NW GWEC- Winter Geri Series

Vitamin And Supplement Use in Older Adults – A 2024 Update

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Learning Objectives

- Assess the benefits and harms of vitamin and trace mineral supplementation in older adults based on current clinical evidence
  - ➢ Focus : Vitamin E and Vitamin D
- Apply the best approach to personalize oral iron supplementation using the newest evidence
- Evaluate the strategy to prevent malnutrition and micronutrient deficiencies in older adults.

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What is the Legal Definition of Dietary Supplements?

- Official definition by the US Congress in the Dietary Supplement Health and Education Act (DSHEA) of 1994:
  "*A dietary supplement is a product intended for ingestion that, among other requirements, contains a "dietary ingredient" intended to supplement the diet.*"

- DSHEA places dietary supplements in a special category under the general umbrella of "foods," unless the product meets the definition of a drug (e.g., because it is labeled to treat or mitigate a disease)
- Dietary supplements in general are **NOT** intended to treat, diagnose, cure, or prevent diseases. Such claims are consistent with drugs, which are under different federal regulations (Federal Drug & Cosmetic Act)
- FDA regulates both finished dietary supplement products and dietary ingredients; however, the FDA does NOT have the authority to approve dietary supplements for safety and effectiveness, or to approve their labeling, before the supplements are sold to the public.

https://www.fda.gov/food/dietary-supplements
https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements

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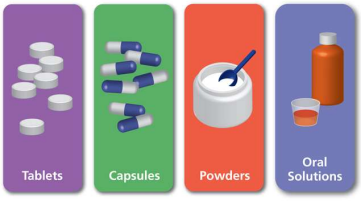
What are examples of dietary supplements?

- "Dietary ingredient" includes vitamins and minerals; herbs and other botanicals; amino acids; "dietary substances" that are part of the food supply
- "Dietary substances" are part of the food supply, such as enzymes and live microbials (commonly referred to as "probiotics"); and concentrates, metabolites, constituents, extracts

- Dietary supplements are intended to be **ingested**

- They may be found in many **ORAL forms**, such as pills, tablets, capsules, gummies, softgels, liquids, and powders. They can also be in the same form as a conventional food category, such as teas or bars
- Dietary supplement labels are required to have nutrition information in the form of a **Supplement Facts** label that includes the serving size, the number of servings per container, a listing of all dietary ingredients in the product, and the amount per serving of those ingredients.



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Example of a Dietary Supplement

Serving size and directions

Clearly labelled as a **supplement**

Among per serving of each ingredients; All ingredients meet the definition of dietary supplement

SUGGESTED USE: **Adults, take 2 caplets daily with water and a meal.**
Take 4-6 weeks to see results. Results may vary.
Store tightly closed, in a cool, dry place, out of reach of children.
Do not use if imprinted seal under cap is broken or missing.
CAUTION: If you are pregnant, nursing, taking medication, or allergic to shellfish, consult your physician before use.

- ✓ No Synthetic Dyes - Color Derived from Natural Source
- ✓ No Artificial Flavors
- ✓ Gluten Free

Supplement Facts
Serving Size 2 Caplets
Servings Per Container 60

Amount Per Serving	% Daily Value
Vitamin D3 50 mcg (2000 IU)	250%
Sodium 75 mg	3%
Glucosamine Hydrochloride 1.5 g (1500 mg)	*
Chondroitin Sulfate Sodium 800 mg	*
Methylsulfonylmethane (MSM) 750 mg	*

*Daily Value not established.

INGREDIENTS: Glucosamine Hydrochloride, Chondroitin Sulfate Sodium (Bovine, Porcine, Avian), Methylsulfonylmethane (MSM), Water, Hypromellose, Color Added, Silicon Dioxide, Magnesium Stearate, Glyceryl Behenate, Polyethylene Glycol, Triethyl Citrate, Polysorbate 80, Sodium Citrate, Vitamin D3 (Cholecalciferol).
CONTAINS: Shellfish (Shrimp & Crab).

DISTRIBUTED BY: **Nature Made Nutritional Products**
West Hills, CA 91309-9903, USA **1-800-276-2878 • www.NatureMade.com**
USP has tested and verified ingredients, potency and manufacturing process.
USP sets official standards for dietary supplements. **www.uspverified.org**
★Based on a survey of pharmacists who recommend branded vitamins and supplements.
Lot:
Exp.:

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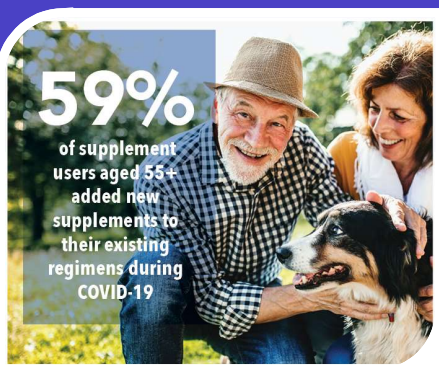
Why do Older Adults use Dietary Supplements?



- To "improve" (45%) or "maintain" (33%) overall health.
- Women used supplements for "bone health" (36%)
- Men were more likely to report supplement use for "heart health or to lower cholesterol" (18%).

(based on responses from adults ≥60 years of age)

Bailey RL et al. JAMA 2013;173(5):355-61

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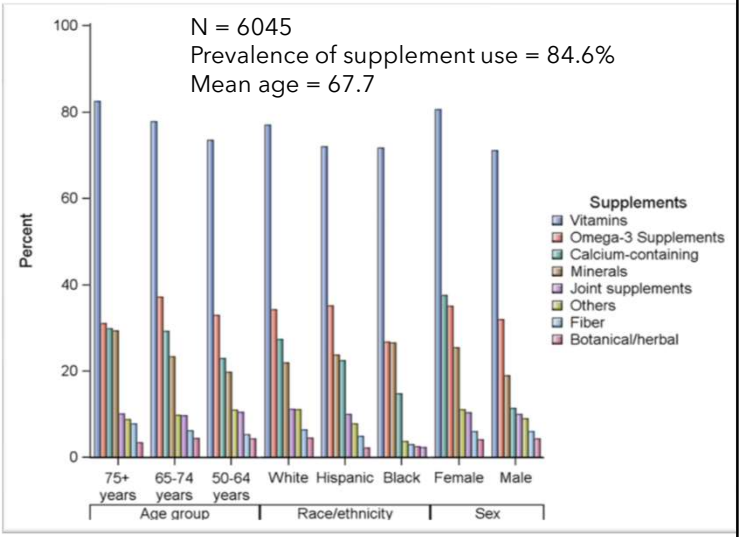
What are the most common dietary supplements used by older adults?

Data source: Health and Retirement Study (HRS), a biennial, nationally representative survey of individuals aged 50 years and older in the U.S. This study combined data from the 2013/14 Health Care and Nutrition Survey (HCNS) and 2012 Core Survey.



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Practice Pearls

1. Always ask what supplements your patients take during intake and information gathering. Ask specifically what vitamins and minerals they take since many may not connect the term "supplements" with vitamins and minerals

2. Review the supplement product, if possible, to determine the exact ingredients and amount of vitamins and minerals in the formulation

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Vitamin E and Mineral Supplements for Cancer Prevention – May not help but won't hurt, right?

I keep hearing that vitamin E may be helpful in preventing dementia or heart diseases. Taking vitamin E supplement may help, right?

Vitamin E

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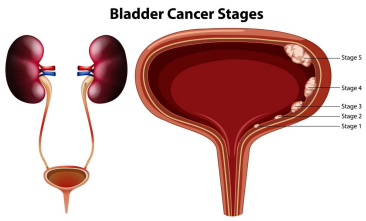
Vitamin E and Selenium as chemoprevention against Bladder Cancer

- Bladder cancer is the 12th most common cancer worldwide
- 75-85% of the cases are non-muscle-invasive bladder cancer (NMIBC)
- Disease recurrence occurs in up to 80% of patients even after treatment



- Chemopreventive properties of selenium was observed over 50 years ago
- Vitamins E use was *associated with* a reduced risk of bladder cancer mortality based epidemiological data published 2002
- **SELENIB trial** - Selenium and vitamin E as adjuvant therapies for NMIBC

Jacobs EJ et al. Am J Epidemiol 2002;156(11):1002-10

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SELENIB Trial

Cohorts: Adults with pathologically confirmed urothelial NMIBC

Enrollment: Patients randomized within 12 months of initial transurethral resection of bladder tumor, follow-up every 6 months for up to 5 years

Cancer Research UK Clinical Trials Unit at the University of Birmingham with 10 sites

Interventions: 2x2 design in 4 groups

(Se + placebo, Vit.E + placebo; Se + Vit.E; double placebo)

Regimens - oral selenium* 200 µg/d; vitamin E 200 IU/d#

Primary outcome : Recurrence-free interval (n=460 to detect 12%)

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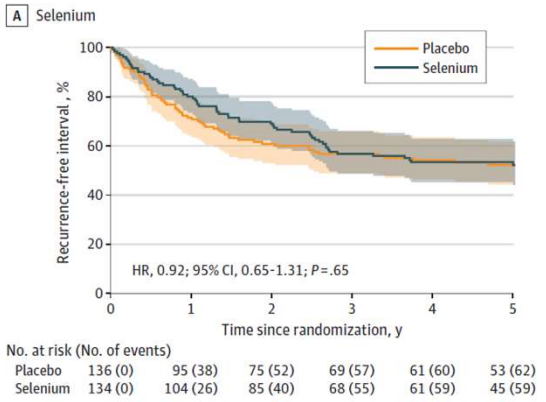
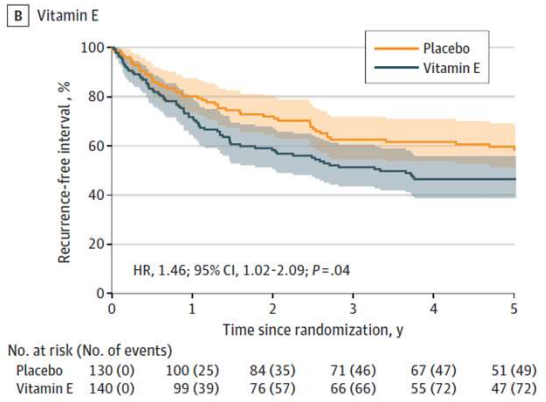
SELENIB - Recurrence-Free Interval





- Median age = 69 years (IQR 63-77)
- M:F - 75%:20%
- 56% categorized as below high risk at enrollment

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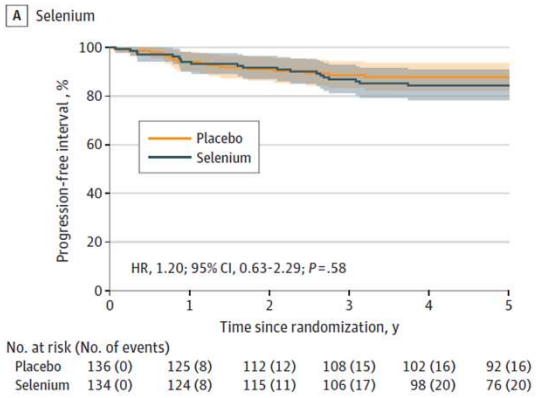
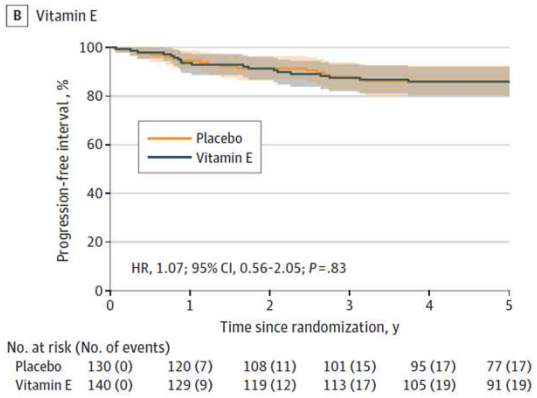
SELENIB – Progression-Free Interval





Progression was defined as recurrence with an increase in grade from grade 1 or grade 2 to grade 3, or an increase in T stage (determined by histopathologic analysis) or the new occurrence of carcinoma in situ (CIS) in a bladder previously free from CIS or the new occurrence of multiple urothelial tumors following the initial diagnosis of a solitary urothelial tumor

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SELENIB – Cox model estimates for RFI adjusted for prognostic factors

	Hazard Ratio	95% Confidence Interval	p-value
Selenium allocation			
Placebo (reference)	—	—	
Active	0.90	0.63, 1.29	0.55
Vitamin E allocation			
Placebo (reference)	—	—	
Active	1.49	1.04, 2.15	0.031
Grade			
Grade 1 (reference)	—	—	
Grade 2	0.88	0.56, 1.40	0.59
Grade 3	0.56	0.31, 1.03	0.064
Time varying effects			
Stage	1.47	0.28, 7.83	0.65

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SELENIB – Takeaways

Amongst patients with newly diagnosed NMIBC:

- High dose Selenium supplementation did not reduce the risk of disease recurrence
- **Vitamin E** supplementation was associated with an **increased risk** of recurrence.
- Neither selenium nor vitamin E influenced progression or overall survival.

PRACTICE IMPLICATIONS :

Vitamin E supplementation may be harmful to patients with NMIBC, and further studies should be conducted for its safety in people without history of NMIBC.

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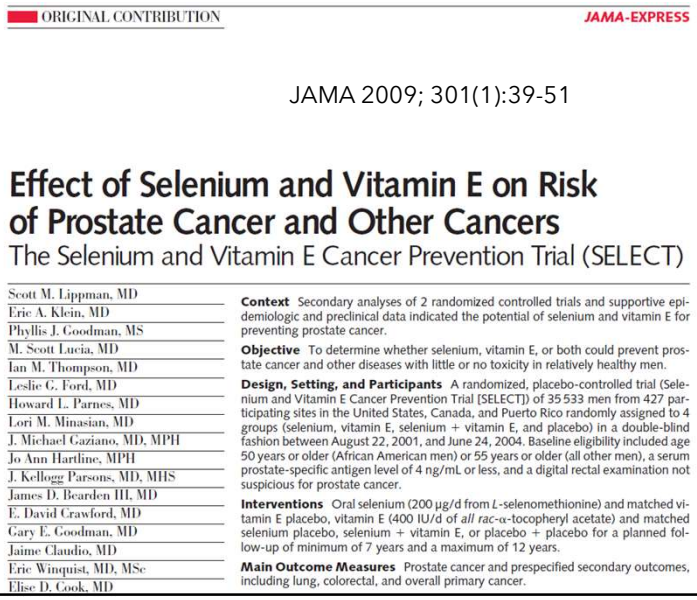
Having déjà vu?



ORIGINAL CONTRIBUTION JAMA-EXPRESS

JAMA 2009; 301(1):39-51

Effect of Selenium and Vitamin E on Risk of Prostate Cancer and Other Cancers

The Selenium and Vitamin E Cancer Prevention Trial (SELECT)

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Context Secondary analyses of 2 randomized controlled trials and supportive epidemiologic and preclinical data indicated the potential of selenium and vitamin E for preventing prostate cancer.

Objective To determine whether selenium, vitamin E, or both could prevent prostate cancer and other diseases with little or no toxicity in relatively healthy men.

Design, Setting, and Participants A randomized, placebo-controlled trial (Selenium and Vitamin E Cancer Prevention Trial [SELECT]) of 35 533 men from 427 participating sites in the United States, Canada, and Puerto Rico randomly assigned to 4 groups (selenium, vitamin E, selenium + vitamin E, and placebo) in a double-blind fashion between August 22, 2001, and June 24, 2004. Baseline eligibility included age 50 years or older (African American men) or 55 years or older (all other men), a serum prostate-specific antigen level of 4 ng/mL or less, and a digital rectal examination not suspicious for prostate cancer.

Interventions Oral selenium (200 µg/d from *L*-selenomethionine) and matched vitamin E placebo, vitamin E (400 IU/d of *all rac*-α-tocopheryl acetate) and matched selenium placebo, selenium + vitamin E, or placebo + placebo for a planned follow-up of minimum of 7 years and a maximum of 12 years.

Main Outcome Measures Prostate cancer and prespecified secondary outcomes, including lung, colorectal, and overall primary cancer.

Objective:

To determine the effects of selenium and vitamin E, alone or in combination, on the risk of prostate cancer

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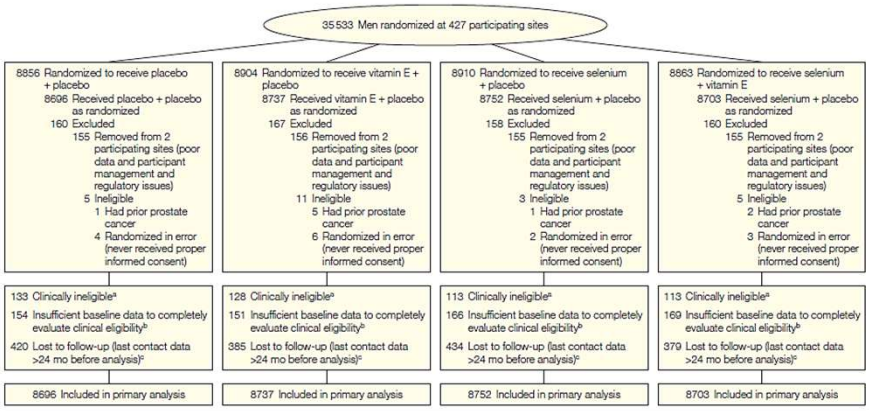
Selenium and Vitamin E Cancer Prevention Trial (SELECT)

Figure 1. Flow of Participants Included in Analysis by Intervention Group



[a] Due to increased blood pressure, high-grade prostatic intraepithelial neoplasia, suspicious digital rectal examination (DRE) or increased prostate-specific antigen (PSA), aspirin dosage, prior cancer less than 5 years before randomization, participation in another clinical trial, or other clinical reason.
[b] Blood pressure, PSA, and/or DRE not performed within required time frame (but normal) or other data-related reason.
[c] All data up until the last contact are included; these men also could have been either clinically ineligible or had insufficient baseline data. For time-to-event analyses, these men were censored at their last follow-up.

Interventions:

- Selenium 200 µg/d (as L-selenomethionine)
- Vitamin E 400 IU/d (all rac-tocopheryl acetate)
- Placebo

Up to 7 years of follow up

Median age of enrollment 62.5 years ; 79% White

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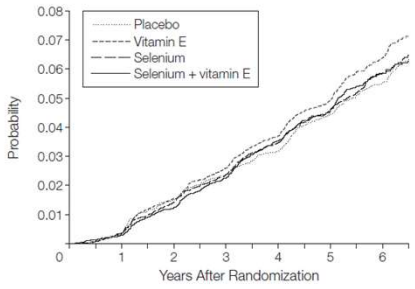
SELECT - Cumulative Incidence of Prostate Cancer and Death

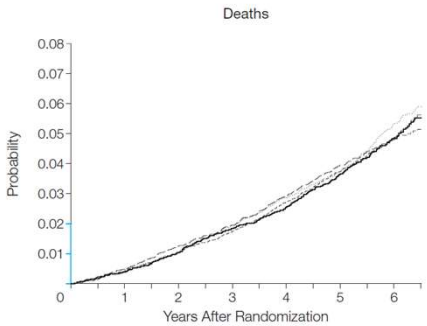
Figure 2. Cumulative Incidence of Prostate Cancer Detected Each Year by Intervention Group



No. at risk							
Placebo	8689	8553	8328	8039	7389	4892	2516
Vitamin E	8732	8610	8373	8098	7401	4867	2537
Selenium	8750	8597	8341	8083	7393	4848	2558
Selenium + vitamin E	8700	8585	8371	8097	7428	4894	2580

Compared with placebo, there was a statistically nonsignificant increase in prostate cancer in the vitamin E group (P=.06) and not in the selenium + vitamin E group (P=.52) or the selenium group (P=.62).

The median follow-up = 5.46 years



No. at risk							
Placebo	8689	8585	8454	8236	7617	5100	2631
Vitamin E	8732	8639	8505	8310	7662	5086	2653
Selenium	8750	8628	8460	8277	7622	5029	2667
Selenium + vitamin E	8700	8610	8475	8285	7679	5089	2684

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SELECT – Lack of Effects for Selenium or vitamin E on Clinical Endpoints

Table 4. Secondary Outcomes Including Diagnosis of Other Primary Cancers, Diabetes, Cardiovascular Events, and Deaths[a]

	Placebo (n = 8696)		Vitamin E (n = 8737)		Selenium (n = 8752)		Selenium + Vitamin E (n = 8703)	
	No. of Men	HR (99% CI)	No. of Men	HR (99% CI)	No. of Men	HR (99% CI)	No. of Men	HR (99% CI)
Any cancer (including prostate)[b]	824	1 [Reference]	856	1.03 (0.91-1.17)	837	1.01 (0.89-1.15)	846	1.02 (0.90-1.16)
Lung	67	1 [Reference]	67	1.00 (0.64-1.55)	75	1.12 (0.73-1.72)	78	1.16 (0.76-1.78)
Colorectal	60	1 [Reference]	66	1.09 (0.69-1.73)	63	1.05 (0.66-1.67)	77	1.28 (0.82-2.00)
Other primary cancer[c]	306	1 [Reference]	274	0.89 (0.72-1.10)	292	0.95 (0.77-1.17)	290	0.94 (0.76-1.16)
	No. of Men	RR (99% CI)	No. of Men	RR (99% CI)	No. of Men	RR (99% CI)	No. of Men	RR (99% CI)
Diabetes[d]	669	1 [Reference]	700	1.04 (0.91-1.18)	724	1.07 (0.94-1.22)	660	0.97 (0.85-1.11)
Cardiovascular events								
Any (including death)	1050	1 [Reference]	1034	0.98 (0.88-1.09)	1080	1.02 (0.92-1.13)	1041	0.99 (0.89-1.10)
Nonfatal strokes								
Hemorrhagic	11	1 [Reference]	7	0.63 (0.18-2.20)	11	0.99 (0.33-2.98)	12	1.09 (0.37-3.19)
Ischemic	56	1 [Reference]	49	0.87 (0.53-1.44)	51	0.90 (0.55-1.49)	67	1.20 (0.75-1.90)
Not specified[e]	25	1 [Reference]	14	0.56 (0.24-1.32)	11	0.44 (0.17-1.11)	20	0.80 (0.37-1.73)
Other nonfatal (worst grade)[f]								
Grade 3	626	1 [Reference]	642	1.02 (0.89-1.17)	685	1.09 (0.95-1.25)	624	1.00 (0.87-1.15)
Grade 4	190	1 [Reference]	203	1.06 (0.82-1.38)	193	1.01 (0.78-1.31)	201	1.06 (0.82-1.37)

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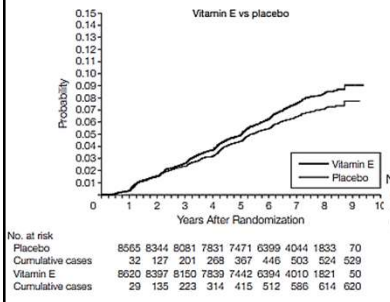
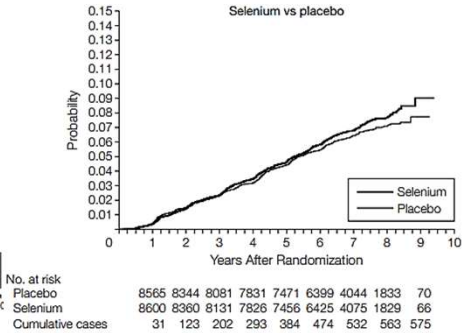
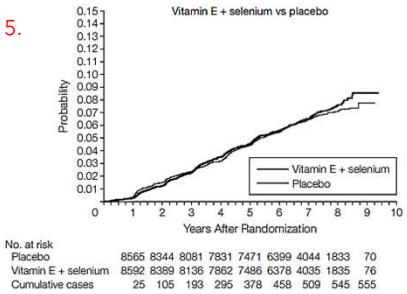
SELECT Trial - 2011 Follow-Up

- The 2011 analysis included 54,464 additional person-years of follow-up since the primary report.
- 521 additional cases of prostate cancer were noted.
- The trendline between vitamin E and placebo started to separate further after year 5.







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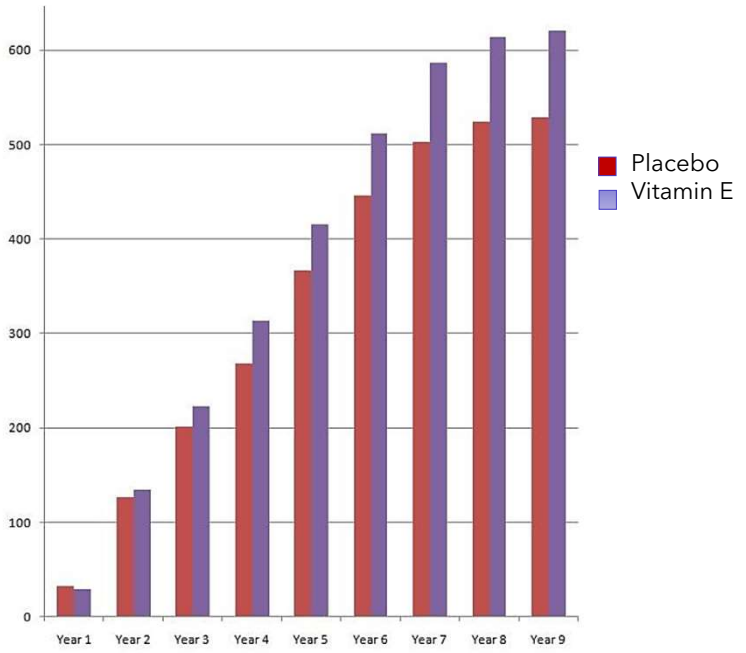

Comparison of the Cumulative Incidence of Prostate Cancer between Vitamin E and placebo

[based on SELECT Trial, Follow-up Data Analysis in 2011]

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SELECT Trial - 2011 Follow-Up Results

Table 3. Number and Risk of Prostate Cancers

	Placebo (n = 8696)	Vitamin E Alone (n = 8737)	Selenium Alone (n = 8752)	Vitamin E + Selenium (n = 8702)
No. of prostate cancers				
October 2008	416	473	432	437
July 2011	529	620	575	555
Hazard ratio, (99% CI)				
October 2008		1.13 (0.95-1.35)	1.04 (0.87-1.24)	1.05 (0.88-1.25)
P value		.06	.62	.52
July 2011		1.17 (1.004-1.36)	1.09 (0.93-1.27)	1.05 (0.89-1.22)
P value		.008	.18	.46
Absolute risk[a]	9.3	10.9	10.1	9.7
Gleason ≥7, No.	133	155	161	164
Hazard ratio (99% CI)		1.16 (0.86-1.58)	1.21 (0.90-1.63)	1.23 (0.91-1.66)
P value		.20	.11	.08

[a]Prostate cancers per 1000 person-years.

Cancers with a **Gleason score of 7 may be called **moderately differentiated** or **intermediate-grade**.*
*Cancers with **Gleason scores of 8 to 10** may be called **poorly differentiated** or **high-grade**.*

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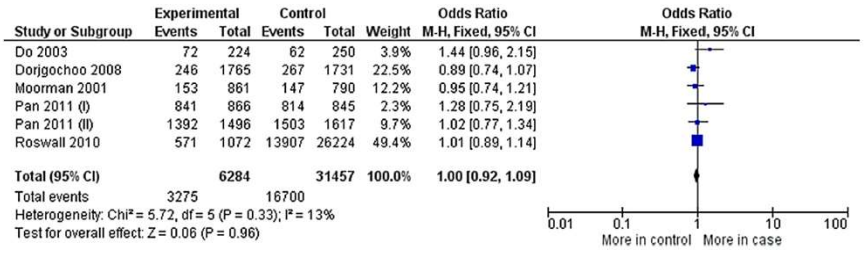
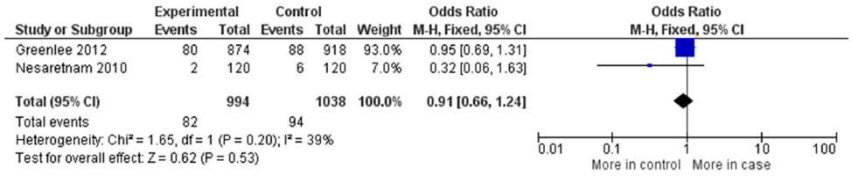
Vitamin E Supplementation on Breast Cancer Risk

Total Vitamin E intake and breast cancer risk



Vitamin E intake and death associated with breast cancer



Note that in Greenlee 2012., vitamin E is consumed along with other antioxidants/ supplements after breast cancer diagnosis 2 years after treatment; Doses of vitamin E not specified

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What have we learned ?

Routine vitamin E (or selenium) supplementation does NOT reduce the risk of any cancer.

The results of SELECT and SELENIB serve as an important reminder that:

1. The use of vitamins, trace minerals, and other dietary and nutritional supplements for the intention of disease prevention must be thoroughly studied before recommended for patients and general population.
2. The assumption that supplement "may not help but it wouldn't hurt either" is a false narrative.
3. Routine, unsupervised vitamin E supplementation may cause harm.

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Everybody living in the Pacific Northwest should take vitamin D supplements because it is cloudy and rainy

All older adults should take supplemental vitamin D because it reduces the risk of falls and bone fracture, yes?

Vitamin D

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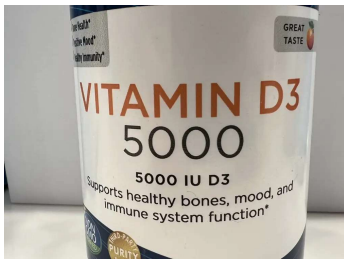
Vitamin D and Health Outcomes – **TRUE / FALSE**



- Common perceptions:
  - Routine vitamin D supplementation reduces a number of chronic illness and improve outcomes of older adults.
  - Vitamin D supplementation is effective in reducing bone loss and fall.

- Meta-analysis and systematic review reinforce these messages:
  - Meta-analysis by Jaiswal V et al (IJC Heart & Vasculature 2022):

    "…low blood levels of vitamin D are associated with MACE [major adverse cardiovascular events], but no such difference in all-cause mortality, myocardial infarction or heart failure was observed"

  - Meta-analysis by Ghahfarrokhi SH et al (J Bone Miner Metab 2022):

    "…28 studies were included, 61,744 elderlies and 9767 cases (15.81%) of hip fractures. In the lowest vs. highest categories of vitamin D in the elderly, pooled OR of hip fractures was 1.80 (95% CI 1.56-2.07, P ≤ 0.001)…. Low serum vitamin D levels in the elderly are associated with an increase in the odds of hip fracture."

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Exercise and Vitamin D in Fall Prevention Among Older Women – 2-year RCT

- To determine the effectiveness of exercise training and vitamin D supplementation in reducing falls
- Settings: Finland, 409 home-dwelling women 70 – 80 years old
- Interventions:
  - Placebo
  - Placebo with exercise
  - Vitamin D 800 IU/day + no exercise
  - Vitamin D 800 IU/day + exercise
- Vitamin D assay –EIA

Category	Placebo No exercise	Vitamin D No exercise	Placebo + Exercise	Vitamin D + Exercise
All fallers	HR = 1.00	HR = 0.77 (0.54 - 1.11)	HR = 0.93 (0.66 - 1.31)	HR = 0.91 (0.64 - 1.28)
Injured fallers	1.00	0.89 (0.47 - 1.69)	0.47 (0.23 - 0.99)	0.38 (0.17 - 0.83)
Multiple fallers	1.00	1.07 (0.71 - 1.62)	1.14 (0.76 - 1.71)	1.14 (0.77 - 1.71)

Uusi-Rasi K, et al, JAMA Intern Med. 2015;175(5):703-711.

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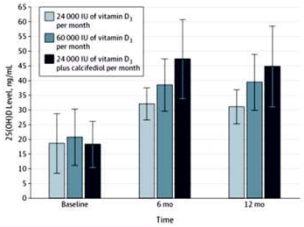
Can High Dose Vitamin D Prevent Functional Decline in Older Adults?

- Goal:
  - To determine if high dose monthly vitamin D prevents functional decline in home-dwelling adults > 70 years old
- Interventions:
  - 24,000 IU vit D3 monthly (~800 IU/day)
  - 60,000 IU vit D3 monthly (~2,000 IU/day)
  - 24,000 IU vit D3 + 300 µg 25(OH)D
- Assessments:
  - Short Physical Performance Battery (SPPB score)
  - Physical examination , Appendicular muscle mass (per DEXA)



Falls Assessment	24,000 IU	60,000 IU	24,000 IU + 25(OH)D	P value
Incidence of falls	47.9%	66.9%	66.1%	0.048
Adjust mean # of falls	0.94	1.47	1.24	0.09

Bischoff-Ferrari HA, et al, JAMA Intern Med. 2016;176:175-183

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Updates from Major Clinical Trials -1

- **VDOP** (Vitamin D supplementation in older people) University of Cambridge.
  - Study aim: To examine the relationship between vitamin D supplementation at a range of doses (12,000 IU/month, 24,000 IU/month or 48,000 IU/month, equivalent to 400 IU/day, 800 IU/day and 1,600 IU/day, respectively) and the change in bone mineral density (BMD) in older people living in private households in the Northeast of England

CONCLUSION

There was no difference in change in BMD over 12 mo between the 3 doses of vitamin D, suggesting no effect of the intervention or a similar attenuation of the anticipated decrease in BMD over 12 mo. The treatment was safe and effective in increasing plasma 25(OH)D concentrations, with no dose-related adverse events.

- This trial was registered at the EU Clinical (ISRCTN35648481).

Am J Clin Nutr 2019;109:207–217.

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Updates from Major Clinical Trials -2

- **VITAL** (Vitamin D and Omega-3 Trial) Harvard Medical School.
  - Study aim: To determine whether taking daily dietary supplements of vitamin D3 (2000 IU) or omega-3 fatty acids (Omacor® fish oil, 1 gram) reduces the risk for developing cancer, heart disease, and stroke in people who do not have a prior history of these illnesses.

CONCLUSION

- Supplementation with n-3 fatty acids did not result in a lower incidence of major cardiovascular events or cancer than placebo.
- Supplementation with vitamin D did not result in a lower incidence of invasive cancer or cardiovascular events than placebo.
  - (Funded by the National Institutes of Health and others; VITAL ClinicalTrials.gov number, NCT01169259 .)

Manson JE et al, N Engl J Med. 2019 Jan 3;380(1):33-44.
Manson JE et al, N Engl J Med. 2019 Jan 3;380(1):23-32.

30

Efficacy of Vitamin D on Fall Prevention –

Vitamin D3 - Omega3 - Home Exercise - Healthy Ageing and Longevity (DO-HEALTH) Trial

Cohorts: Community dwelling older adults ≥ 70 years in 5 European cities

Enrollment:
Absence of major health events in 5 years
MMSE score of ≥ 24

Interventions:
2x 2x 2 RCT
(i) Vitamin D3, 2000 international units/day; and/or
(ii) marine omega-3 FA1 g/day (EPA and DHA in 1:2 ratio); and/or
(iii) a simple home exercise program (SHEP)
compared with placebo and/or control exercise over 3 years

Primary outcome : Incidence rate of total falls

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DO-HEALT Trial –

Treatment Effects on Incidence rate of **total falls**

	Vitamin D	
Falls over 3 years	Vitamin D	No Vitamin D
Crude estimates		
No. of participants	1076	1081
No. of participants who sustained at least 1 fall	657	654
No. of falls	1660	1673
Incidence rate per person-year (95% CI)	0.56 (0.52–0.61)	0.56 (0.52–0.60)
Incidence rate ratio (95% CI)	1.00 (0.90–1.12)	
Adjusted estimates		
Incidence rate per person-year (95% CI)	0.52 (0.48–0.56)	0.51 (0.47–0.55)
Incidence Rate Ratio (95% CI)	1.03 (0.92–1.14)	
P value	0.64	

- Mean age = 74.9 years
- BMI 26.3 kg/m^2
- 41.9% had prior falls

- Baseline 25(OH)D conc: 22.4 ng/mL

- Adjusted incidence rate for omega 3 FA vs placebo: 0.90 (0.81 – 1.00)
- Adjusted incidence rate for SHEP vs no exercise: 1.10 (0.99 – 1.22)

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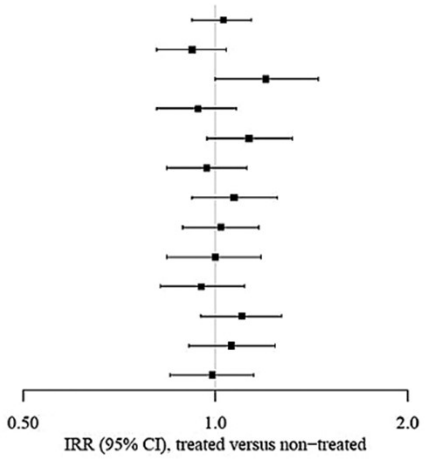
DO-HEALTH Trial –

Sub-group analysis of Vit. D Supplementation on Fall Rate

Groups Vitamin D	N[a] Treated | Non-treated	Adjusted IRR (95% CI)[b] Treated vs Non-treated
All	1076 | 1081	1.03 (0.92, 1.14)
Women	667 | 664	0.92 (0.81, 1.04)
Men	409 | 417	1.20 (1.00, 1.45)
Age 70–74	606 | 631	0.94 (0.81, 1.08)
Age 75+	470 | 450	1.13 (0.97, 1.32)
Omega-3 PUFA levels < 100µg/ml	541 | 527	0.97 (0.84, 1.12)
Omega-3 PUFA levels ≥ 100µg/ml	529 | 546	1.07 (0.92, 1.25)
25(OH)D levels < 20 ng/ml	427 | 445	1.02 (0.89, 1.17)
25(OH)D levels ≥ 20 ng/ml	639 | 629	1.00 (0.84, 1.18)
Prior falls	446 | 457	0.95 (0.82, 1.11)
No prior fall	630 | 624	1.10 (0.95, 1.27)
PA volume < 26.3 MET-hr/wk	559 | 517	1.06 (0.91, 1.24)
PA volume ≥ 26.3 MET-hr/wk	517 | 563	0.99 (0.85, 1.15)



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DO-HEALTH Trial –

Treatment effects on the odds of **falling at least once**

	Vitamin D	
	Vitamin D	No Vitamin D
Falls over 3 years		
Crude estimates		
No. of participants	1076	1081
No. of fallers	657	654
OR (95% CI)	1.02 (0.85–1.22)	
Adjusted estimates		
OR (95% CI)	1.02 (0.85–1.23)	
Injurious falls over 3 years		
Crude estimates		
No. of participants	1076	1081
No. of fallers	570	548
OR (95% CI)	1.10 (0.92–1.30)	
Adjusted estimates		
OR (95% CI)	1.11 (0.93–1.33)	

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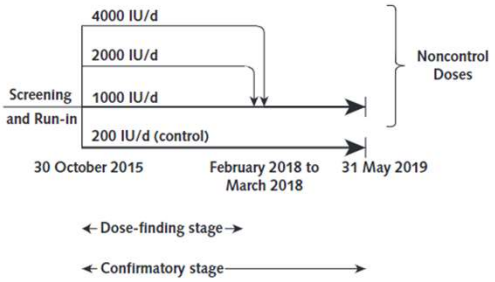
STURDY- (Study To Understand Fall Reduction and Vitamin D in You) clinical trial

- Community-dwelling adults aged 70 years or older with elevated fall risk and low serum 25(OH)D concentrations
- Participants were enrolled in the trial at 2 community-based research units (Hagerstown or Woodlawn, Maryland),each at approximately 39°latitude



Baseline serum 25(OH)D concentration 25 – 72.5 nmol/L (10 ng/mL – 29 ng/mL)
Median 55.3 nmol/L (22.7 ng/mL)

Median daily vitamin D intake 700 IU

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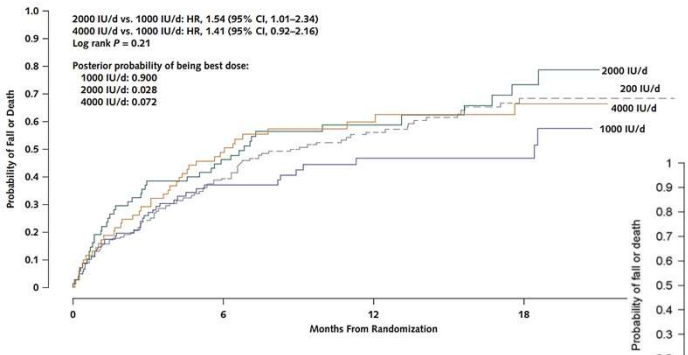
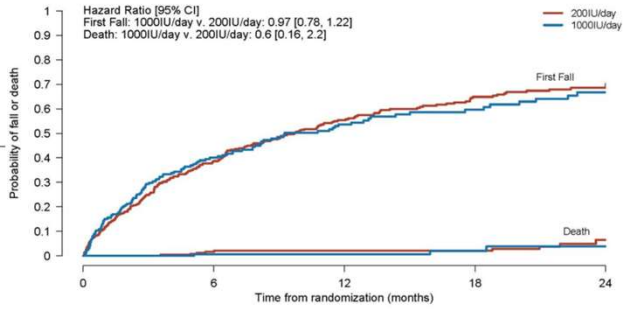
STURDY Trial –
First fall or death based on vitamin D Regimen

Dose Finding Stage



Confirmatory Stage



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STURDY Trial- Sub-analyses

- Amongst older persons with elevated fall risk and low serum 25-(OH)D concentrations at baseline, high-dose vitamin D supplementation (1000 IU/d) did not prevent falls compared with 200 IU/d.
- There is evidence to raise safety concerns about vitamin D3 doses of 1000 IU/d and higher.
- Additional analysis also showed that high dose vitamin D supplementation did not prevent frailty
- vitamin D3 supplementation of 1000 IU/day or higher did not attenuate declines in physical activity compared with 200 IU/day.
- In fact, the risk of fall-related fracture was higher in patients receiving 1,000 IU/day compared with 200 IU/day [HR 2.66 (1.18-6.00)]

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VITAL Ancillary Study- Vitamin D Supplementation on Frailty

- Study Cohorts:
  - 25,871 men aged ≥50 years and women aged ≥55 years free of CVD and cancer at baseline.
  - Patients were recruited across all 50 US states from Nov 2011 to Mar 2014, and followed up through Dec 31, 2017.
  - Data analysis for the ancillary study was conducted from Dec 1, 2019, to Mar 30, 2022.
- Interventions:
  - Vitamin D3, 2000 IU, and/or marine omega-3 fatty acids, 840mg (including EPA 460mg, and DHA 380mg)
- Definition of frailty:
  - Based on criteria developed by Rockwood frailty index (FI).
  - 36 variables were included

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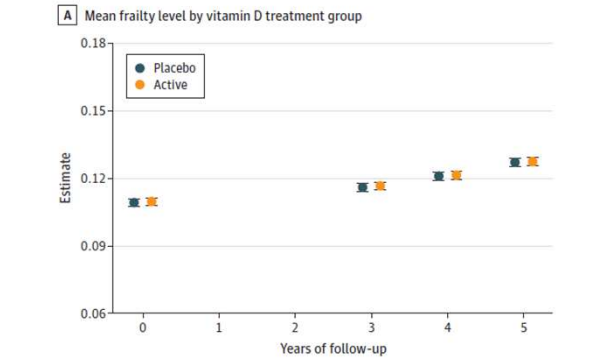
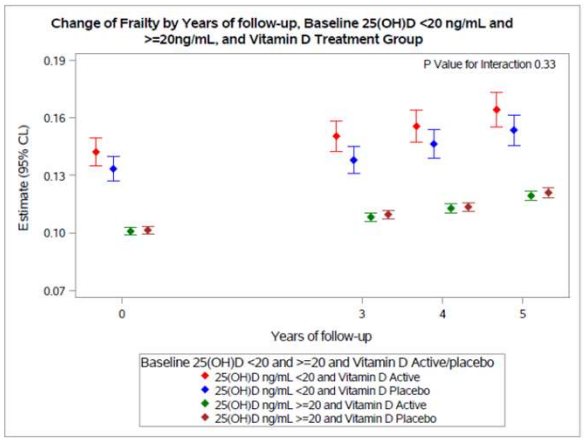
VITAL Ancillary Study-
Vitamin D Supplementation on Frailty

Figure 2. Change in Mean Frailty Levels During the Study





Orkaby AR, et al. JAMA Netw Open 2022;5(9):e2231206.

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VITAL Ancillary Study-
Vit. D Supplementation on Frailty incidence over time

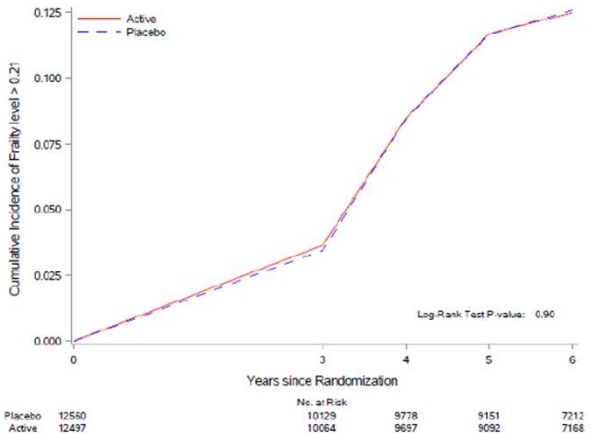
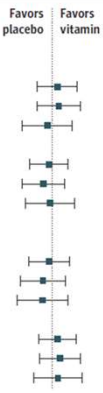


Figure 3. Mean Change in Frailty Score at Each Year Since Randomization According to Vitamin D_3 Groups by Baseline Subgroups

Parameter	No. in parameter group	Mean difference ×1000 (95% CI)
Age, y		
<66.8		
Year 3	11164	0.61 (-1.65 to 2.87)
Year 4	10342	0.79 (-1.66 to 3.23)
Year 5	6431	-0.51 (-3.30 to 2.29)
≥66.8		
Year 3	11597	-0.32 (-2.45 to 1.81)
Year 4	11107	-0.92 (-3.27 to 1.43)
Year 5	7856	-0.18 (-2.94 to 2.57)
Sex		
Female		
Year 3	11477	-0.31 (-2.60 to 1.97)
Year 4	10794	-0.98 (-3.50 to 1.54)
Year 5	7365	-1.04 (-3.91 to 1.84)
Male		
Year 3	11284	0.63 (-1.48 to 2.74)
Year 4	10655	0.90 (-1.39 to 3.19)
Year 5	6922	0.68 (-2.03 to 3.39)



Orkaby AR, et al. JAMA Netw Open 2022;5(9):e2231206.

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What is the takeaway ?

- DO-HEALTH is one of many RCTs published in the last decade showing a lack of effect for routine vitamin D supplementation in reducing fall and bone fracture
- Vitamin D supplementation is critical for patients with hypovitaminosis D, defined as serum 25(OH)D concentration < 20 ng/mL
- The benefit of Vitamin D supplementation in patients with adequate vitamin D status (>20 ng/mL) is doubtful
- High doses of vitamin D may increase short-term fall risk

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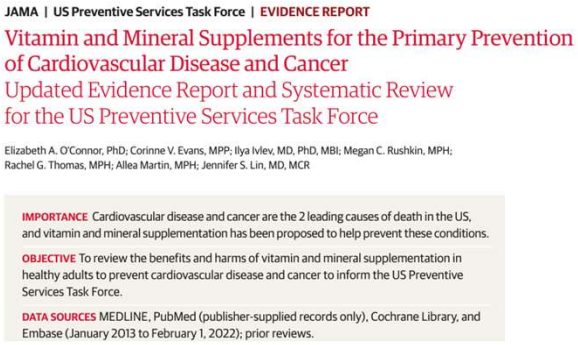
USPSTF Recommendation on Vitamin Supplementation



JAMA | US Preventive Services Task Force | EVIDENCE REPORT

Vitamin and Mineral Supplements for the Primary Prevention of Cardiovascular Disease and Cancer

Updated Evidence Report and Systematic Review for the US Preventive Services Task Force

Elizabeth A. O'Connor, PhD; Corinne V. Evans, MPP; Ilya Ivlev, MD, PhD, MBI; Megan C. Rushkin, MPH; Rachel G. Thomas, MPH; Allea Martin, MPH; Jennifer S. Lin, MD, MCR

IMPORTANCE Cardiovascular disease and cancer are the 2 leading causes of death in the US, and vitamin and mineral supplementation has been proposed to help prevent these conditions.

OBJECTIVE To review the benefits and harms of vitamin and mineral supplementation in healthy adults to prevent cardiovascular disease and cancer to inform the US Preventive Services Task Force.

DATA SOURCES MEDLINE, PubMed (publisher-supplied records only), Cochrane Library, and Embase (January 2013 to February 1, 2022); prior reviews.

Beta-carotene –
Significantly associated with an increased risk of lung cancer (OR,1.20 [95%CI,1.01-1.42] and cardiovascular mortality (OR,1.10 [95%CI,1.02-1.19])

Vitamin D –
NOT significantly associated with all-cause mortality (OR,0.96 [95%CI,0.91-1.02],cardiovascular disease (OR,1.00 [95%CI,0.95-1.05],or cancer outcomes (OR,0.98[95%CI,0.92-1.03])

Vitamin E –
NOT significantly associated with all-cause mortality (OR,1.02 [95%CI,0.97-1.07], cardiovascular disease events (OR,0.96 [95%CI,0.90-1.04]), or cancer incidence (OR,1.02[95%CI,0.98-1.08]).

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Practice Pearls

1. Routine supplementation is not warranted in healthy patients with a balanced diet and have no predisposing risk factors for micronutrient deficiencies. Meeting the DRI or RDA is the primary goal for most individuals, including older adults.

2. For at risk patients, identify the risk factors, signs and symptoms of micronutrient deficiencies, and then treat/prevent deficiency.

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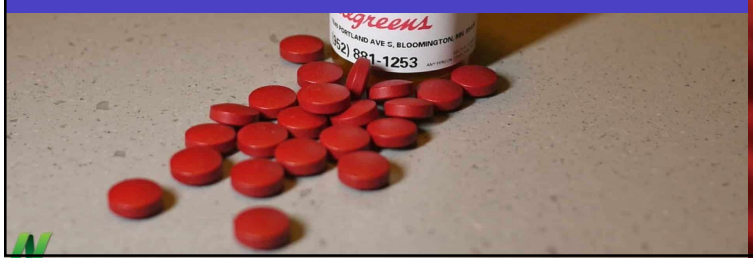
Assessing Iron Deficiency in Older Adults



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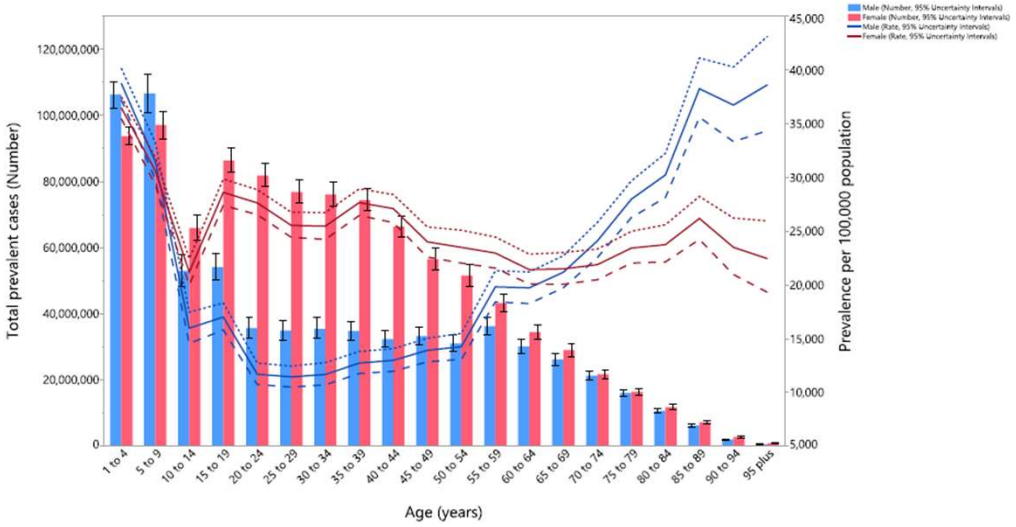
Global Prevalence of Anemia per 100,000 population, by Age and Sex in 2019



Dotted and dashed lines indicate 95% upper and lower uncertainty intervals, respectively.
Source: Generated from data available from http:// ghdx. healt hdata. org/ gbd-results-tool

Safiri *et al. J Hematol Oncol (2021) 14:185*

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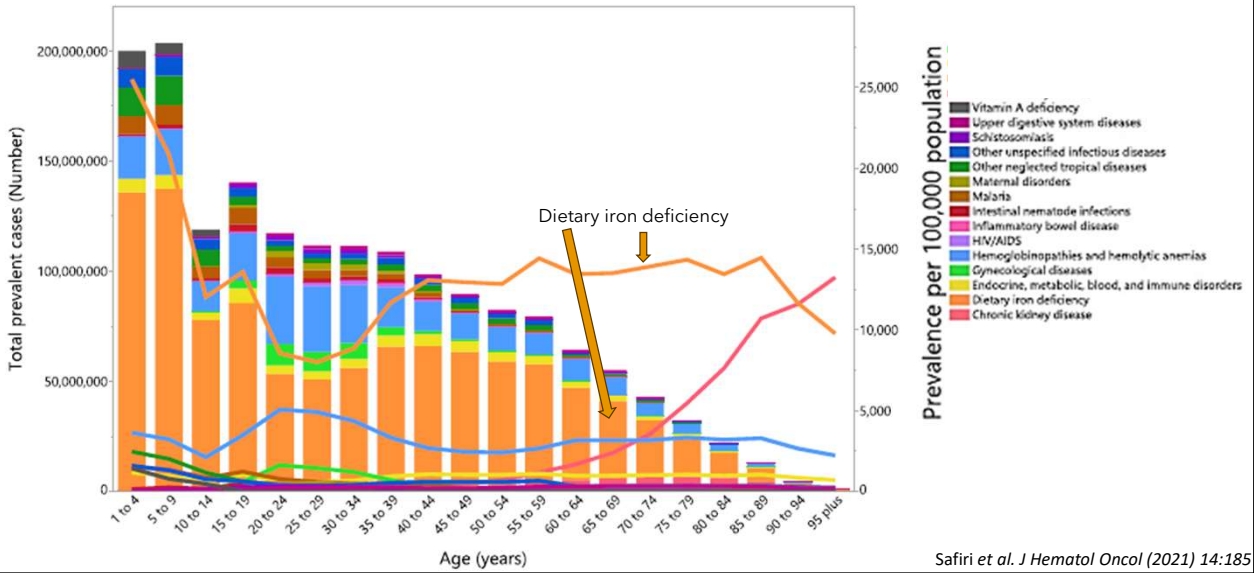
Global Prevalence of Anemia, Based on Underlying Cause (2019)



Safiri *et al. J Hematol Oncol (2021) 14:185*

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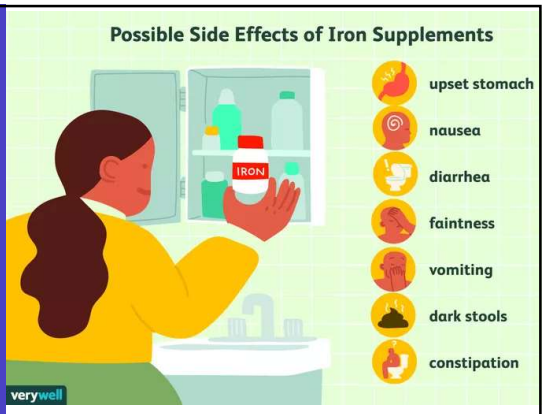
Challenges of Iron Supplementation



Graphic credits: Verywell / JR Bee

- Out-of-pocket costs to patients
- Gastrointestinal (GI) side effects
- Iron overload with IV iron therapy and transfusion

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Basis of Historical TID Regimens for Iron Supplementation

- Assuming 0.2 – 0.25 g of Hgb / 100mL of blood /day is the max rate of Hgb regeneration, *and*
- Assuming 3.4 mg Fe / 1 g Hgb
  - Thus, 5,000 mL of blood ~ 42.5 mg of elemental iron

- 325 mg $FeSO_4$ provide 20% elemental Fe ~ 65 mg
- Assuming bioavailability ~ 20%, each dose provides ~ 13 mg elemental Fe
- Thus 325 mg thrice daily (3x) → 40 - 50 mg elemental Fe

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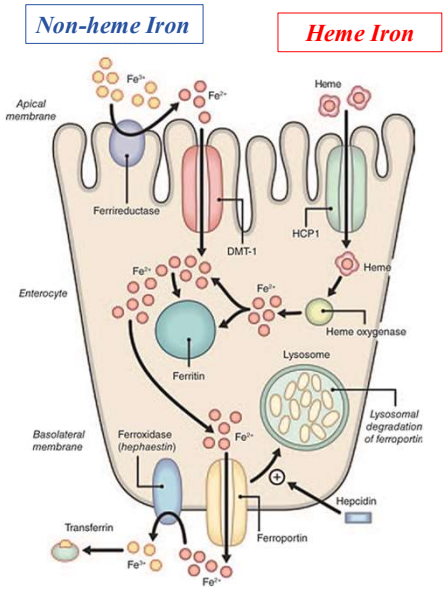
Intestinal Absorption of Iron



- Duodenum is the primary site where iron, especially non-heme iron, is absorbed
- Iron transport is a saturable process; thus, increasing the oral dose of iron does not translate to a proportional increase in the amount absorbed
- Iron uptake also takes place in the colon, although the relative absorption efficiency is only about 1/10 of that from the duodenum
- Heme iron has higher fractional absorption (15%–35%) than does non-heme iron (2%–20%)
- The bioavailability of iron sulfate from iron supplements can approach 60% in severe cases of iron-deficiency anemia

Figure adapted from: Rizvi S et al. Am J Gastroenterol 2011; 106:1872-1879
Chan L-N, Mike LA. J Parenter Enteral Nutr 2014;38:656-72

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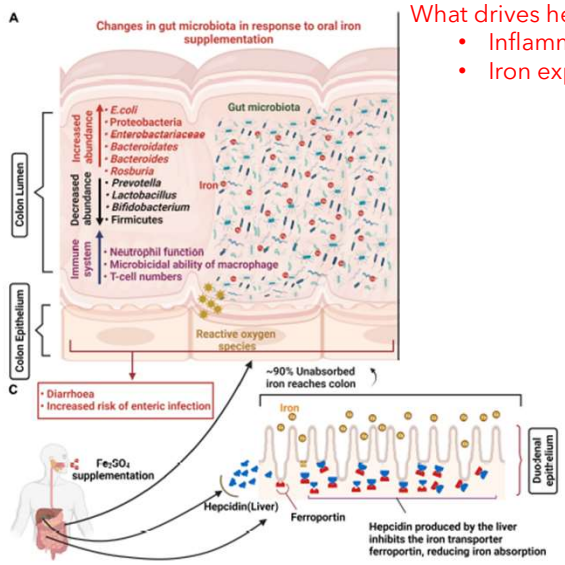
Potential Contributions to GI Side Effects by Oral Iron



What drives hepcidin releases?
- Inflammation
- Iron exposure

- A single dose of oral iron leads to an immediate increase in serum iron, serum ferritin and transferrin saturation (TSAT)
- These serum iron markers induce the release of hepcidin
- Increased serum hepcidin negatively affects the bioavailability of the following doses of oral iron
- Decreased oral iron absorption causes an increased in GI luminal iron, which increases GI side effects
- This also leads to decreased treatment efficacy

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Comparison of Iron Bioavailability Between Daily vs Twice-daily Administration

	Time and day of administration	Iron bioavailability: Fractional Fe absorption (%)†	Iron bioavailability: Fe absorbed (mg)†	Plasma Hepcidin (nM)
Daily*	8:00 AM, d1	NA	NA	0.6 (0.5-8.9)
	8:00 AM, d2	22.9 (10.5-49.4)	13.8 (6.3-29.6)	0.8 (0.4-6.1)
	8:00 AM, d3	14.6 (7.2-28.3)§	8.8 (4.6-17.0)§	1.5 (0.3-8.5)‖
	8:00 AM, d15	NA	NA	ND
Twice daily*	10:00 AM, d1	17.1 (8.5-37.3)	10.2 (5.1-22.4)	0.9 (0.3-3.7)
	4:00 PM, d2	12.5 (6.3-19.2)**	7.5 (3.8-11.5)**	4.1 (0.5-10.7)††
	8:00 AM, d3	9.9 (4.4-16.3)**	5.9 (2.6-9.8)**	6.3 (1.3-14.1)††, §
	8:00 AM, d15	NA	NA	ND

60 mg Fe QD on days 2 and 3

60 mg Fe BID on day 2
60 mg x1 dose on day 3

Moretti D et al, Blood 2015;126(17):1981-9

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What we know so far . . .

- Multiple daily doses of oral iron supplementation is associated with a progressive decline in oral bioavailability
- Decreased oral bioavailability is associated with increased plasma hepcidin concentration
- Giving a daily double-dose (instead of twice daily) does not improve bioavailability

- Oral iron leads to ↑ TSAT (4 hrs), then ↑ hepcidin (~ 8 hrs), then serum ferritin (~ 24 hrs)
- Serum hepcidin declines after 24 hrs, ferritin remains ↑ for about 72 hrs

Question -

- **Is reducing iron supplementation regimen to alternate day (e.g., every other day), with a same dose, just as effective as daily regimen?**

Stoffel NU et al, Lancet Haematol 2017;4:524-33

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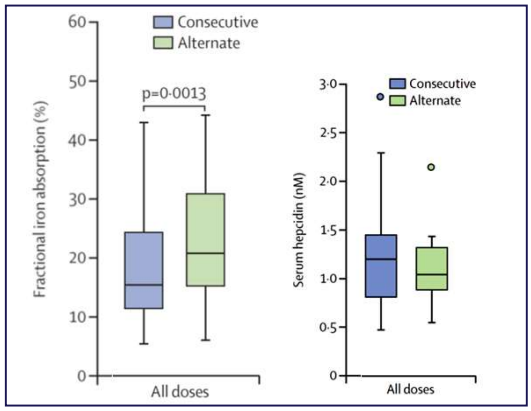
Comparison of Oral Iron Bioavailability : Consecutive vs Alternate Day (60 mg Fe)

Oral Iron Bioavailability

- 16.3% vs 21.8% (p = 0.0013)
- Relative difference 33.7%
- Total Fe absorbed 131.0 vs 175.3 mg (p = 0.0010)



Incidence of Adverse Events

	Study 1			
	Consecutive-day dosing		Alternate-day dosing	
	Number of events (n=24)	Number of people (n=21)	Number of events (n=25)	Number of people (n=19)
Nausea	11 (46%)	6 (29%)	6 (24%)	2 (11%)
Abdominal pain	5 (21%)	2 (10%)	3 (12%)	3 (16%)
Headache	4 (17%)	3 (14%)	11 (44%)	7 (37%)
Upper respiratory tract infection	4 (17%)	4 (19%)	5 (20%)	5 (26%)

Stoffel NU et al, Lancet Haematol 2017;4:524-33

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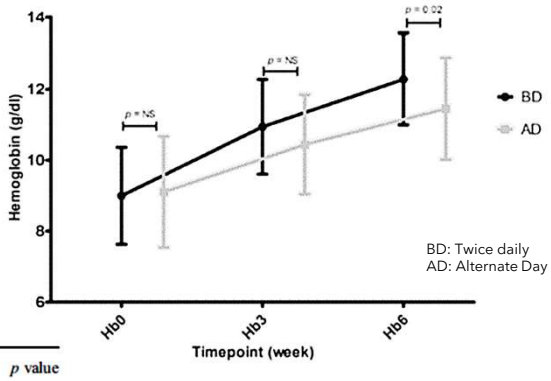
Twice Daily vs Alternate Daily Oral Iron Therapy in the Treatment of Iron Deficiency Anemia

Primary Treatment Endpoint (≥2 g/dL↑ in Hemoglobin)

- Baseline Hgb 8.9 g/gL
- Baseline ferritin 11.8 ng/mL



Adverse Drug Events

Adverse event (CTCAE Grade 1-2)	BD (*n* = 31) (%)	AD (*n* = 31) (%)	*p* value
Dyspepsia	2 (6.5%)	3 (9.7%)	NS
Nausea	12 (38.7%)	7 (22.5%)	0.01
Vomiting	1 (3.2%)	1 (3.2%)	NS
Constipation	2 (6.5%)	1 (3.2%)	NS
Diarrhea	2 (6.5%)	3 (9.7%)	NS

BD twice a day, *AD* alternate day, *NS* not significant

Kaundal R et al. Ann Hematol 2020;99:57-63

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Oral iron – Recommended Approach

- Multiple times per day dosing regimen of oral iron supplementation should be discouraged
- Increased oral doses or higher dosing frequency induces more hepcidin being release, which downregulates oral iron absorption, leading to ↓ oral absorption

- Once daily, or once every other day approach appears to maximize oral iron absorption in non-anemic, iron deficient individuals
- Efficacy of this regimen needs to be confirmed in patients with anemia

Extend oral dosing interval is the recommended approach based on current knowledge

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JAMA Network | Open

Original Investigation | Hematology

The Efficacy and Safety of Vitamin C for Iron Supplementation in Adult Patients With Iron Deficiency Anemia
A Randomized Clinical Trial

Nianyi Li, MD, PhD; Guangjie Zhao, MD; Wanling Wu, MD; Mengxue Zhang, MD; Weiyang Liu, MD; Qinfen Chen, MD; Xiaoqin Wang, MD, PhD

OBJECTIVE To compare the equivalence and assess the safety of oral iron supplements plus vitamin C or oral iron supplements alone in patients with IDA.

Li N, et al. JAMA Network Open.2020;3(11):e2023644

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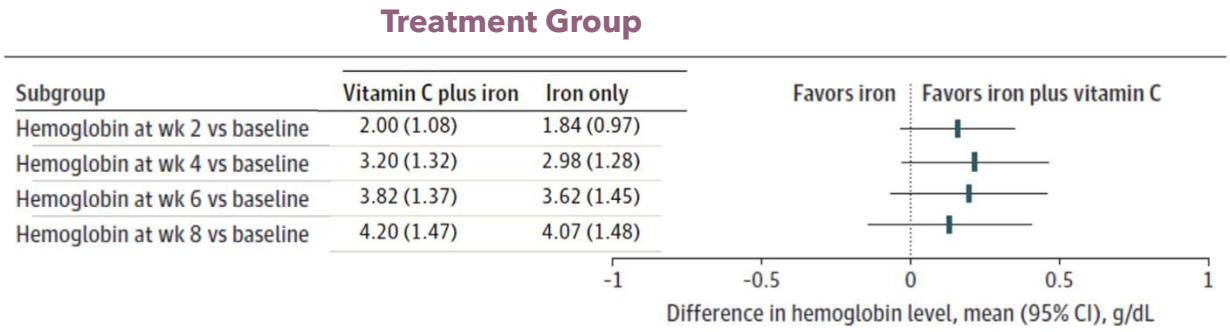
Hemoglobin Changes between Oral Iron with and without Vit. C



No difference in ADR; most common stomach upset, nausea (13%) in both groups

Li N, et al. JAMA Network Open.2020;3(11):e2023644

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Iron Deficiency Anemia in Heart Failure

- Prevalence of *iron deficiency** is ~50% in patients with symptomatic heart failure
- Iron deficiency is an independent predictor of mortality in patients with heart failure
- 25 - 42% of patients with heart failure have iron deficiency in the absence of anemia

Beavers CJ, et al. Iron Deficiency in Heart Failure: A Scientific Statement from the Heart Failure Society of America. J Card Fail 2023 Jul;29(7):1059-1077

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Journal of Cardiac Failure Vol. 29 No. 7 2023

Iron Deficiency in Heart Failure: A Scientific Statement from the Heart Failure Society of America

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ESC European Society of Cardiology

European Heart Journal (2021) 42, 3599 – 3726
doi:10.1093/eurheartj/ehab368

ESC GUIDELINES

2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

Developed by the Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)

With the special contribution of the Heart Failure Association (HFA) of the ESC

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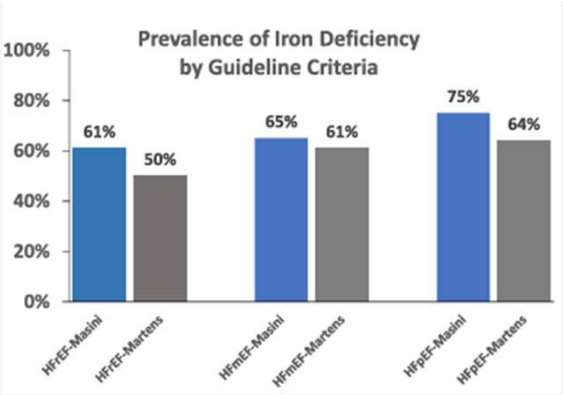
Current Definition of Iron Deficiency in Heart Failure

Definition	Prevalence in HF	Comment
Ferritin < 100 or 100-299 with Tsat <20%	See Panel C	Most common definition of iron deficiency in HF guidelines and HF clinical trials



Iron deficiency as defined by:
(i) Serum ferritin of <100mg/dL; or
(ii) Serum ferritin100 – 299 mg/dL with a TSAT<20%

was found to have a sensitivity of 82% and a specificity of 72% for detecting iron deficiency in patients with HFrEF. (Based on bone aspiration with iron staining)

Beavers CJ, et al. J Card Fail 2023 Jul;29(7):1059-1077
Grote Beverborg N, et al. Circ Heart Fail 2018;11e004519

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Iron Supplementation in Heart Failure

- Oral supplementation has only shown limited success after 16 weeks (increased TSAT by 2 % and ferritin by 18 ng/mL) ~IRONOUT-HF
- Intravenous iron has been shown to increase functional performance, decreased in NYHA functional class, improved QoL, decreased hospitalization, although contradictory findings exist.
  - Ferric Carboxymaltose, has the most experience based on published data (6 RCTs)
  - Iron Sucrose (2 RCTs)
  - Ferric Derisomaltose (1 RCT)

Pivotal Trials: (positive results) CONFIRM-HF, AFFIRM-HF, FAIR-HF, EFFECT-HF, IRONMAN
(negative results) IRONOUT-HF, HEART-FID

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IV Iron Therapy for Heart Failure –

Level of Evidence - ??
Issues Requiring Further Research

- The optimal dosing regimen is unclear
  - FCM dose ranged from 200 – 1000 mg, or 15 mg/kg
  - Dosing frequency is not clear
  - Regimen for other IV iron products is unknown
- IV iron products are not interchangeable
- Target TSAT and ferritin concentrations unknown
- Long-term safety unknown (longest F/U 52 weeks)
- Costs of IV iron infusion major issue for equity and access
- Oral iron study used BID and TID regimen which may have predisposed to treatment failure due to hepcidin upregulation

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Currently available parenteral iron formulations in the U.S. market that have been approved by the FDA

Table 6. Currently available parenteral iron formulations in the U.S. market that have been approved by the FDA

Product	Test dose	Rate of administration	Half-life
Iron dextran (low molecular weight)	Needed, 25 mg or 0.5 mL before the first dose	Not to exceed 50 mg/minute	Free iron: 5 hours; Total iron: 20 hours
Iron sucrose	No	~20 mg/minute	6 hours
Ferric gluconate	Recommended	12.5 mg/minute	~1 hour
Ferumoxytol	No	30 mg/second or infuse over 15 minutes	~15 hours
Ferric carboxymaltose	No	100 mg/minute as push or infuse up to 1,000 mg over at least 15 minutes	~10 hours
Ferric derisomaltose	No	1,000 mg over at least 20 minutes	27 hours

** All IV iron products are prescription drugs

Chan L-N. Support Line 2023;45(5):2-11

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Practice Pearls

1. Iron deficiency (ID) is common among older adults. When treating ID, start oral iron as daily or every other day regimen, and NOT multiple times daily.
2. Co-administration of oral iron supplement (Ferrous salt) with vitamin C is not necessary.
3. You may start seeing older adults with HF receiving IV iron therapy even in the absence of anemia. Despite the guideline recommendation for this approach, the best regimen is not clear and long-term safety data are lacking.

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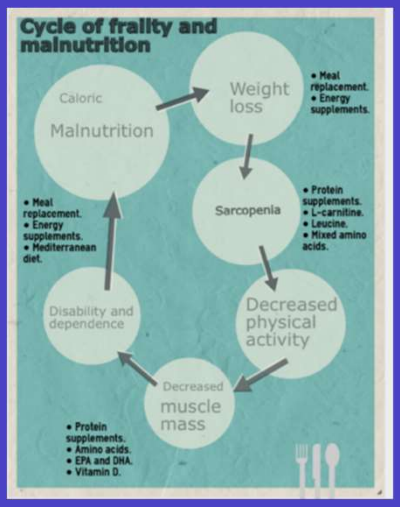

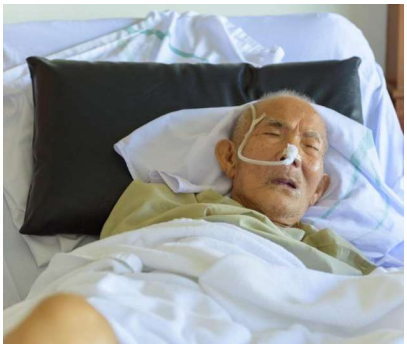

Preventing malnutrition and micronutrient deficiencies in older adults

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Malnutrition in Older Adults

- Malnutrition prevalence is unclear and varies depending on the criteria and assessment tools used

  Based on Mini Nutritional Assessment (MNA)
  - 3·1% in community dwelling older adults,
  - 8·7% of older adults receiving home-care services,
  - 22·0% of older adults in hospitals, and 28·7% of older
  - Additionally, 26.5% of community dwelling older adults are at-risk for malnutrition
- **Sarcopenia** is present in 10 – 27% of adults ≥60 years of age
- Sarcopenia increases the risk of falls, injuries related to falls, mobility, cognitive impairment, depressed mood, hospitalization, in addition to mortality
- Loss of muscle mass and strength, typical of sarcopenia, is a major component of **frailty**.
- High risk groups:
  - Prevalence rates tend to be higher in women, rural populations, > 80 years of age, and those with chronic illness.

Leij-Halfwerk S, et al. Maturitas 2019; 126: 80–89.

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Risk factors leading to Malnutrition

- Eating problems (low appetite, eating dependency)
- Oral health problems (dentition issues, denture, dry mouth)
- Dysphagia
- Chronic illness with an inflammatory component (obesity, CV diseases)
- GI problems
- Cognitive decline

- Low physical function (ADL, performance, strength)
- Lifestyle factors (smoking, alcohol, low physical activity)
- Socioeconomic factors; food insecurity; limited access
- Loss of interest in life/ depression
- Polypharmacy; Drug-nutrient interactions

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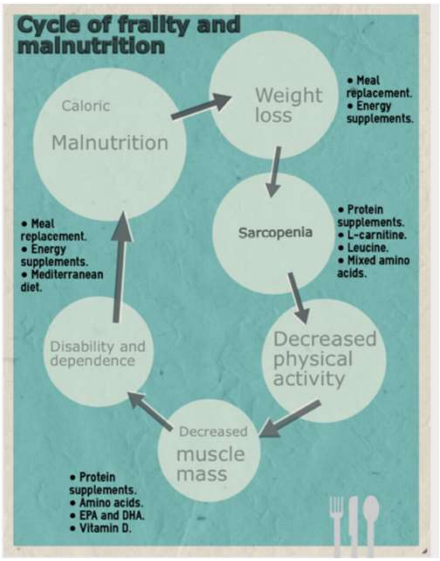
Multivariate logistic regression analysis of risk factors related to Frailty



Parameters	Crude OR [95% CI]	Adjusted OR [95% CI]	p value
Female gender	1.25 [2.64 - 6.83]	2.37 [1.24 - 4.53]	0.009
Age > 75 years	2.33 [1.46 - 3.71]	3.31 [1.76 - 6.21]	< 0.01
Living at home	2.15 [1.19 - 3.87]		NS
Polypharmacy (≥ 5 drugs/day)	1.65 [1.03 - 2.62]		NS
Fall in the past 12 months	3.89 [2.10 - 7.91]	1.91 [1.31 - 3.25]	0.016
Anemia (based on hemoglobin)	**3.45 [1.87 - 6.34]**	**2.45 [1.19 - 5.03]**	**0.015**
Physical activities ≥ 3hr/week	**0.31 [0.12 - 0.38]**	**0.23 [0.15 - 0.35]**	**< 0.01**

Pérez-Ros P. et al, Nutrients; 2020, 12, 1041

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Spanish Malnutrition Risk Study in Older Adults with HF

- **Question :** Do Older Adults Presenting to the ED with Heart Failure with Worse Outcomes if they have HIGHER RISK of MALNUTRITION?

- Cohorts:
  - National patient registry
  - Consecutive patients ≥65 years
  - Presented to 16 EDs across various regions of Spain for AHF
- Findings:
  - Hospital admission rate was 83.4% (85.4% vs 76.1% for malnutrition vs normal nutritional status, respectively; p=0.006)
  - Average 30-day mortality rate was 8.8% (66/749 patients)
  - The 30-day mortality was 4x higher in older patients at risk of malnutrition in comparison with those with a normal nutritional status (10.4% vs 2.6%; p=0.002).

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What can be done to prevent malnutrition in older adults ?

- Make sure micronutrient intake is adequate and meeting DRI, address food insecurity
- Preemptive supplementation of vitamins and trace minerals in older adults with reduced oral intake to meet DRI
- In patients receiving calories through oral supplements, ensure micronutrient intake is adequate
- Older adults have slightly increased daily requirements for vitamin B6, calcium, and vitamin D
- Screen for nutrient deficiency-associated anemia (Vit. B12, iron, zinc, folate, copper)
- Physiological changes such as achlorhydria may also impair micronutrient absorption
- Screen for drug-nutrient interactions

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Summary

- Empirical vitamin supplementation can cause harm in some individuals
- Unless there is documented vitamin E deficiency, older adults should NOT receive empirical Vitamin E supplementation.

- Vitamin D supplementation to treat and prevent deficiency is helpful
- Empirical Vitamin D supplement in non-vitamin D deficiency individuals consistently failed to demonstrate clinical benefits

- Iron deficiency is common in older adults
- Treatment regimen for iron deficiency should be oral iron once daily, not multiple times per day
- Malnutrition negatively affect hospital course and surgical recovery in older adults