

## VITAMIN D & CALCIUM REPORT from Food & Nutrition Board

The Institute of Medicine at the National Academies issued its long-awaited report on the new levels of vitamin D for all age groups. The Food and Nutrition Board<sup>1</sup> volunteers and staff were responsible for this report which is the first since 1997 that Daily Reference Intakes (DRIs) for vitamin D have been officially increased. Almost anyone who reads the newspaper knows that in the past few years vitamin D has been uncovering new secrets about this vitamin. The task for sorting all of this out fell to the study committee, chaired by A. Catharine Ross, Professor of Nutrition at The Pennsylvania State University.

This report is over 1,000 pages, so there is some danger that there will not be that many readers who work with patients on a daily basis. But it contains a good 12-page summary at the beginning. This supplement is a further summary of these 12 pages.

The summary of the report does not mention the October 2004 Surgeon General's Report on Bone Health & Osteoporosis, now archived at: [www.surgeongeneral.gov/library/bonehealth/content.html](http://www.surgeongeneral.gov/library/bonehealth/content.html), that few people read because it was over 400 pages.

The study committee was asked to use a risk assessment framework and therefore they had to keep in mind that DRIs are values meant to improve the general public health. The DRIs now incorporate the statistical concept of distribution, including the distributions of requirements and intakes. Components of DRI include Estimated Average Requirement (EAR), Recommended Daily Allowance (RDA), Tolerable Upper Intake Level (UL), and Adequate Intake (AI). Therefore the recommendations made had to be thought of lasting a lifetime, not just a day, a week or a few months. The report was written to meet the needs of the United States and Canadian governments and both participated in the project.

Potential indicators of health outcomes for nutrient adequacy for both vitamin D and calcium were considered by the study committee. The data collection and review of it account for three chapters and the reports claim to have considered relationships "that appeared marginal by standard scientific principles" as well as relationships suggested by stakeholders. While they looked for nutrient and disease relationships, this area remains elusive for many reasons including the isolation of a single ingredient from "the confounding effects of other nutrients and non-nutrient factors; the multifactorial etiology of many chronic diseases; the lack of data from randomized, controlled clinical trials, and the best results from observational studies.

Another process was undertaken for indicators of excess intakes of calcium and vitamin D. For calcium these indicators included: hypercalcuria, vascular and soft tissue calcification, nephrolithiasis, prostate cancer, interactions with iron and zinc, and constipation. For vitamin D the indicators for excess intakes included intoxication and related hypercalcemia and hypercalcuria, serum calcium, measures in infants such as retarded

---

<sup>1</sup> The FNB was established in 1940 to study issues of national importance pertaining to the safety and adequacy of the nation's food supply, to establish principles and guidelines for adequate nutrition, and to render authoritative judgment on the relationships of food intake, nutrition, and health, at the request of various agencies.

For more food and nutrition information, please contact the U.S. Department of Agriculture's Food and Nutrition Information Center website at: [www.nal.usda.gov/fnic](http://www.nal.usda.gov/fnic)

© 2011 MUSCATATUCK PUBLISHERS, INC.  
P. O. Box 741261  
Boynton Beach, Florida 33474-1261  
866-664-2900

[www.natmedlaw.com](http://www.natmedlaw.com)

*Continued from page 1...*

growth and hypercalcemia, and emerging evidence for all-cause mortality, cancer, cardiovascular risk, falls and fractures.

One key challenge was what to do about vitamin D produced by sunlight. In the end, the committee proceeded to estimate vitamin D requirements under conditions of minimal sun exposure. Another key challenge was to try to understand the activated vitamin D's function as a hormone that is regulated by metabolic feedback loops. When vitamin D and calcium were used together in studies, this made it difficult to distinguish the health outcomes for one nutrient versus the other.

Dietary intake assessment by the committee found that median calcium intakes from food in both countries are close to EAR values with few exceptions. The assessment for vitamin D from foods in both countries for all life stage groups was below the EAR of 400 IU. The exceptions were noted in the summary and full report.

The final step in assessment of risk characterization that requires consideration of adiposity, living at upper latitudes in North America, people who have dark skin, use sun screen, or are in an indoor environment most of the time, alternative diets that exclude dairy, and dietary patterns of indigenous Canadian populations, the use of calcium supplements, oral contraceptive use, premature infants, and interactions of vitamin D with prescription drugs.

Many uncertainties were noted in the report, too numerous to list in this condensed summary. Serum 25-hydroxyvitamin D (25OHD) concentrations have been used to measure deficiencies of vitamin D as they reflect intake from diet and supplements. But the committee was concerned that 25OHD cut-points have not undergone a systematic evidence-based development process. Therefore the committee believes there is an overestimation of deficiency today. The committee believes people are at risk of deficiency at levels of 25OHD below 30 nmol/L (20ng/mL). Practically all people are sufficient at 50 nmol/L and those with 75 nmol/L levels are not associated with benefits.

The committee said there may be concerns for levels of 125 nmol/L. The lack of evidence-based consensus guidelines is problematic and of concern because individuals with serum 25OHD levels above 50 nmol/L (20ng/mL) may at times be classified as deficient and treated with high-dose supplements of vitamin D containing many times the levels of intake recommended by this report.

In closing the report stated, in part: "The data do not, however, provide compelling evidence that either nutrient is causally related to extra-skeletal health outcomes or that intakes greater than those established in the DRI process have benefits for health. The last chapter of this report specifies the research needs and reflects an urgent and worthwhile agenda. If carried out, this research will assist greatly in clarifying DRIs for vitamin D and calcium in the future."

Further, the committee stated in its concluding remarks in chapter 9: "The committee found that the greatest information gaps, and thus the most critical research needs, are related to the so-called hazard identification and hazard characterization steps in which the relationship between the nutrient and health outcomes are established. These needs for calcium and vitamin D DRI development relate to further exploring and describing both skeletal as well as non-skeletal health outcomes, long-term adverse effects of high levels of intake, and data to clarify the dose-response to intake. In the case of vitamin D, understanding the impact of sun exposure presents many challenges. Specific to the selected indicator (i.e., bone health), there is a need for more and better data related to the relatively unstudied life stage groups of children and young adults and the differences among racial/ethnic groups. Furthermore, the committee found a pressing public health need for development of consensus, science-based guidelines to establish cut-point levels for vitamin D deficiency and insufficiency."

---

The Report is still being corrected, but the Prepublication Copy can be downloaded at [www.nap.edu/catalog.php?record\\_id=13050](http://www.nap.edu/catalog.php?record_id=13050). There are various choices given.

The tables at S-6 and S-7 would contain the basic dosage recommendations for supplementation purposes.

The complete 482 page book and a PDF file of the book are priced at \$78.50 as prepublication combination.

Chapters can be downloaded for a fraction of the cost of the book. Or you can order the hardback now to be delivered later for \$53.96 from the National Academies Press.

© 2010 MUSCATATUCK PUBLISHERS, INC.

P. O. Box 741261

Boynton Beach, Florida 33474-1261

866-664-2900

[www.natmedlaw.com](http://www.natmedlaw.com)

## ASSOCIATION OF VITAMIN D AND BREAST CANCER

Joint effects of dietary vitamin D and sun exposure on breast cancer risk: results from the French E3N cohort by Pierre Engel, Guy Fagherazzi, Sylvie Mesrine, Marie-Christine Boutron-Ruault, and Francoise Clavel-Chapelon, *Cancer Epidemiol Biomarkers Prev* cebp.1039.2010; Published OnlineFirst December 2, 2010; doi:10.1158/1055-9965.EPI-10-1039

67,721 women of the French E3N cohort were evaluated on the association between vitamin D intake, mean daily Ultraviolet Radiation dose (UVRd) at the place of residence and the risk of breast cancer. After 10 years of follow-up, 2,871 cases of breast cancer were diagnosed. Dietary and supplemental vitamin D were not associated with breast cancer risk, but regions where the UVRd was highest, postmenopausal women with high vitamin D intake had significantly lower breast cancer risk when compared to women with the lowest vitamin D intake. These researchers concluded that there are threshold levels of sun and vitamin D that prevents breast cancer, but more research is needed to learn of the associations.

[Note - E3N is a prospective cohort study conducted in France on risk factors for female cancers. The cohort comprised 100,000 women, aged 40-65 years at baseline in 1990. Participants were asked to complete questionnaires every 18 months. The main hypotheses studied concern the relationship between diet and cancer and between hormonal treatments and cancer. All cancers diagnosed are registered, together with other diseases (cardiovascular diseases, diabetes, osteoporosis). *Eur J Cancer Prev.* 1997 Oct;6(5):473-8. – Ed.]

## VITAMIN D DEFICIENCY AND COGNITIVE DECLINE

In this study collaborators found 752 women 75 or older from the Epidémiologie de l'Ostéoporose (EPIDOS) cohort, and divided them into 2 groups according to serum 25(OH)D concentrations (either deficient, <10 ng/mL, or nondeficient, ≥10 ng/mL). The Pfeiffer Short Portable Mental State Questionnaire (SPMSQ) score greater than 8 was used to define cognitive impairment. The women with deficient serum 25(OH)D had a lower SPMSQ score, but this was not a linear association. "However, serum 25(OH)D deficiency was associated with cognitive impairment (crude odds

ratio [OR] = 2.08 with  $p = 0.007$ ; adjusted OR = 1.99 with  $p = 0.017$  for full model; and adjusted OR = 2.03 with  $p = 0.012$  for stepwise backward model)." So the conclusion was made that vitamin D deficiency was associated with cognitive decline in this particular group.

*Neurology*, Volume 74, Issue 1, Pages 27 – 32, doi: 10.1212/WNL.0b013e3181fd6352, "Association of vitamin D deficiency with cognitive impairment in older women: Cross-sectional study" by C. Annweiler, A.M. Schott, G. Allali, S.A. Bridenbaugh, R.W. Kressig, P. Allain, F. R. Herrmann, O. Beauchet from the Department of Internal Medicine and Geriatrics (C.A., O.B.) and Neuropsychological Unit, Department of Neurology (P.A.), Angers University Hospital; UPRES EA 2646, University of Angers, UNAM, France; Department of Medical Information (A.M.S.), Lyon University Hospital, France; Departments of Neurology (G.A.) and of Rehabilitation and Geriatrics (F.R.H.), Geneva University Hospitals and University of Geneva, Switzerland; and Department of Acute Geriatrics (S.A.B., R.W.K.), Basel University Hospital and University of Basel, Switzerland.

[Note – How the levels of serum concentrations compare to the Food and Nutrition Board's recommendations in the just released report. FNB opined that Vitamin D deficiency was less than 20 ng/mL (30 nmol/L) whereas the above study divided the deficiency level at 10 ng.mL. – Ed.]

## VITAMIN D KNOWLEDGE

These researchers say that the sun is the main source of vitamin D but knowledge of sun protection and exposure practices was confused among office workers in Brisbane, Australia. Only 69 % of 1971 participants had heard of vitamin D. Eighteen percent were unaware of the bone benefits of vitamin D. There was some confusion about sun exposure and vitamin D which might lead to reduced use of sun protection.

Knowledge and Attitudes about Vitamin D and Impact on Sun Protection Practices among Urban Office Workers in Brisbane, Australia by Lan H. Vu, Jolieke C. van der Pols, David C. Whiteman, Michael G. Kimlin, and Rachel E. Neale, *Cancer Epidemiol Biomarkers Prev* July 2010 19:1784-1789; Published OnlineFirst June 22, 2010; doi:10.1158/1055-9965.EPI-10-0127

## VITAMIN A PREVENTS DEATH IN CHILDREN

Vitamin A Supplementation (VAS) is effective in reducing all-cause mortality by about 24% compared to no treatment. In our opinion, given the evidence that VAS causes considerable reduction in child mortality, further placebo-controlled trials of VAS in children between 6 months and 5 years of age are not required. There is a need for further studies comparing different doses and delivery mechanisms (for example, fortification).

Imdad A, Herzer K, Mayo-Wilson E, Yakoob MY, Bhutta ZA. *Vitamin A supplementation for preventing morbidity and mortality in children from 6 months to 5 years of age*. Cochrane Database of Systematic Reviews 2010, Issue 12. Art. No.: CD008524. DOI: 10.1002/14651858.CD008524.pub2

The use of vitamin A in young children could save 1 million lives per year since 190 million children get childhood diseases and vitamin A reduces death and morbidity by 25 percent in a large number of studies already completed. Large doses of vitamin A could cause vomiting.

Source: <http://www2.cochrane.org/reviews/en/ab008524.html>

---

## BIG PHARMA MAY HAVE A SAY IN VITAMIN D REPORT

In early December 2010, the Alliance for Natural Health USA issued a news release concerning the influence of big pharmaceutical companies on the outcome of the Institute of Medicine's Food and Nutrition Board's report on vitamin D and calcium.

The ANH asks the public to sign a petition to Congress to investigate what happened during the deliberations on vitamin D. First, there was an accusation that pharmaceutical companies are researching an analog of vitamin D for a prescription medication and that this caused them to hold down the recommendations for increased vitamin D usage in the FNB report. ANH says the FNB recommendations "fly in the face of scientific evidence." Second, ANH says that Americans could save \$1,346 per year properly utilizing vitamin D and this would amount to \$4.4 trillion over a decade.

Although the vitamin D levels were raised 300%, this was insufficient according to ANH. Harvard Medical School and others recommend as much as 5,000 IUs per day, way above the

FNB recommendations. The FNB recommends 600 IU per day for people between 1 and 70 years of age.

Fourthly, ANH says that the FNB wants to reduce the amount of vitamin D considered to be deficient, thus altering the need for vitamin D. "(The IOM suggests the new standard should be changed to 20 ng/ml, whereas previously anything under 30 ng/ml was considered deficient. The Vitamin D Council recommends between 50 and 80 ng/ml.)" Fifthly, ANH says that vitamin D is being held to the higher standard for pharmaceuticals requiring randomized clinical trial evidence for any claims.

Sixth, the ANH says that the Vitamin D Council states that fifteen vitamin D experts, like Prof. Robert Heaney at Creighton University or, as in the case of Professor Walter Willett at Harvard, reported to the FNB what they thought of the FNB report and FNB suppressed every one of those reports. ANH has filed a Freedom of Information request for the experts' responses.

Finally, for now, ANH says that "[t]here is, unfortunately, a hidden agenda afoot. A pharmaceutical company [10] is developing a patentable man-made vitamin D analog—yes, a synthetic drug version of vitamin D. And Glenville Jones, PhD, one of the committee members who determined the new vitamin D guidelines and who is quoted as saying that under these guidelines, most people 'probably don't have vitamin D deficiency [11]' and 'We think there has been an exaggeration of the public's interest in vitamin D deficiency,' is an advisor for that same pharmaceutical company [12]." The company's website was listed as [www.cytochroma.com](http://www.cytochroma.com).

ANH calls on Congress appoint a new scientific committee to review all of the available evidence to see if there are health benefits, other than for bone health, including the 15 reports the FNB received from experts. ANH says that the General Accountability Office is empowered to investigate this study since the Institute of Medicine and FNB gets over 80% of its money from the Federal government. The GAO to conduct an investigation into why the news management for the FNB report caused so many news organizations to report vitamin D as a danger while the amounts recommended were raised.

Read more at: [www.anh-usa.org/action-alert-is-the-institute-of-medicine-in-bed-with-big-pharma](http://www.anh-usa.org/action-alert-is-the-institute-of-medicine-in-bed-with-big-pharma).

© 2010 MUSCATATUCK PUBLISHERS, INC.  
P. O. Box 741261  
Boynton Beach, Florida 33474-1261  
866-664-2900

[www.natmedlaw.com](http://www.natmedlaw.com)