

CFDR Semi Annual Research Showcase – May 1st, 2014

Foods specially fortified with vitamin D preserve winter-time status and BMD in elderly men

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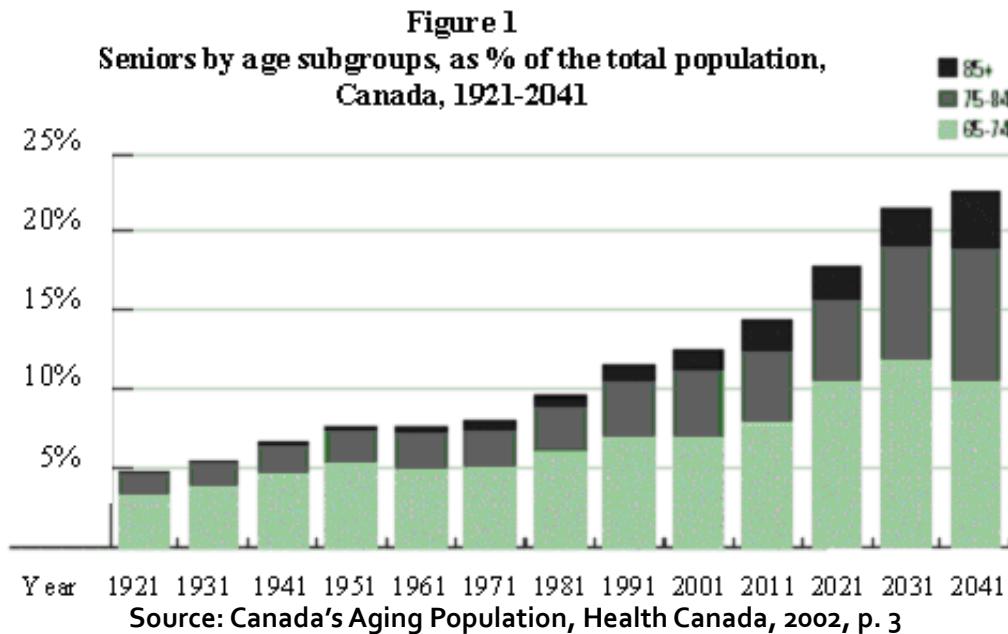


Veterans Affairs
Canada
Ste. Anne's Hospital

Anciens Combattants
Canada
Hôpital Sainte-Anne

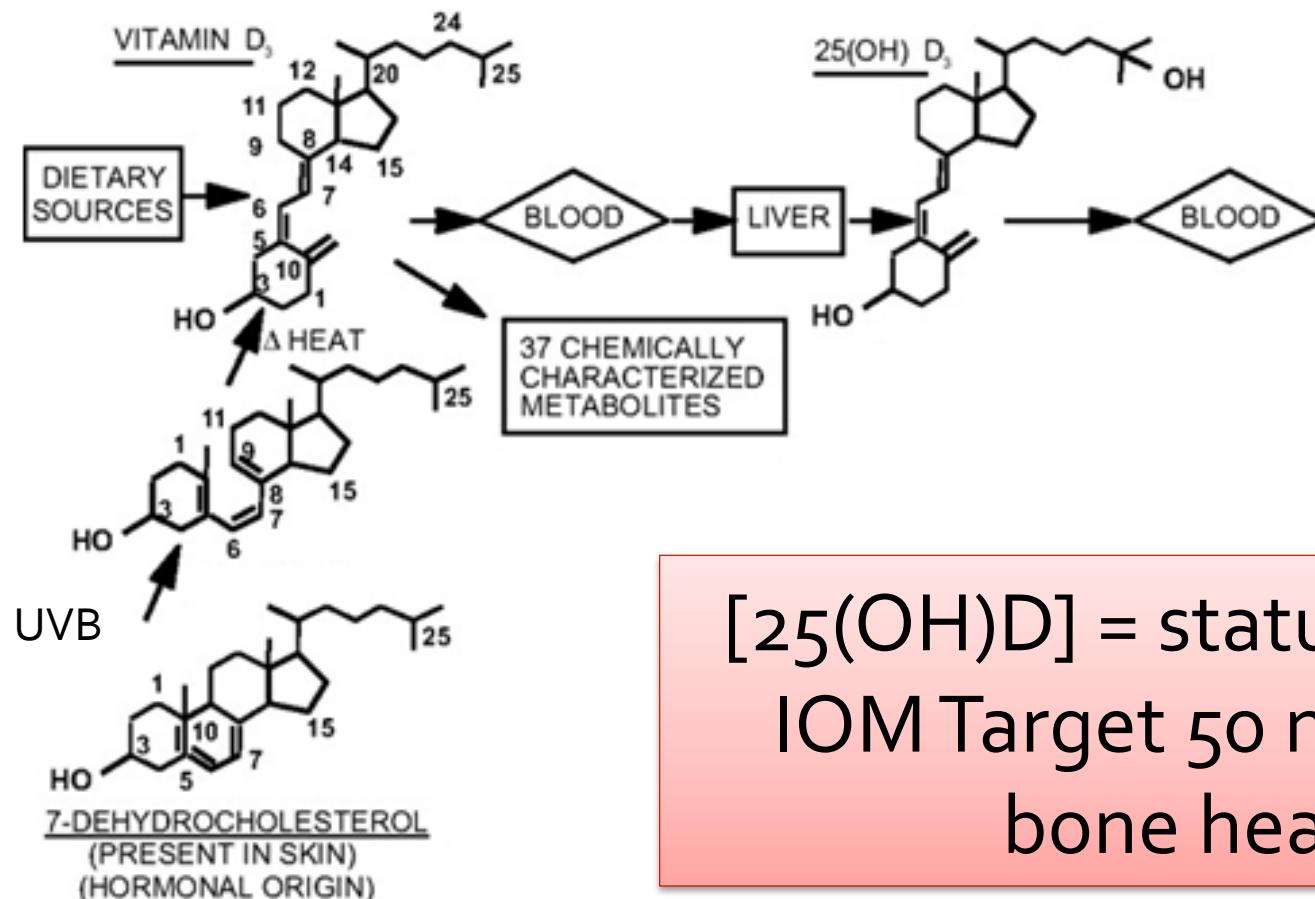


Aging Canadian Population



- ◆ The 2006 Census revealed that 4.3 million Canadians were > 65 y
- ◆ Almost 7% lived in health care and related facilities
- ◆ Bone health is an important driver of functional capacity
- ◆ Fractures ↓ mobility and ↑ institutionalization
- ◆ Key element: Vitamin D

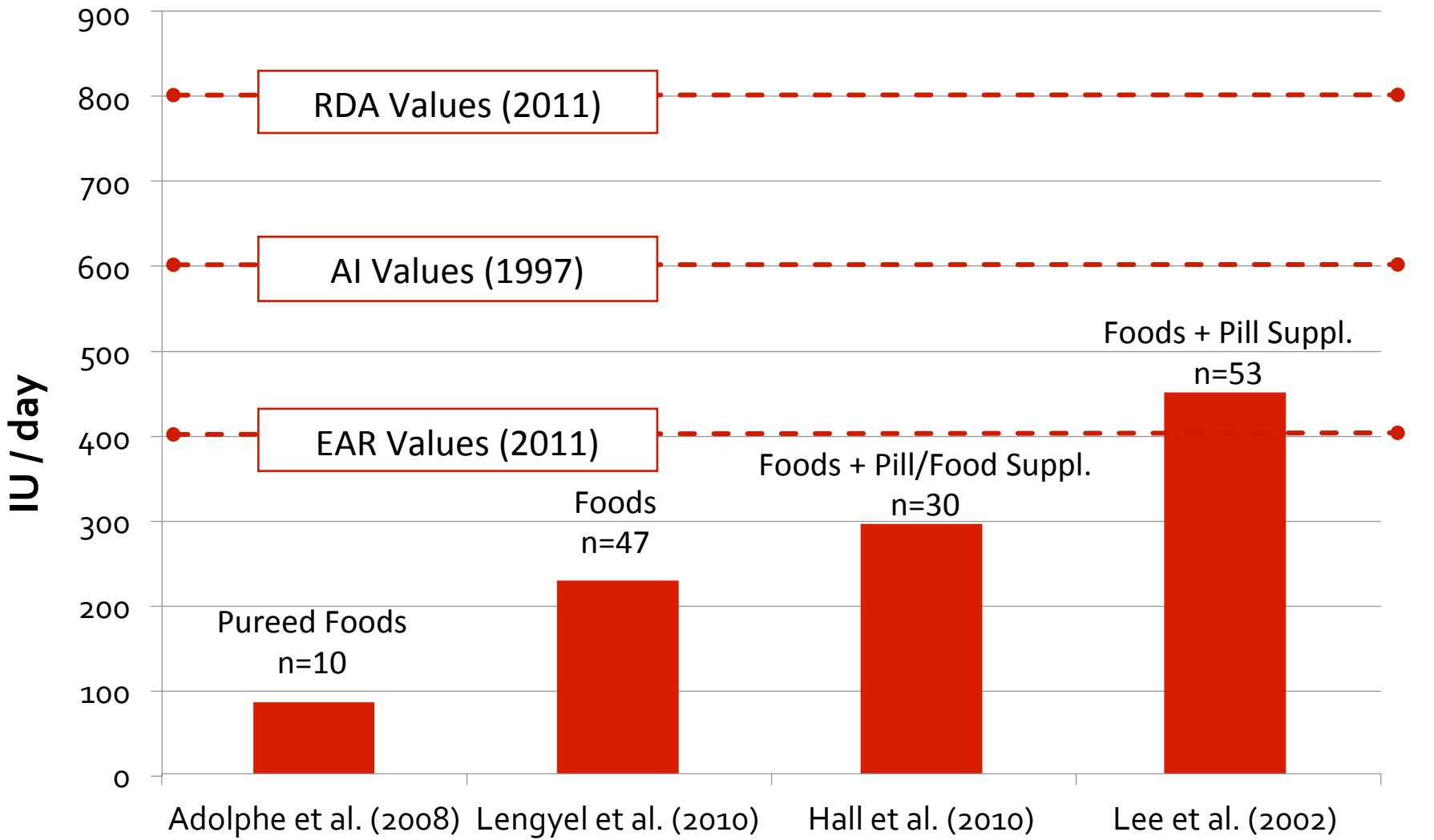
Sources of vitamin D



[25(OH)D] = status indicator
IOM Target 50 nmol/L for
bone health

Modified from Norman, A. W
Am J Clin Nutr 2008;88:1455-1456

Vitamin D Intake in Long-Term Care



RDA = Recommended Dietary Allowance (97-98%)

EAR = Estimated Average Requirement (50%)

AI = Adequate Intake

Vitamin D Intake and Status of Elderly in Ste-Anne's Hospital

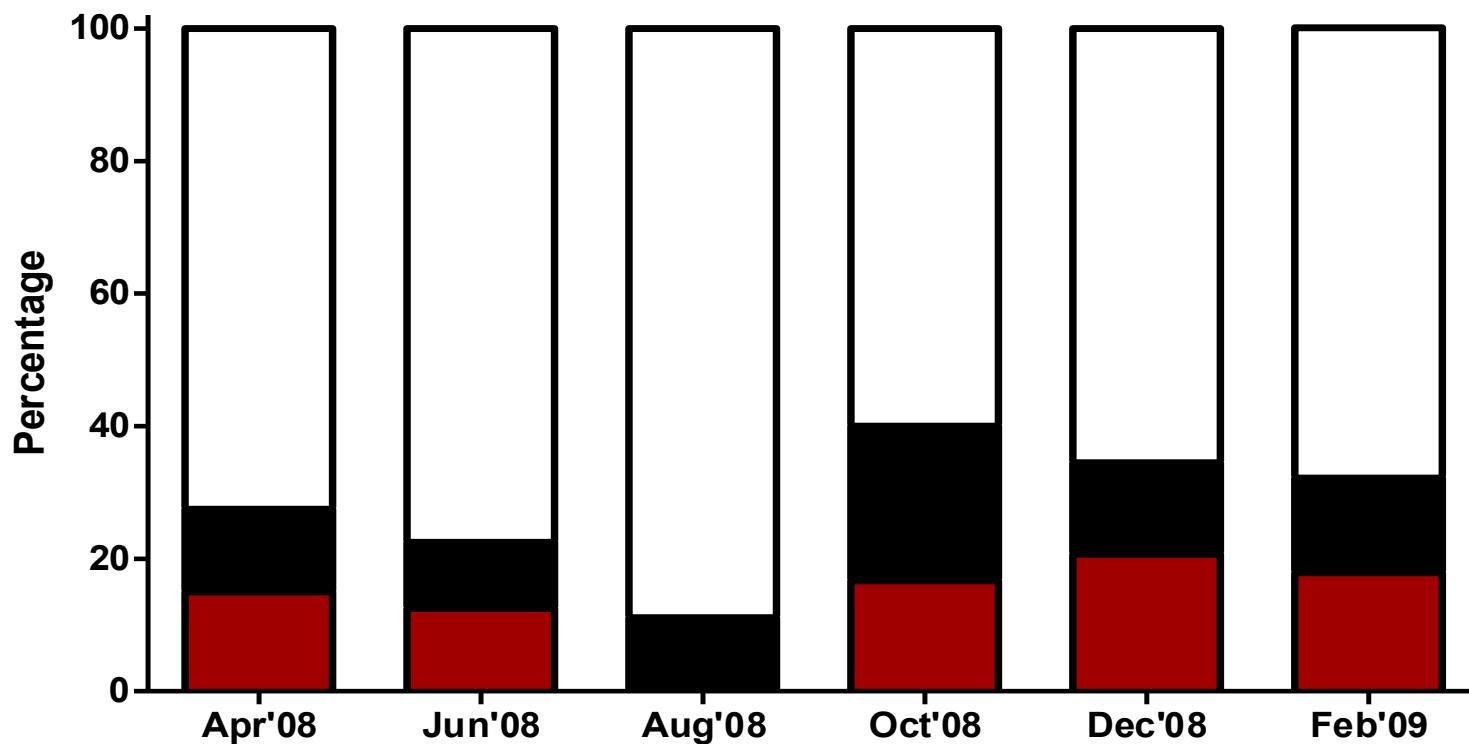
	Phase I (n=40) Spring - Summer	Phase II (n=30) Fall - Winter
	Average ± SD	Average ± SD
Age (y)	85.2 ± 3.3	84.9 ± 3.6
Weight (kg)	76.0 ± 12.7	74.7 ± 13.2
BMI (kg/m ²)	26.1 ± 4.1	26.0 ± 4.3
MMSE (score/30)	23 ± 7	24 ± 3
Nb medications – (Including Vitamin Tablets)	11 ± 5	11 ± 5

- Sun exposure was minimal for the majority of participants
- 33% participants received vitamin D supplements in tablet form
- 16 week follow-up each phase

Seasonal Variation

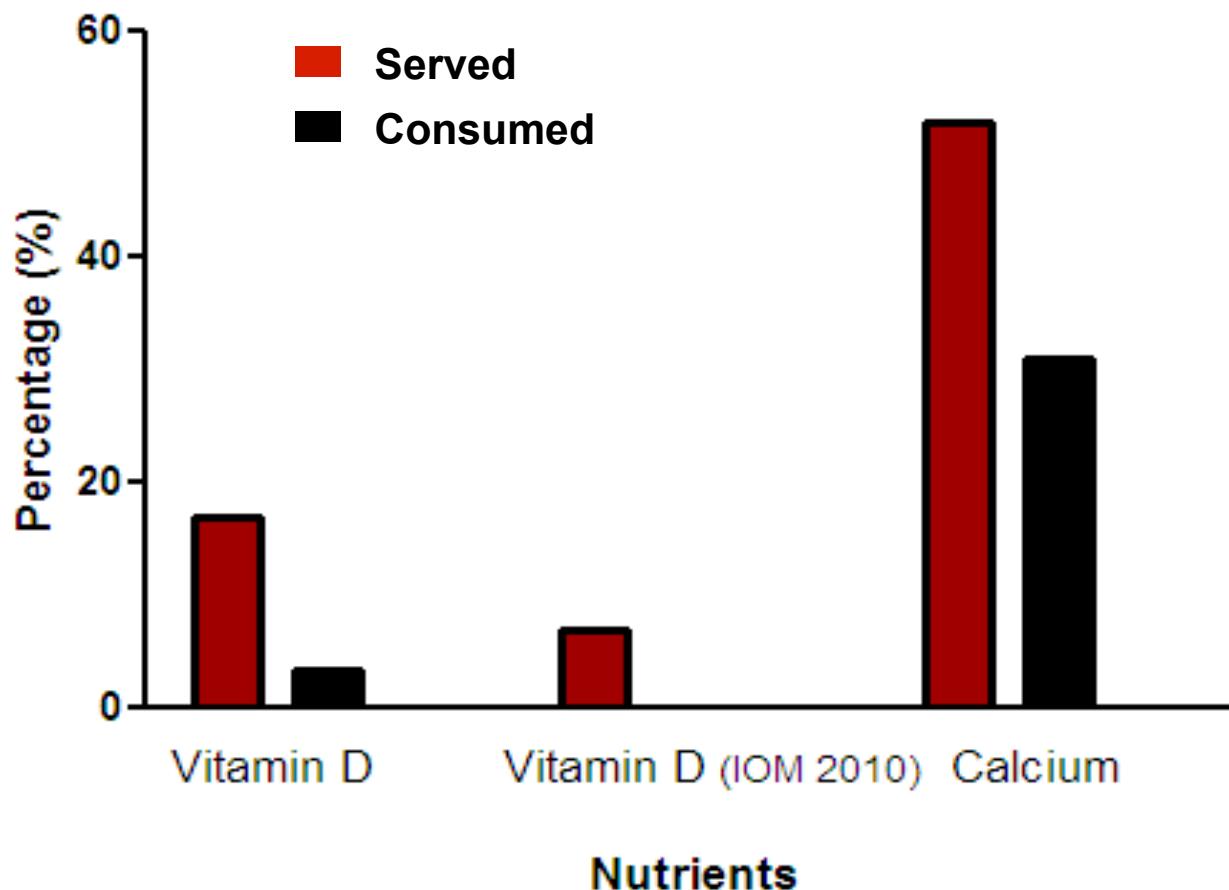
Participants (%) per Category of 25(OH)D Status

- $\leq 37,4 \text{ nmol/L}$
- $37,5 - 49,9 \text{ nmol/L}$
- $\geq 50 \text{ nmol/L}$

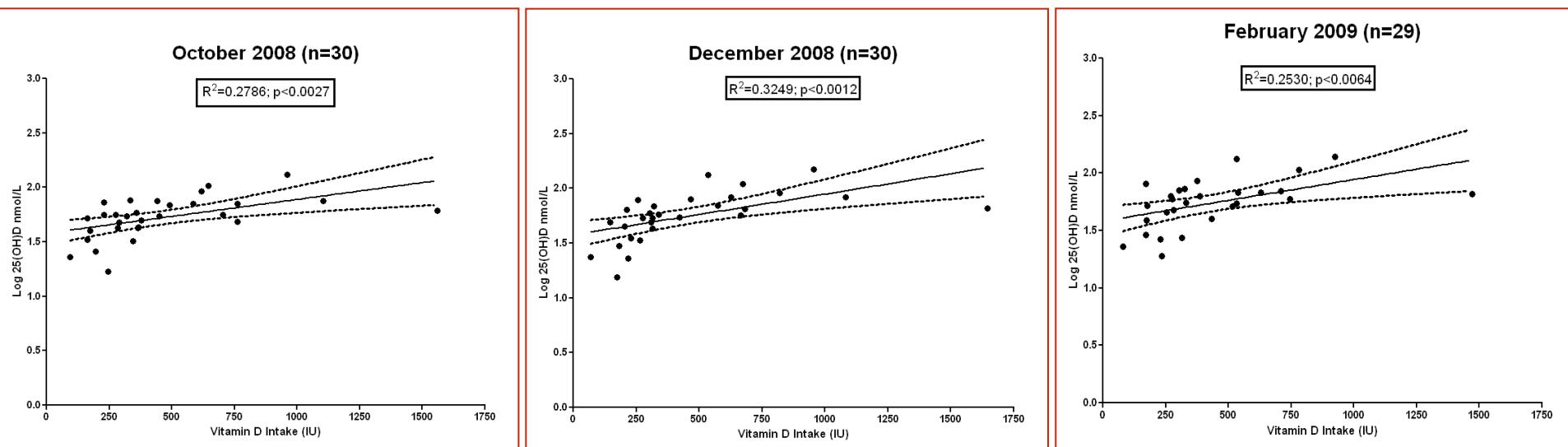


Vitamin D and Calcium

Percentage (%) of Participants that reached AI/RDA
for Vitamin D and Calcium in February (n=29)

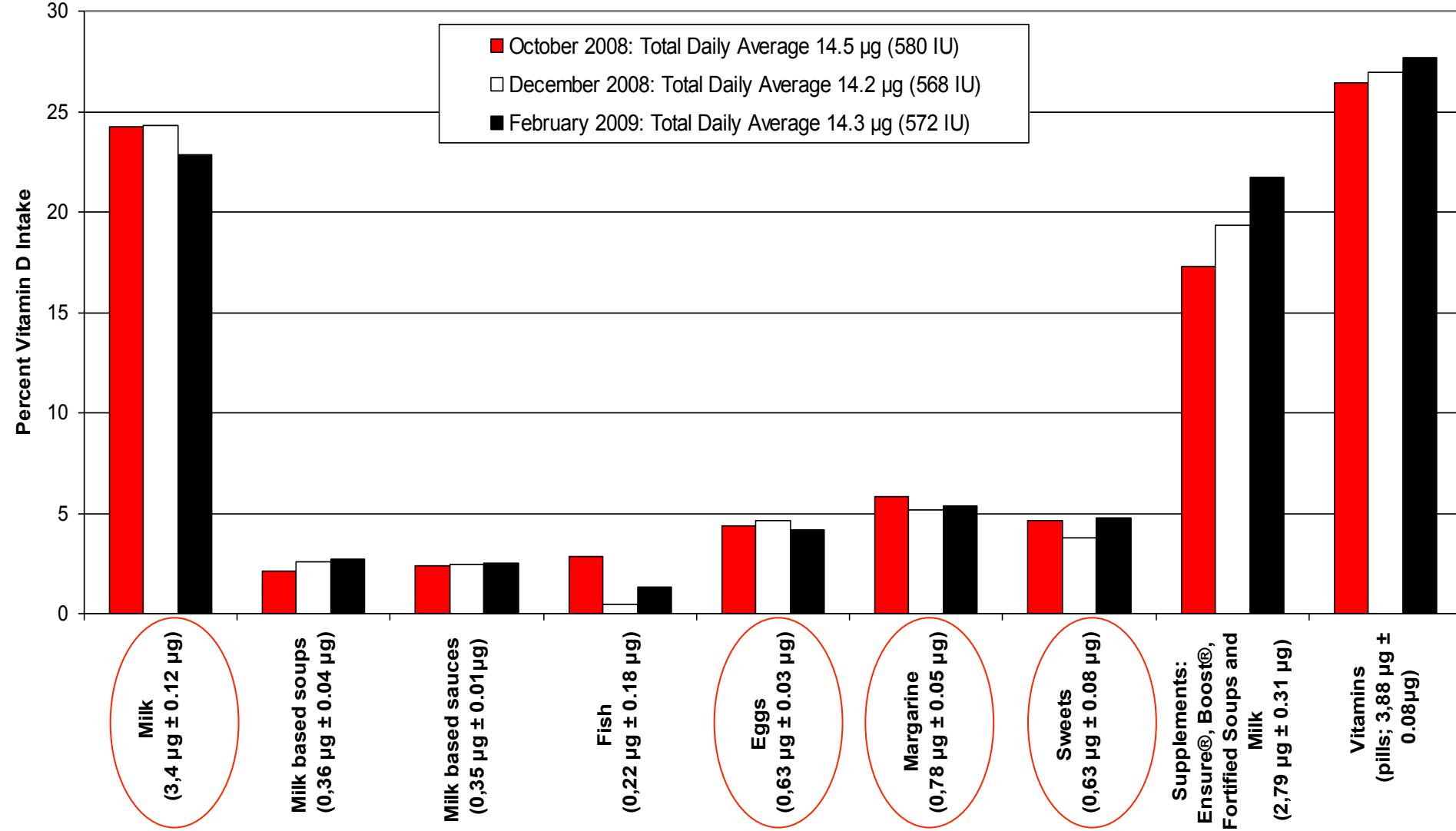


25(OH)D Status and Vitamin D Intake



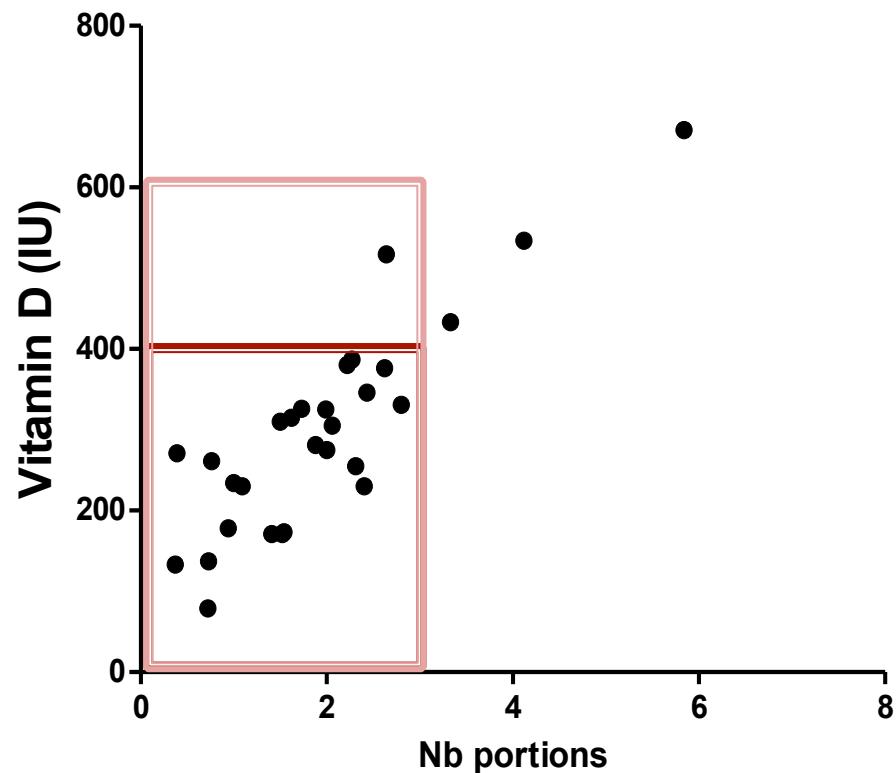
Study Phase II - Percentage of Theoretical Intake per Food Group, including Meal Supplements and Vitamins

Study Phase II - Percentage of Theoretical Intake per Food Group, including Meal Supplements and Vitamins



Vitamin D and Milk and Alternatives Intake as per Canada's Food Guide

Relationship between Number of Portions of Milk and Alternatives (Canada's Food Guide) and Vitamin D intake at Final (Feb'09)



Spearman R Correlation: 0.8076

Goals and Objectives

Phase I – Before and After Study (8 weeks)

- Evaluate the impact of 2000 IU per day of vitamin D₃ on serum concentrations of 25(OH)D, PTH and other biomarkers of bone health

Phase II – Randomized Controlled Trial (24 weeks)

- Serum 25(OH)D response to foods fortified
 - Placebo
 - 500 IU
 - 1000 IU

Ethical Approval

- Ethical approval was obtained from Institutional Review Board of McGill University
- Letter of no objection from Health Canada
- Approval from Scientific Review Committee of Ste. Anne's Hospital (Veteran Affairs Canada)



Interventions

Fortified foods:

- ◆ Bite size portion: ↓ Energy
↓ Nutrients
- ◆ ↓ Appetite impact
- ◆ Selection of flavors
- ◆ Selection of texture and consistency
- ◆ Q/C for vitamin D content via HPLC
(Health Canada and McGill laboratories)



Inter-Laboratory Q/C



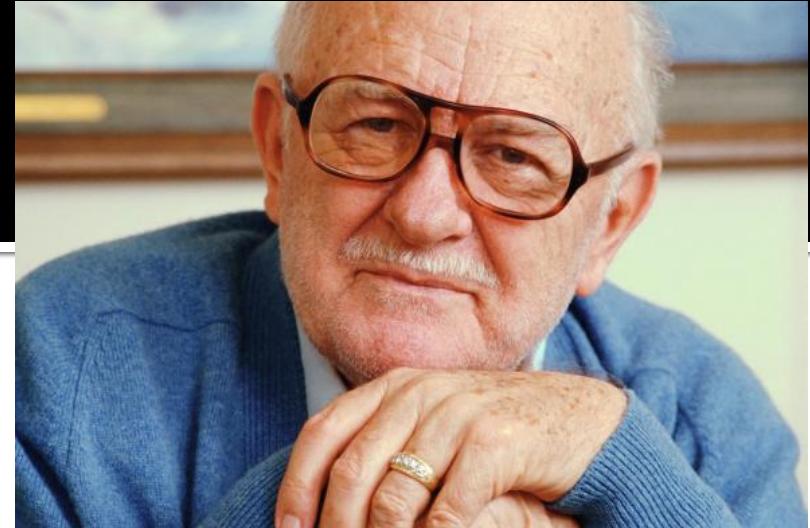
% Vitamin D₃ Recovery – Quality Control:

% Recovery McGill Laboratory	% Recovery Health Canada Laboratory
$124.8\% \pm 28.8$	$107.4\% \pm 13.4$

HPLC Method has a precision of $\pm 30\%$



Participants



- ◆ Male veterans
- ◆ Age : ≥ 70 years of age
- ◆ MMSE score ≥ 18 (/30) with capacity to collaborate
- ◆ Exclusion:
 - ◆ Palliative Care (Level of Care 4)
 - ◆ End stage liver disease
 - ◆ End stage renal disease or using vitamin D analogues
 - ◆ Untreated hyperparathyroidism
 - ◆ Oral feeding not permitted (NPO, TPN or Enteral only)

Assessments

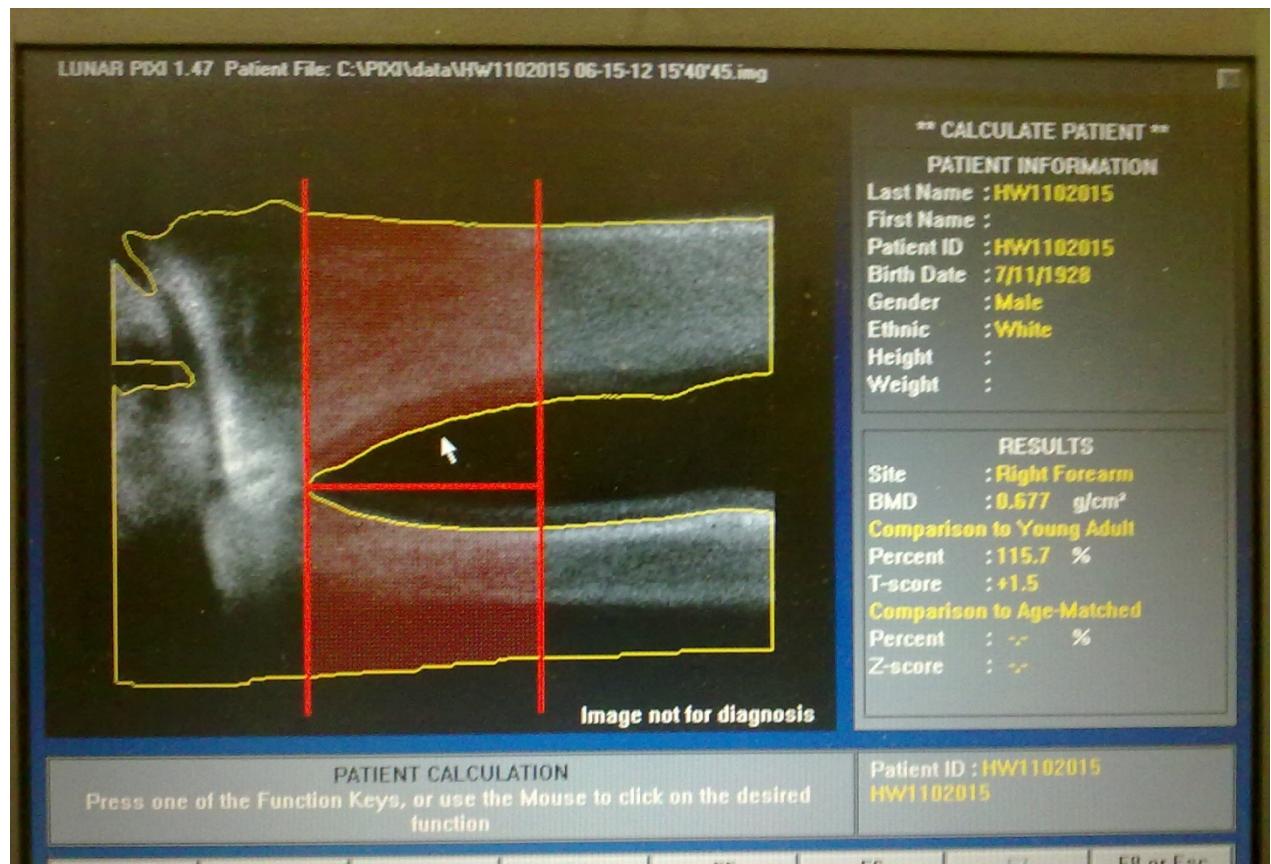
	Phase I – Before/ After 2000 IU/d			Phase II – RCT 1000 IU/d or 500 IU/d or Placebo					
	0	4	8	0	4	8	12	16	24
25(OH)D and PTH (Liaison)	✓	✓	✓	✓	✓	✓	✓	✓	✓
Routine and bone biomarkers	✓			✓		✓		✓	✓
Anthropometry	✓	✓		✓	✓	✓	✓	✓	✓
Functional quest.	✓								✓
Handgrip	✓			✓		✓	✓	✓	✓
Food Intake (3days)	✓			✓		✓		✓	✓
Bone Mineral Density				✓					✓

Radiology Assessments

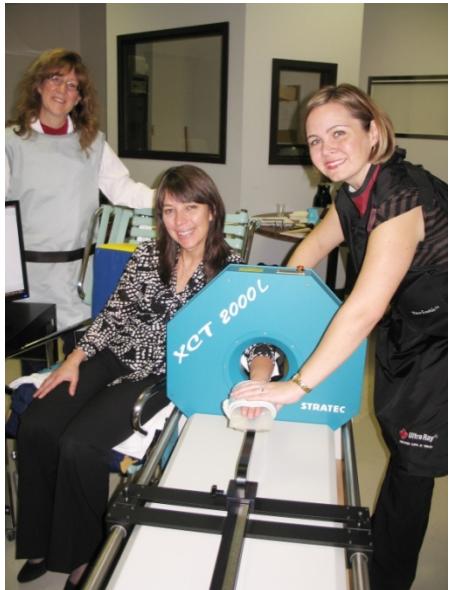


Areal Bone Mineral Density

PIXI, GE Medical Systems Lunar

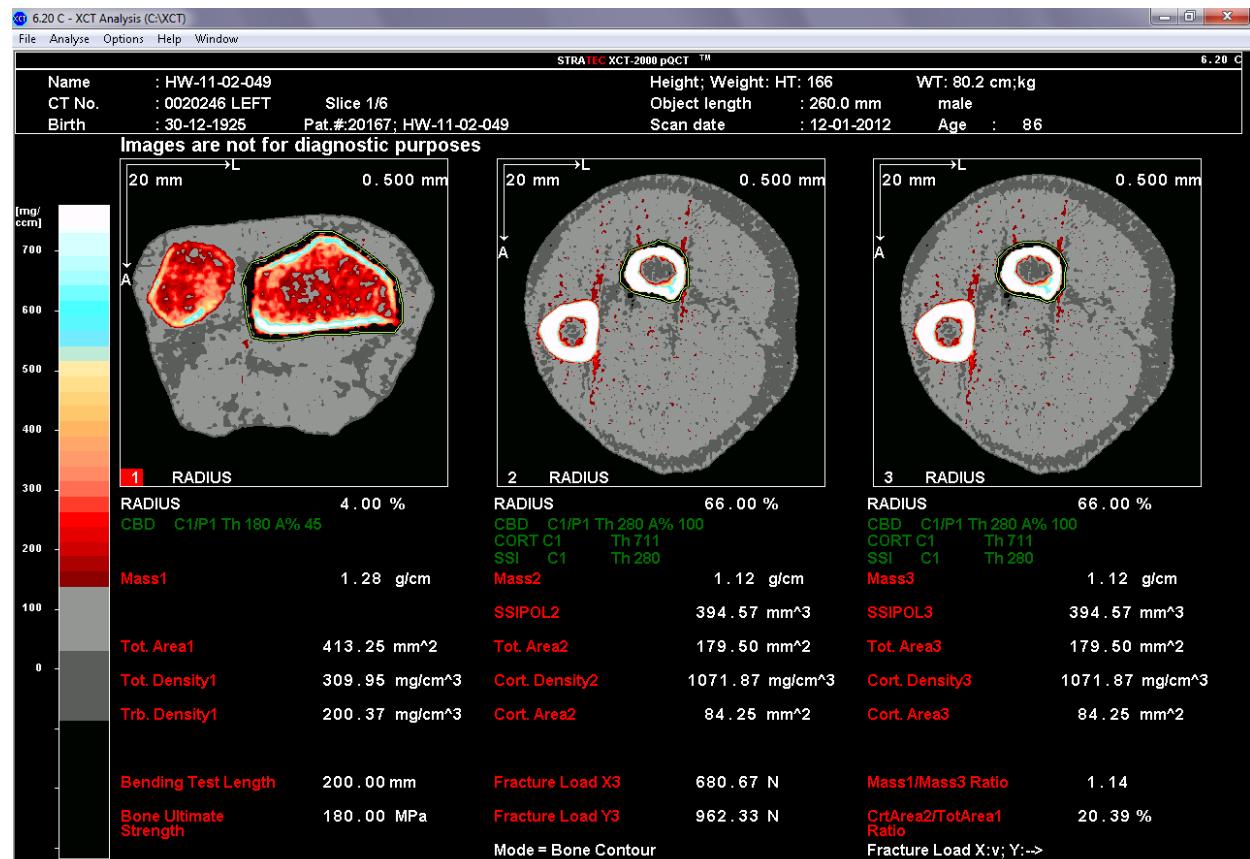


Radiology Assessments

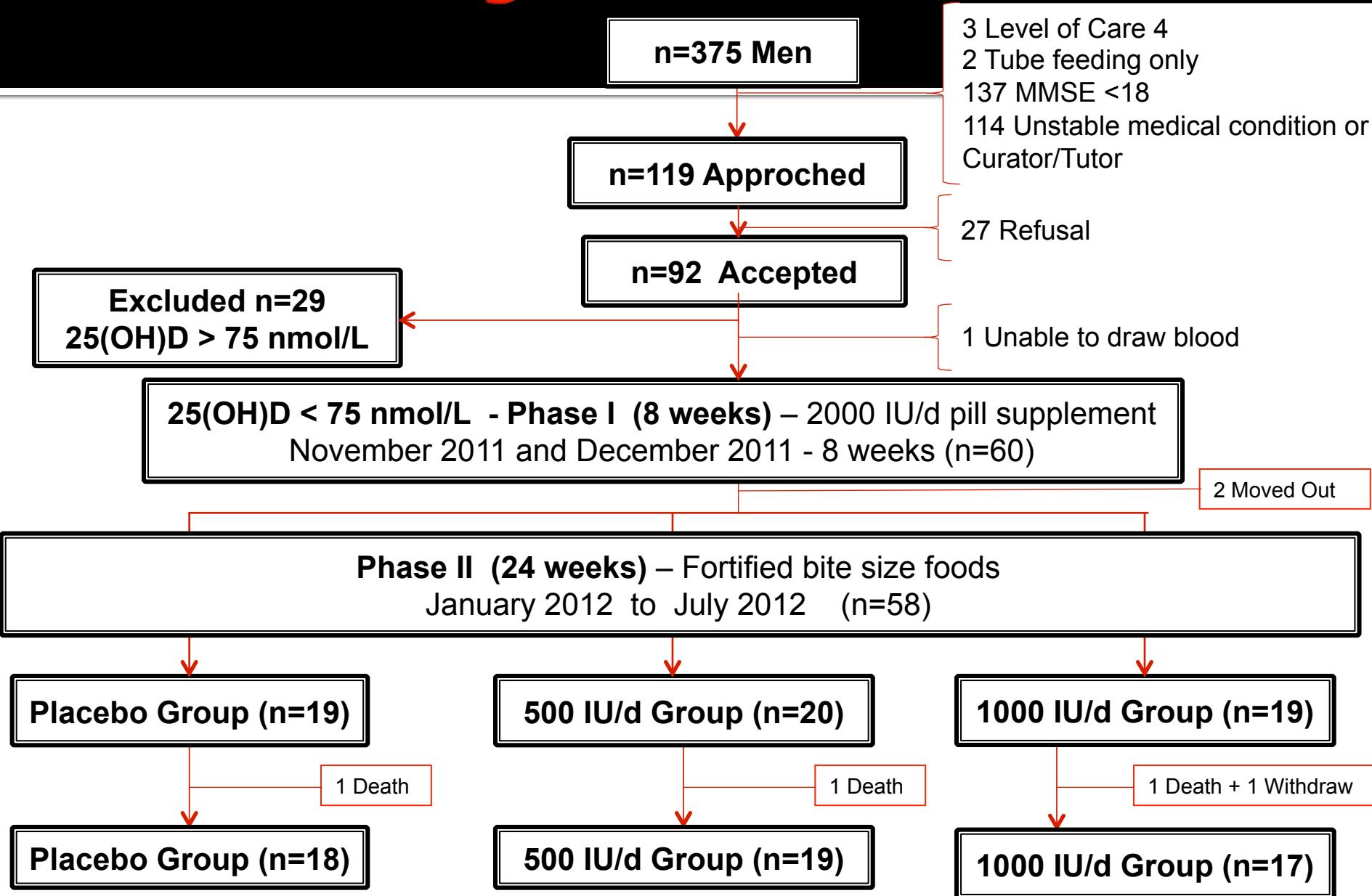


Volumetric Bone Mineral Density

pQCT, SCT-2000, Stratec Medizintechnik



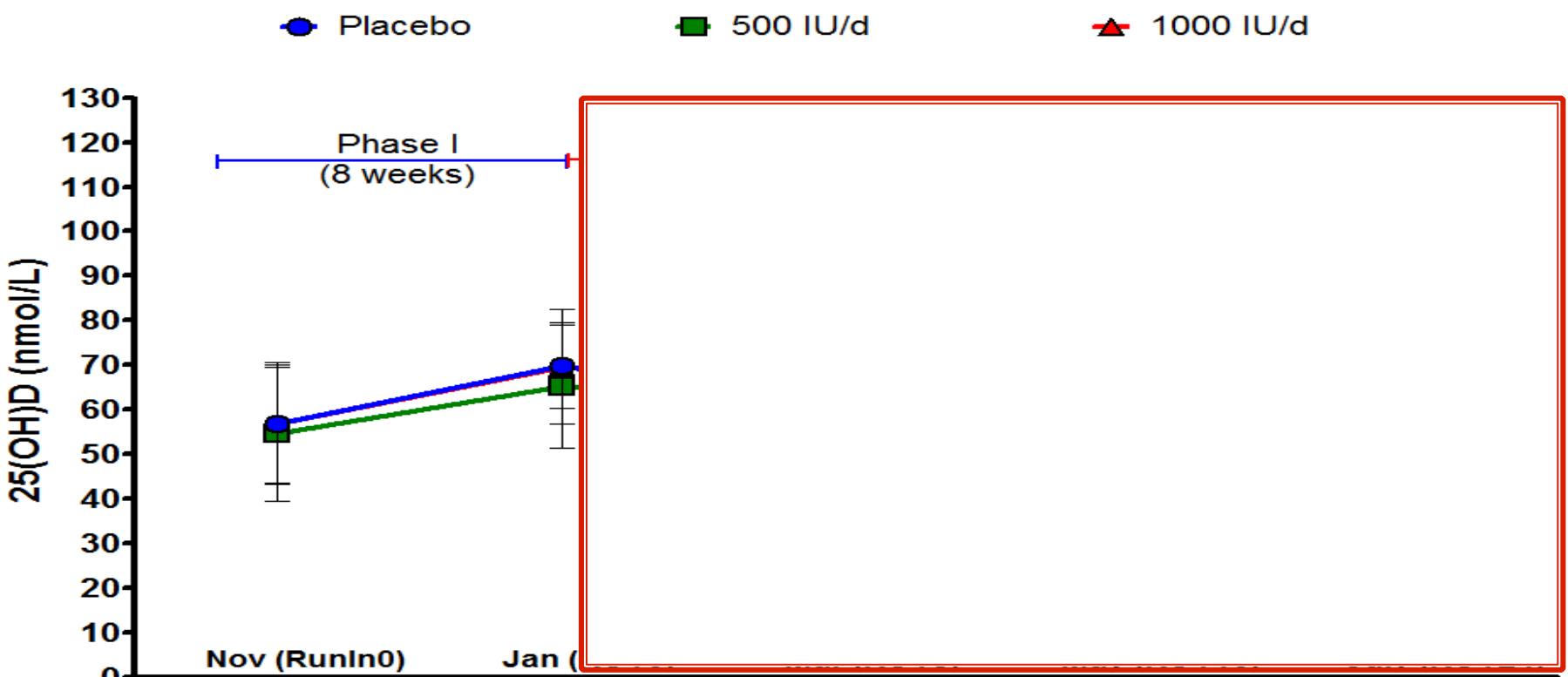
Consort Diagram



Descriptives Characteristics Before and After Phase I

	November 2011	January 2012		
		Placebo	500 IU/d	1000 IU/d
		Mean ± SD	Mean ± SD	Mean ± SD
Anthropometry				
Age	89.5 ± 3.4	88.9 ± 3.1	89.2 ± 3.2	90.9 ± 3.6
BMI (kg/m ²)	26.3 ± 4.6	26.5 ± 4.0	26.5 ± 5.5	26.1 ± 4.1
Grip Strength (kg)	N/A	19.5 ± 7.9	17.5 ± 3.2	17.8 ± 3.4
Biochemistry (Serum)				
iCalcium	1.06 ± 0.08	1.06 ± 0.05	1.07 ± 0.05	1.06 ± 0.06
25(OH)D (nmol/L)	55.5 ± 14.1	69.6 ± 12.8	65.2 ± 13.8	70.0 ± 9.7
1-84 PTH (pmol/L)	2.9 ± 1.8	2.8 ± 1.9	3.1 ± 2.0	2.7 ± 1.4
Dietary Intake (3-day food intake)				
Energy (kcal)	1720 ± 355	1643 ± 319	1605 ± 383	1816 ± 339
Protein (g)	67 ± 17	65 ± 18	64 ± 19	71 ± 16
Vitamin D (IU)	291 ± 144	307 ± 210	268 ± 151	295 ± 77
Calcium (mg)	994 ± 424	1008 ± 624	917 ± 440	973 ± 285

Vitamin D concentration (nmol/L) in Elderly Veterans (Nov. 2011 – July 2012)



Group 0:	$56.9 \pm 13.3^{\text{ab}}$ A	$69.8 \pm 9.7^{\text{cgh}}$ A*	$59.1 \pm 9.7^{\text{ab}}$ A	$60.3 \pm 10.5^{\text{ib}}$ A	$56.1 \pm 10.3^{\text{abj}}$ A
Group 1:	$54.6 \pm 15.0^{\text{bdjk}}$ A	$65.2 \pm 13.8^{\text{lm}}$ A*	$65.0 \pm 16.7^{\text{lmu}}$ A*	$71.2 \pm 17.3^{\text{e}}$ AB**	$74.1 \pm 16.1^{\text{ceno}}$ B**
Group 2:	$56.9 \pm 13.7^{\text{bkpqu}}$ A	$69.6 \pm 12.8^{\text{om}}$ A*	$69.3 \pm 17.7^{\text{fr}}$ A*	$81.0 \pm 19.1^{\text{cegstv}}$ B**	$78.5 \pm 17.3^{\text{cegt}}$ B**

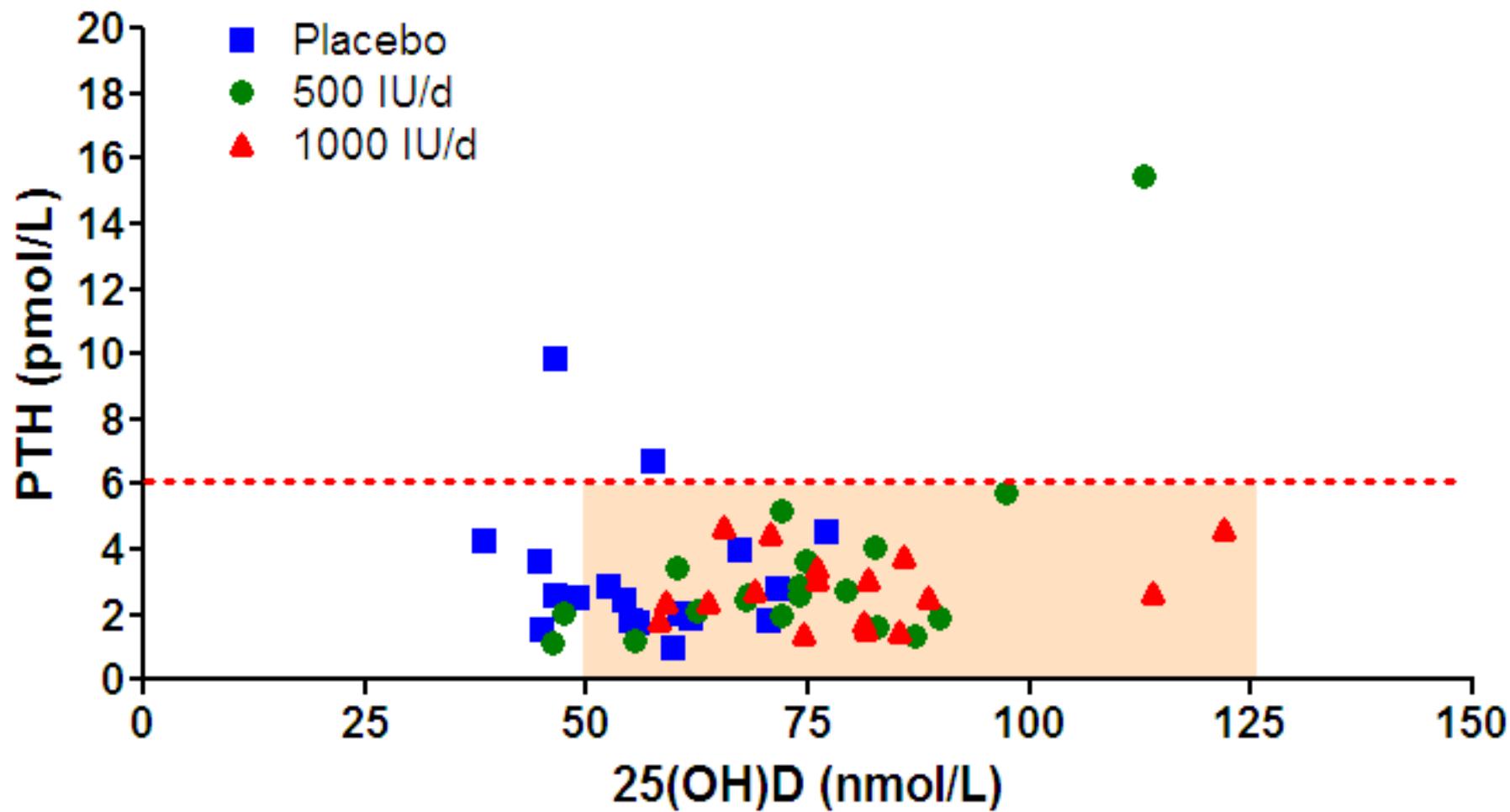
Means followed by different superscript lowercase letters differ for group by time interactions ($P < .05$)

Means followed by different superscript in uppercase letters within columns differ ($P < .05$)

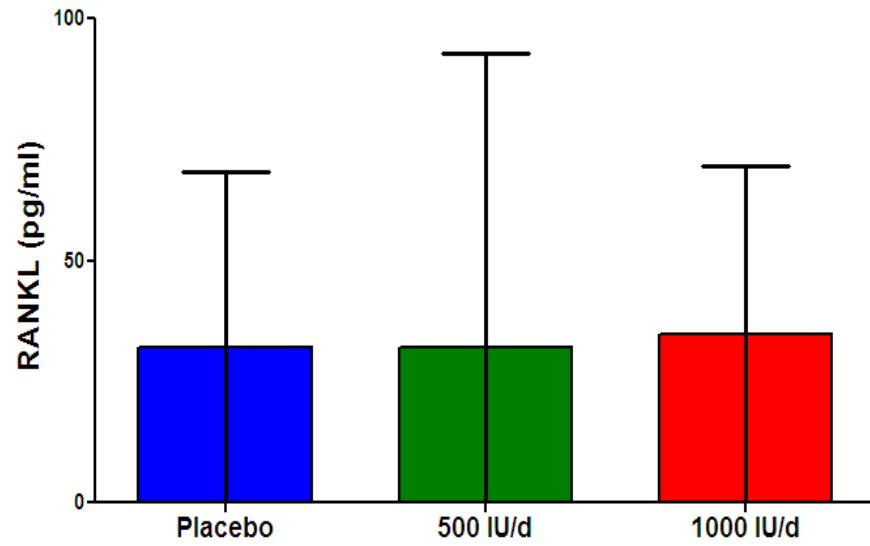
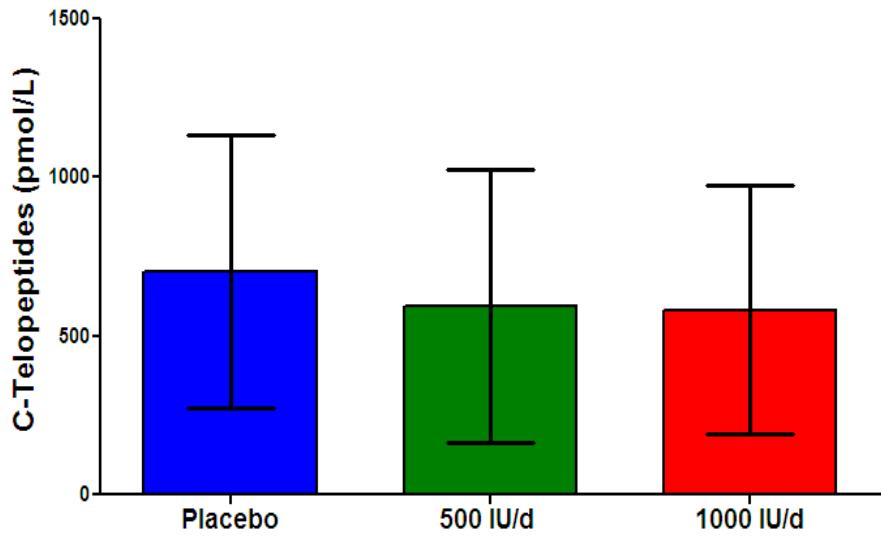
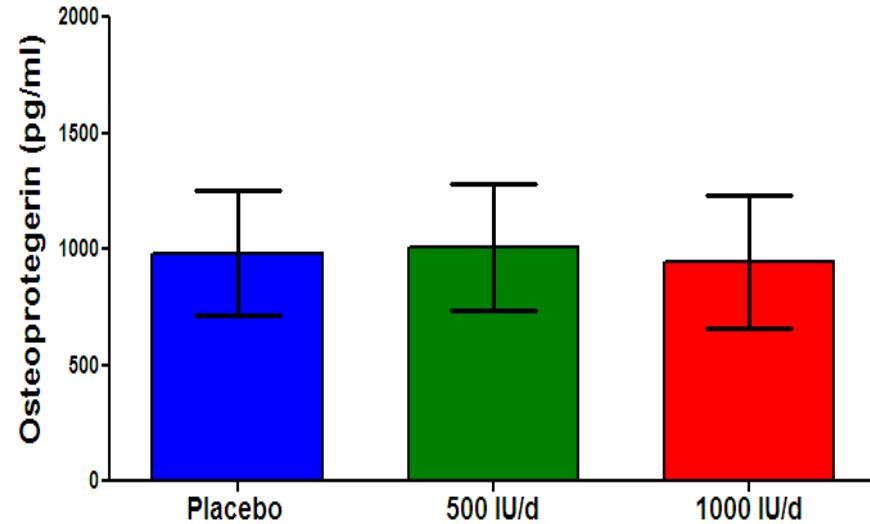
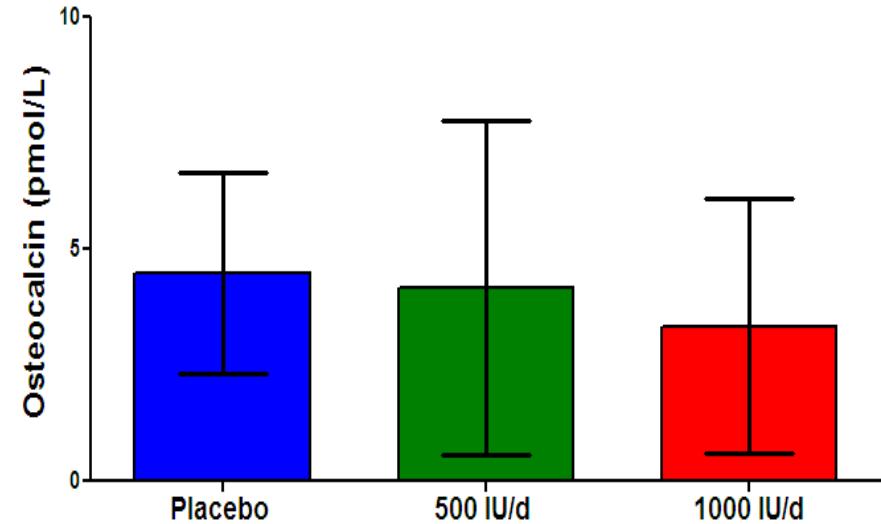
Means followed by an asterisk (*) differ from November values in same group ($P < .05$)

Means followed by 2 asterisks (**) differ from November, January and March values in same group ($P < .05$)

Parathyroid Hormone in July 2012



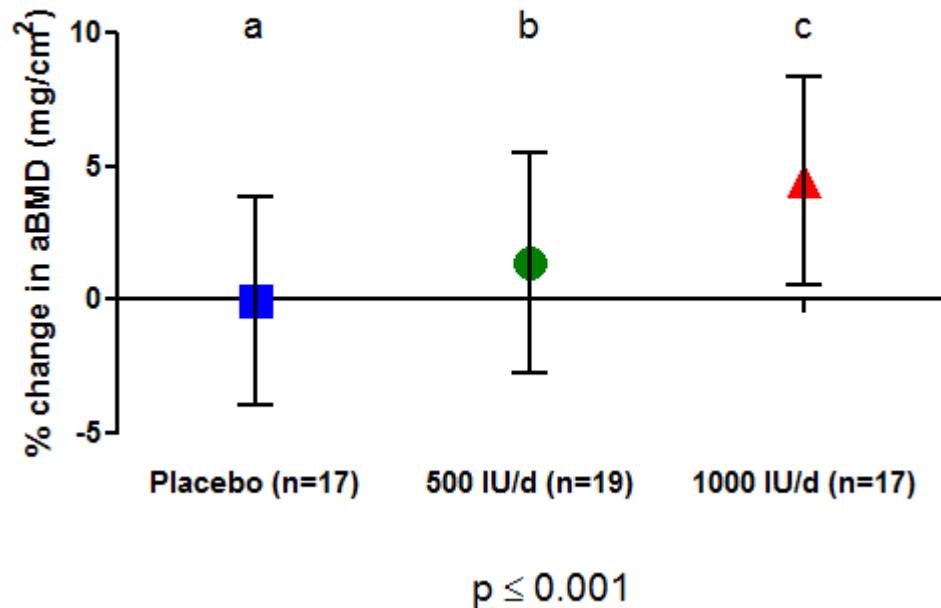
Bone Biomarkers in July 2012



Results – BMD Distal Forearm

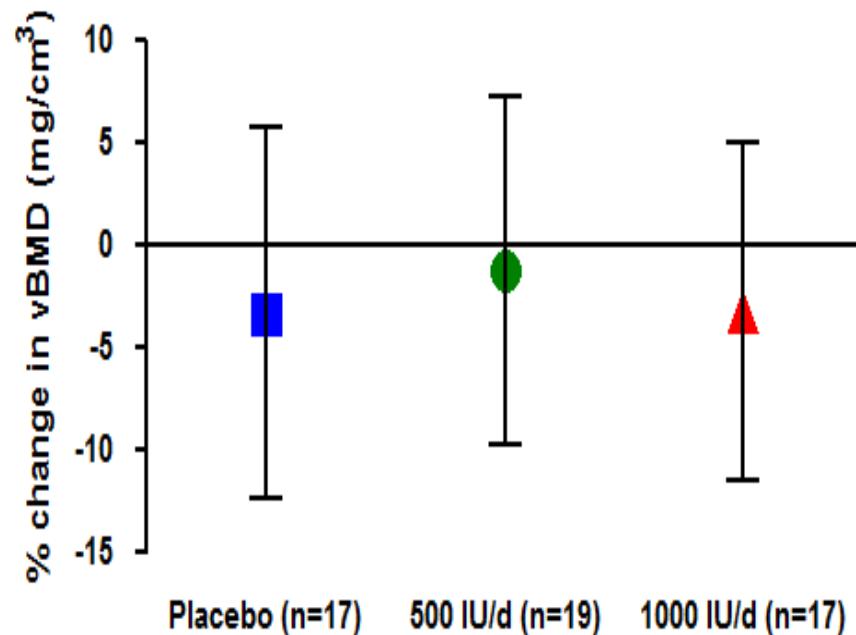
PIXI Evaluations

Percent change in aBMD
between January and July 2012



pQCT Evaluations

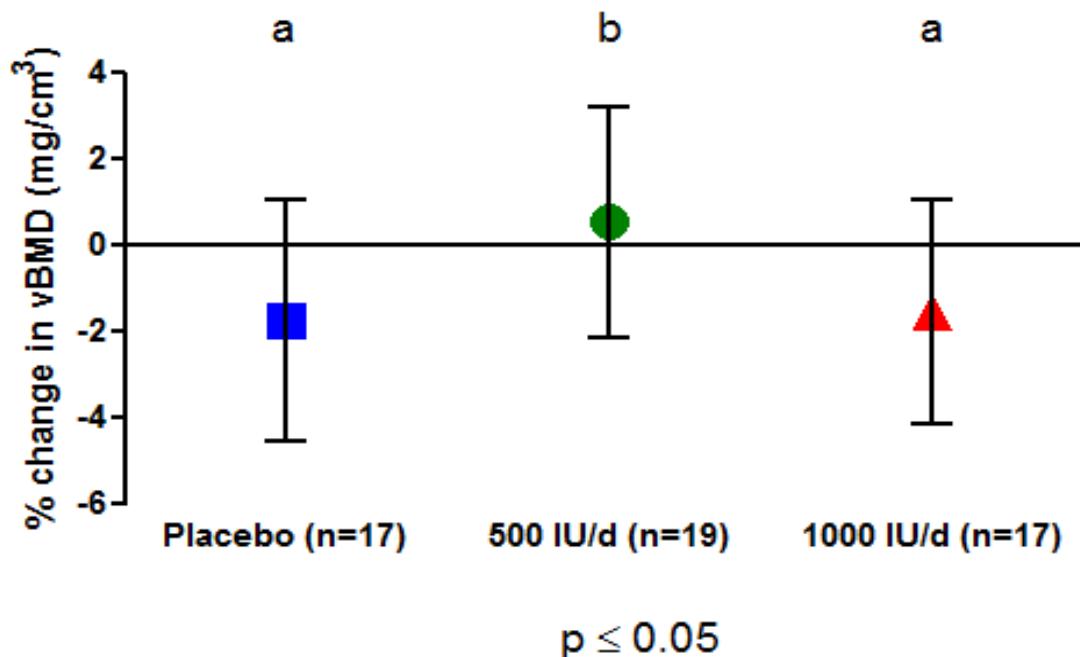
Percent change in vBMD - 4% radius
between January and July 2012



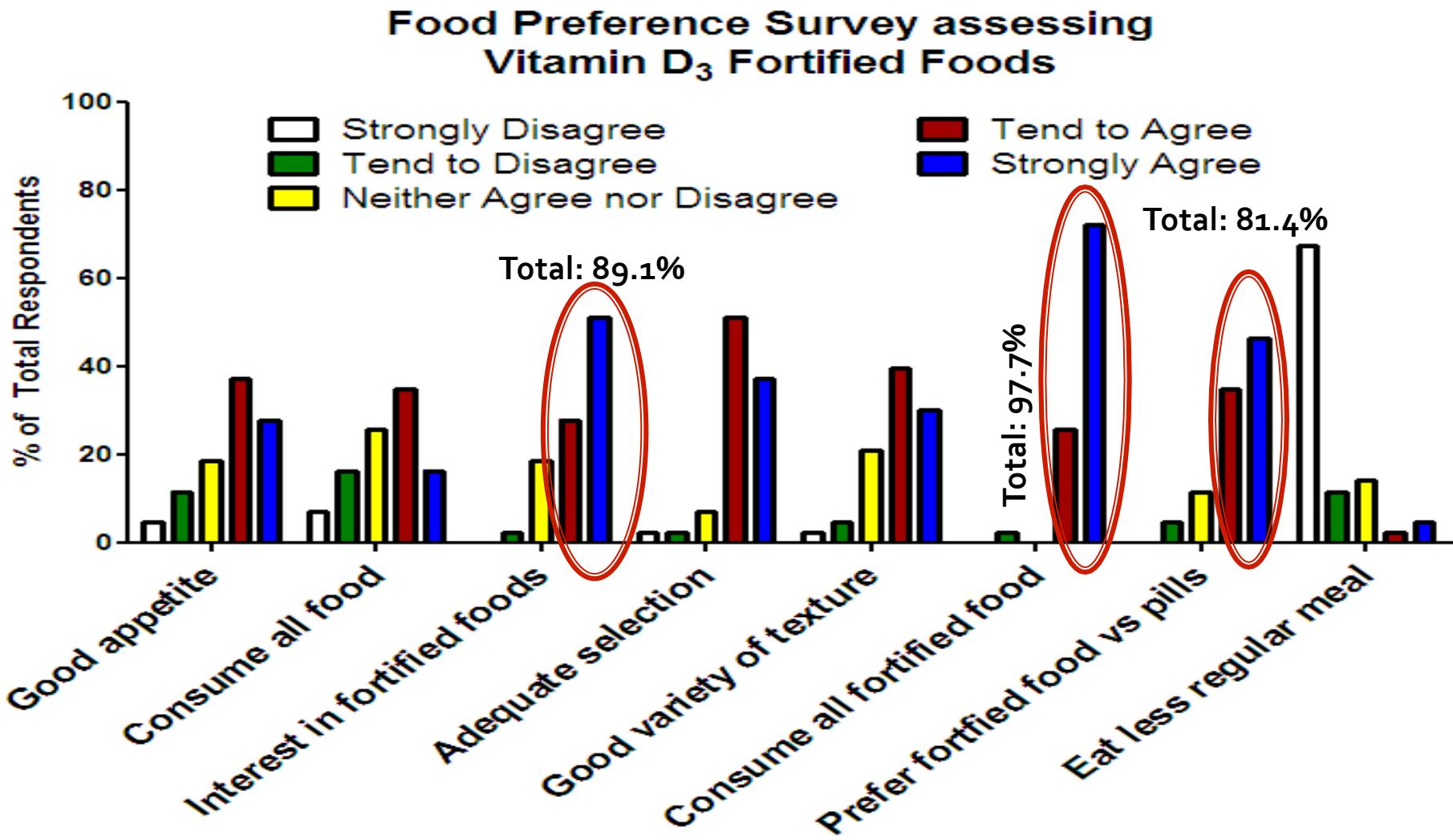
Results – BMD Distal Forearm

pQCT Evaluations

Percent change in vBMD - 66% radius
between January and July 2012



Appreciation of Foods



Strengths and Limitations

Strengths:

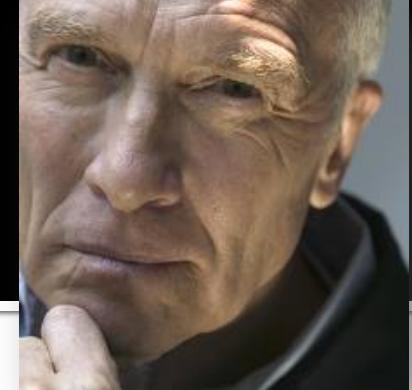
In this very old population, first RCT:

- to look at maintenance of vitamin D status and its impact of dosage on BMD for 24 wks
- to study the food-delivery formulations
- in a tightly controlled environment

Limitations:

- Men living in LTC facility, which is a tightly controlled environment
- Sample size

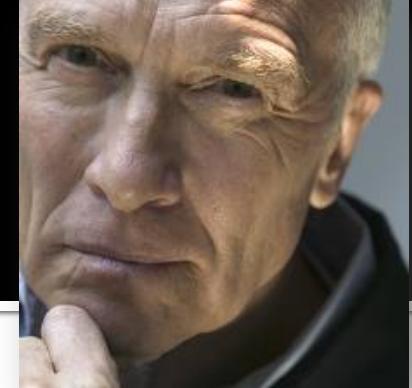
Conclusion



This research has provided *new insight on potential impact of optimized vitamin D status on bone health in elderly men:*

Providing 500 IU to 1000 IU of vitamin D₃ maintained 25(OH)D > 65 nmol/L and prevented seasonal declines in radial BMD.

Conclusion



The use of fortified foods was well accepted and created *new alternatives to the elderly population in long-term care facilities* and perhaps for community dwelling elders.



Acknowledgments



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