

# 2010 Symposia Series 2

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**Embassy Suites**  
Cary, North Carolina  
June 12, 2010



# Osteoporosis Update: Prevention, Diagnosis, and Treatment

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**Bruce S. Zitkus, EdD, ARNP, CANP,  
CFNP, CDE**

Clinical Associate Professor  
School of Nursing  
Stony Brook University  
Stony Brook, New York

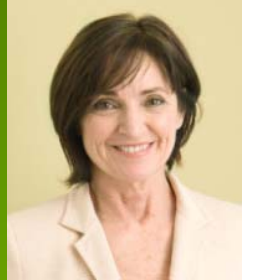
**BOSTON  
UNIVERSITY**



# Faculty Disclosure

- **Dr Zitkus:** *speakers bureau:* Eli Lilly and Company.

# Case Presentation: Ginger



- Age: 63 years
- Height: 5 ft 4 in
- Weight: 140 lb
- 45-year history of smoking; currently smokes 1/2 pack of cigarettes per day
- Takes a supplement containing calcium 1200 mg/d
- Received hormone therapy for 2 years at age 50 to ameliorate moderate postmenopausal vasomotor symptoms

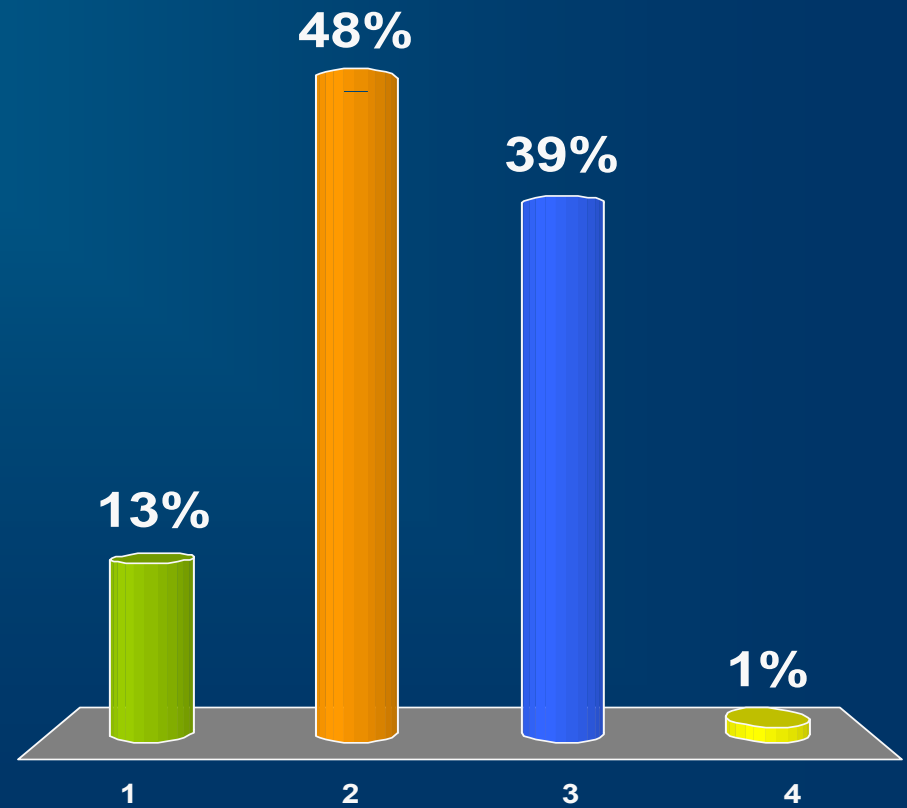
# Ginger should undergo BMD testing because of her:

DECISION POINT

?



1. Age
2. Menopausal status
3. Smoking history
4. Weight

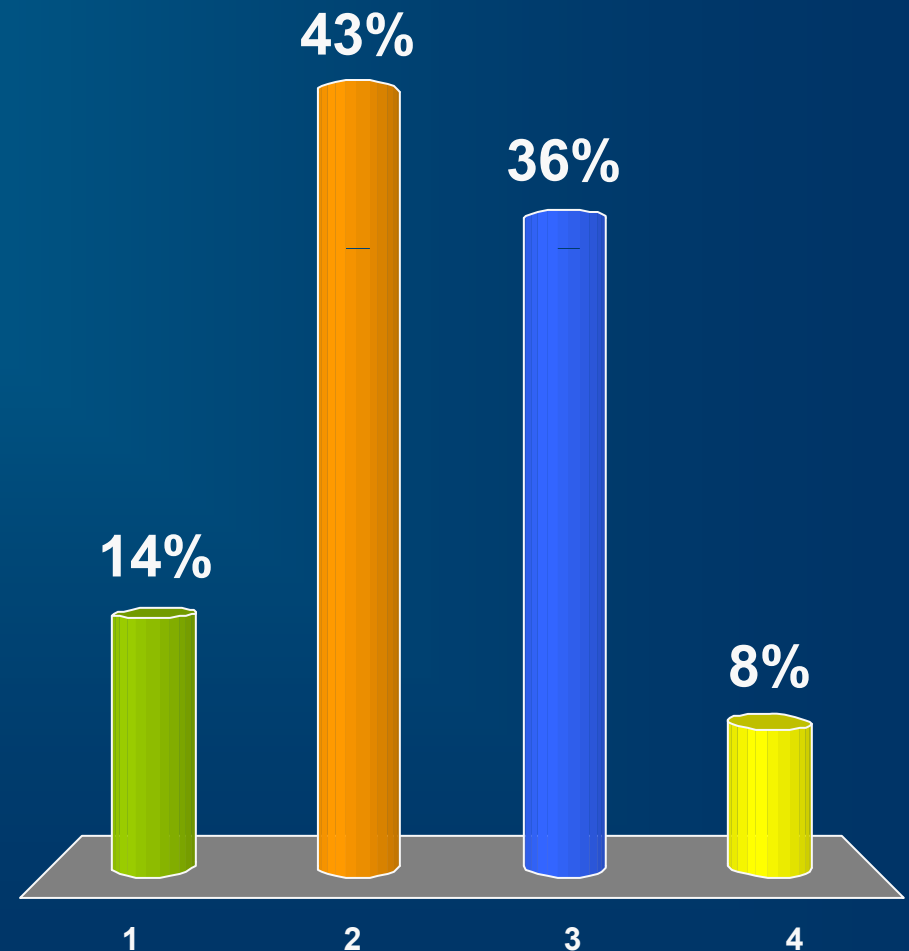


Use your keypad to vote now!

A T-score between  $-1$  and  $-2.5$  is considered:

KEY  
QUESTION  
?

1. Normal
2. Low bone mass
3. Osteoporosis
4. Severe or established osteoporosis

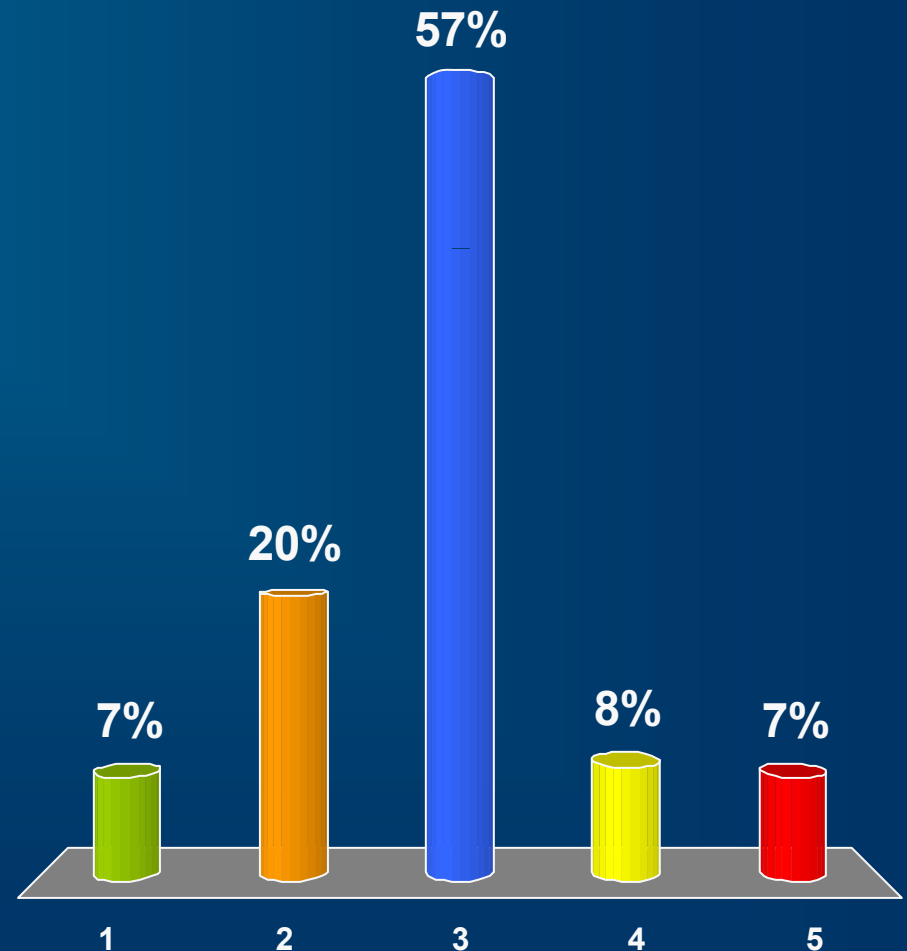


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# A patient is considered vitamin D-deficient when serum 25(OH)D is:

KEY  
QUESTION  
?

1. <10 ng/mL
2. <20 ng/mL
3. <30 ng/mL
4. <40 ng/mL
5. <50 ng/mL



Use your keypad to vote now!

# Learning Objectives

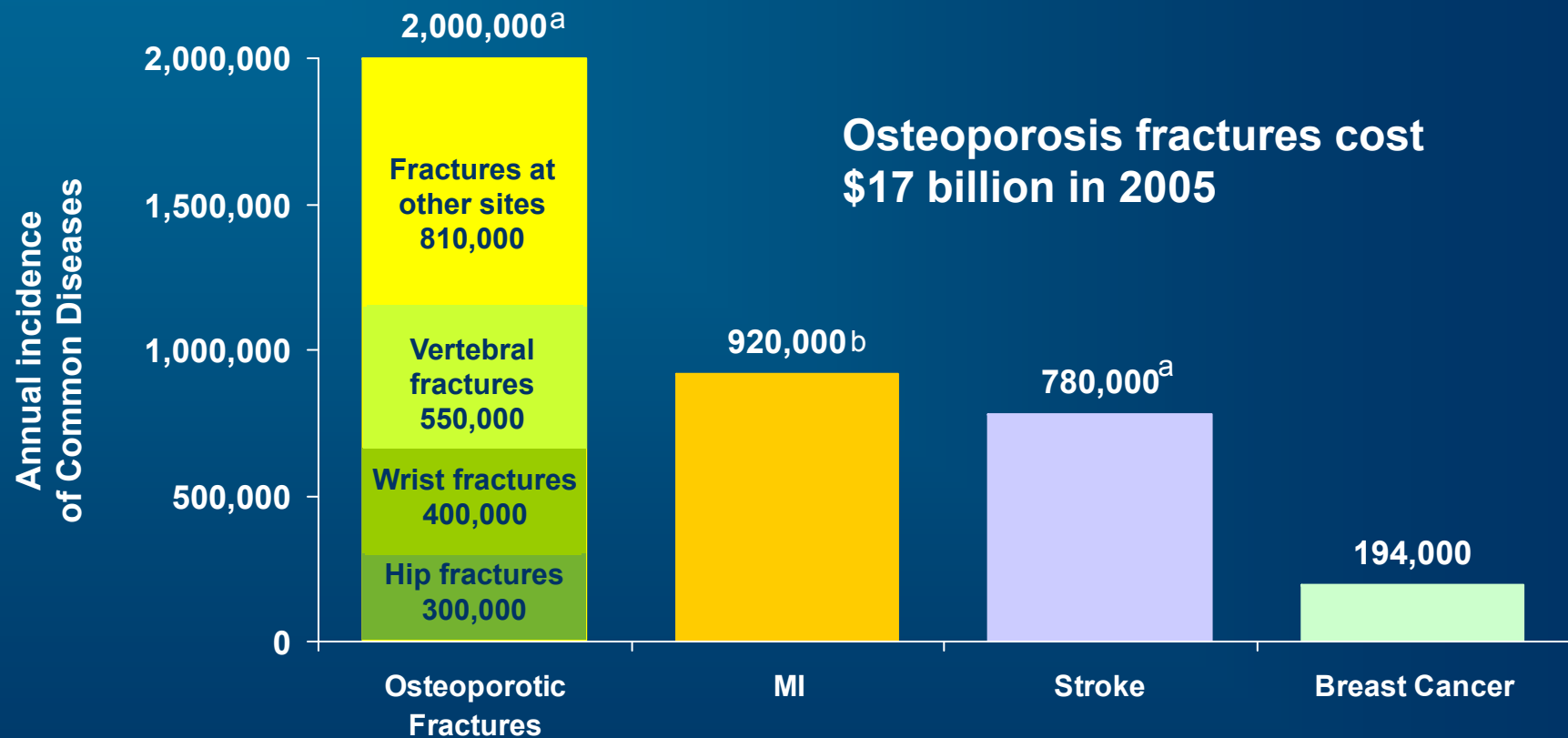
- Assess the risk factors associated with osteoporosis
- Identify patients for whom BMD testing is appropriate
- Evaluate nonpharmacologic preventive approaches as well as efficacy and safety of pharmacologic management

# Osteoporosis Defined

- A skeletal disorder characterized by compromised bone strength predisposing to increased risk of fracture<sup>1</sup>
- Bone density T-score  $\leq 2.5$  standard deviations (T-score) below normal peak values for young adults<sup>2</sup>
- Bone density = bone density + bone quality<sup>1</sup>
  - Bone density = grams of mineral per area or volume
  - Bone quality = architecture, turnover, damage accumulation, and mineralization

1. NIH Consensus Statement. 2000;17:1-45; 2. World Health Organ Tech Rep Ser. 1994;843:1-129.

# Prevalence of Osteoporosis



<sup>a</sup>Annual incidence all ages; <sup>b</sup>annual estimate women 35+.

MI = myocardial infarction.

American Cancer Society. Cancer Facts & Figures: 2009. <http://www.cancer.org/downloads/STT/500809web.pdf>. Accessed May 27, 2010;

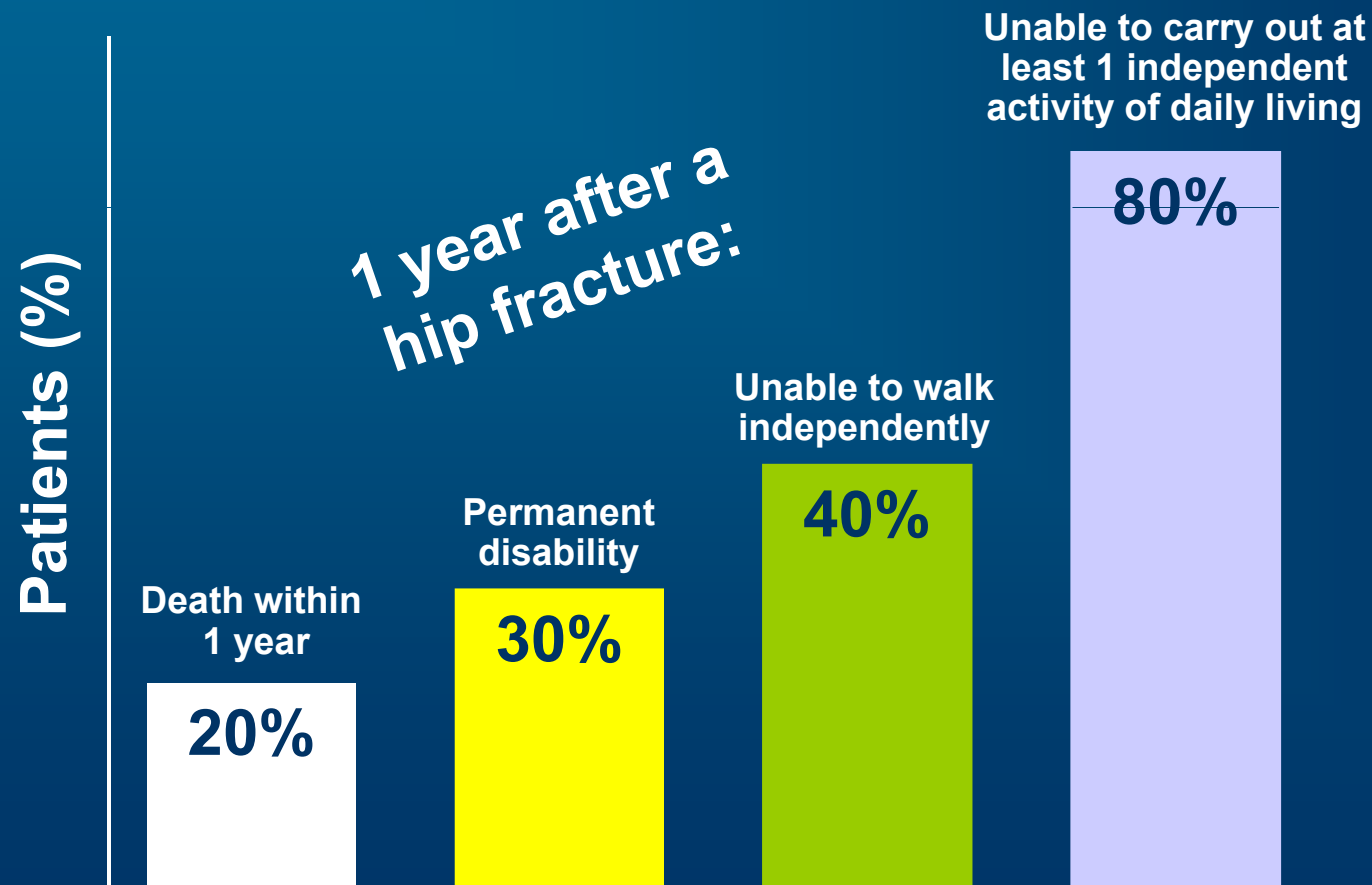
American Heart Association. Heart Disease and Stroke Statistics: 2008 Update At-a-Glance.

[http://www.americanheart.org/downloadable/heart/1200082005246HS\\_Stats%202008.final.pdf](http://www.americanheart.org/downloadable/heart/1200082005246HS_Stats%202008.final.pdf).

Accessed May 27, 2010; Burge R et al. *J Bone Min Res.* 2007;22:465-475.

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# All Fractures Are Associated With Morbidity



# Case Study

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# Case Study: Judy



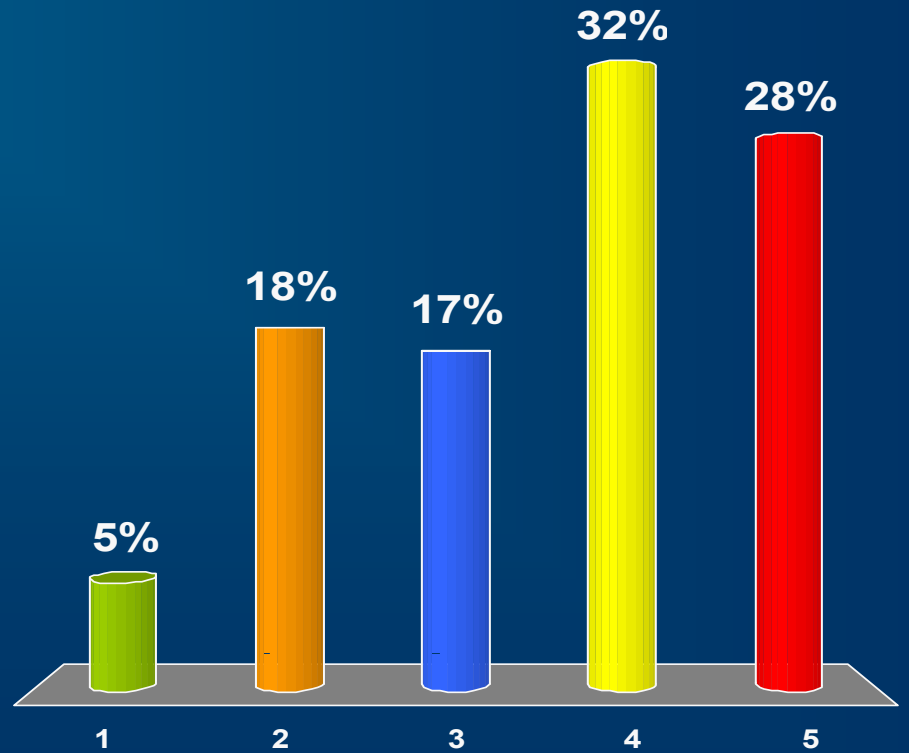
- Annual physical examination for a 50-year-old Caucasian woman
  - Height: 5 ft 2 in; weight: 101 lb; BMI: 18.5 kg/m<sup>2</sup>
  - Postmenopausal for 4 years
  - No HRT
  - Medications: omeprazole for GERD
  - No known drug allergies
  - Family history: mother had a hip fracture at age 76 years

# Which of the following is a major risk factor for osteoporosis for Judy?

DECISION POINT ?



- 1. Age
- 2. Estrogen deficiency
- 3. Family history
- 4. Menopausal status
- 5. Low BMI



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# Risk Factors for Osteoporotic Fracture

## Major (RR $\geq 2$ )

- Aged >70 years
- Menopause aged <45 years
- Hypogonadism
- Fragility fracture
- **Hip fracture in parents**
- **Glucocorticoids**
- **Malabsorption**
- High bone turnover
- Anorexia nervosa
- BMI <18 kg/m<sup>2</sup>
- Immobilization
- Chronic renal failure
- Transplantation

## Moderate (RR 1-2)

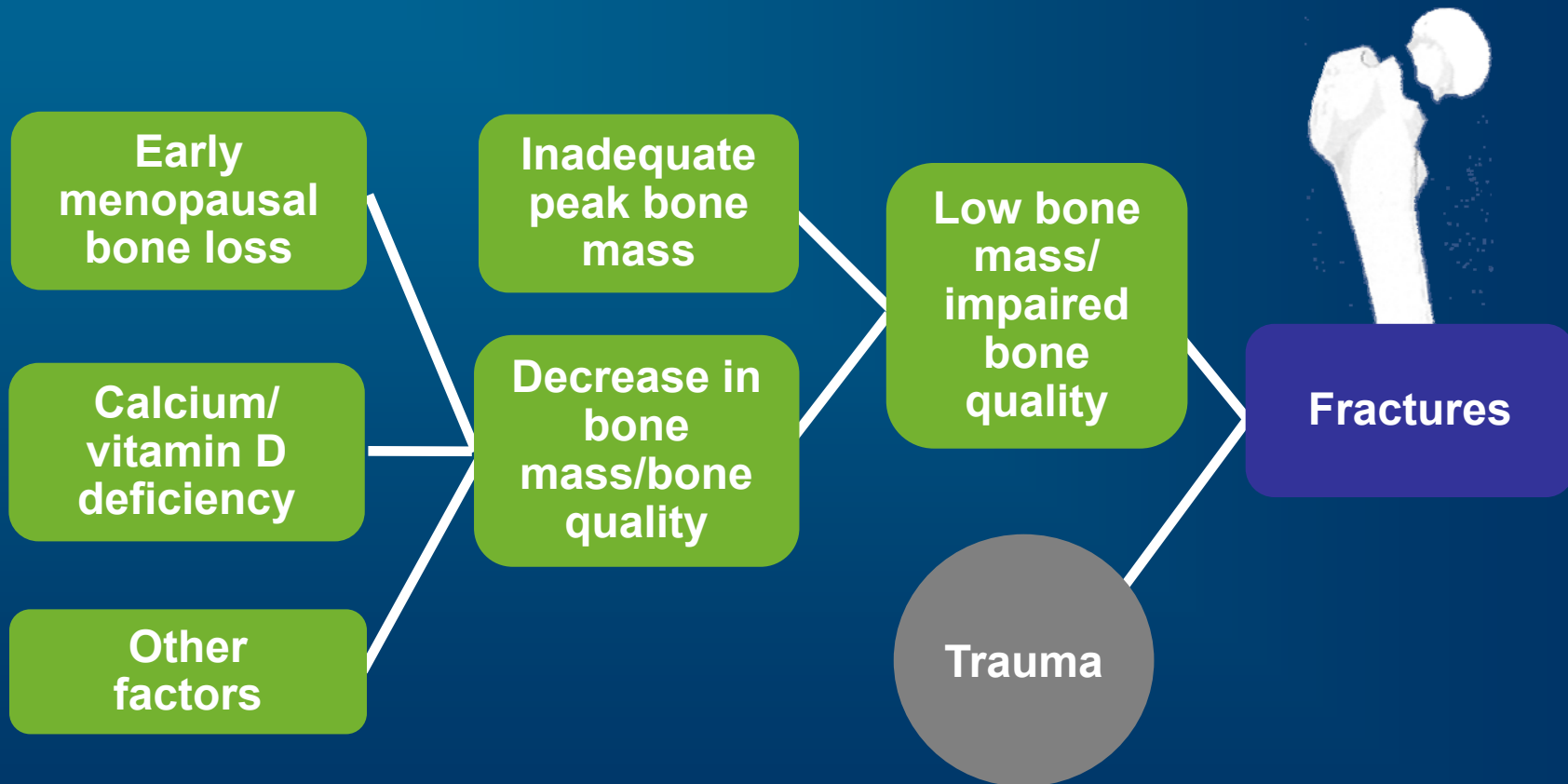
- **Estrogen deficiency**
- **Calcium intake <500 mg/d**
- Primary hyperparathyroidism
- Rheumatoid arthritis
- Ankylosing spondylitis
- Anticonvulsants
- Hyperthyroidism
- Diabetes mellitus
- Smoking
- Alcohol in excess

# Factors Contributing to Secondary Osteoporosis

- Lifestyle factors
- Genetic factors
- Hypogonadal states
- Endocrine disorders
- Gastrointestinal disorders
- Hematologic disorders
- Rheumatic and autoimmune diseases
- Miscellaneous conditions and diseases
- Medications

AACE Osteoporosis Task Force. *Endocr Pract.* 2001;7:293-312; NOF. *Clinician's Guide to Prevention and Treatment of Osteoporosis.* [http://www.nof.org/professionals/NOF\\_Clinicians\\_Guide.pdf](http://www.nof.org/professionals/NOF_Clinicians_Guide.pdf). Accessed May 27, 2010.

# Pathophysiology of Osteoporosis



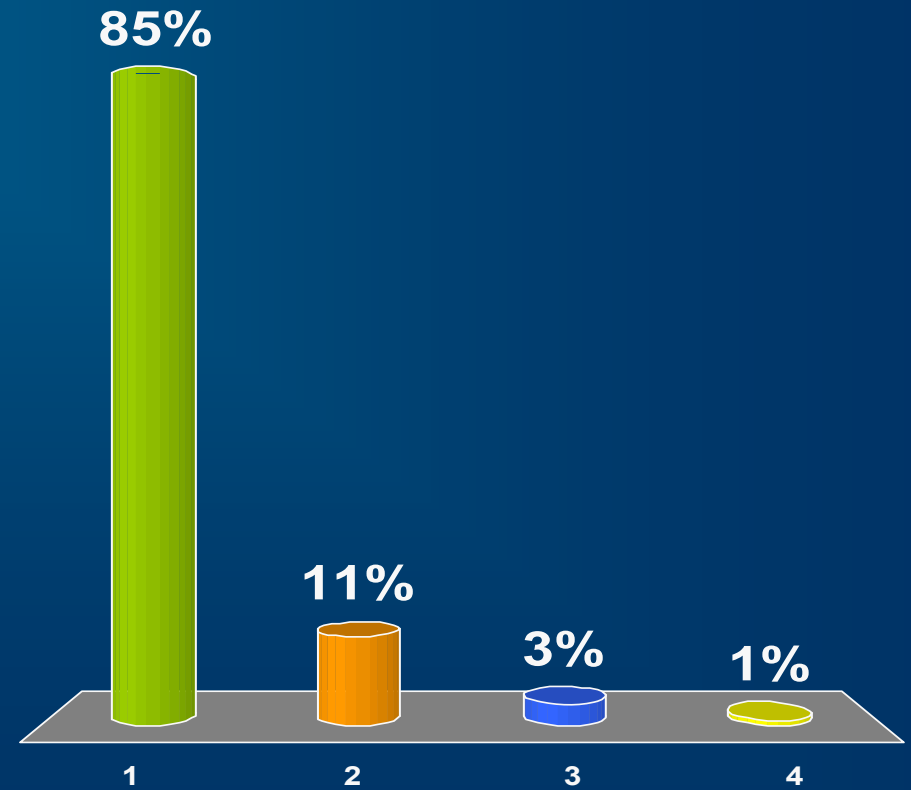
# How would you screen Judy for osteoporosis?

DECISION  
POINT

?



1. BMD
2. FRAX
3. 25(OH)D
4. Quantitative ultrasound



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# Diagnosing Osteoporosis



Diagnosis can be based on:

- Presence or history of low-trauma fracture
  - However, a fracture is not required for diagnosis.
- BMD

Clinical evaluation:

- Medical history
  - Risk factors
  - Signs and symptoms
    - Physical examination
    - Height assessment (with stadiometer)
    - BMD testing
    - Laboratory tests

# Who Should Have a Bone Density Test?



## Recommendations from the NOF

- Women  $\geq 65$  years of age, men  $\geq 70$  years of age
- Younger postmenopausal women and men 50-69 with risk factors
- Menopausal women with risk factors associated with increased fracture risk, (i.e., low body weight, prior low-trauma fracture, or high-risk medication)
- Adults who have a fracture after age 50
- Diseases/conditions/drugs associated with low bone mass or bone

### Action Item:

• Consider a patient's fracture risk profile and skeletal health when deciding whether to perform BMD assessment

NOF = National Osteoporosis Foundation.

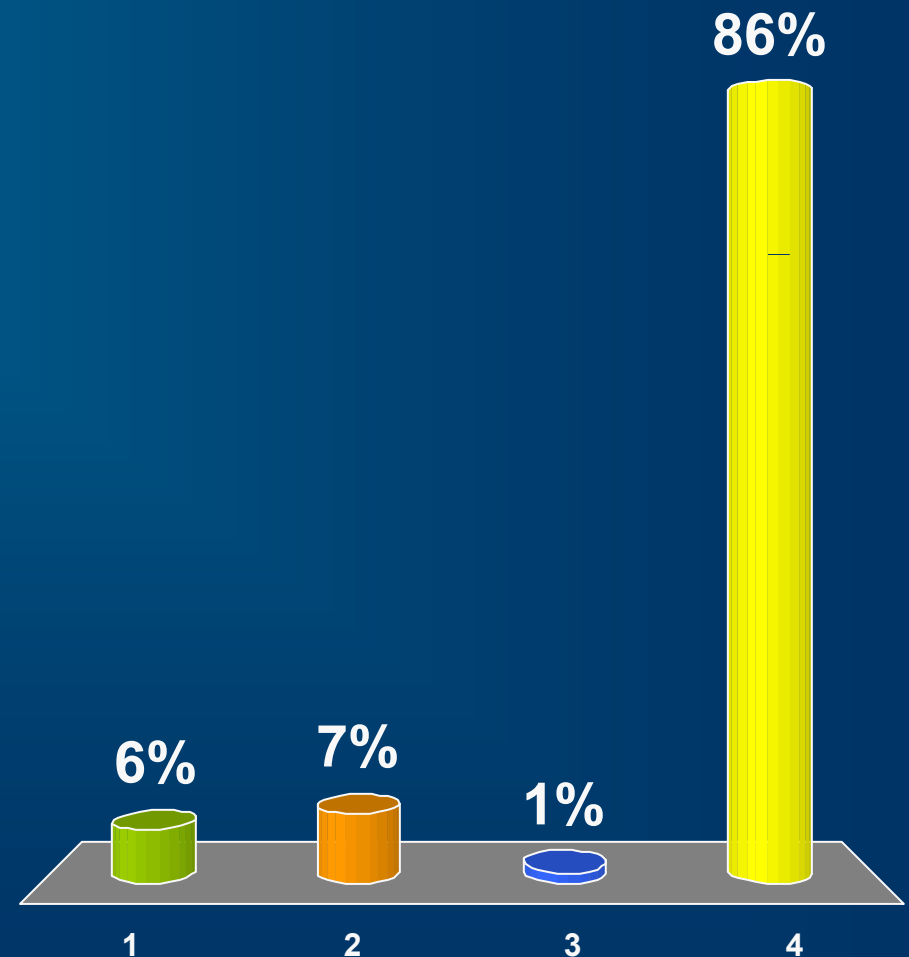
NOF. Clinician's Guide to Prevention and Treatment of Osteoporosis.

[http://www.nof.org/professionals/NOF\\_Clinicians\\_Guide.pdf](http://www.nof.org/professionals/NOF_Clinicians_Guide.pdf). Accessed May 27, 2010.

# Which of the following applies to the WHO/NOF criteria for diagnosis of osteoporosis?

KEY QUESTION  
?

1. T-score  $> -1.0$
2. T-score between  $-1.0$  and  $-2.0$
3. T-score is not a WHO/NOF criterion for diagnosing osteoporosis
4. T-score  $\leq -2.5$



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# WHO/NOF Criteria for Classification of Bone Status

## Diagnostic criteria<sup>a</sup>

- T-score  $> -1$
- T-score between  $-1$  and  $-2.5$
- T-score  $\leq -2.5$
- T-score  $\leq -2.5$  + fragility fracture(s)

## Classification

- Normal
- Low bone mass
- Osteoporosis
- Severe or established osteoporosis

<sup>a</sup>T-score = number of standard deviations below or above average peak bone mass in young adults.

NOF. Clinician's Guide to Prevention and Treatment of Osteoporosis.

[http://www.nof.org/professionals/NOF\\_Clinicians\\_Guide.pdf](http://www.nof.org/professionals/NOF_Clinicians_Guide.pdf). Accessed May 27, 2010.

# FRAX™ WHO Fracture Risk Assessment Tool

HOME

CALCULATION TOOL

PAPER CHARTS

FAQ

REFERENCES

Select a Language

## Welcome

The FRAX™ integrate the

The FRAX™ Australia. In versions, ba

The FRAX™ probability o

China
France
Italy
Japan
Spain
Sweden
Turkey
UK
US (Caucasian)
US (Black)
US (Hispanic)
US (Asian)

developed by WHO to evaluate fracture risk of patients. It is based on individual patient models that integrate clinical risk factors as well as bone mineral density (BMD) at the femoral neck.

Developed from studying population-based cohorts from Europe, North America, Asia and Australia. In addition, the FRAX™ tool is computer-driven and is available on this site. Several simplified paper versions, based on different sets of risk factors, are also available, and can be downloaded for office use.

The FRAX™ tool provides a 10-year probability of fracture. The output is a 10-year probability of hip fracture and the 10-year probability of major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture).

This is a beta version



**Dr. John A Kanis**

Professor Emeritus, University of Sheffield

### Links :

International Osteoporosis Foundation : <http://www.iofbonehealth.org/>

National Osteoporosis Foundation : <http://www.nof.org/>

Japan Osteoporosis Foundation : <http://www.jpof.or.jp/>

## Calculation Tool

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



### Weight Conversion:

pound:

105 pound = 47.63 kg

### Height Conversion:

inch:

60 inch = 152.4 cm

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

**Questionnaire:**

1. Age (between 40-90 years) or Date of birth  
Age:  Date of birth: 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

10. Secondary osteoporosis  No  Yes

11. Alcohol 3 more units per day  No  Yes

12. Femoral neck BMD  
T-score

**BMI 20.3**  
The ten year probability of fracture (%)

**with BMD**

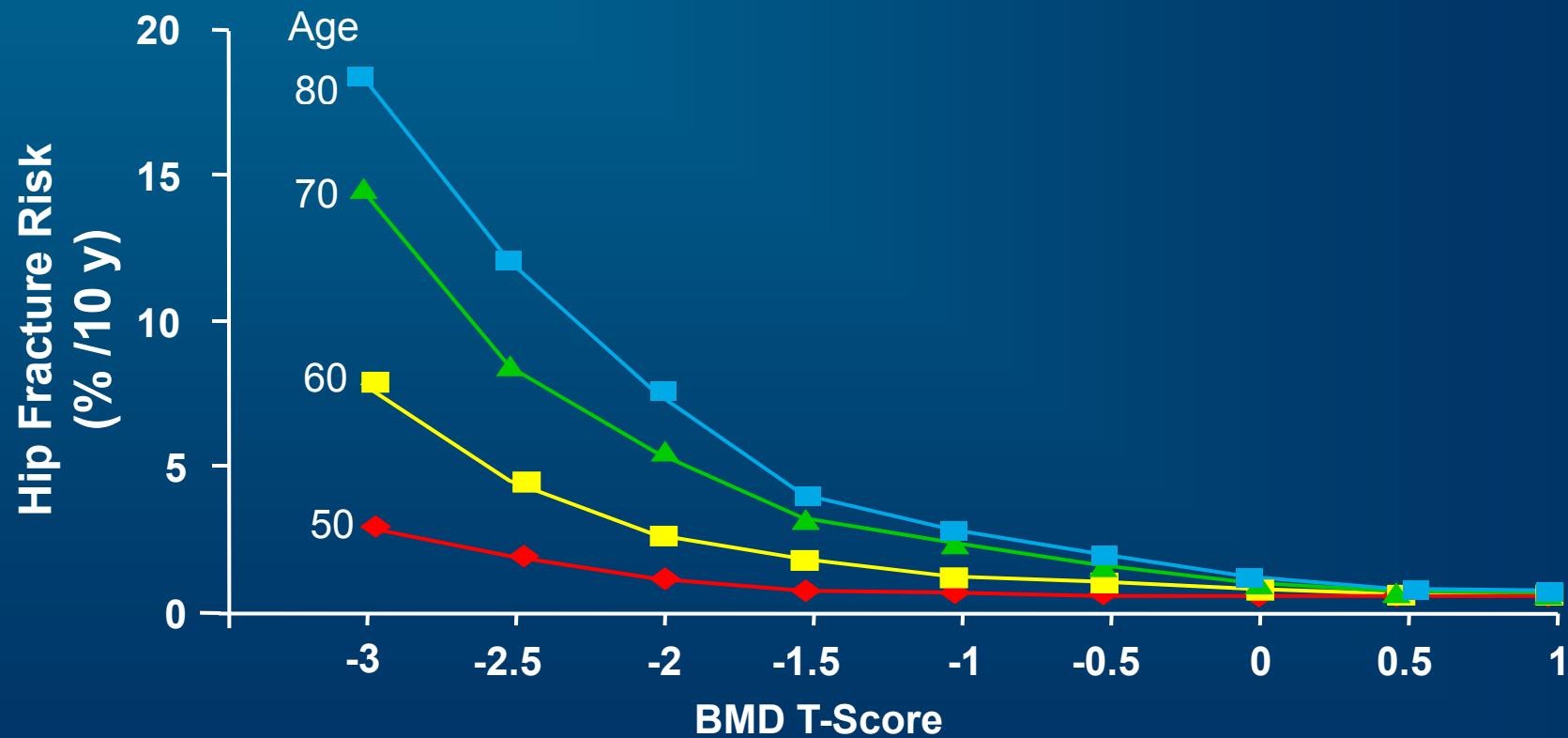
Major osteoporotic	40
Hip fracture	8.5



**Action Item:**  
**Calculate 10-year probability of fracture using FRAX in patients with low BMD.**

# 10-Year Fracture Risk: Age and BMD

For a given BMD, risk increases with age



# Case Study: Judy's Test Results



- BMD:  $-1.5$
- Serum 25(OH)D: 25 ng/mL
- Serum calcium: normal
- TSH: normal
- Height: loss of 1 inch during past 2 years
- FRAX 10-year probability of fracture
  - Major osteoporotic fracture: 7.5%
  - Hip fracture: 0.6%

# Indications for Treatment of Postmenopausal Osteoporosis: US Guidelines

	<b>NOF</b>	<b>AACE</b>	<b>NAMS</b>
<b>Prior fragility fracture</b>	Vertebral or hip	Any fracture with low BMD	Vertebral only
<b>T-score</b>			
<b>Without risk factor</b>	< -2.0	< -2.5	< -2.5
<b>With risk factor</b>	< -1.5	< -1.5	< -2.0
<b>Risk factors</b>	5 major, 8 additional	Several, including risk of falling	Thin, family history, prior fracture
<b>FRAX indications:</b> 10-year hip fracture risk >3% 10-year all major osteoporosis-related fracture risk >20%			

# What treatment would you recommend for Judy?

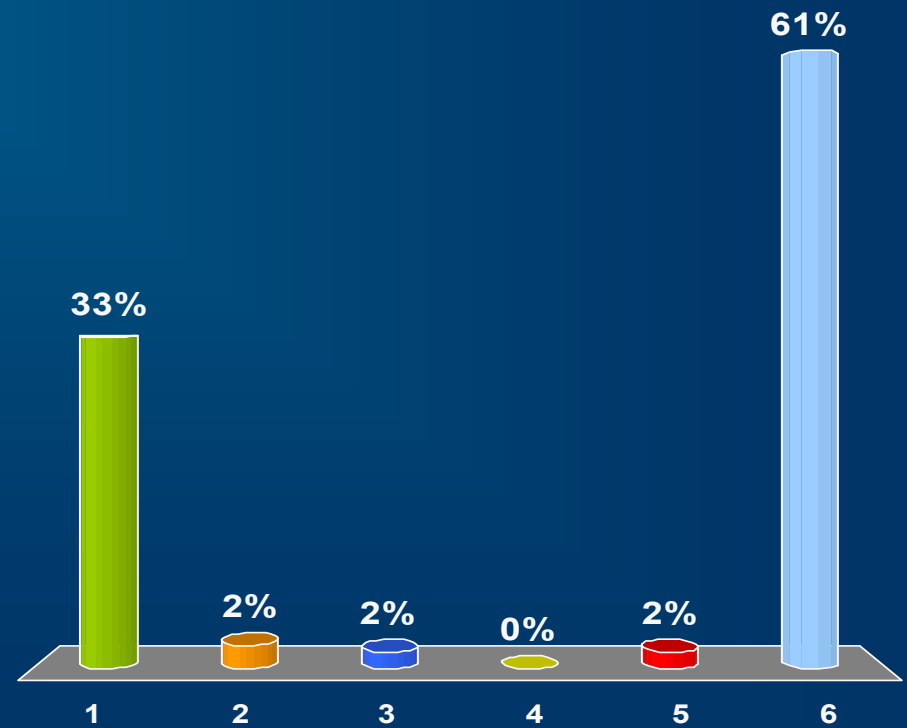
DECISION  
POINT

?



1. Bisphosphonate
2. SERM
3. Calcitonin
4. PTH
5. HRT
6. Calcium and vitamin D supplementation

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# Osteoporosis Treatment

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# Behavioral/Lifestyle Measures to Prevent Osteoporosis

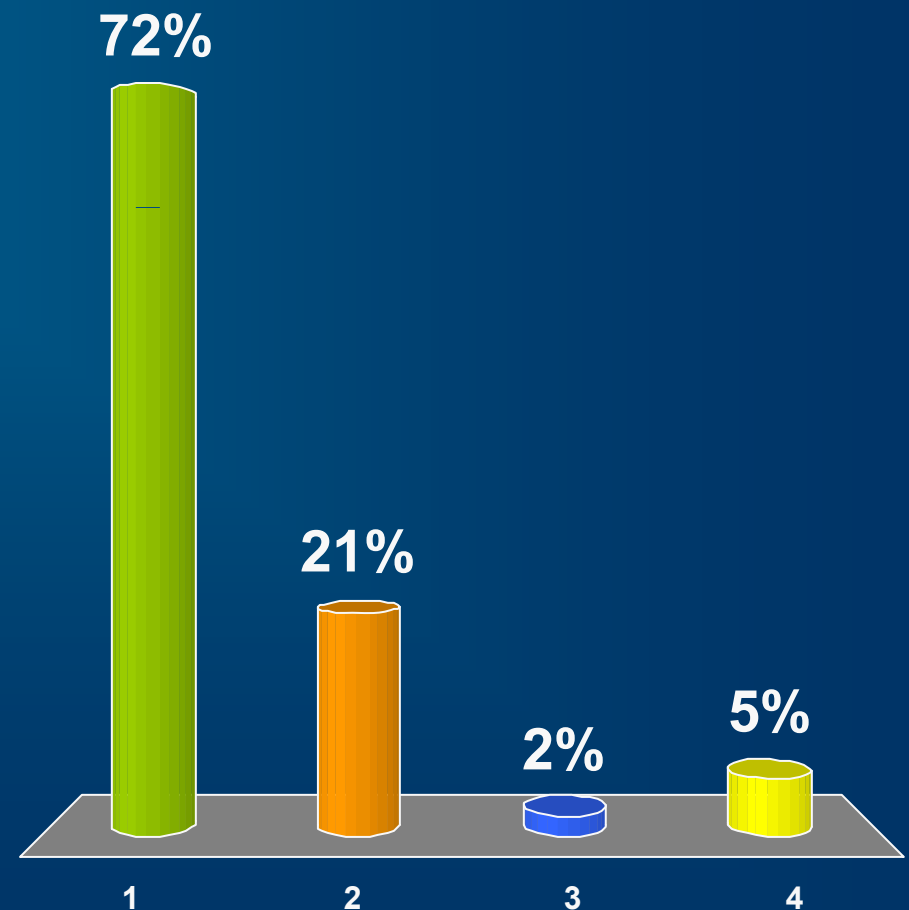
- Adequate intake of dietary calcium, vitamin D, and protein throughout life
- Regular physical activity; load-bearing exercise
- Minimize alcohol intake
- Stop smoking
- Take measures to prevent falls
- Use of hip protectors by patients prone to falling

Ebeling PR. *N Engl J Med*. 2008;358:1474-1482; NOF. Clinician's Guide to Prevention and Treatment of Osteoporosis. [http://www.nof.org/professionals/NOF\\_Clinicians\\_Guide.pdf](http://www.nof.org/professionals/NOF_Clinicians_Guide.pdf). Accessed May 27, 2010.

# Which of the following is true with regard to vitamin D and bone health?

KEY QUESTION  
?

1. Oral vitamin D reduces risk of hip fractures by 26%
2. Oral vitamin D has no benefit in preventing falls in osteoporotic patients
3. Only vitamin D absorbed through the skin is effective in preventing osteoporosis
4. Vitamin D supplementation has no effect on nonvertebral fractures



**Use your keypad to vote now!**

# Vitamin D Protects Against Osteoporosis



- NOF recommends at least 800-1000 IU/d vitamin D; however, these recommendations may be too low and will likely be revised<sup>1</sup>
- Oral vitamin D supplementation 700-800 IU/d reduces risk of
  - Hip fracture 26%
  - Nonvertebral fracture 23%
  - Falls 22% (↑ muscle strength, better balance)<sup>2</sup>
- Best sources

**Action Item:**  
**Advise patients to increase daily intake of  
vitamin D to 800-1000 IU/d.**

1. NOF. Clinician's Guide to Prevention and Treatment of Osteoporosis. [http://www.nof.org/professionals/NOF\\_Clinicians\\_Guide.pdf](http://www.nof.org/professionals/NOF_Clinicians_Guide.pdf). Accessed May 27, 2010; 2. Bischoff-Ferrari HA, et al. *JAMA*. 2005;293:2257-2264.

# Serum 25(OH)D Concentration

- Best laboratory indicator of vitamin D adequacy
- Lower limit normal for 25(OH)D levels varies depending on the geographic location and sunlight exposure of the reference population
  - Deficiency <20 ng/mL
  - Insufficiency <30 ng/mL

# Serum 25(OH)D Testing

- No consensus on optimal 25(OH)D concentration for skeletal or extraskeletal health
- Minimum level of 30 ng/mL (75 nmol/L) generally is necessary
  - Serum PTH level typically is inversely related to 25(OH)D levels, and is a useful secondary indicator of vitamin D insufficiency

# Risk Factors for Vitamin D Deficiency

- Age >65
- Breastfed exclusively without vitamin D supplementation
- Dark skin
- Insufficient sun exposure
- Medication use that alters vitamin D metabolism
- Obesity BMI >30 kg/m<sup>2</sup>
- Sedentary lifestyle

# National Institutes of Health Recommendations for Calcium Intake

Age (y)	Calcium Intake (mg/d)
1-3	500
4-8	800
9-18	1300
19-50	1000
>51	1200
>65	1500

# Pharmacologic Options for Osteoporosis Treatment

- Antiresorptive
  - Bisphosphonates
    - Alendronate, risedronate, ibandronate, zoledronic acid
  - SERMs
    - Raloxifene
  - Estrogen
  - Calcitonin
  - RANKL inhibitor
    - Denosumab
- Anabolic
  - PTH

# Bisphosphonates: Evidence for Fracture Reduction

Drug	Vertebral Fracture	Nonvertebral Fracture	Hip Fracture
Alendronate	✓	*	✓
Ibandronate	✓		
Risedronate	✓	✓	*
Zoledronic acid	✓	✓	✓

\*Evidence for effect, but not an FDA-approved indication.

MacLean C, et al. *Ann Intern Med.* 2008;148:197-213.

# Evidence for Fracture Reduction

Drug	Vertebral Fracture	Nonvertebral Fracture	Hip Fracture
Raloxifene	✓		
Estrogen	✓	✓	
Calcitonin	✓		
Teriparatide	✓	✓	
Denosumab	✓	✓	✓

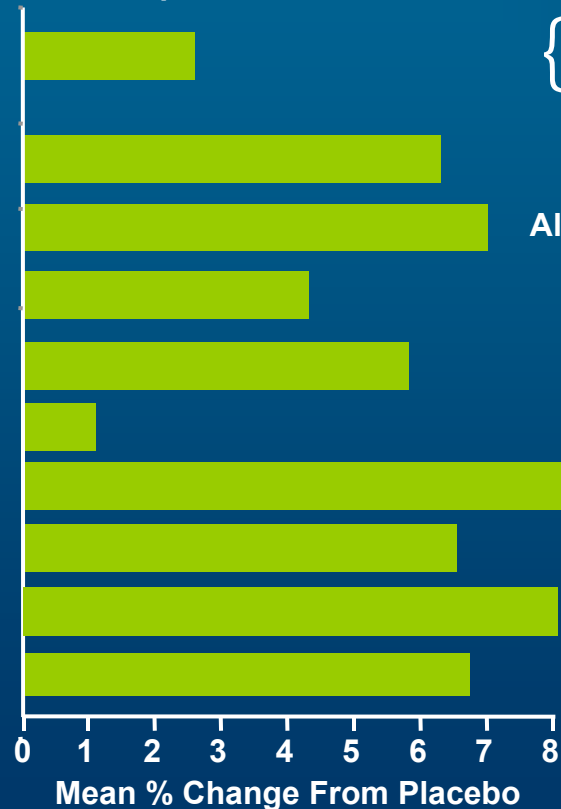
MacLean C, et al. *Ann Intern Med.* 2008;148:197-213.

39 © 2010. National Osteoporosis Foundation. All rights reserved. [www.nof.org](http://www.nof.org)

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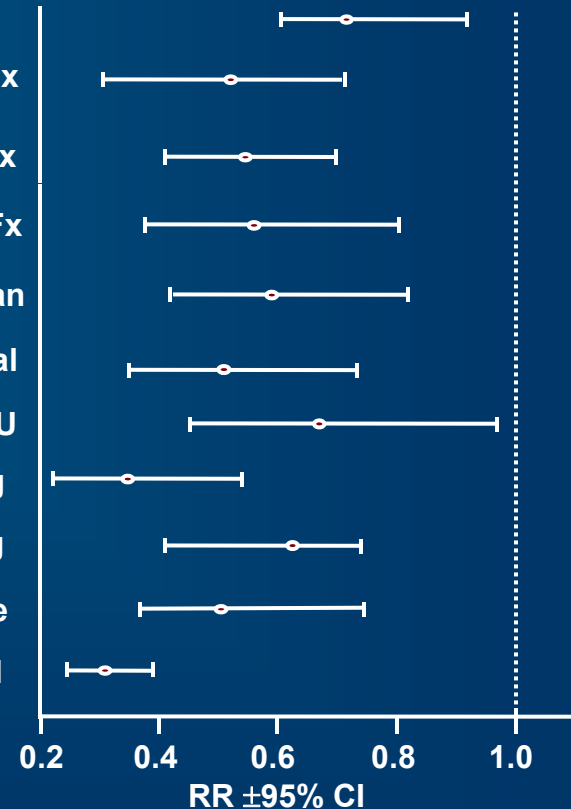
# Effect of Drugs for Osteoporosis on BMD and Vertebral Fracture Risk

Lumbar Spine BMD



- { Raloxifene 60 mg, prevalent VFx
- { Raloxifene 60 mg, no prevalent VFx
- Alendronate 5/10 mg, prevalent VFx
- Alendronate 5/10 mg, no prevalent VFx
- Risedronate 5 mg, North American
- Risedronate 5 mg, multinational
- Nasal calcitonin 200 IU
- Teriparatide 20 µg
- Ibandronate 2.5 mg
- Strontium ranelate
- Zoledronic acid

RR of Incident Vertebral Fractures



CI = confidence interval; VFx = vertebral fracture.

Marcus R, et al. *Endocr Rev.* 2002;23:16-37; IBMS. [http://www.bonekey-](http://www.bonekey-ibms.org/education/slides/clinical_osteoporosis/pp/BoneKEy_Intro_Osteoporosis_Treatment.ppt)

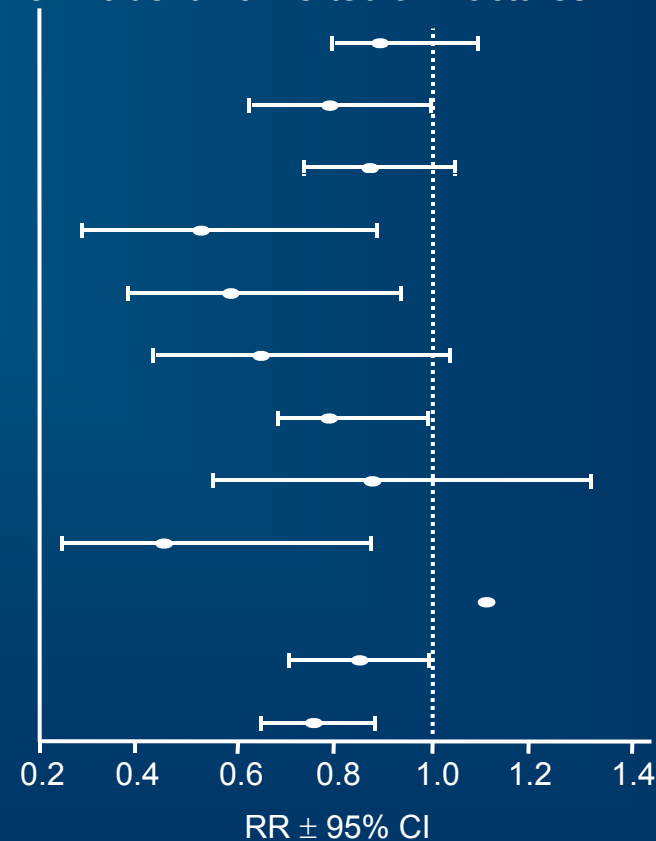
[ibms.org/education/slides/clinical\\_osteoporosis/pp/BoneKEy\\_Intro\\_Osteoporosis\\_Treatment.ppt](http://www.bonekey-ibms.org/education/slides/clinical_osteoporosis/pp/BoneKEy_Intro_Osteoporosis_Treatment.ppt).

Accessed May 27, 2010.

# Effect of Drugs for Osteoporosis on Nonvertebral Fracture Risk

Raloxifene 60 & 120 mg, prevalent & no prevalent VFx  
 Alendronate 5/10 mg, prevalent VFx  
 Alendronate 5/10 mg, no prevalent VFx  
 Alendronate 10 mg, low BMD  
 Risedronate 5 mg, prevalent VFx  
 Risedronate 5 mg, prevalent VFx  
 Risedronate 2.5 & 5 mg, osteoporosis  
 Nasal calcitonin 200 IU, prevalent VFx  
 Teriparatide 20  $\mu$ g, prevalent VFx  
 Ibandronate  
 Strontium ranelate  
 Zoledronic acid

RR of Incident Nonvertebral Fractures



Marcus R, et al. *Endocr Rev.* 2002;23:16-37; IBMS. [http://www.bonekey-ibms.org/education/slides/clinical\\_osteoporosis/pp/BoneKEy\\_Intro\\_Osteoporosis\\_Treatment.ppt](http://www.bonekey-ibms.org/education/slides/clinical_osteoporosis/pp/BoneKEy_Intro_Osteoporosis_Treatment.ppt). Accessed May 27, 2010.

# Bisphosphonate Indications

Agent	Indication
Alendronate	<ul style="list-style-type: none"><li>• Prevention and treatment in postmenopausal women</li><li>• Treatment of osteoporosis in men</li><li>• Treatment of glucocorticoid-induced osteoporosis</li></ul>
Ibandronate	<ul style="list-style-type: none"><li>• Prevention and treatment in postmenopausal women</li></ul>
Risedronate	<ul style="list-style-type: none"><li>• Prevention and treatment in postmenopausal women</li><li>• Treatment of osteoporosis in men</li><li>• Prevention and treatment of glucocorticoid-induced osteoporosis</li></ul>
Zoledronic acid	<ul style="list-style-type: none"><li>• Prevention and treatment in postmenopausal women</li><li>• Treatment of osteoporosis in men</li><li>• Prevention and treatment of glucocorticoid-induced osteoporosis</li><li>• Prevention of recurrent fracture in women and men with recent low-trauma hip fracture</li></ul>

# Bisphosphonates: Adverse Effects

May include:

- All dosage forms<sup>a</sup>
  - Nausea
  - Heartburn
- Oral
  - Irritation or burning of the esophagus
  - Difficulty swallowing
  - Painful swallowing
- IV
  - Arthralgia
  - Myalgia
  - Bone pain
  - Fever
  - Flulike symptoms

<sup>a</sup>Osteonecrosis of the jaw has been reported with oral bisphosphonates, but is extremely rare (affecting 1 in 10,000 patients). A greater degree of risk has been reported in cancer patients treated with high doses of IV bisphosphonates, exceeding levels used in osteoporosis.

Khosla S, et al. *J Bone Miner Res*. 2007;1479-1491. NOF. Clinician's Guide to Prevention and Treatment of Osteoporosis. [http://www.nof.org/professionals/NOF\\_Clinicians\\_Guide.pdf](http://www.nof.org/professionals/NOF_Clinicians_Guide.pdf).

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# Calcitonin

- Indications: treatment of osteoporosis in women at least 5 years postmenopausal
  - Significantly reduces risk of new vertebral fractures
  - Available as nasal spray (recommended daily dose: 1 activation [200 IU])
- Not considered first-line monotherapy for osteoporosis
- Efficacy not demonstrated for nonvertebral or hip fractures

# Calcitonin: Adverse Effects

- Mild and of low incidence
- No serious adverse effects with long-term administration
- Most common adverse effects:
  - Rhinitis: 12%
  - Nasal symptoms: 11%

*Physicians' Desk Reference*. 64th ed. Montvale, NJ; 2010.  
NOF. Clinician's Guide to Prevention and Treatment of Osteoporosis.  
[http://www.nof.org/professionals/NOF\\_Clinicians\\_Guide.pdf](http://www.nof.org/professionals/NOF_Clinicians_Guide.pdf). Accessed May 27, 2010.  
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# Raloxifene

- Indications: prevention and treatment of osteoporosis in postmenopausal women
- Significantly reduces risk of vertebral fracture
- Not shown to reduce risk of nonvertebral or hip fractures

# Raloxifene: Adverse Effects

	Incidence vs Placebo	
Adverse Effect	Treatment	Prevention
Hot flashes	10% vs 6%	25% vs 18%
Leg cramps	7% vs 4%	6% vs 2%
Fluid retention	5% vs 4%	3% vs 2%

Serious Adverse Event	Hazard Ratio (95% CI)
Deep vein thrombosis	2.4 (1.2-4.5)

Physicians' Desk Reference. 64th ed. Montvale, NJ; 2010.

# Teriparatide

- Indicated for:
  - Treatment of osteoporosis in postmenopausal women and men at high risk for fracture
  - Treatment of women and men with glucocorticoid-induced osteoporosis at high risk for fracture
  - Increasing bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture
- Significantly reduces risk of vertebral and nonvertebral fractures

# Teriparatide: Adverse Effects<sup>a</sup>

Adverse Event	Incidence vs Placebo
Leg cramps	3% vs 1%
Dizziness	8% vs 5%
Arthralgias	10% vs 8%
Transient hypercalcemia	11% vs 2%

<sup>a</sup>The FDA assigned a black box warning because of osteosarcoma findings in animal studies (no excess osteosarcomas were reported in human populations). Use limited to maximum of 2 years in a patient's lifetime.

*Physicians' Desk Reference*. 64th ed. Montvale, NJ; 2010.

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# Denosumab: Newest Approved Agent

- Fully human monoclonal antibody against RANKL
- Indications: treatment of osteoporosis in postmenopausal women at high risk for fractures
- Increases BMD<sup>1</sup>
- Reduces risk of fracture versus placebo<sup>2</sup>
  - 20% nonvertebral
  - 40% hip
  - 68% new vertebral
- Available as twice yearly injection

# Denosumab: Adverse Effects

- Most common: back pain, pain in the extremities, musculoskeletal pain, high cholesterol levels, urinary bladder infections
- Serious adverse reactions: infections of the skin, cellulitis
- Long-term safety being evaluated in 7-year extension to the FREEDOM trial

FREEDOM = Fracture Reduction Evaluation of Denosumab in Osteoporosis.  
FDA Approves New Injectable Osteoporosis Treatment for Postmenopausal Women [news release]. Silver Spring, MD: US Food and Drug Administration; June 1, 2010.  
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm214150.htm>.  
Accessed June 2, 2010.

# Quality of Evidence for Antifracture Efficacy In Postmenopausal Osteoporosis

	Spine	Nonvertebral	Hip
Alendronate	A	A	A
Calcitonin	C	C	D
Calcitriol	C	C	-
Calcium + vitamin D	-	C	C
Cyclic etidronate	B	D	D
Ibandronate	A	-	-
Estrogen	A	A	A
Raloxifene	A	-	-
Risedronate	A	A	A
Strontium ranelate	A	A	-
Teriparatide	A	A	-
Zoledronic acid	A	A	A

A = large RCT; B = small RCT; C = RCT are inconsistent; D = observational studies.  
RCT = randomized controlled trial.

Updated from WHO Osteoporosis Taskforce Report (WHO 2003)

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# When to Refer Patients

Referral to an osteoporosis specialist is appropriate when a patient:

- Is intolerant of approved therapies
- Fails to respond to treatment
  - Apparent loss of BMD on serial studies
  - Fractures despite treatment

# Assessing “Treatment Failure”

- If the BMD declines beyond least significant change:
  - Rule out undiagnosed secondary problems
  - Evaluate compliance and absorption issues

# Case Study: Judy's Follow-up

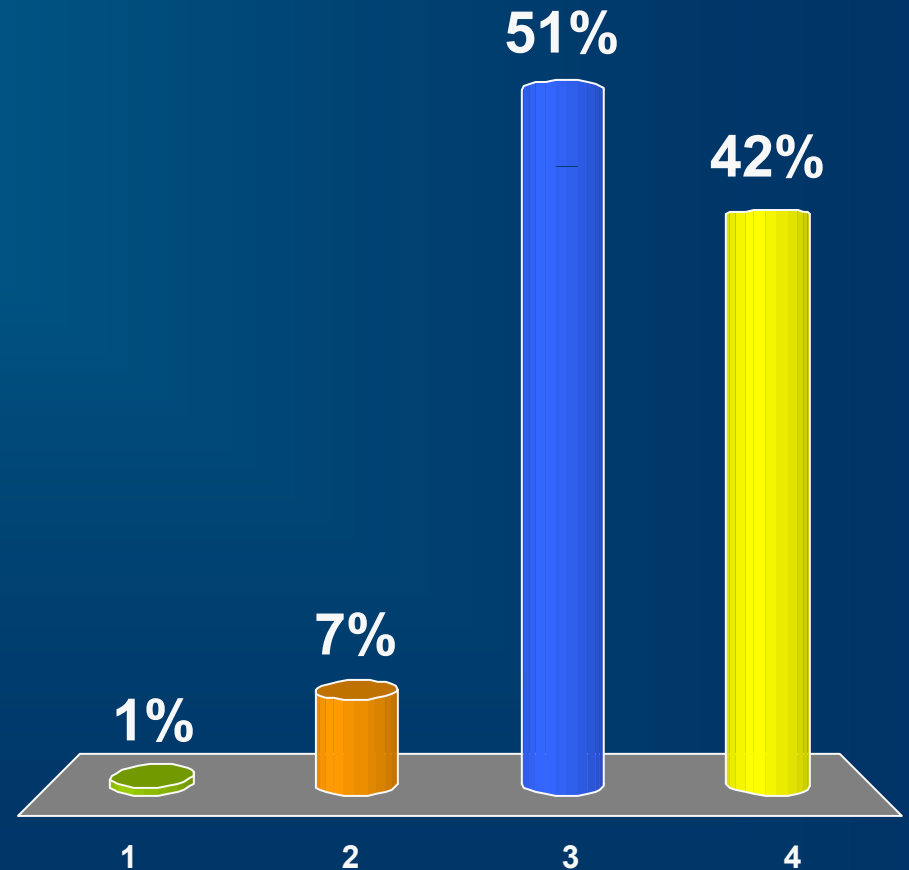


- Judy is put on weekly bisphosphonate with calcium and vitamin D supplementation
- She comes in for 6-month follow-up
- BMD same/worse
- She admits she hasn't refilled her prescription in 8 weeks
  - Heard about side effects of the drug

What percent of patients will stop their medications within 6-12 months of initiation?

KEY QUESTION  
?

1. <10%
2. 10%-15%
3. 20%-30%
4. 40%-50%



Use your keypad to vote now!

# Adherence and Persistence



- 20%-30% of patients taking oral osteoporosis medications suspend their medications within 6-12 months of initiation due to:
  - Side effects
  - Lack of knowledge
  - Reluctance to take regular medications

**Action Item:**  
**Educate patients about the importance of taking osteoporosis medications.**

# FLEX Study: Persistence

- FLEX
  - Compared effects of discontinuing alendronate treatment after 5 years versus continuing treatment for 10 years
  - Women who discontinued treatment after 5 years experienced a moderate decline in BMD, increase in biochemical markers, no higher fracture risk except clinical vertebral fractures

FLEX = Fracture Intervention Trial Long-Term Extension.

# Osteonecrosis of Jaw

- Osteonecrosis of jaw
- Potential complication of bisphosphonate
- Rare
  - 60% occur after dental extraction
  - Most cases occur in cancer patients
- Most cases associated with high-dose IV bisphosphonate treatment in metastatic cancer patients

# Q & A

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# PCE Action Plan

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# PCE Action Plan



- ❑ Consider a patient's risk of fracture profile and skeletal health when deciding whether to perform BMD assessment
- ❑ Calculate 10-year probability of fracture using FRAX in patients with low BMD
- ❑ Advise patients to increase daily intake of vitamin D to 800-1000 IU/d
- ❑ Educate patients about the importance of taking osteoporosis medications

## PCE Promotes Practice Change

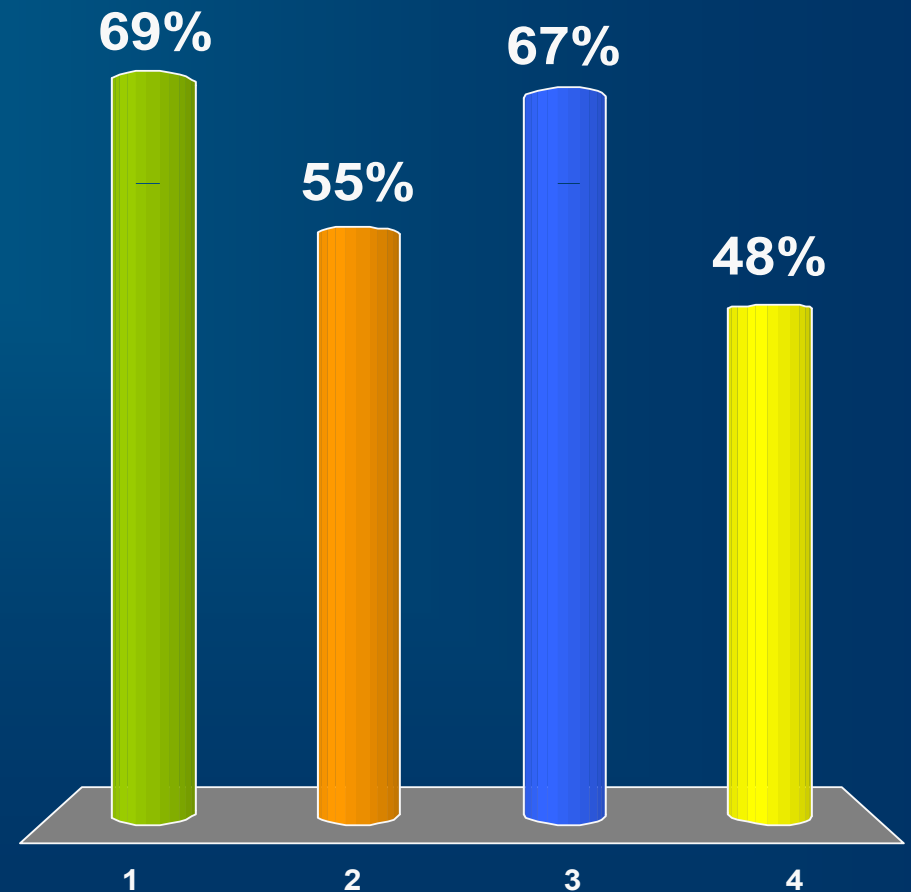
# Which of these Action Plan items do you plan to incorporate into your practice? (Select all that apply)

DECISION  
POINT

?

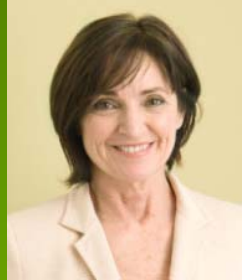


1. Consider a patient's risk of fracture profile and skeletal health when deciding whether to perform BMD assessment
2. Calculate 10-year probability of fracture using FRAX in patients with low BMD
3. Advise patients to increase daily intake of vitamin D to 800-1000 IU/d
4. Educate patients about the importance of taking osteoporosis medications



**Use your keypad to vote now!**

# Case Presentation: Ginger



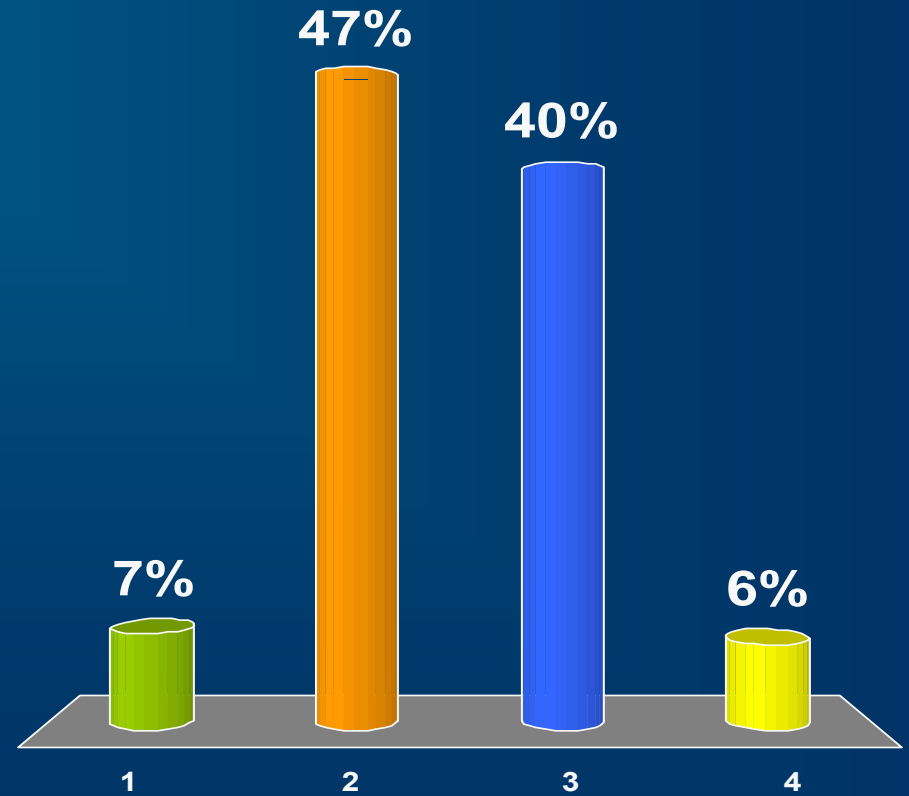
- Age: 63 years
- Height: 5 ft 4 in
- Weight: 140 lb
- 40-year history of smoking; currently smokes ½ pack of cigarettes per day
- Takes a supplement containing calcium 1200 mg/d
- Received hormone therapy for 2 years at age 50 to ameliorate moderate postmenopausal vasomotor symptoms

# Ginger should undergo BMD testing because of her:

DECISION POINT

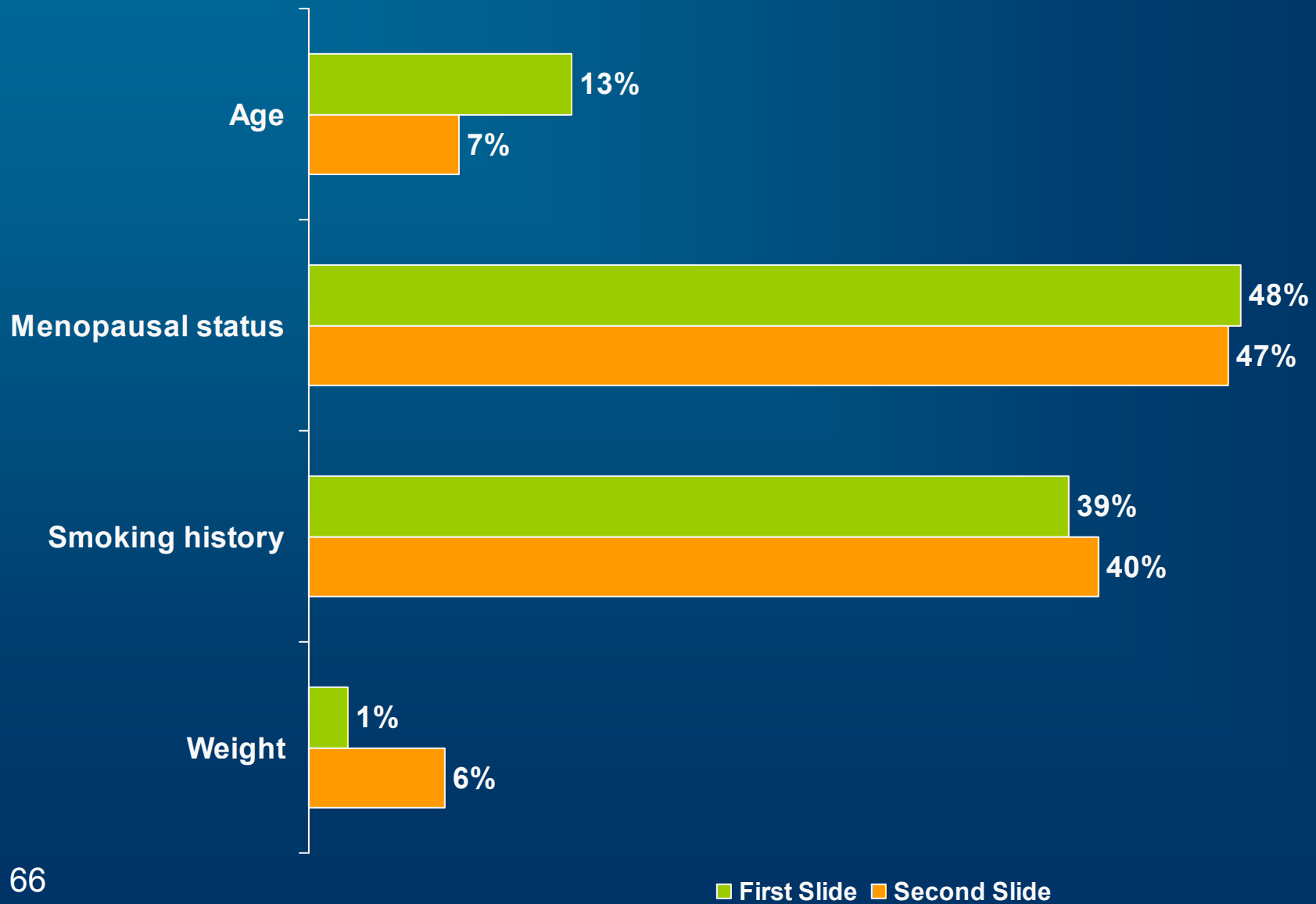


1. Age
2. Menopausal status
3. Smoking history
4. Weight



Use your keypad to vote now!

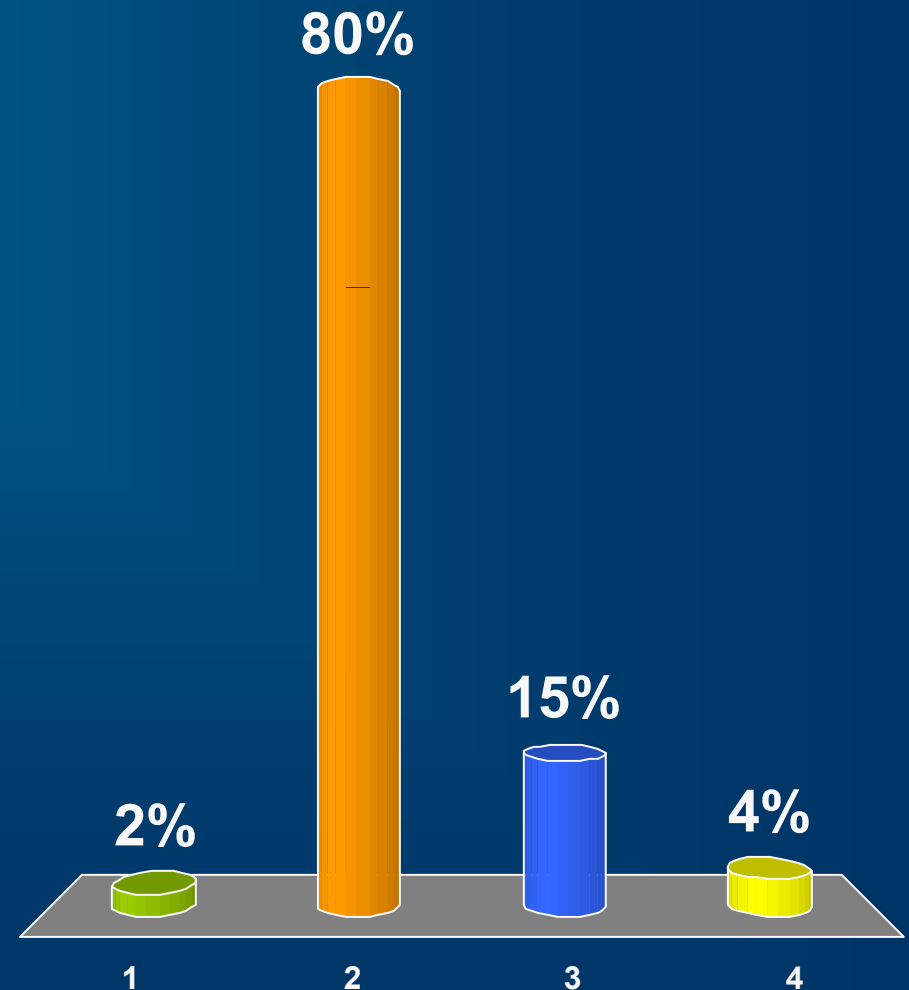
# Ginger should undergo BMD testing because of her:



# A T-score between $-1$ and $-2.5$ is considered:

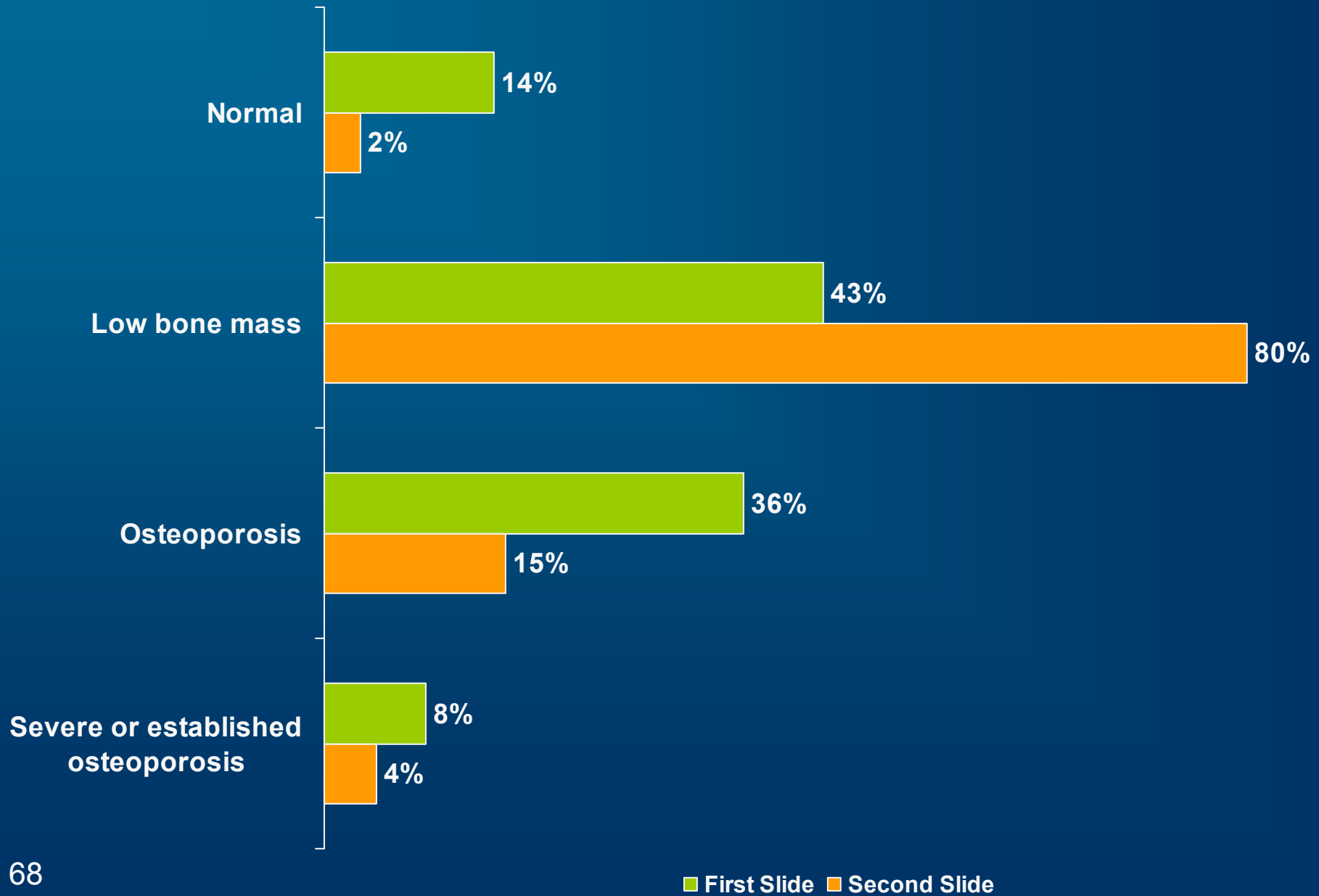
KEY  
QUESTION  
?

1. Normal
2. Low bone mass
3. Osteoporosis
4. Severe or established osteoporosis



Use your keypad to vote now!

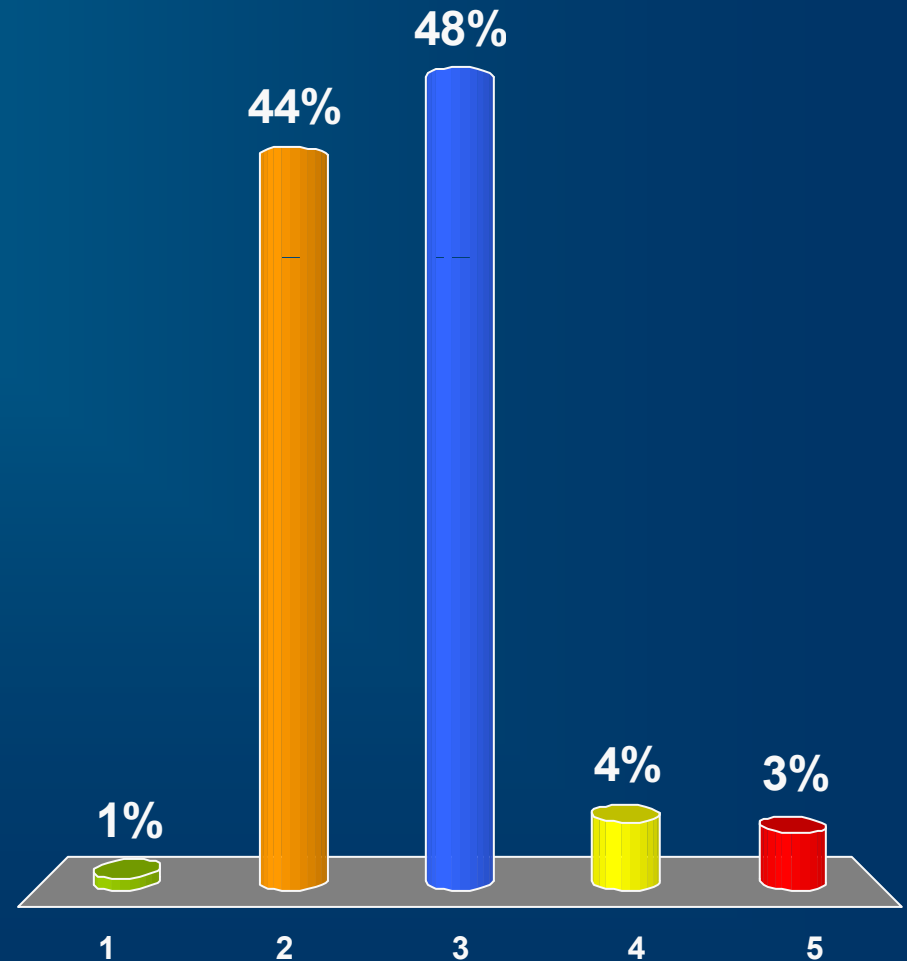
## A T-score between $-1$ and $-2.5$ is considered:



# A patient is considered vitamin D-deficient when serum 25(OH)D is:

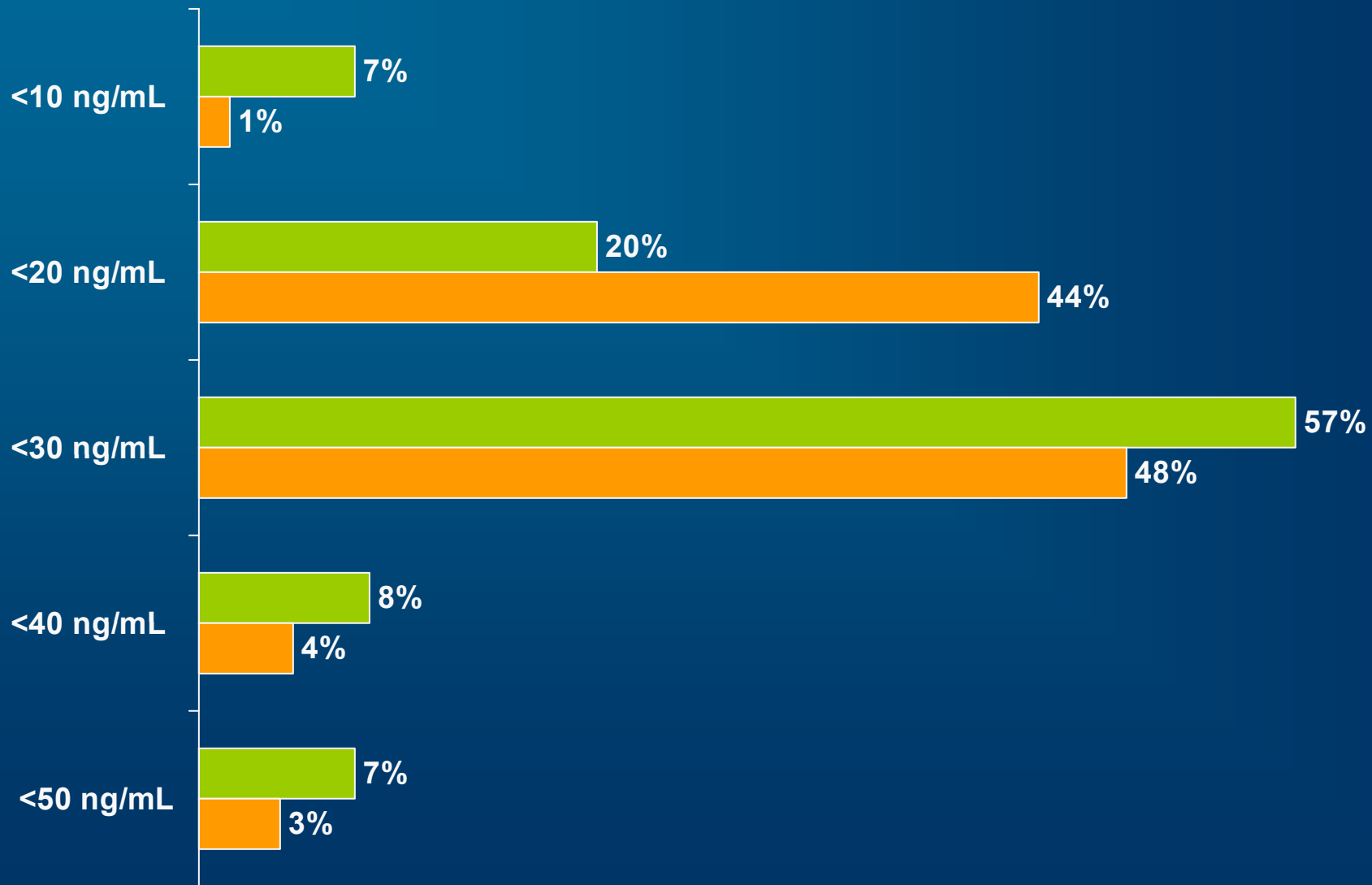
KEY  
QUESTION  
?

1. <10 ng/mL
2. <20 ng/mL
3. <30 ng/mL
4. <40 ng/mL
5. <50 ng/mL



Use your keypad to vote now!

## A patient is considered vitamin D- deficient when serum 25(OH)D is:



# 2010 Symposia Series 2

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**Embassy Suites**

Cary, North Carolina

June 12, 2010

