
- Haematological: multiple myeloma
- Respiratory: Cystic fibrosis; COPD
- Metabolic: Homocystinuria, Hypercalciuria
- Chronic renal disease

Drug therapy with increased fracture risk

- Long-term antidepressants
- Antiepileptics
- Aromatase inhibitors (consensus guidelines recommend a DXA at start of Rx)
- Long-term DMPA (>2 years, but effect wears off)
- GnRH agonists (in men with prostate cancer)
- Proton Pump Inhibitors
- Oral glucocorticoids
- TZDs (Thiazolidinediones)

NOGG 2017:

Clinical guideline for the prevention and treatment of osteoporosis

National Osteoporosis Guideline Group on behalf of:

Bone Research Society
British Geriatrics Society
British Orthopaedic Association
British Orthopaedic Research Society
International Osteoporosis Foundation
National Osteoporosis Society
Osteoporosis 2000
Osteoporosis Dorset
Primary Care Rheumatology Society
Royal College of General Practitioners
Royal Pharmaceutical Society
Society for Endocrinology

Updated March 2017

www.shef.ac.uk/NOGG



 **BONE RESEARCH SOCIETY**

 **National Osteoporosis Society**



BGS
British Geriatrics Society
Improving healthcare
for older people

 **IOF**
International Osteoporosis Foundation



OD
Osteoporosis Dorset
www.odonset.org.uk

Osteoporosis
2000

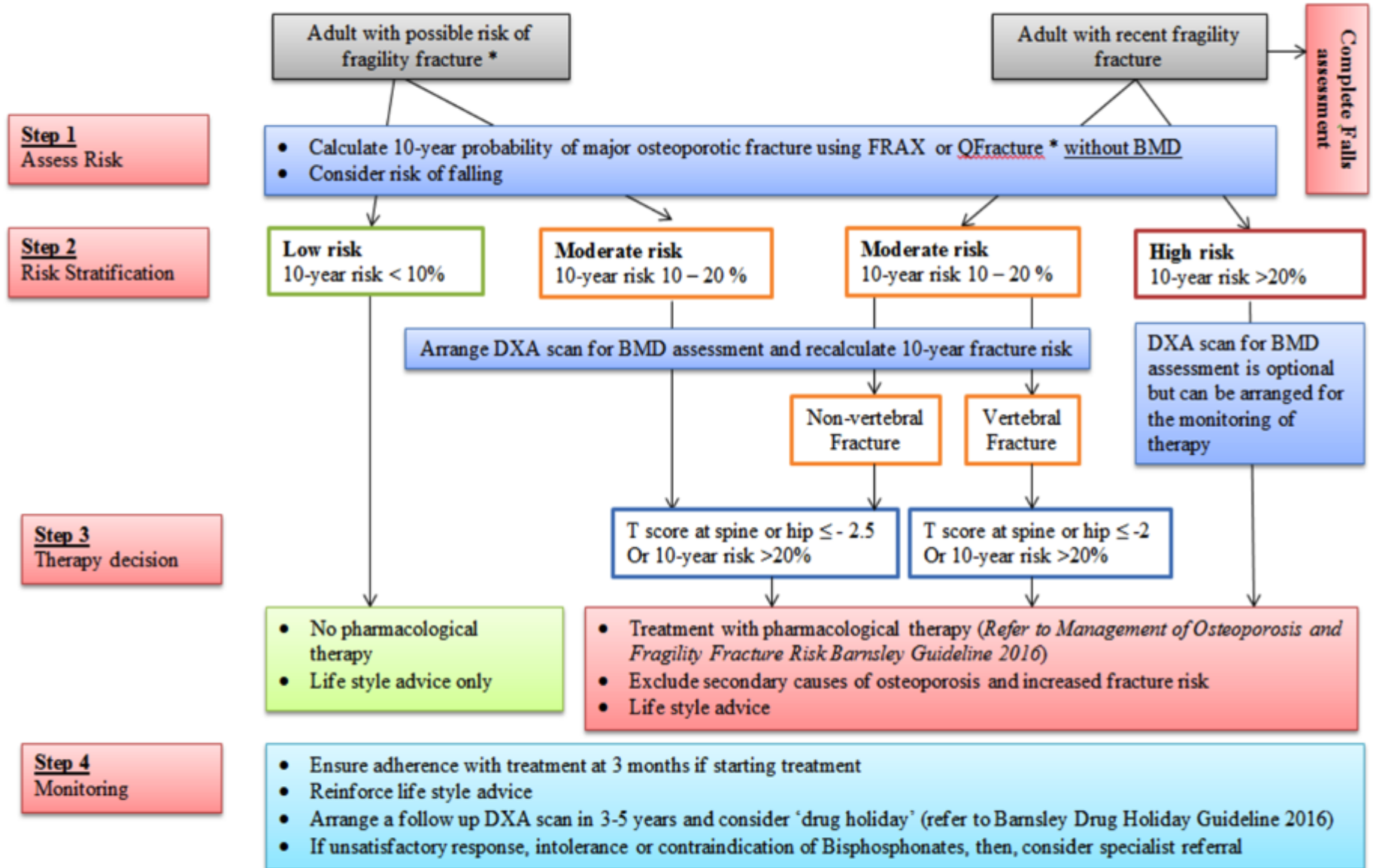
Endorsed by

 **ROYAL PHARMACEUTICAL SOCIETY**

Quantifying the risk of fracture

- Consider **fracture risk assessment** in
 - postmenopausal women, and men age 50 years or more, who have risk factors for fracture, **using FRAX**
 - Under age 50 years if premature menopause, prior fracture, long term glucocorticoid use
- In individuals at **intermediate risk, BMD measurement** should be performed using DXA and fracture probability re-estimated using FRAX.
- **Vertebral fracture assessment** should be considered in postmenopausal women and men age >50 years if
 - history of ≥ 4 cm height loss
 - Kyphosis
 - recent or current long-term oral glucocorticoid therapy
 - BMD T-score ≤ -2.5

MANAGEMENT OF OSTEOPOROSIS AND FRAGILITY FRACTURE RISK: BARNSELY CAREPATHWAY



Major risk factors for osteoporosis and fragility fracture: Prior fragility fractures, Parental history of hip fractures, Current glucocorticoid treatment for ≥ 3 months at a dose of prednisolone of 5mg daily or more (or equivalent doses of other glucocorticoids), Current smoker, Alcohol intake of ≥ 3 units per day

Calculation Tool

Please answer the questions below to calculate the ten year probability of fracture with BMD.

Country: **UK** Name/ID: [About the risk factors](#)

Questionnaire:

1. Age (between 40 and 90 years) or Date of Birth
 Age: Y: M: D:

2. Sex Male Female

3. Weight (kg)

4. Height (cm)

5. Previous Fracture No Yes

6. Parent Fractured Hip No Yes

7. Current Smoking No Yes

8. Glucocorticoids No Yes

9. Rheumatoid arthritis No Yes

10. Secondary osteoporosis No Yes

11. Alcohol 3 or more units/day No Yes

12. Femoral neck BMD (g/cm²)

Select BMD

BMI: 25.0
 The ten year probability of fracture (%)

without BMD	
Major osteoporotic	11
Hip Fracture	2.3
View NOGG Guidance	

[Print tool and information](#)

Risk factors

For the clinical risk factors a yes or no response is asked for. If the field is left blank, then a "no" response is assumed. See also notes on risk factors.

The risk factors used are the following:

Age	The model accepts ages between 40 and 90 years. If ages below or above are entered, the programme will compute probabilities at 40 and 90 year, respectively.
Sex	Male or female. Enter as appropriate.
Weight	This should be entered in kg.
Height	This should be entered in cm.
Previous fracture	A previous fracture denotes more accurately a previous fracture in adult life occurring spontaneously, or a fracture arising from trauma which, in a healthy individual, would not have resulted in a fracture. Enter yes or no (see also notes on risk factors).
Parent fractured hip	This enquires for a history of hip fracture in the patient's mother or father. Enter yes or no.
Current smoking	Enter yes or no depending on whether the patient currently smokes tobacco (see also notes on risk factors).
Glucocorticoids	Enter yes if the patient is currently exposed to oral glucocorticoids or has been exposed to oral glucocorticoids for more than 3 months at a dose of prednisolone of 5mg daily or more (or equivalent doses of other glucocorticoids) (see also notes on risk factors).



Weight Conversion

Pounds kg

Height Conversion

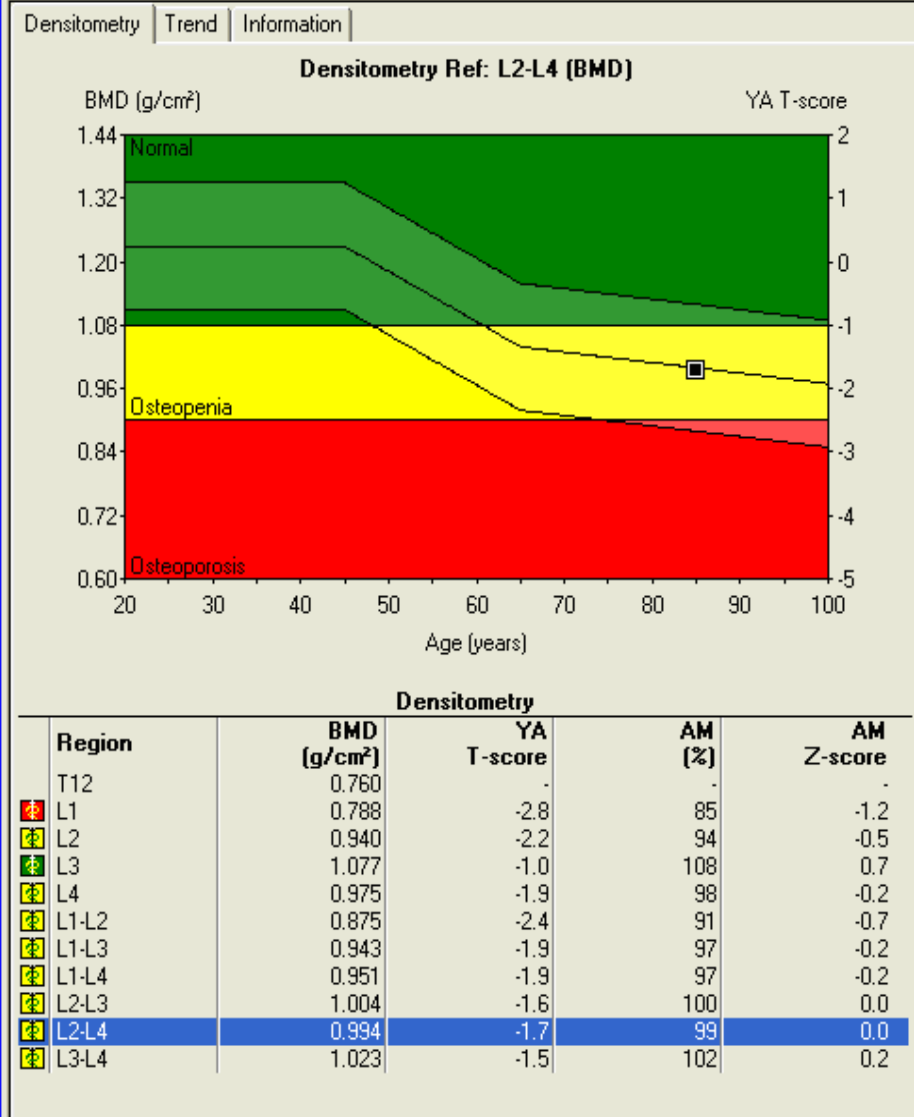
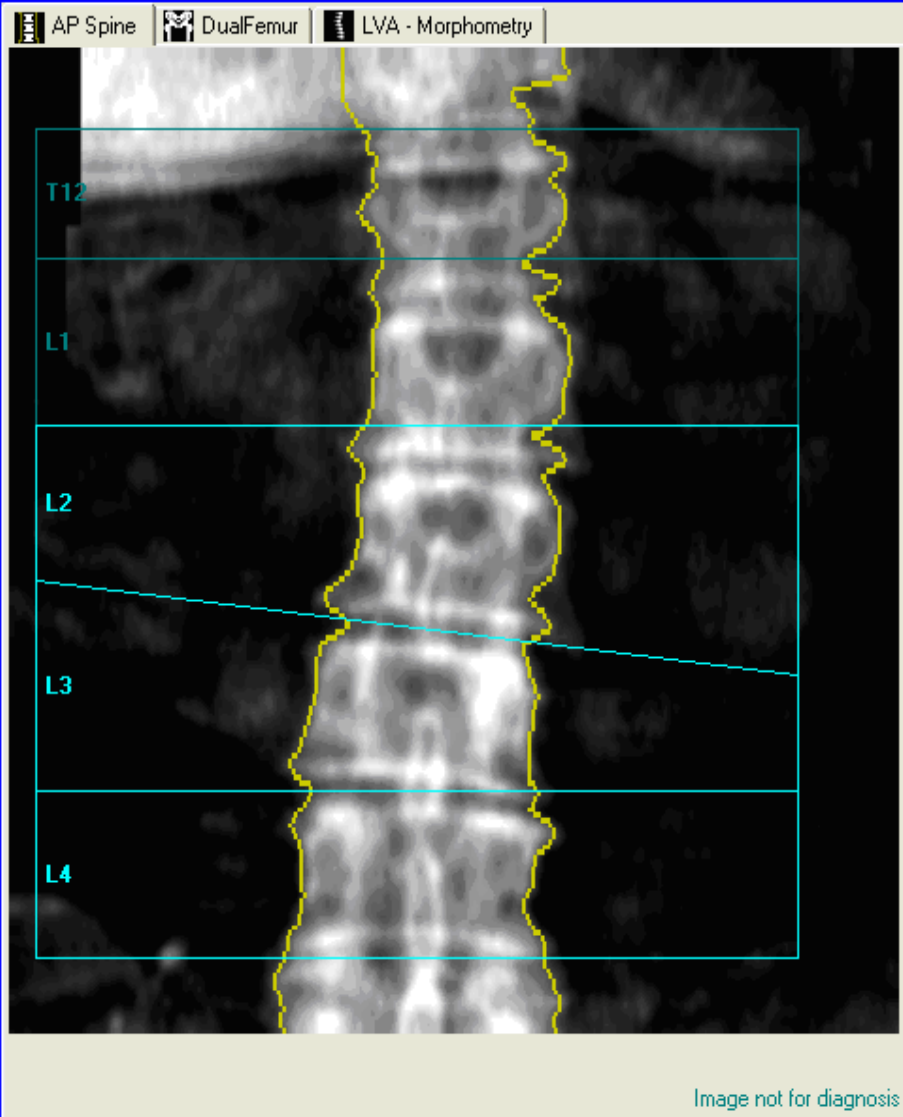
Inches cm

05018694

Individuals with fracture risk assessed since 1st June 2011

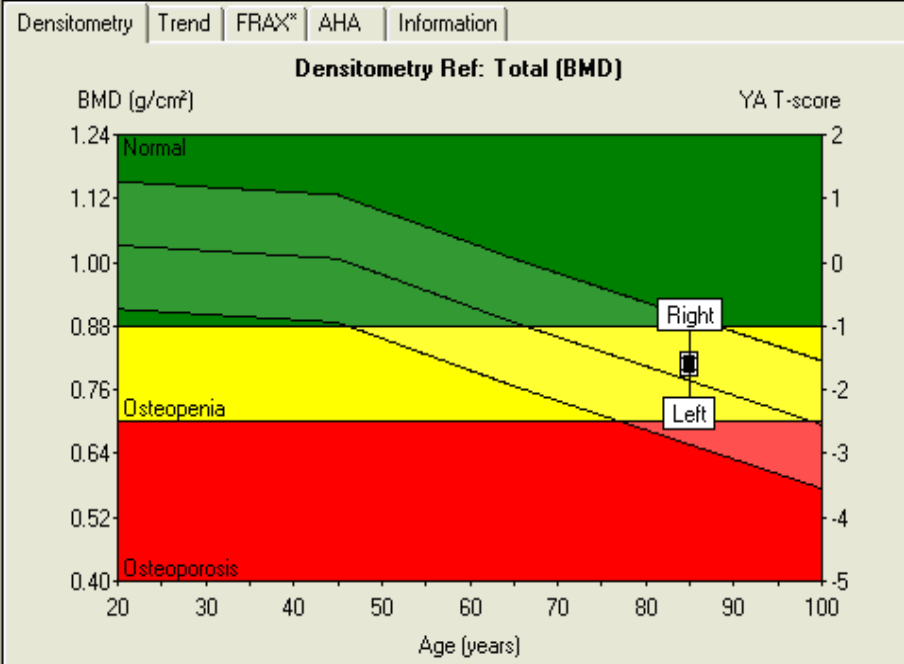
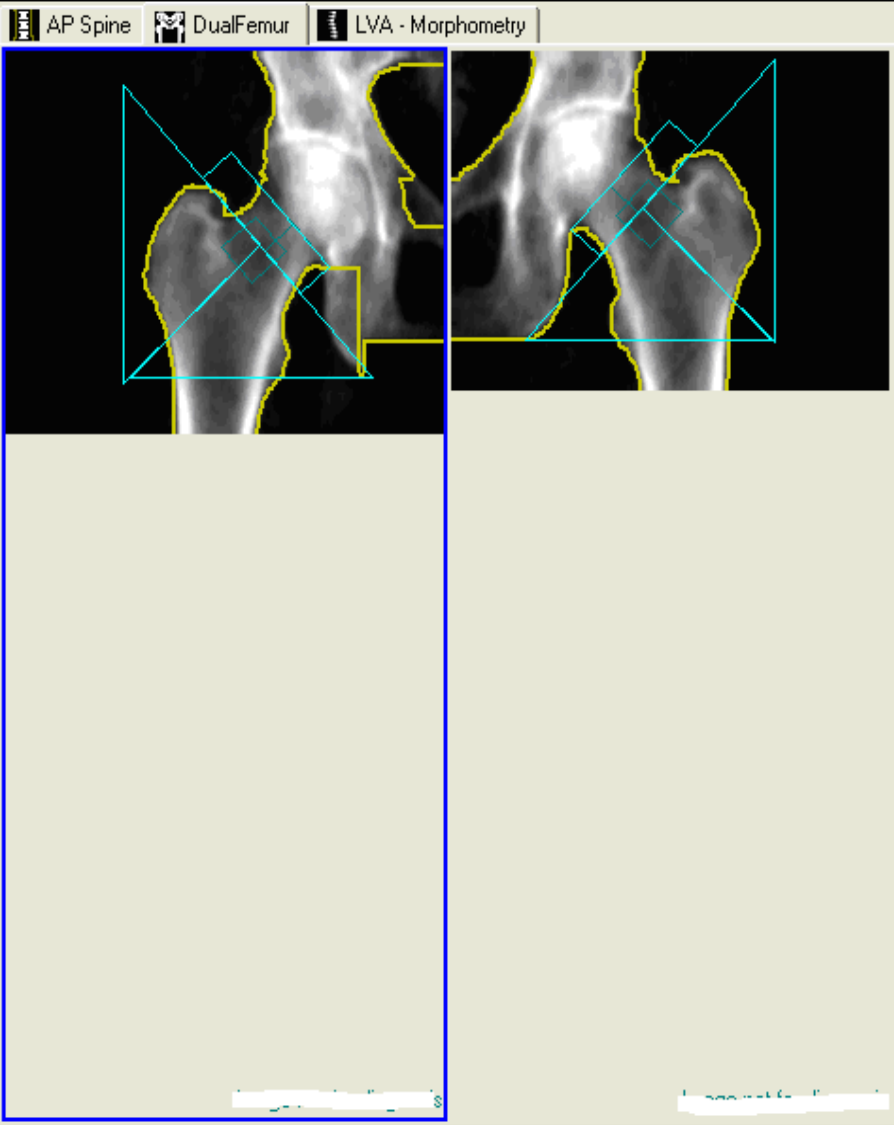
www.nos.org.uk





Standard Results
 Select region: up/down arrows
 Results tab: left/right arrows
 Image tab: tab/shift+tab

Summary
 Born 04/02/1927 (85.0 years) 164.3 cm 72.3 kg White Female
 436 096 4129



Densitometry

Region	BMD (g/cm ²)	YA T-score	AM (%)	AM Z-score
Troch Left	0.790	0.0	121	1.3
Troch Right	0.787	0.0	121	1.2
Troch Mean	0.788	0.0	121	1.2
Troch Diff.	0.003	0.0	0	0.0
Shaft Left	0.822	-	-	-
Shaft Right	0.855	-	-	-
Shaft Mean	0.839	-	-	-
Shaft Diff.	0.032	-	-	-
Total Left	0.801	-1.7	103	0.2
Total Right	0.813	-1.6	105	0.3
Total Mean	0.807	-1.6	104	0.3
Total Diff.	0.013	0.1	2	0.1

Standard Results
 Select region: up/down arrows
 Results tab: left/right arrows
 Image tab: tab/shift+tab

Born 04/02/1927 (85.0 years) 164.3 cm 72.3 kg White Female
 436 096 4129



Image for vertebral deformation assessment only

Region	Morphometry						
	Avg. Ht. [cm]	Avg. Ht. [%]	Avg. Ht. Z-Score	M/P Ratio [%]	M/P Ratio Z-Score	A/P Ratio [%]	A/P Ratio Z-Score
T5	1.54	89	-1.3	92	0.2	93	0.0
T6	1.84	94	-0.8	95	0.8	85	-0.7
T7	1.76	99	-0.2	92	0.3	95	0.9
T8	1.96	107	0.9	96	0.8	93	0.4
T9	1.96	103	0.4	88	-0.6	91	-0.4
T10	2.07	102	0.3	92	0.1	94	0.0
T11	2.11	98	-0.3	90	-0.2	87	-0.9
T12	2.20	94	-0.7	94	0.4	94	0.0
L1	2.60	104	0.5	89	-0.6	95	0.6
L2	1.25	48	-6.4	66	-4.2	51	-7.3
L3	2.54	100	0.0	95	0.2	105	0.6
L4	1.72	65	-4.4	67	-4.8	81	-3.6

- Severe wedge
- Severe biconcavity

Normal (grade 0)

	Wedge	Biconcavity	Compression
Mild fracture (Grade 1)			
Moderate fracture (Grade 2)			
Severe fracture (Grade 3)			

Investigations

All patients

- FBC,
- ESR (if raised measure serum paraproteins and urine Bence Jones protein to exclude multiple myeloma)
- UEs and eGFR
- Bone function (Calcium, Phosphate, ALP) and Liver function test
- Vitamin D
- TFT
- PTH
- Serum testosterone, LH, FSH and SHBG, PSA (men)
- Coeliac screen
- Bone marker - P1NP
- Lateral radiographs of lumbar and thoracic spine

For specialist use

- 24 hour urinary calcium excretion
- 24 hour urinary cortisol/dexamethasone suppression test
- Isotope bone scan

Management of osteoporosis and fracture risk

Lifestyle measures

- Increasing the level of physical activity , stopping smoking, reducing alcohol intake to ≤ 2 units/day,
- Regular weight bearing exercise (the equivalent of 30mins walk 3 times per Week)
- Falls risk assessment and their prevention
- ensure adequate calcium and vitamin D intake [RNID for calcium 700mg/day with 400IU vitamin D for over 65s]
- Hip protectors in institutionalised patients
- To maintain good protein intake and normal body weight

Pharmacological intervention

Table 2. Anti-fracture efficacy of approved treatments for postmenopausal women with osteoporosis when given with calcium and vitamin D.

Intervention	Vertebral fracture	Non-vertebral fracture	Hip fracture
Alendronate	A	A	A
Ibandronate	A	A*	NAE
Risedronate	A	A	A
Zoledronic acid	A	A	A
Calcitriol	A	NAE	NAE
Denosumab	A	A	A
HRT	A	A	A
Raloxifene	A	NAE	NAE
Teriparatide	A	A	NAE

A; grade A recommendation

NAE: not adequately evaluated

* in subsets of patients only (post-hoc analysis)

HRT: hormone replacement therapy

Which drug should be used as a first line osteoporosis treatment

1. Alendronic acid
2. Risedronic acid
3. Ibandronic acid
4. Strontium
5. Denosumab

Drug name	Dose	Indication	Yearly cost
First line			
Alendronic acid	70mg / Week		£12
Risedronic acid	35 mg / week		£15
Second line			
Ibandronic acid	150 mg / month		£13
Alendronic acid Effervescent (Binosto)	70 mg / week		£296
Third line			
Denosumab s.c.	60 mg / 6 months		£366
Zoledronic acid i.v.	5 mg / year		£20
Fourth line (Specialist only)			
Teriparatide s.c.	20 mcg OD for 18-24 months		£7068 for 24 months

Monitoring of therapy

- 3 months: Check compliance and tolerance (Pharmacist)
- 6 months: P1NP
- 3 years:
 - Recheck BMD and fracture risk to assess treatment response
 - Treatment review for Zoledronic acid (to consider drug holiday)
- 5 years: Treatment review for Alendronate, Risedronate, Ibandronate and Denosumab (to consider drug holiday)
- If treatment is discontinued, fracture risk should be reassessed:
 - after a new fracture regardless of when this occurs
 - if no new fracture occurs, after 18 months to 3 years

Monitoring osteoporosis treatment with oral bisphosphonates

Decision to treat with oral bisphosphonate (alendronic acid 70 mg weekly 1st line)

Calcium & vitamin D supplement

Patient information sheet

• Indication for treatment

- Fracture risk assessment report
- FRAX score
- Clinical guideline, eg RCP steroid guidelines

• Check whether alendronic acid is appropriate

- Adequate renal function (eGFR>35 m/min)
- Contra-indications, eg oesophagitis

• **High PINP (>80 ng/mL)** indicates further investigation for underlying cause of high bone turnover eg vit D deficiency - discuss with MBC

• **Low PINP (<35 ng/mL)** is not a contra-indication to treatment as this will restore remodelling balance and increase bone strength

Measure PINP at prescription
Gold top bottle to STH clinical chemistry – no special preparation or storage

Compliance check at 1- 2 months
(GP, practice nurse, pharmacist)
In surgery or by telephone

• Check understanding of treatment (aims, duration)

• Check for side effects

• Check treatment is being taken correctly:

- 1st thing in morning, fasting, with tap water
- Remain upright for minimum 30 minutes prior to food/drink
- At least 3 hours before taking calcium and vitamin D supplement

At 6 months, repeat PINP
Check for compliance and side-effects
Check calcium and vitamin D adequate (via supplements or lifestyle)

PINP below 35 ng/mL and/or decrease by >10 ng/mL
Good response

Encourage continued compliance
At 5 years refer to MBC for fracture risk assessment to consider break from treatment

PINP above 35 ng/mL and decrease by <10 ng/mL
Suboptimal response – identify cause

1. Compliance issues (most likely)
2. Recent fracture (within 6-12 months)
3. Hepatic or renal impairment
4. Untreated underlying cause of osteoporosis/poor response - Measure bone profile, PTH, FBC, ESR, TFT, anti-endomysial antibody, vitamin D, myeloma screen

Ongoing compliance problems or irreversible cause identified

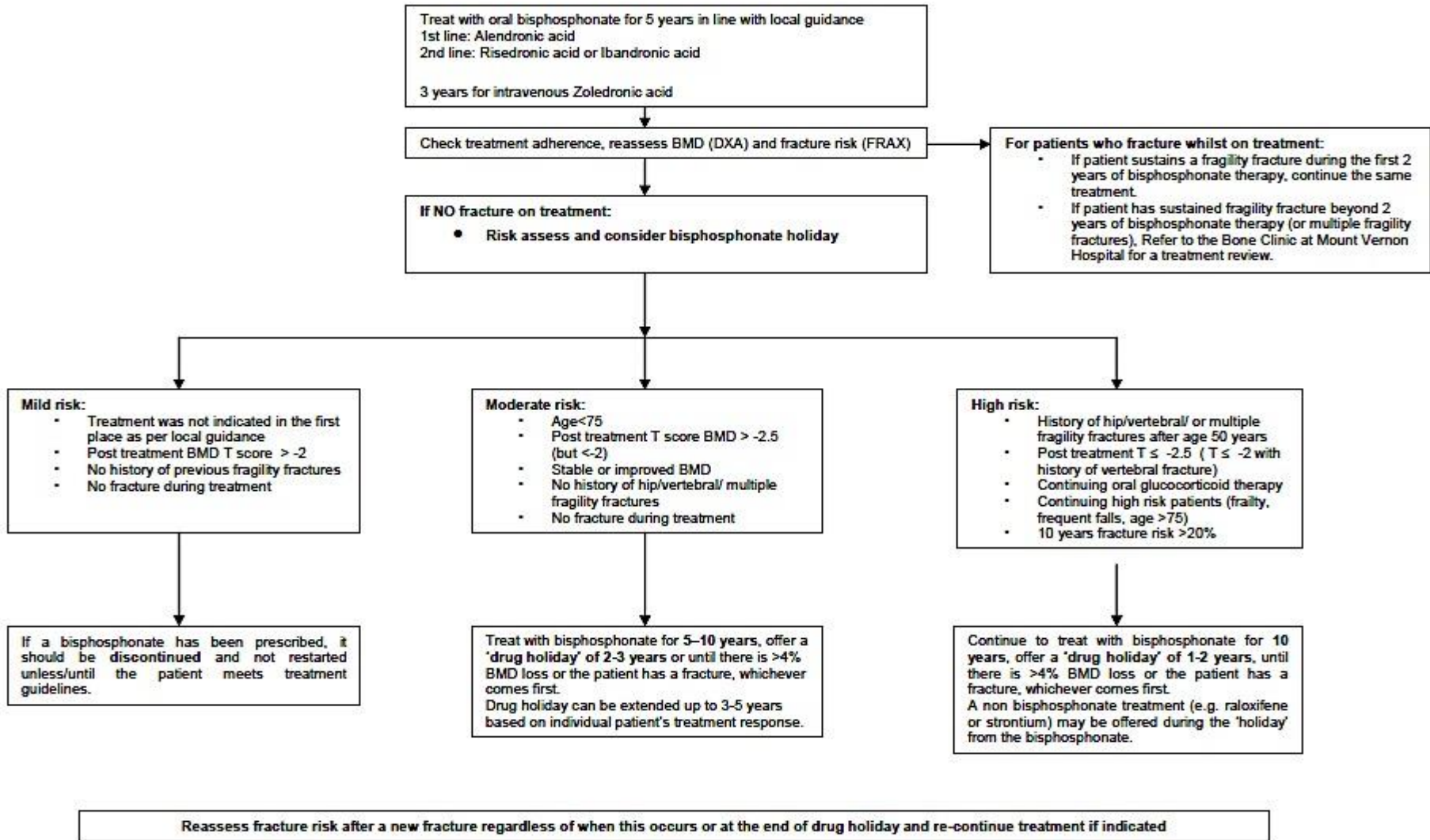
- Consider **change in treatment** (eg risedronate, raloxifene, strontium ranelate, denosumab)
- or **referral** for annual infusion of zoledronic acid or MBC assessment

Reversible cause identified

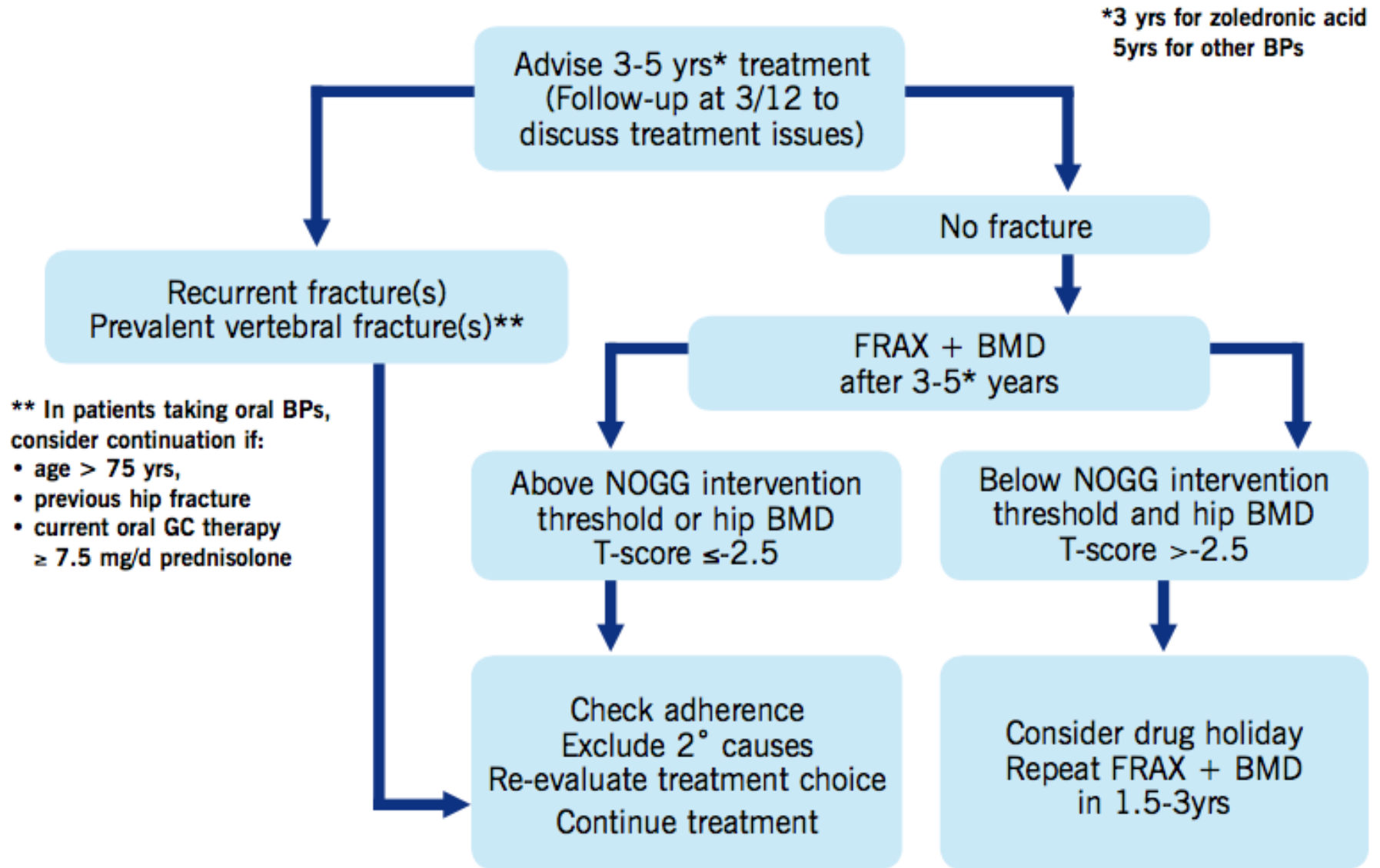
eg poor compliance
Correct underlying cause
Repeat PINP in another 6 months

Barnsley Drug Holiday Guideline 2016

Treatment Algorithm



Bisphosphonates: algorithm for long-term treatment monitoring

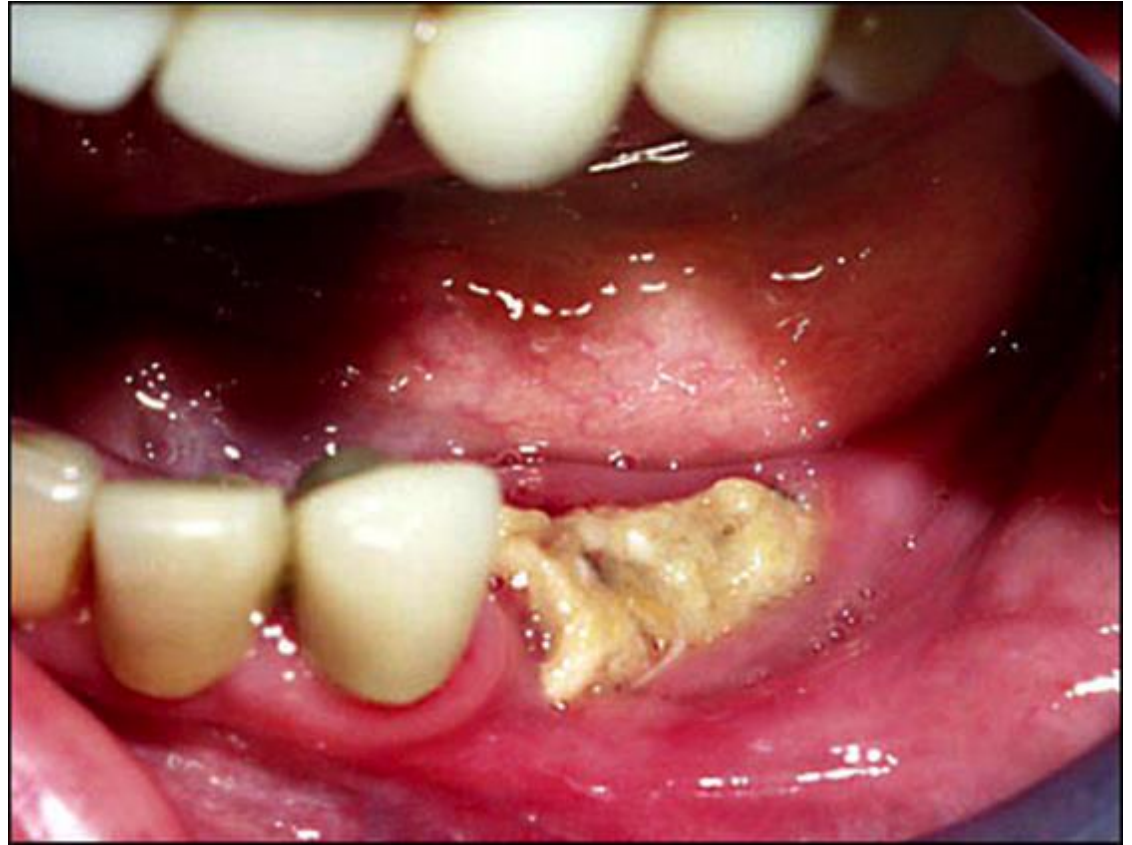


Continuation of bisphosphonate treatment beyond 3-5 years

- age 75 years or more
- previous history of a hip or vertebral fracture
- occurrence of one or more low trauma fractures during treatment, after exclusion of poor adherence to treatment (for example less than 80% of treatment has been taken) and after causes of secondary osteoporosis have been excluded
- current treatment with oral glucocorticoids ≥ 7.5 mg prednisolone/day or equivalent

What is the risk of developing MRONJ with bisphosphonate treatment for osteoporosis?

1. 1 in 1000
2. 1 in 10,000
3. 1 in 50,000
4. 1 in 100,000



Medication-related osteonecrosis of the jaws (MRONJ)

- ONJ is uncommon but not rare
- Risk factors - poor oral hygiene, dental disease, dental interventions, cancer, chemotherapy or glucocorticoid therapy
- Signs and symptoms = abscesses, fistulae, unexplained or sudden tooth mobility, periimplantitis
- Patients should complete any invasive dental procedures before initiating BP
- Those taking BP should not delay emergency dental procedures or dental implants.
- For those patients who have taken BP for >3 years, should consider discontinuation for 3 months prior to oral surgery.
- If possible, the bisphosphonate should not be restarted until osseous healing has occurred.



Atypical subtrochanteric and diaphyseal femur fracture (AFF)

- Location: subtrochanteric region or femur shaft
- minimal or no trauma
- transverse or short oblique fracture line
- fractures can be complete or incomplete
- often bilateral (2/3rd of cases)
- Minor features often include prodromal thigh pain, cortical thickening, periosteal reaction in the lateral cortex

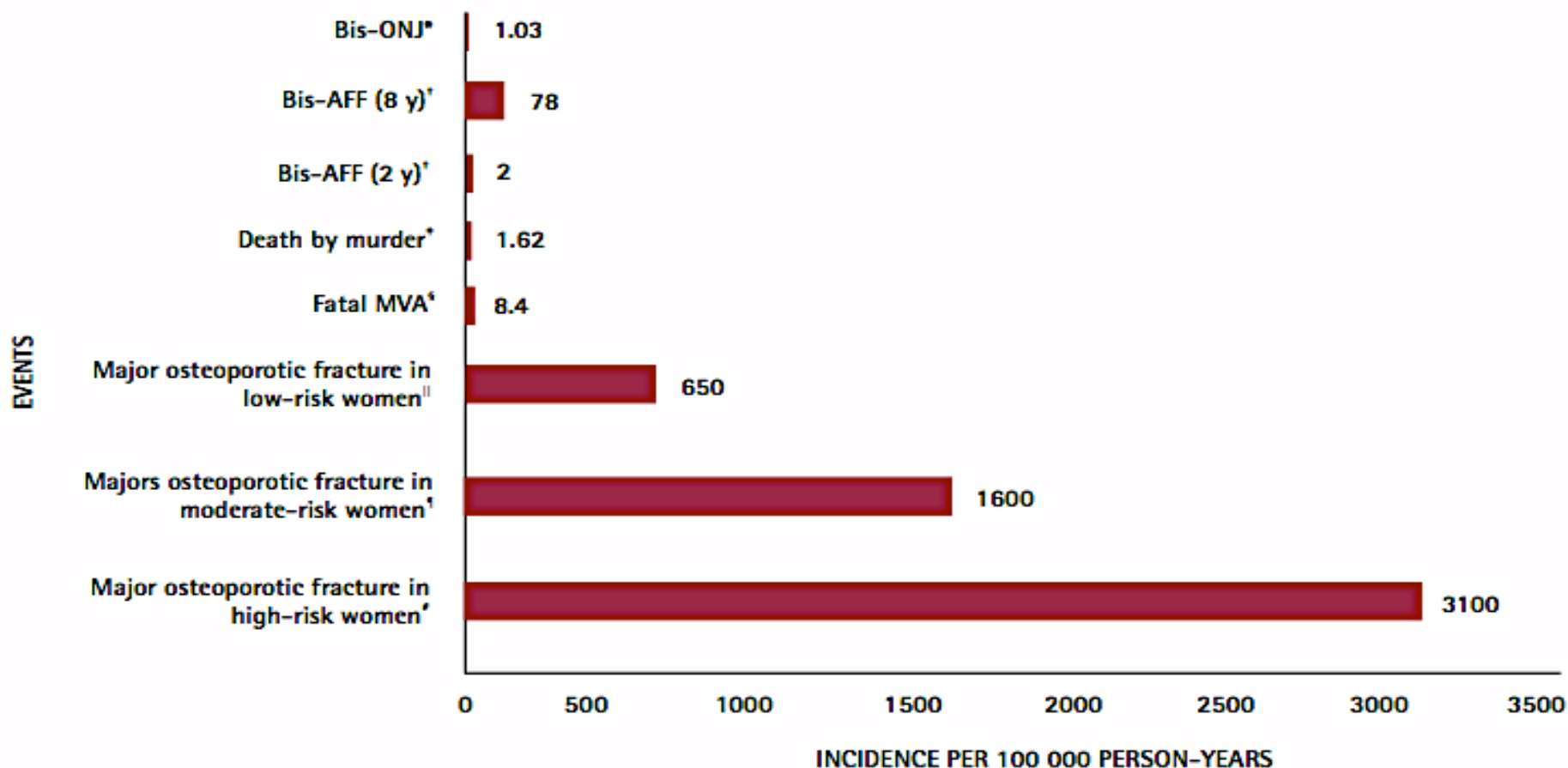
AFF

Presence of prodromal **thigh or groin pain** should trigger x-ray scan of the full-length femurs or radioisotope bone scan to investigate for signs of AFF

Risk of AFF increases with duration of BP use

- 2 cases per 100 000 patient- years for 2 years of treatment
- 78 cases per 100,000 patient-years for 8 years of treatment

Figure 1. Risks of major osteoporotic fracture and other rare events



Bis-AFF—bisphosphonate-associated atypical subtrochanteric and diaphyseal femur fracture, Bis-ONJ—bisphosphonate-associated osteonecrosis of the jaw, BMD—bone mineral density, FN—femoral neck, FRAX—Fracture Risk Assessment Tool, MVA—motor vehicle accident.

*Data from Khan et al.³³ (Canadian data).

[†]Data from Dell et al.³⁶ (American data).

[‡]Data from Statistics Canada⁷⁷ (Canadian data).

[§]Data from Transport Canada⁷⁸ (Canadian data).

^{||}The 10-year risk of major osteoporotic fracture in a low-risk woman by Canadian FRAX (65-year-old woman, weighing 60 kg with a height of 168 cm; BMD FN T-score -1.2).

[†]The 10-year risk of major osteoporotic fracture in a moderate-risk woman by Canadian FRAX (65-year-old woman weighing 60 kg with a height of 168 cm; parent hip fracture history; BMD FN T-score -2.0).

[†]The 10-year risk of major osteoporotic fracture in a high-risk woman by Canadian FRAX (65-year-old woman weighing 60 kg with a height of 168 cm; parent hip fracture history; previous fracture; BMD FN T-score -2.6).

Osteoporosis in men

- Alendronate, Risedronate, Zoledronic acid, Denosumab and Teriparatide are approved for the treatment of osteoporosis in men
- Secondary causes of osteoporosis are commonly found amongst men, so this population requires thorough investigation
- Intervention thresholds for men are similar to those recommended for women
- All men starting on androgen deprivation therapy should have their fracture risk assessed
- Consideration should be given to referring men with osteoporosis to specialist clinic, particularly younger men or those with severe disease

Specialist referral indications

- Intolerance of oral treatment
- Premenopausal osteoporosis
- Osteoporosis in men
- Osteoporosis with eGFR <30 ml/min
- Hypercalcaemia
- Unsatisfactory response to treatment

Case history

- 83 F. Had an unexplained fall at home and broke her right hip. Not sure about LOC.
- PMH – Left wrist fracture at age 65 after a fall
Known to suffer with hypertension.
- Drug history – Paracetamol, Ramipril,
Amitriptyline, Zopiclone

Fracture prevention services

An economic evaluation



Falls and fracture consensus statement Supporting commissioning for prevention

Produced by Public Health England with the National Falls Prevention Coordination
Group member organisations

January 2017

- provide fracture liaison services in line with clinical standards including access to effective falls interventions when necessary

To be reviewed January 2019

November 2009

January 2017

Fracture Liaison Service (FLS)

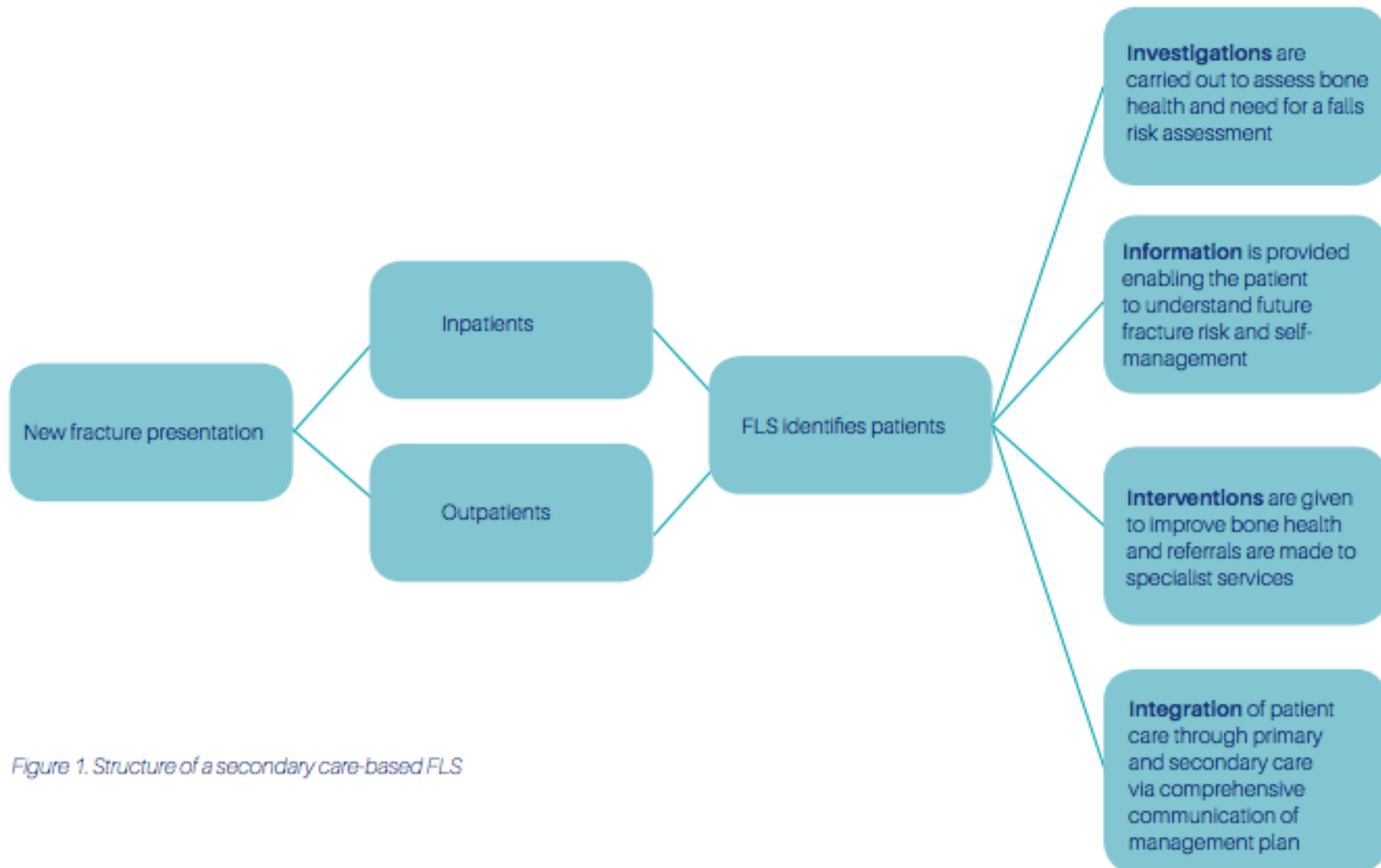


Figure 1. Structure of a secondary care-based FLS

Effectiveness of FLS in Barnsley

- Population (2016) = 239,300
- Above age 50 = 95,069

Predicted number of FLS patients by category

Hip fracture (inpatient)	Other fracture site (inpatient)	Other fracture site (outpatient)	Clinical vertebral	All
265	150	300	300	1015

Predicted number of patients to be treated each year (includes population growth where data entered)

Year	Patient Numbers
2017	1015
2018	1031
2019	1051
2020	1065
2021	1065
All yrs	5227

Number of fractures prevented in each of 5 years for patients treated all years

Year	Hip fracture (inpatient)	Other fracture site (inpatient)	Other fracture site (outpatient)	Clinical vertebral
2017	7	5	5	2
2018	12	7	7	4
2019	17	9	9	6
2020	20	11	11	7
2021	22	12	12	8
All yrs	78	44	44	27

Cost of managing fractures (Barnsley)

	Hip fracture (inpatient)	Other fracture site (inpatient)	Other fracture site (outpatient)	Clinical vertebral
Acute Care	£8,060	£1,802	£359	£1,959
Community and Primary Care	£448	£57	£57	£59
Social Care	£8,237	£150	£150	£2,908
Total cost	£16,745	£2,009	£566	£4,926

Benefit of FLS per year (Barnsley)

Year	Hip fracture (inpatient)	Other fracture site (inpatient)	Other fracture site (outpatient)	Clinical vertebral	Total
2017	£117,213	£10,047	£2,832	£9,852	£139,944
2018	£200,937	£14,067	£3,965	£19,704	£238,673
2019	£301,406	£18,085	£5,098	£29,556	£354,145
2020	£351,640	£20,095	£5,665	£34,482	£411,882
2021	£385,129	£22,105	£6,231	£39,408	£452,873
All yrs	£1,306,090	£88,418	£24,925	£133,004	£1,552,437

Average benefit per year = £310,487
(Investment per year = £70,000)

In Barnsley, FLS is required to manage non-hip fractures more effectively

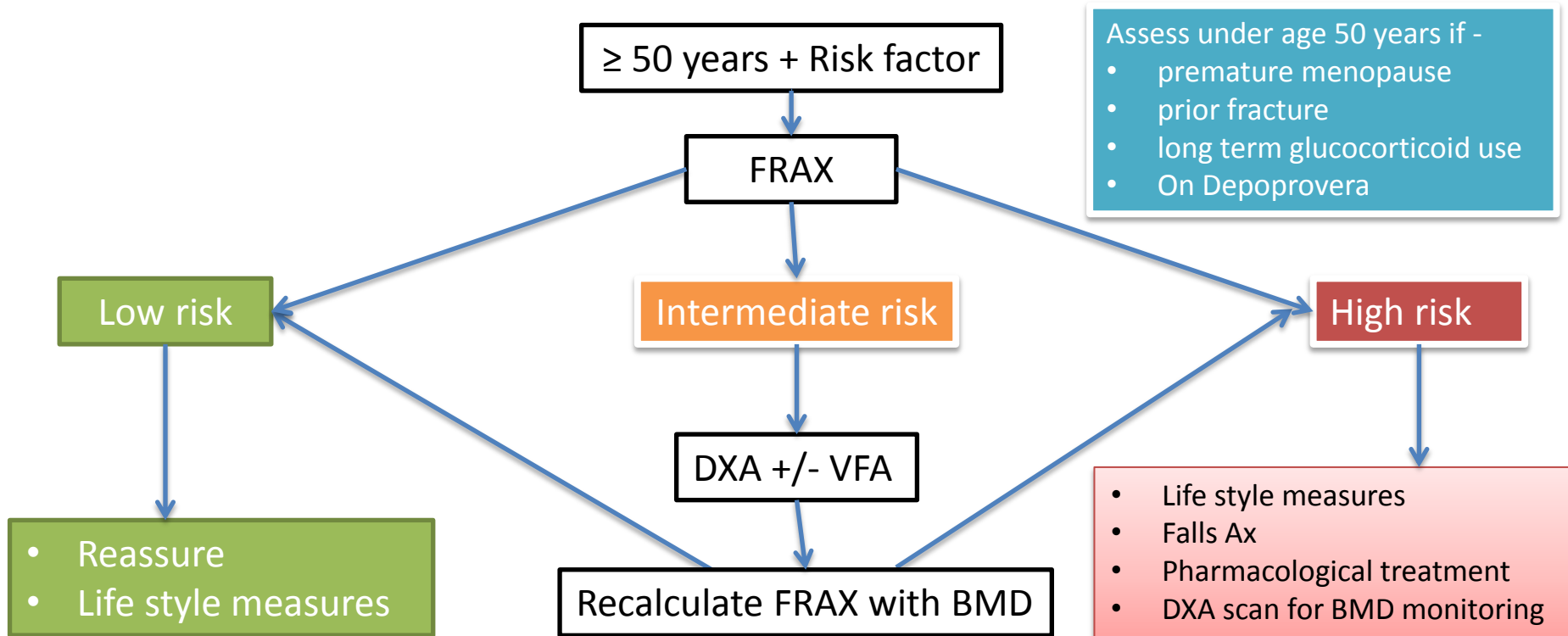
1. YES

1. NO

Current service provision in Barnsley

- DXA scanning
 - SWYPFT
 - BHNFT
- Lack of FLS
- Lack of cost effective Zoledronic acid infusion service
- Need of 'drug holiday' management
- Lack of dedicated metabolic bone clinic

Summary



1. Exclude secondary osteoporosis if initiating treatment
2. 3 months: Check compliance and tolerance (Pharmacist)
3. 6 months: P1NP
4. 3 years:
 - Recheck BMD and fracture risk to assess treatment response
 - Treatment review for Zoledronic acid (to consider drug holiday)
5. 5 years: Treatment review for Alendronate, Risedronate, Ibandronate and Denosumab (to consider drug holiday)
6. If treatment is discontinued (Drug holiday), fracture risk should be reassessed with FRAX + DXA -
 - after a new fracture regardless of when this occurs
 - if no new fracture occurs, after 18 months to 3 years

I feel confident in managing osteoporosis and fragility fractures

1. Strongly disagree
2. Somewhat disagree
3. Neither agree or disagree
4. Somewhat agree
5. Strongly agree

Any Question?



Case 2

- 78 Female – Indian origin
- Admitted with spontaneous right hip pain
- Xray
- Investigation
- Treatment



Statistic

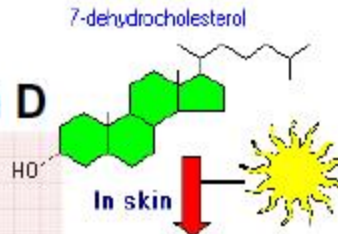
- 1 in 2 postmenopausal women and 1 in 5 men will develop a fracture in life time.
- 35% population after age 65 years suffers fall
- 92% England population has VitD below 50 nmol/L
- 23% England population has VitD below 25 nmol/L (1 in 4 has deficiency)

The National Diet & Nutrition Survey: adults aged 19 to 64 years Food Standards Agency and the, Departments of Health (2004)

Cholecalciferol (D₃)



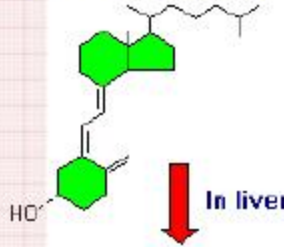
Provitamin D



UV 290 – 315 nm (297 peak)
 Converts provitamin D to
 previtamin D
 Warmth converts previtamin D to
 cholecalciferol

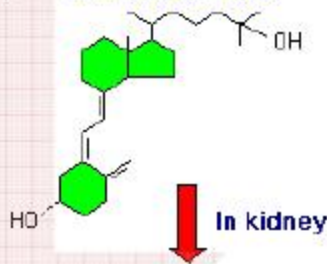
vitamin D

cholecalciferol (vitamin D₃)

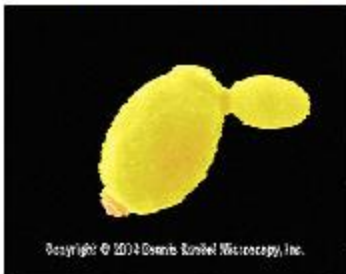


25 vitamin D

25-hydroxycholecalciferol
 [25-hydroxy vitamin D₃]

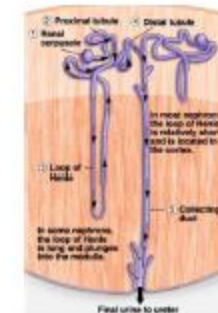
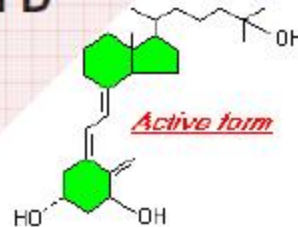


Ergocalciferol (D₂)



1,25 vitamin D

1,25-dihydroxycholecalciferol
 [1,25-dihydroxy vitamin D₃]



1 ng/ml = 2.5 nM & 10 mcg = 400 IU
 < 25 nM = deficiency
 25 – 50 nM = insufficiency

Action

80% of Vit D synthesised from skin

The amount of vitamin D synthesised in the skin depends on skin exposure to UVB radiation and efficiency of cutaneous synthesis.

March to September (9am – 3pm): 70% is delivered during the four hours centred around noon.

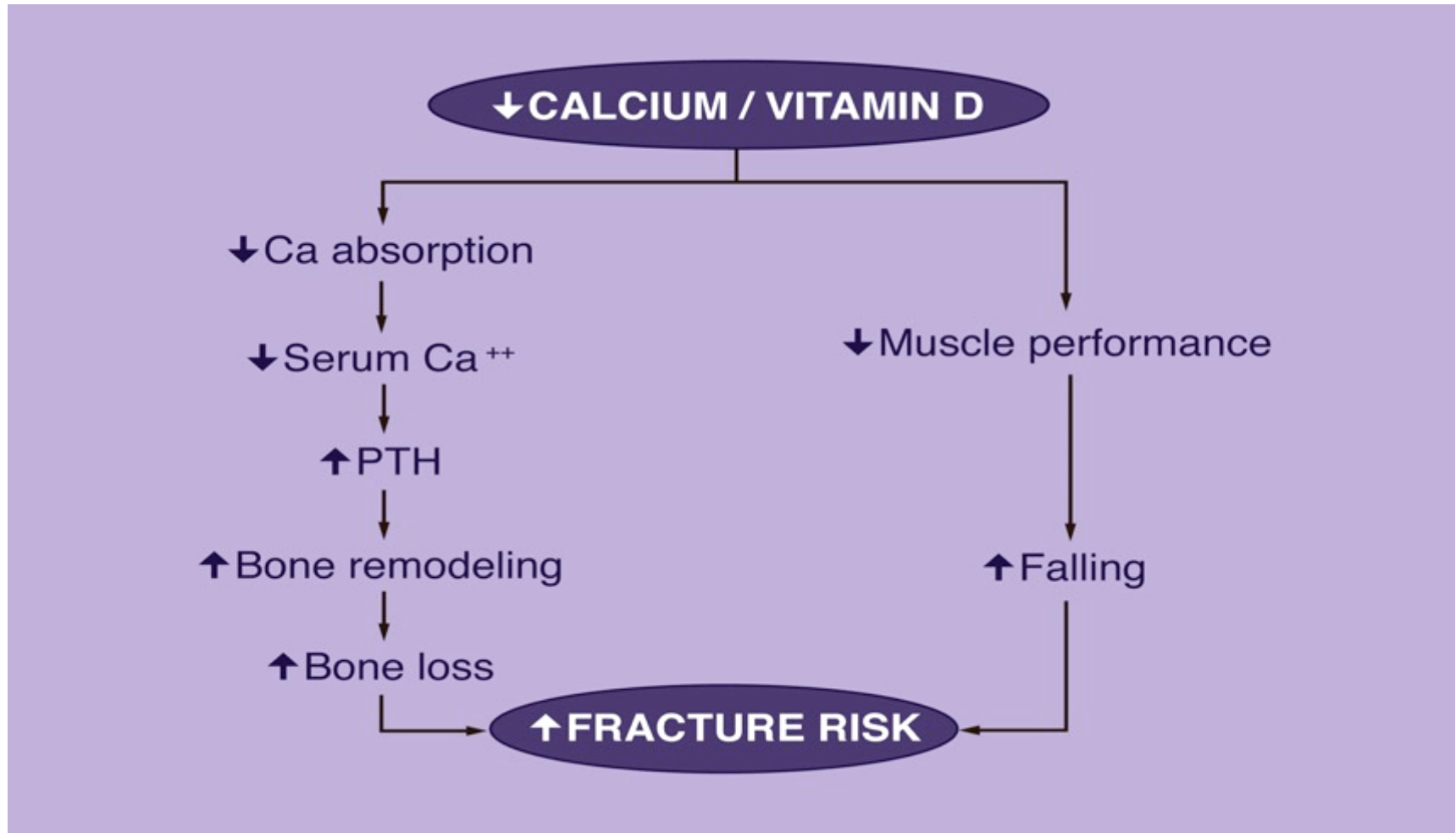
Serum 25(OH)D concentration decreases from October onwards throughout the winter months.

80% of Vit D synthesised from skin

Main source of vitamin D is exposure to sunlight

- whole body exposure **10-15 min midday** sun in summer (~ 1 MED) \equiv 15 000 IU (375 μ g) orally
- exposure of hands, face and arms ($\sim 15\%$ body surface) to $\sim 1/3$ MED should produce ~ 1000 IU
- less vitamin D synthesised in winter, in those with dark skin or older, and those who cover up for cultural reasons or sun protection
- short exposures to UV are more efficient: prolonged exposure to high UV doses may degrade pre-vitamin D

Vitamin D is required to prevent bone loss and fractures



Vitamin D level (Serum 25OHD)

- < 25 nmol/L = deficient
- 30–50 nmol/L may be inadequate in some people (Insufficiency)
- > 50 nmol/L is sufficient for almost the whole population (Adequate)

Serum level of other 'bone health markers' should also be checked such as Calcium, Parathyroid hormone (PTH), Alkaline phosphatase (ALP), Phosphate and eGFR (or Creatinine clearance).

Vitamin D and health outcomes

Musculoskeletal health outcomes

- Rickets (<25 nmol/l)
- Osteomalacia, aches & pain (<20 nmol/l)
- bone health indices (BMC, BMD, biochemical markers of bone turnover)
 - positive association between maternal 25(OH)D concentration during pregnancy and bone health indices in the fetus/newborn
 - beneficial effects of vitamin D supplementation on bone health indices at some skeletal sites in adults aged > 50 years.
- no effect on fracture risk in older men and women
- Improve muscle strength and function (>30 nmol/l)
- Decreased risk of falls 22% (> 60nmol/l)
- Increased falls and fracture risk - 500,000 IU for 3-5 years (>120 at 1 month; >90 at 3 months))

Causes of deficiency

- Reduced intake or synthesis of cholecalciferol
 - ↓sunlight: ageing, veiling, illness, immobility
 - ↓synthesis for a given UV exposure: ageing, dark skin
 - as above combined with low dietary intake
- Disorders associated with abnormal gut function and malabsorption
 - small bowel disorders: coeliac disease, sprue, IBD, infiltrative disorders, small bowel resection
 - pancreatic insufficiency: chronic pancreatitis, cystic fibrosis
 - biliary obstruction: 1° biliary cirrhosis, external biliary drainage
- Reduced synthesis or enhanced degradation of 25OHD
 - chronic hepatic disorders: hepatitis, cirrhosis
 - drugs: rifampicin, anticonvulsants

Who is at risk?

An individual who has one or more of the following risk factor(s) ('at risk' group):

- Age above 65 years
- Institutional care or housebound
- Black and ethnic minority patients with darker skin
- Routine covering of face or body or routine use of sun screen with SPF8 and above
- Vegan or vegetarian diet
- Intestinal malabsorption, liver or renal disease
- Drugs including anticonvulsants, cholestyramine, rifampicin, glucocorticoids, anti-retrovirals

Who should be tested?

	Patient Group	Recommendation
1	<p>Patients with bone diseases that -</p> <p>a) may be improved with vitamin D treatment. Such as -</p> <ul style="list-style-type: none"> •Osteomalacia •Insufficiency fracture •Paget's disease <p>or</p> <p>b) where correcting vitamin D deficiency before starting osteoporosis treatment is necessary. Such as -</p> <ul style="list-style-type: none"> •Unexpectedly low bone mineral density •Bone mineral loss while on osteoporosis treatment •treatment with a potent antiresorptive agent such as Zoledronate, Denosumab or Teriparatide 	<p>Testing of 25-OHD level is recommended</p> <p>(Routine testing may not be necessary in patients with fragility fracture, where a Vitamin D supplement is empirically prescribed in addition to an oral osteoporosis treatment).</p>
2	<p>Patients with musculoskeletal symptoms as chronic aches and pains that could be attributed to vitamin D deficiency</p>	<p>Testing of 25-OHD level is recommended</p>
3	<p>Asymptomatic individuals at higher risk of developing vitamin D deficiency ('at risk' group)</p>	<p>Routine testing is not recommended</p>
4	<p>Asymptomatic healthy individuals without any risk factor</p>	<p>Testing not recommended</p>

Who should receive treatment?

Vitamin D status	Treatment recommendation
Vitamin D Deficiency (below 25 nmol/L)	Treatment recommended
Vitamin D Insufficiency (level 25–50 nmol/L)	Treatment is ONLY advised in patients with the following: <ul style="list-style-type: none">• Increased risk of developing vitamin D deficiency in future ('at risk')• Symptoms suggestive of low Vitamin D level• Fragility fracture, osteoporosis or high fracture risk• Treatment with antiresorptive medication for bone disease• raised PTH
Adequate Vitamin D (Level above 50 nmol/L)	No treatment required. Reassurance and General advice only

Vitamin D testing

- Routine laboratory testing for 25(OH)D serum concentrations before supplementation begins is not necessary.
- It is not necessary for clinicians to routinely monitor 25(OH)D for safety or efficacy when supplementation is within the recommended limits.
- The exceptions are patients who are obese with BMI > 30 kg/m²; malabsorption syndromes; and/or patients who use medications that either bind vitamin D in the gut or accelerate the breakdown of vitamin D.
- If clinicians choose to monitor 25(OH)D, they are advised to test after 4 months of vitamin D₃ supplementation to confirm that appropriate levels have been achieved.

Vitamin D and Bone Health: A Practical Clinical Guideline for Patient Management

Managing low Vitamin D level

National Osteoporosis Society Practical Guides

Endorsed by:



Non-Pharmacological treatment

This information should be made available to all individuals

- **Diet** provides, at most, 20% of daily requirements.
- **Exposure to sunlight** is the main source of vitamin D in most individuals
 - Aim to spend 20-30 minutes outdoors at least 3 times a week between March and October (this increases to 3-10 times for dark pigmented skin)
 - Face and arms exposed without sunscreen
- **Asymptomatic 'at risk' individuals** should be advised taking a OTC Colecalciferol supplement 10 mcg (400 IU) daily or intermittently at higher equivalent dose as a prophylaxis (DH 2012).
- **Patient >65years** who are housebound or institutionalised or a faller should be prescribed Accrete D3 1 Tab BD or equivalent unless contraindicated (NICE CG21).

Pharmacological treatment

- **Practical aspects:** Personal religious and cultural beliefs, nut allergy
- **Key aims :**
 - Use adequate doses to ensure correction of vitamin D deficiency
 - Reverse the clinical consequences of vitamin D deficiency in a timely manner
- Vitamin D3 (**Colecalciferol**) is recommended as the preparation of choice
- **Oral** administration of Vit D is recommended
- Treatment based on fixed-loading doses and maintenance therapy

Treatment regimen

- Loading dose and Maintenance dose
 - Where **rapid correction** of vitamin D deficiency is required, such as in patients with symptomatic disease or about to start treatment with a potent antiresorptive agent (Zoledronate or Denosumab or Teriparatide), the recommended treatment regimen is based on **fixed loading doses followed by regular maintenance therapy**.
 - Where correction of vitamin D deficiency is **less urgent** and when co-prescribing vitamin D supplements with an oral antiresorptive agent, **maintenance therapy may be started without the use of loading doses**.
- If patients with osteoporosis are found to not be reliably or regularly consuming at least 700 mg calcium per day, titrated supplementation with either calcium-only supplements or calcium and vitamin D combined supplements is recommended.
- Special situations

To maximize absorption, the vitamin D supplements should be taken with meals that provide some fat or oils

Treatment regimen: Loading

(Total of approximately 300,000 IU given over 6-12 weeks)

- Stexerol D3 25,000iu tablet. Two tablets weekly for 6 weeks.
- InVita D3 50,000units/1ml liquid once a week for 6 weeks.
- Thorens 25,000units/2.5ml liquid twice a week for 6 weeks.

Treatment regimen: Maintenance

1 month after loading

Given long term


800 to 2000 IU daily (occasionally up to 4,000 IU daily)

given either daily or intermittently at a higher equivalent dose

- Stexerol 25,000iu tablet, 1-3 tablets once a month
- Thorens 25,000units/2.5ml, 2.5-7.5ml liquid once a month.
- Stexerol 1000iu tablet, take one tablet daily.

Calcium Calculator | Internet x

www.iofbonehealth.org/calcium-calculator

THE DEVELOPMENT OF THIS CALCIUM CALCULATOR WAS SUPPORTED BY 

LANGUAGE **ENGLISH** COUNTRY

STEP 1 OF 2

For your country, the IOM recommendations are being used.

Are you getting ENOUGH CALCIUM?

Calcium is essential for building and maintaining healthy bones at all ages. Find out whether you are getting enough of this important mineral in your daily diet by using this simple calculator.

GENDER male female AGE





HAVE YOU EVER BEEN DIAGNOSED WITH OSTEOPOROSIS OR OSTEOPENIA?

yes no

What is your calcium intake in a typical week?

CALCIUM RICH FOODS

In order to calculate your approximate daily calcium intake, please select from the list below the types and quantity of food you eat in a typical week.

FOOD	SERVING SIZE	CALCIUM QUANTITY PER SERVING	NUMBER OF WEEKLY SERVINGS
SUPPLEMENTS			
Calcium 	500 mg	500 mg	<input type="text" value=""/>
MILK			
Milk 	200 mL	240 mg	<input type="text" value=""/>
Milkshake 	300 mL	360 mg	<input type="text" value=""/>
Sheep milk 	200 mL	380 mg	<input type="text" value=""/>

15:12 16%

IOF Calcium Calculator

Are you getting ENOUGH CALCIUM?

Calcium is essential for building and maintaining healthy bones at all ages. Find out whether you are getting enough of this important mineral in your daily diet by using this simple calculator.

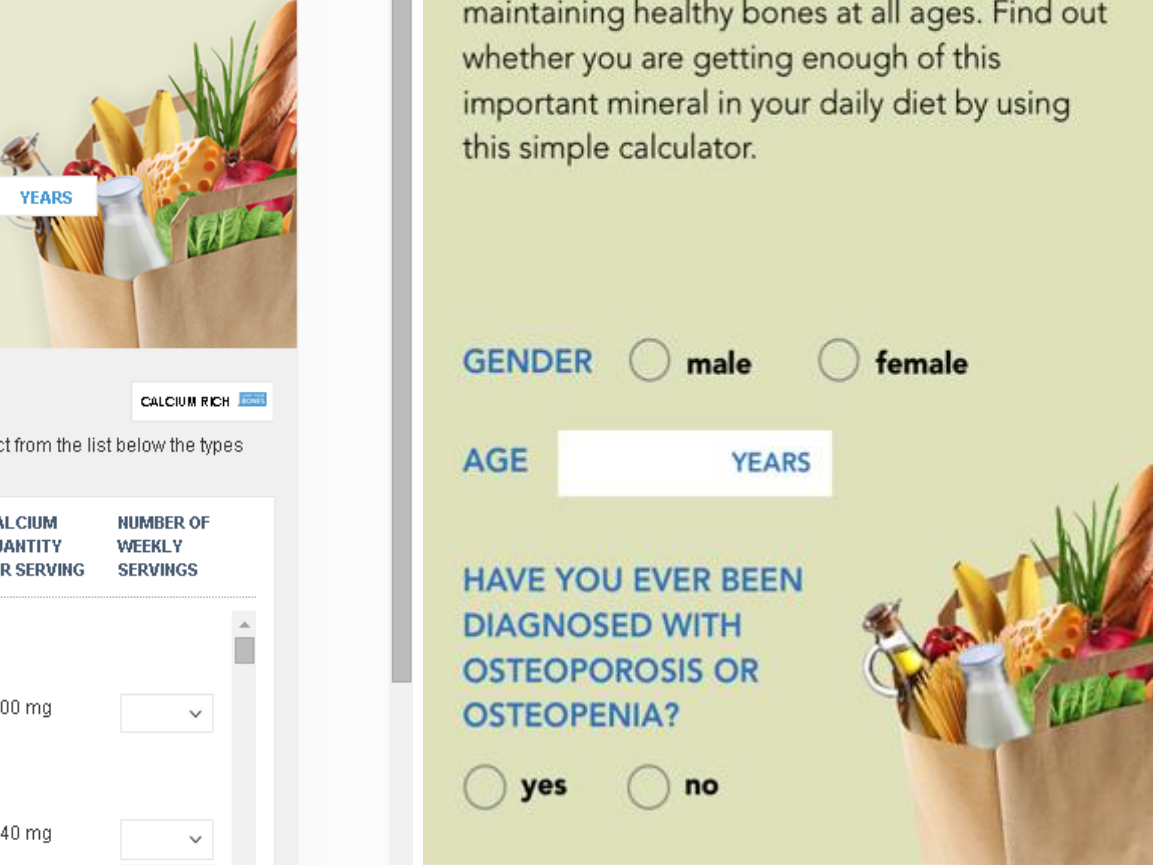
GENDER male female

AGE

HAVE YOU EVER BEEN DIAGNOSED WITH OSTEOPOROSIS OR OSTEOPENIA?

yes no

GET STARTED!



Dose for Vitamin D Prophylaxis (SACN UK)

- A Reference Nutrient Intake (RNI) for vitamin D of **10 µg/d** is therefore proposed for the UK population aged 4 years and over throughout the year.
- This is the amount needed for 97.5% of the population to maintain a serum 25(OH)D concentration of 25 nmol/L when UVB sunshine exposure is minimal. (includes pregnant and lactating women).

Vitamin D Toxicity

Indicator of toxicity-Hypercalcaemia

- Serum 25(OH)D > 300 nmol/L and more usually >500 nmol/L
- Vitamin D intake below 10,000 IU/day (or equivalent) is not usually associated with toxicity

Upper limit of dosage

- for **age >11 years** (including for pregnant and lactating women)
: 100 µg/d (4,000 IU) per day
- Children aged **1-10 years**: 50 µg/d (2,000 IU) per day
- For infants (**0-12 months**): 25 µg/d (1,000 IU)

Yearly high-dose vitamin D is ineffective and may cause increased risk of fracture

Treatment monitoring

Aims

1. detect those who remain deficient after loading
 2. detect those who become deficient during maintenance
 3. detect those patients in whom vitamin D therapy uncovers sub-clinical primary hyperparathyroidism
- **Adjusted serum calcium:** 1 month after completing the loading regimen
 - **Serum Vitamin D (25OHD)** at 6 months. Routine monitoring is unnecessary but may be appropriate in patients with symptomatic vitamin D deficiency or malabsorption and where poor compliance with medication is suspected.

When to refer to specialist?

- Atypical clinical manifestations, renal stones, hypercalcaemia
- Lack of clinical response to 2 courses of loading Vitamin D therapy (exclude non-compliance)
- Chronic renal impairment (eGFR <35 ml/min)
- Secondary causes – malabsorption, liver disease, renal disease, lymphoma, metastatic cancer, Parathyroid disorders, sarcoidosis and tuberculosis.



Summary

- Vitamin D is essential for musculoskeletal health
- Vitamin D prevents fall and with calcium reduces risk of fracture
- Vitamin D deficiency or insufficiency is more prevalent than expected
- Vitamin D status is currently best assessed by measurement of serum 25OHD
- Oral vitamin D3 is the treatment of choice in vitamin D deficiency.

Thank you