USPSTF – Comment Form Questions and Answers Vitamin D and Calcium Supplementation to Prevent Cancer and Osteoporotic Fractures in Adults

submissions made by Pramod Vora <u>spaceage2008@space-age.com</u> on Monday July 09, 2012 at 9:13 am

http://www.uspreventiveservicestaskforcecomments.org/comments.aspx?dno=VjFFNER UT2dYTUEIM2Q\$

Q. How could the USPSTF make this draft Recommendation Statement clearer?

A. There seems to be some ambiguity in the statement regarding the dose of vitamin D and calcium which is "associated with a small but significantly increased likelihood of developing painful kidney stones".

If 400 IUs of vitamin D and 1000 mg of calcium "is associated with a small but significantly increased likelihood of developing painful kidney stones", it is also evident that 800 IUs of vitamin D and 1200 mg of calcium are going to increase this risk. If some thing is harmful at a particular dose, it logically follows that, it will become more harmful at a higher dose.

Particular care should be taken to remove this ambiguity in wording in your draft to avoid misleading ideas on dosage. If 1000 mg of calcium has already been determined to be detrimental to the health of the human body, how could this dose be "low"? It must he "high" enough to cause injury. I suggest that "low dose" be edited to "high dose" in this draft.

Again, if <400 IUs of vitamin D and <1000 mg of calcium is found harmful for the human body (in terms of increased risk for formation of kidney stones), why is it so difficult for the USPSTF to clearly say that at still higher doses >400 IUs for vitamin D and >1000 mg for calcium the risk will naturally be higher? Why is the USPSTF not able to clearly say it will therefore not recommend >400 Ius of vitamin D and >1000 mg of calcium and give these higher doses a clear "Grade D – Not recommended"?

I have researched the meta-analysis supporting these findings. Nowhere do I see any data published regarding the serum levels of vitamin D and calcium to justify the long term usage of higher levels of supplementation. Also, there isn't any reference as to at what doses were safe serum values encountered which did not exceed the standard references ranges as per the standards laid out in Harrison's <u>Principles of Internal Medicine</u>.

This particular information is essential because vitamin D can be highly toxic at certain doses. Once vitamin D levels exceed the normal limits in the human body, it is very difficult to bring these levels down since vitamin D is stored in body fat. It takes months and sometimes a whole year or more to bring these levels back to normal once they have exceeded the safe limits.

Elsewhere on this comment form, I have included a small refresher course in vitamin D, from a standard undergraduate textbook of nutrition, along with my commentary to amplify and clarify certain points in connection with the USPSTF draft statement. From this study it will be clear that it has been known for decades, and even a part of standard undergraduate textbooks on nutrition, that vitamin D toxicity causes kidney stones. So the "findings" of USPSTF are not new. The author goes on later to say it also causes calcification of arteries, heart valves, etc. Again, these are not new findings.

Q. What information, if any, did you expect to find in this draft Recommendation Statement that was not included?

A. Informing people about the withdrawal of the NIH's support with regards to the use of 1200 mg of calcium for adults as a safe dose, as published in the consensus on calcium in June 1994 and in the consensus on osteoporosis in March 2000.

The links to these are:

http://consensus.nih.gov/1994/1994OptimalCalcium097html.htm and http://consensus.nih.gov/2000/2000Osteoporosis111html.htm

The NIH's removal of support to both these consensuses has been longstanding. Yet there is no public awareness about this important change in thinking at the NIH, even though more than five years has elapsed since this shift in thinking occurred. There is a remark in bold red on the above links saying:

"This statement is more than five years old and is provided solely for historical purposes. Due to the cumulative nature of medical research, new knowledge has inevitably accumulated in this subject area in the time since the statement was initially prepared. Thus some of the material is likely to be out of date, and at worst simply wrong."

I am sure many are still not aware of this dynamic change in thinking and many of our health practitioners worldwide are continuing to blindly prescribe calcium supplements containing carbonates (e.g. chalk) for the prevention of osteoporosis.

Furthermore, your draft fails to mention that many other nutrients (magnesium, zinc, boron, manganese, copper, phosphorus, vitamin C, D, K, etc.) are required in a synergistic manner for bone building in addition to calcium. In addition, calcium taken in isolation of other supporting nutrients for prolonged periods is also toxic to the human body.

All around us we see toxicity of calcium, in the form of calcified arteries / heart valves, stents and bypass surgeries, heel spurs, osteophytes, etc.

It has been long known and is also a part of every nutrition textbook for undergraduate studies that vitamin D is highly toxic at higher doses; and that prolonged use of even low doses without proper and periodic monitoring of serum levels can be toxic.

Since the USPSTF Draft Recommendation Statement does not recommend healthy people to take calcium and vitamin D for the prevention of osteoporosis, because it is found detrimental of the health of the people, it does not go further to explain what they need to do to prevent osteoporosis and fractures or what other supplements are recommended. The present draft leaves the consumer totally confused and directionless.

The long history of high dose calcium supplementation has been very well brought out by Ms. Melinda Beck in the Wall Street Journal article: "Dutifully Taking Your Calcium Pill? It May Be Too Much". The links are:

http://online.wsj.com/article/SB10001424052702304708604577502660615577758.html and http://online.wsj.com/search/term.html?KEYWORDS=calcium%20video&mod=DNH_S

Also, we still have places where much higher doses of calcium and vitamin D supplements are recommended as safe, such as the Institute of Medicine (IOM); where 2000 mg of calcium and 4000 IUs of Vitamin D supplements are considered as safe!

The USPSTF Draft also fails to recommend a corrective course of health care for the millions of people who took high dose calcium supplements during the last few decades or who continued daily drinking large amounts of milk (up to 3 glasses per day), because it is a rich source of calcium, well after reaching adulthood, when the body stopped growing.

I propose to answer the above issues in the following comments.

Q. Based on the evidence presented in this draft Recommendation Statement, do you believe that the USPSTF came to the right conclusions? Please provide additional evidence or viewpoints that you think should have been considered.

A. The USPSTF is moving in the right direction. However, the USPSTF needs to give a more complete picture about calcium, osteoporosis, and the methods for reducing the risk of fractures.

It is also important to convey that the calcification of arteries, heart valves, heel spurs, and osteophytes are also deposits due to calcium toxicities in the body. Such deposits need not necessarily come from calcium supplementation. Deposits can also come from prolonged use of large quantities of dairy products rich in calcium and other foods fortified with calcium, especially if taken for prolonged periods after adulthood, when the body stops growing.

The presence of calcium oxalate crystals in an urine report is the first indication that too much calcium is being put into the body.

The problem with all these NIH doses and now USPSTF doses is they talk about calcium carbonate (chalk), something which is not easily absorbed or retained in the human body, and hence has to be excreted. So it is less than ideal to take carbonates as it will increase the load on the kidneys. In addition, carbonates neutralize the hydrochloric acid in the stomach which results in poor digestion and decreased nutrition to the body. Organic compounds of calcium like gluconates, lactates, and citrates are preferred as they do not deplete hydrochloric acid and do not result in "gastrointestinal intolerance to calcium".

This does not mean that I am recommending the use of calcium in isolation of numerous other supporting nutrients (such as magnesium, zinc, boron, manganese, copper, phosphorus, vitamin C, D, K, etc.) for increasing bone density or preventing fractures. I also haven't understood why this old standard of "calcium carbonate / chalk", which was used for prophylactic doses way back in World War I, is still being pursued for use as therapeutic doses for the investigation of the reversal of osteoporosis and to increase bone density. Organic compounds of calcium are ideal as therapeutic doses (to be given only when found necessary) as they do not increase the load on the kidneys or cause depletion of hydrochloric acid in the stomach and have a far better rate of absorption and retention in the body.

Basically, you need just a few milligrams of organic calcium each day to maintain good bone health, provided all other essential nutrients (such as magnesium, zinc, boron, manganese, copper, phosphorus, vitamin C, D, K, etc.) are also present to support bone building. This calcium comes from the diet for most people. Osteoporosis develops when some other critical ingredient(s) is/are missing from the diet or body. The missing ingredient is normally not calcium.

We now live in a calcium toxic society with calcified arteries / heart valves, kidney stones, stents and bypass surgeries. The number of people with such problems strongly

suggests that we have too many undiagnosed cases of calcium toxicity. The USPSTF has the capacity to reduce the gap between medicine and nutrition by rising to the challenge and making sure that informed nutritional experts are a part of the policy making process.

When I look at the credentials of the USPSTF members involved in the decision making process, I see that the majority are all MDs, some RNs, but no Ph.D.s or D.Sc.s in Nutrition. The United States has many such fine persons who will be able to guide not only the United States but the entire world better. The time has come to have equal representation of medical experts and nutritional experts in health care. Please add a dozen or more names of Ph.D.s specializing in nutrition to this committee. It is better to delay this project by a few more weeks and do it well, than to rush through only to revise it a few months later.

Q. What resources or tools could the USPSTF provide that would make this Recommendation Statement more useful to you in its final form?

Please provide the following extract taken from a textbook on nutrition and my commentaries in support of your draft recommendations: (with my parenthetical commentary in italics where I found the need to amplify and clarify)

Murray, Michael T. <u>Encyclopedia of Nutritional Supplements</u>. Roseville: Prima Publishing, 1996. ISBN 0-7615-0410-9

Pages 159 – 163

Magnesium Deficiency Signs and Symptoms

"Magnesium deficiency is extremely common in Americans, particularly in geriatric population and in women during the premenstrual period. Deficiency is often secondary to factors that reduce absorption or increase secretion of magnesium, such as high calcium intake, alcohol, surgery, diuretics, liver disease, kidney disease, and oral contraceptive use."

(Note- The words "extremely common" and "magnesium deficiency" is a direct result of high calcium intake. Excessive calcium intake is a prevalent health issue in our society since a very long time. This was known to nutritional scientist since a few decades).

"Low levels of magnesium in the diet and in our bodies increases susceptibility to a variety of disease, including heart disease, high blood pressure, kidney stones, cancer, insomnia, PMS, and menstrual cramps. Signs and symptoms of magnesium deficiency are fatigue, mental confusion, irritability, weakness, heart disturbances, problems in nerve conduction and muscle contraction, muscle cramps, loss of appetite, insomnia, and predisposition to stress."

(It is important to note here the potential risk associated with low levels of magnesium in the form of increased susceptibility to kidney stones and various cardiac diseases, such as hypertension).

"Low magnesium levels are common in the elderly, but most cases go unnoticed because most physicians rely on serum magnesium levels to indicate magnesium levels. Most of the body's magnesium store lies within cells, however, not in the serum (noncellular portion of blood). A low magnesium level in the serum reflects end-stage deficiency. A more sensitive test of magnesium status is the level of magnesium within the red blood cell (erythrocyte magnesium level)."

(The concept conveyed here is that the serum tests doctors normally rely on contributes to an undiagnosed magnesium deficiency).

"Some of the conditions associated with or causing magnesium deficiency are acute pancreatitis, congestive heart failure, and increased magnesium loss through the kidneys."

(Congestive heart failure is due to a case of serious magnesium deficiency. Mostly, it is an end stage deficiency as referenced in an earlier paragraph. An end stage deficiency is usually one in which it is too late to remedy the condition. Magnesium shots are usually administered in the ICU as a last resort).

Principal Uses

"Magnesium supplementation is effective treatment for a large number of health conditions. $^{\rm 1}$

"Oral magnesium therapy is an effective measure to raise body magnesium stores. It usually takes 6 weeks to achieve significant elevations in tissue magnesium concentrations."

"These are some conditions which benefit from magnesium supplementation: cardiovascular disease, asthma and chronic obstructive pulmonary disease, high blood pressure, acute myocardial infarction, stroke, cardiac arrhythmias, congestive heart failure, cardiomyopathy, diabetes and osteoporosis."

(Magnesium is used to treat osteoporosis, a large number of heart conditions including high blood pressure and even type 2 diabetes).

References:

1. Gullestad L, et al., "Oral versus intravenous magnesium supplementation in patients with magnesium deficiency." <u>Magnes Trace Elem</u> 10 (1991) 11-16.

Q. This draft Recommendation Statement includes a graphic to depict the USPSTF's statements on using vitamin D for prevention. Do you find this graphic helpful? How can it be improved?

A. It should mention that high dose vitamin D taken over a prolonged period is highly toxic to the human body. Once you exceed the normal limits it is difficult to remove this excess from the human body.

Excessive vitamin D causes calcium to deposit in various organs / tissues of the body and can also lead to to the formation of kidney stones, calcification of arteries / heart valves, heel spurs, osteophytes, etc.

Prolonged use of vitamin D can result in toxicity, body aches and pains, and can mimic the symptoms of osteoporosis.

Try to maintain your Vitamin D3 levels around 40 ng/mL. Above 80 ng/mL may be toxic. Ref: Harrison's Principals of Internal Medicine, 12th Edition, Pages 1892 to 1901.

The above notes should form a very essential and important part of the graphic depiction.

Please provide the following extract taken from a textbook on nutrition and my commentaries in support of your draft recommendations: (with my parenthetical commentary in italics where I found the need to amplify and clarify)

Murray, Michael T. <u>Encyclopedia of Nutritional Supplements</u>. Roseville: Prima Publishing, 1996. ISBN 0-7615-0410-9

Pages 42 and 43.

"Principal Uses of Vitamin D The principal use of vitamin D is the prevention of vitamin D deficiency."

(It is important to note that the author doesn't say that vitamin D is used for the treatment of osteoporosis, cancer or any other disease)

"Dosage Ranges

The RDA for vitamin D is 200 to 400 I.U. daily. For elderly people not exposed to sunlight for living in the northern latitudes, a daily intake of 400 to 800 I.U. is recommended. Supplementation greater than 400 I.U. per day in most adults, young children, and adolescents, is unwarranted."

(The author refers to doses higher than 400 IUs for most adults as "unwarranted". He discloses below that vitamin D is highly toxic to the human body)

"Safety Issues

Vitamin D has the greatest potential among all the vitamins to cause toxicity. Dosages greater than 1,000 I.U. per day are certainly not recommended. Increased blood concentration of calcium (a potentially serious situation), deposition of calcium into internal organs, and kidney stones are some of the characteristics of vitamin D toxicity."

(Note the words "greatest potential" to cause toxicity. This means highly toxic. It has been known for decades, and even a part of standard undergraduate textbooks on nutrition, that vitamin D toxicity causes kidney stones. So the "findings" of USPSTF are not new. The author goes on later to say it also causes calcification of arteries, heart valves, etc. Again, these are not new findings).

"Many researchers suggest that long-term over consumption of vitamin D in fortified foods contributes to atherosclerosis and heart disease, possibly as a result of decreasing magnesium absorption."²

(Note the author stresses on the risk of excessive vitamin D reducing absorption of magnesium. The author indirectly indicates that magnesium is very important and not to do anything to reduce its levels in the body).

"References:

2. Seelig MS, Magnesium deficiency with phosphate and vitamin D excess: Role in pediatric cardiovascular nutrition. <u>Cardio Med</u> 3(1978), 637-650"

It is important that the knowledge (available in standard textbooks) be brought to the attention of health practitioners and consumers so that a safe and healthy lifestyle can be maintained.

High dose vitamin D therapy for cancer should no longer be attempted. Since vitamin D is known as a highly toxic substance, (note the words "greatest potential to cause toxicity"), there is no sense in doing research at many higher IUs of vitamin D in a bid to find out a "magical dose" at which cancer can be treated. The basic tenet of medicine is that the "doctor will do no harm to the patients' body".

Q. The USPSTF is committed to understanding the needs and perspectives of the public it serves. Please share any experiences that you think could further inform the USPSTF on this draft Recommendation Statement.

A. For an update on calcium please go through the discussion on LinkedIn under "Calcium From Food" in the Nutrition Group. Here you will find a lot more information and the opinion of various people from the nutritional field. The link is:

http://www.linkedin.com/groups/Calcium-From-Food-4513679.S.130677237?qid=af8b285f-338d-4280-980e-52055c78e0bc&trk=group_most_popular-0-bttl&goback=.nmp_*1_*1_*1_*1_*1_*1_*1_*1_*1_smp_4513679

or this entire transcript can also be download from: <u>http://www.space-age.com/CalciumFromFood.doc</u>

I am providing below the link to various articles I have written during the last decade on the evolving subjects of calcium & osteoporosis. The link for all this information is: http://www.space-age.com/osteoporosis.html

The articles of interest are:

http://www.space-age.com/calcium_osteoporosis.doc and http://www.space-age.com/Osteoporosis2007.doc

Here you will also find a case study where we increased bone mineral density by 39% over a twenty-two month period by administering magnesium and stopping the calcium supplementation, which was administered for 3 prior years with continued deterioration of bone density during that period. Thereafter, the patient was successfully taken from serious osteoporosis to a not so serious osteopenia. The T-Score changed from -3.1 to - 1.75 i.e. 43% increase in a 22 month period. Please refer to the case study given at: http://www.space-age.com/BMD01.doc

This was done by giving magnesium supplementation along with other essential nutrients in a synergistic manner, without any calcium supplementation. The information in this case study is vital to the USPSTF draft.

In one of my articles I write:

" Gone are the days, when calcium deficiency used to cause osteoporosis / fractures. Today, we need to preach that magnesium deficiency causes osteoporosis and fractures." The importance of magnesium supplementation with other supporting nutrients needs to be brought out in your draft as it is very relevant to the topic of osteoporotic fractures. Your draft is silent on this. The importance of magnesium to treat osteoporosis and reduce calcium toxicity has already been a part of undergraduate nutritional textbooks for the past few decades.

We also need to give a solution to those people who are presently suffering from calcium toxicity to consider the use of magnesium to remove the calcium deposits in their bodies. Magnesium, known as an antagonist to calcium, is a safe way to remove excess calcium deposits in the body. Magnesium deficiency is quite common today.

Reproduced below is an extract taken from: (with my parenthetical commentary in italics where I found the need to amplify and clarify)

Werbach, Melvyn R., M.D., Assistant Clinical Professor, UCLA School of Medicine, Los Angeles, CA, <u>Textbook of Nutritional Medicine</u>. Third Line Press, Inc., 1999. ISBN 0-9618550-9-6

Pages 38 to 39 Magnesium

"Chronic primary magnesium deficit, which is estimated to be present in 15 to 20 % of the population, is the most common form of magnesium deficiency.³ (*Durlach*)"

(Durlach's estimate of chronic primary magnesium deficit was published in 1994. Today, this estimate is much higher. My estimate, based on thousands of blood reports seen in the last decade, is that more than 60% of the population today has very severe magnesium deficiency by the age of 50, which is further confirmed by manifestation of symptoms of hypertension. This percentage goes up to 75% as the by the age of 75 years, which is further confirmed by the manifestation of type 2 diabetes and hypertension symptoms. This is due to over cultivation of the land and the use of synthetic fertilizers. The soil is totally depleted of minerals. There are figures on the "shrinking values of nutrition" released by USDA to validate this).

References:

3. Durlach J et al. Magnesium and therapeutics. Magnes Res 7(3-4):313-28, 1994

Q. Do you have other comments on this draft Recommendation Statement?

A. Please involve more experts in nutrition in to your decision making process. I would like to recommend the name of Professor Michael J. Gonzalez, Ph.D., D.Sc. at the the University of Puerto Rico, Medical Sciences Campus. He is a Professor of Nutrition and has authored over 130 scientific publications.

Three other names of gurus of nutrition come to my mind whose textbooks I have read and referred to:

1. Michael T. Murray, N.D. - who wrote the book Encyclopedia of Nutritional Supplements 1996 ISBN 0-7615-0410-9

2. Melvyn R. Werbach, M.D. - Textbook of Nutritional Medicine 1999ISBN 0-9618550-9-6He was Assistant Clinical Professor at UCLA, School of Medicine, Los Angeles, CA

3. James F. Balch, M.D. - Prescription for Nutritional Healing 3rd Edition, 2000, ISBN 1-58333-077-1

All the above experts in nutrition have done considerable work in the field of nutrition and have published many research papers and textbooks on this subject.

Perhaps we can motivate them to actively take part in the decision making process on your committee and contribute to the USPSTF Draft by incorporating more accurate, relevant and updated information on nutrition.

Presently there exists a great divide between medicine and nutrition, which is affecting the health of people worldwide. Allopathy has it own merits, as it can saves the lives of people. But preventive health care has it own merits as well, as it can prevent a disease from manifesting itself. It is said: "An ounce of prevention is worth a pound of cure". Preventive health care is the need of the hour. Why not train people "not to start fires", (to prevent diseases), rather than only train them in "putting out fires" (treating diseases)?

A great responsibility rests on the shoulders of the USPSTF to bring down the great divide between present day medicine and preventive health care based on nutrition. As world leaders in medicine, the United States should lead by setting an example for the rest of the world to follow.

The USPSTF should prevail upon other bodies to uniformly change their standards on calcium, vitamin D and other nutrients so that the consumer is not confused, left directionless and disillusioned with government body recommendations and repeated and periodic contradictions. I would like to see some uniformity in the National Institute of Health (NIH), Institute of Medicine (IOM), and National Health Information Center (NHIC), healthfinder.gov, and other organizations.

Some of the links with calcium and vitamin D information are: <u>http://healthfinder.gov/prevention/PrintTopic.aspx?topicID=40&catId=</u>

http://ods.od.nih.gov/factsheets/Calcium-HealthProfessional/#h3

http://www.iofbonehealth.org/bonehealth/calcium-calculator-1

http://www.bestbonesforever.gov/parents/foods/food_label.cfm

http://ods.od.nih.gov/factsheets/VitaminD-QuickFacts/#h2

http://www.nichd.nih.gov/milk/kids/kidsteens.cfm

http://www.bestbonesforever.gov/parents/recipes/index.cfm

http://www.nhic.org

At all these places there should be some uniformity of information.

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Your comments for Vitamin D and Calcium Supplementation to Prevent Cancer and Osteoporotic Fractures in Adults have been submitted successfully!

All comments will be considered as the USPSTF finalizes the document. Currently the USPSTF cannot provide responses to individual comments.

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