



Russell Jaffe, MD, Ph.D., CCN, FRSM
FASCP, FACN, FACAAI, FACLMI, NACB
Senior Fellow, Health Studies Collegium



Proactive Primary Prevention:

Evidence of \$avings through
use of supplements to treat
dietary deficiencies

Background on supplements and savings

- *Limited* studies, data, support & incentive
- Savings observed *when sought*
- Absence of data *often* taken as data of absence
- Product quality standards / GMP
- Dietary deficits common *or* rare
- Adverse events compared to Rx medications



FDA Disclaimer

- These statements have not been evaluated by the Food and Drug Administration.
- This *information* is not intended to diagnose, treat, cure, or prevent any disease.



Daily Value Dietary Deficiencies Confirmed

NHANES III & NHANES IV surveys

- 87% people had 1 or more deficiency
- 58% people had 2+ deficiencies
- Daily Value Deficit (*not* optimum intake)
Dietary deficiencies common & growing

<http://www.cdc.gov/nchs/nhanes.htm>

Von Leibig's Law: Limiting Factor

Growth is controlled not by the total amount of resources available but by the scarcest resource (limiting factor).

Justus von Leibig / Carl Sprengel, 1828; updated by Jaffe, 1990

Guggenheim K Y, Johannes Müller & Justus Liebig on nutrition, *Korot* 1985; 8 (11–12): 66–76.

The Joy of Eating The Alkaline Way, 18th ed, Health Studies Collegium, Ashburn, VA 20147.



Von Leibig's Update: Deficits Rule

Deficit of *any* essential part of multi-part system controls biological system efficiency, resilience & health.

Justus von Leibig / Carl Sprengel, 1828; updated by Jaffe, 1990

Guggenheim K Y, Johannes Müller & Justus Liebig on nutrition, *Korot* 1985; 8 (11–12): 66–76.

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Health care savings (>\$50-100 Bn):

- **Calcium with vitamin D:** Hip fracture decrease *alone* could save health care ~\$13.9 Bn through reduced hospital, nursing facility & physician costs.
- **Folate** (less neural tube defects) \$0.25 bn.
- **Omega-3 EFA** (less CHD): \$0.6 Bn
- **Glucosamine** (less Osteo): \$0.5 Bn
- **Saw Palmetto** (less BPH): \$0.1 Bn
- **lutein + zeaxanthin** for age-related macular degeneration (AMD): \$2.5 Bn through sight saved
- **Multivitamin** (Daily): \$15 Bn
- **Ascorbates** (Daily for scurvy): \$17-70 Bn

Source: The Lewin Group, Health Impact Study IV &
http://intelegen.com/ImmuneSystem/vitamin_c.htm

Glucosamine sulphate in knee osteoarthritis: Save \$1-2 Bn in Europe

- **Abstract INTRODUCTION:**

Explore **cost-effectiveness** of glucosamine sulphate (GS) with paracetamol & placebo (PBO) in treatment of knee osteoarthritis. For this purpose, a 6-month time horizon and a health care perspective was used.

- **MATERIAL AND METHODS:**

Cost & effectiveness (Western Ontario & McMaster U Osteoarthritis Index of Glucosamine Unum In Die; once-a-day) efficacy trial by Herrero-Beaumont *et al.* Clinical **effectiveness** converted into utility scores allow computation of **cost** per quality-adjusted life year (QALY). 3 treatment arms. Incremental **Cost-Effectiveness** Ratio calculated & statistical uncertainty explored using bootstrap simulation.

- **RESULTS:**

Considering mean mobility score changes, no difference at 3 months; significant difference from at 6 months ($p = <0.047$). Comparing GS & paracetamol, mean baseline incremental **cost-effectiveness** ratio (ICER) dominant & mean ICER after bootstrapping was **-1376 euro/QALY...** better outcome (79% probability). Comparing GS with PBO, mean baseline & after bootstrapping ICER were -3617.47 & **-4285 euro/QALY**, respectively.

- **CONCLUSION:**

The results of the present **cost-effectiveness analysis** suggests GS is highly **cost-effective** therapy alternative compared with paracetamol and PBO to treat patients diagnosed with primary knee OA.

Scholtissen S, Bruyère O, Neuprez A, Severens JL, Herrero-Beaumont G, Rovati L, Hiligsmann M, Reginster JY.

Source: Department of Public Health, University of Liege, Liege, Belgium. *Int J Clin Pract.* 2010 May;64(6): 756-762.

Diabetes: Supplements benefit

- Diabetics taking dietary supplements regularly (34%) report themselves in radically better health than diabetics who do not (66%). Diabetic supplement users also report being in better health than year ago compared to diabetics who do *not* take supplements.
- Incremental & avoidable healthcare costs: **\$135 Bn** (2010) [Diet, supplements, & activity]

Source: CDC (Economics of diabetes an annotated bibliography)

Diabetes Kills, Costs & is a Choice

- **Adequate protective antioxidants:**
Ascorbates, polyphenolics, carotenoids, vitamins E, B complex, D3, minerals, carnitine, choline, Omega 3 EFAs, prebiotics, probiotics & CoQ10... **75-95%** reduction diabetes risks & consequences
- **Add 15' walking & 15' stretching** each day... **80-98%** reduction diabetes risks & morbidity.

Kim W, Khan N A, McMurray D N, Prior I A, Wang N, Chapkin R S.
Regulatory Activity of Polyunsaturated Fatty Acids in T-Cell Signaling Prog Lipid Res. 2010 July; 49(3): 250–261.



Diabetes Kills, Costs & is a Choice

Remember von Leibig's Law & personalized care:

Daily: Calibrated ascorbates, polyphenolics (quercetin dihydrate & LMW OPC, 1-10 g), carotenoids (fruits & veggies colors, 50 mg), vitamins E (tocopherols/tocotrienols, 400-3600 IU), B complex (Bs, folates, PABA, Biotin), D3 (2-10,000 IU), minerals (K, Ca, Mg, Zn, Cu, Cr, V, Mo, Mn, I, 1st AM Ur pH 6.5-7.5), carnitine fumarate in MCT (250-750 mg), choline citrate, Omega 3 EFAs (EPA/DHA 3-9 g/day), prebiotics (40 g fiber), probiotics (40 Bn bugs) & CoQ10 (60-1200 mg)...

75-85% reduction diabetes risks & consequences

Add 15' walking & 15' stretching each day...

80-98% reduction diabetes risks & consequences.

Jaffe R. Diabetes as an Autoimmune-immune Dysfunction Syndrome in *Bioactive Foods in Chronic Disease States*. Edited by Ronald Ross Watson, Elsevier, Inc: 2012.

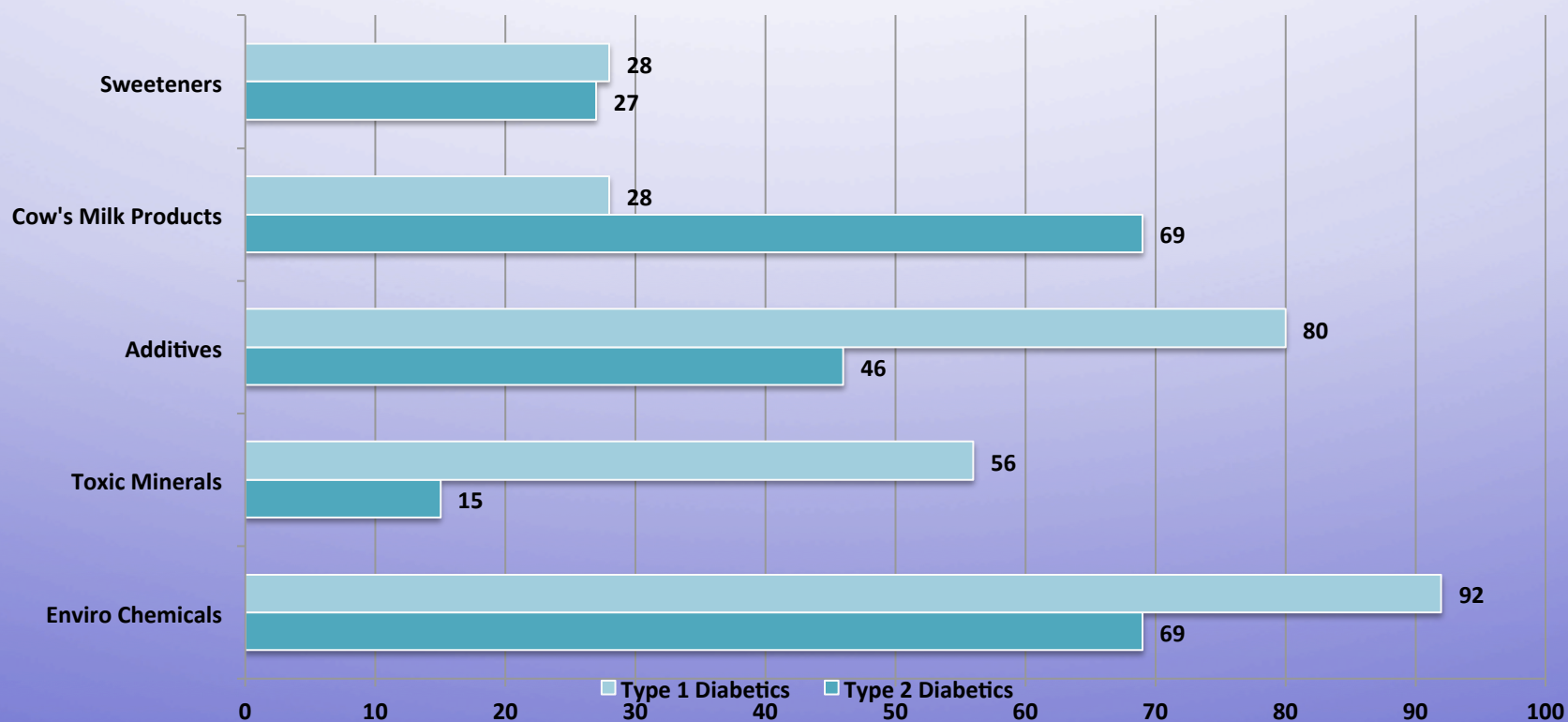
<http://www.healthyamericans.org/>

Glucose / Insulin / Energy Regulation: RCT NIDDM Type 2 study results...

Results _____	<u>Experimental</u>	<u>Control</u>
<u>after 6 mos.</u>	<u>T+6</u>	<u>T +6</u>
■ Glucose (Fasting)	↓20%	↑ 9%
Glucose (2° PP)	↓13%	↓ 6%
(both p<0.05)		
■ Insulin (Fasting)	↓18%	↓12%
■ HbA1c (p < 0.01)	↓13%	↓ 3%

- Jaffe R, Mani J, DeVane J, Mani H. Tolerance loss in diabetics: Association with foreign antigen exposure. *Diabetic Medicine*: 2006 Aug;23(8): 924-925

Type 1 Diabetes Study: LRA tests



Jaffe R, Mani J. Diabetes: Food and Nutrients in Primary Practice in *Food and Nutrients in Disease Management*. Ingrid Kohlstadt (Ed), CRC Press, Feb 2009:281-300.

Diabetes: 84% Risk Reduction

- Nurses Health Study suggests that women, maintaining desirable body weight, eating healthy diet, exercising regularly, not smoking, & consuming moderate alcohol account for 84% risk reduction, yet only 3% of women studied were in that category. Clearly, majority of causes of cardiovascular disease are known & modifiable.
- **AHA Guidelines for Primary Prevention of Cardiovascular Disease and Stroke: 2002 Update, *Circulation*. 2002; 106: 388-391.**
- **Stampfer MJ, Hu FB, Manson JE, *et al*. Primary prevention of coronary heart disease in women through diet and lifestyle. *N Engl J Med*. 2000; 343: 16–22.**

Supplements pre & post op GI Surg

Abstract / Background:

- Postoperative oral nutritional supplementation shown to be of clinical benefit. **This study examined the clinical effects and cost of administration of oral supplements both before and after surgery.**

Methods:

- RCT Patients undergoing lower gastrointestinal tract surgery randomized into four groups: group CC received no nutritional supplements, group SS took supplements both before and after surgery, group CS received 1 month postoperative supplements only, and group SC were given supplements only before surgery ~ 1 month. Data collected included weight change, complications, length of stay, nutritional intake, anthropometrics, quality of life and detailed costs covering all aspects of care.

Results: N = 179; 27 withdrew and 152 analyzed (CC = 44, SS = 32, Cs = 35, SC = 41)

- Dietary intake similar in all 4 groups throughout study. Significantly less postoperative weight loss in SS group than CC & CS groups ($P < 0.050$), & significantly fewer minor complications in SS & CS groups than CC group ($P < 0.050$). No differences in major complications rate, anthropometrics & quality of life. Mean overall costs greatest in CC group, although differences between groups not significant.

Conclusion:

- **Perioperative oral nutritional supplementation started before hospital admission for lower gastrointestinal tract surgery significantly diminished the degree of weight loss and incidence of minor complications, and was cost-effective.**

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Smedley F, Bowling T, James M, Stokes E, Goodger C, O'Connor O, Oldale C, Jones P, Silk D. Randomized clinical trial of the effects of preoperative and postoperative oral nutritional supplements on clinical course and cost of care.

British Journal of Surgery, 2004; 91 (8): 983–990.

Benign prostatic hyperplasia (BPH): 45-90 million affected NA & EU = \$90-\$180 MM/year

Abstract OBJECTIVES:

Pharmacoeconomic study BPH F/U compare 2 drugs: Alpha-blocker (tamsulosin) & lipido-sterolic extract of **Serenoa repens** (Permixon).

MATERIAL AND METHODS:

Direct BPH costs (diagnosis & treatment) were determined according to International Prostate Symptom Score (IPSS): mild, moderate & severe. Clinical efficacy obtained from PERMAL clinical study, where therapeutic equivalence between 2 studied drugs was observed.

RESULTS:

BPH average annual **cost** of diagnostic tests & medical visits (Costs Eu) related to mild (Eu 124), moderate (Eu 207) or severe (Eu 286) symptoms; **cost** of the drugs, including adverse effects treatment, was **Eu 211 for Permixon & Eu 346 for tamsulosin**.

DISCUSSION:

BPH costs increases with symptoms. Permixon more **cost**-effective than tamsulosin, ave yearly savings Eu 135 / patient.

RESULTS of efficacy from same group:

12 months, total IPSS decreased by 7.8 (Permixon) & 5.8 (tamsulosin) ($p=0.051$); irritative symptoms improved more ($p=0.049$) Permixon (-2.9 versus -1.9 with tamsulosin) at 3 and more so 12 ($p=0.03$) months.

CONCLUSION:

Permixon 320 mg/day slightly superior to tamsulosin 0.4 mg/day in reducing LUTS in severe BPH patients after 3 months & 12 months.

Men affected in US and EU: **60% of men over 60 and 14% of men 40-60**

Actas Urol Esp. 2008 Oct;32(9):916-925. Carballido J, Ruiz-Cerdá JL, Unda M, Baena V, Campoy P, Manasanch J, Slof J.

Source: Servicio de Urología, Hosp. Univ. Puerta de Hierro, Madrid.

Cell Metabolic Deficits Create Risk: Supplements Essential

- *Scant* data **strongly** suggests opportunity

**Chronic, degenerative, autoimmune ills
Stress of high tech living & soil depletion
add cells & systems at risk 2^o deficits**

- *Added* costs: Essential nutrient *deficits*
increase morbidity, mortality & expense

Supplement Quality: Safer & Effective Means...

- 1. Full good manufacturing practices (GMPs)**
- 2. Production certification NSF, USP**
- 3. 3rd party post production assays**
- 4. Full disclosure labels**
- 5. Use evidence source & quality ingredients**
- 6. Participate in CBRCT, DBPCT & case registries**
- 7. Safer means always mixed natural forms**

Supplements *do* save \$ & Lives

- *Limited* studies, data, support & incentive
- Concurrent *savings* **observed**
- Absence of data *often* taken as data of absence
- Quality standards *inconsistent*
- *Adverse* events **rare** relative to Rx medications
- Available data is *strongly* **support available savings of \$135 Bn for diabetes + \$50-\$100 Bn from other deficit corrections**



America can save lives & treasure

By correcting essential nutrient deficits. Studies & data are limited, available data for diabetes *alone* **\$135 billion annually** can be saved while improving quality of life & health status. Evidence based supplements can save an additional **\$50-\$100 billion** while improving human function. *Limitations* to benefits from supplements include products whose quality control is undocumented, use of borrowed science where ingredients look alike yet do not work alike, & lack of research resources to further document potential benefits. Deficit in nutrients are common. Adverse events to dietary supplements are rare.

...a few references

1. Jaffe R. Diabetes as an Autoimmune-immune Dysfunction Syndrome in *Bioactive Foods in Chronic Disease States*. Edited by Ronald Ross Watson, Elsevier, 2012.
2. Jaffe R, Brown S. Acid-Alkaline balance and its effect on bone health. *Intl J Integrative Med* 2000; 2 (6): 7-18.
3. Jaffe R. Autoimmunity: Clinical relevance of biological response modifiers in diagnosis, treatment, and testing, Part I: *Intl J Integrative Med* 2000; 2 (2): 16-22 & Part II: *Intl J Integrative Med* 2000; 2 (4): 58-65.
4. Jaffe R. Platelet interaction with connective tissue. In *Physiological reaction of blood platelets* (Gordon, Ed.) Elsevier 1976, 261-292.
5. Jaffe R, Deykin D. Evidence for the structural requirement for the aggregation of platelets by collagen. *J Clin Invest* 1974; 53:875-883.
6. Jaffe R, Kasten B, MacLowry K, Young D. False negative occult blood tests caused by ascorbic acid. *Ann Int Med* 1975;83:824-826.
7. Jaffe R, Zierdt W. An occult blood test procedure not subject to inhibition by reducing substances. *J Lab Clin Med* 1975; 93: 879-886.
8. Pitas R, Nelson C, Jaffe R, Mahley R. 15,18-Tetracosadienoic Acid content of sphingolipids from platelets and erythrocytes of animals fed diets high in saturated or polyunsaturated fats. *Lipids* 1978; 13: 551-556.

Jaffe... a few more references

1. Jaffe R. **Diabetes as an Autoimmune-immune Dysfunction Syndrome** in *Bioactive Foods in Chronic Disease States*. Edited by Ronald Ross Watson, Elsevier, 2012. [Three chapters]
2. Jaffe R. **Cardioprotective Nutrients** in *Bioactive Foods in Chronic Disease States*. Edited by Ronald Ross Watson, Elsevier, 2012.
3. Jaffe R. **The Role of the Alkaline Way in Gastrointestinal Health** in *Bioactive Foods in Chronic Disease States*. Edited by Ronald Ross Watson, Elsevier, 2012.
4. Jaffe R. **The Alkaline Way: Integrative Management of Rheumatoid Arthritis and Other Autoimmune Conditions** in *Bioactive Foods in Chronic Disease States*. Edited by Ronald Ross Watson, Elsevier, 2012.

Questions and Answers

We make our world significant by the courage of
our questions and the depth of our answers.

--Carl Sagan



Thank you for your time and attention.



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