

VITAMIN D SUPPLEMENTATION IS REQUIRED DURING THE WINTER TO OBTAIN OPTIMAL VITAMIN D STATUS

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INTRODUCTION

Vitamin D is unique in that not only is very little obtained through a normal diet, but the principal source of serum vitamin D is endogenous production in the skin upon exposure to the UVB (290-315nm) portion of the solar spectrum⁽¹⁾. Thus, factors that limit sun exposure and/or endogenous vitamin D synthesis greatly reduce serum 25-hydroxyvitamin D (25(OH)D) concentrations. Some of these limiting factors include geographic latitude, season of the year, melanin content of the skin, use of sunscreen or sun obscuring clothing, and lack of outdoor activity. Obesity, diet, and age can further limit serum vitamin D levels⁽²⁻⁷⁾. Any of these factors, among others, can lead to chronic vitamin D deficiency.

Deficiencies of vitamin D are common. It is currently estimated that more than 1 billion people worldwide and 30 to 40% of the population between 15 and 49 years of age in the United States suffer from vitamin D deficiency⁽⁸⁻⁹⁾. Additionally, the "Vitamin D Winter" occurs from approximately November until March at latitudes greater than 35-37° north⁽¹⁾. During this time, the wavelength of light required to synthesize vitamin D is filtered out due to the change in incident angle of sunlight resulting from seasonal tilting of the earth. Thus, for people living in the affected region, sun exposure is not sufficient to produce adequate levels of vitamin D during the winter months. Moreover, for most of the U.S. population, our modern lifestyles keep us out of the sun during the prime vitamin D-producing hours, even in the most southern latitudes.

While typical medical guidelines have advised that serum levels over 30ng/mL are adequate, scientific evidence is building that an optimal level may be significantly higher⁽⁸⁻¹¹⁾. Thus, a healthy target range for most people would be at least 40-60ng/mL. Because relatively small amounts of vitamin D are obtained through the diet and so many lifestyle factors reduce endogenous vitamin D synthesis, supplementation is critical to achieve and maintain an optimal vitamin D status, particularly during the winter. However, the daily dose of vitamin D required to achieve specific serum levels of vitamin D, in the background of other lifestyle characteristics, remain in question.

The purpose of this study was three-fold: 1. To determine if USANA Associates/Customers have, on average, higher serum vitamin D levels than the general public. 2. To correlate serum vitamin D levels to factors known to influence vitamin D status. 3. To determine optimal supplemental dose at the end of winter when vitamin D levels are traditionally the lowest.

MATERIALS AND METHODS

This was a retrospective, cross-sectional, cohort study involving 411 healthy volunteers from across the United States. The experimental group consisted of 231 active USANA Associates/Customers who regularly (daily) consumed the USANA Essentials, My HealthPak, HealthPak, and/or USANA's Vitamin D product for at least two consecutive months prior to the start of their enrollment. Each Associate/Customer was asked to recruit one "Guest" of similar physical characteristics who had not used any USANA products containing vitamin D for at least the previous two consecutive months (however, all other supplementation, with or without vitamin D, was allowed). Of the recruited Guests, 180 completed the study (see Table 1 for Subject Characteristics). Subjects were screened for, and excluded, if they had vacationed in a sunny location or used a tanning bed in the previous two months or reported taking prescription vitamin D medication(s).

The study consisted of two parts: 1. A requisition was initiated by Private MD Labs and blood drawn and analyzed at a LabCorp facility located in the United States. The blood test was administered between February 1st, 2010 and April 30th, 2010. 2. The blood test was followed by an online survey which captured parameters known to affect vitamin D status. These included: gender, ethnicity, height, weight, age, geographic location, duration of daily sun exposure, use of sunscreen and sun-obscuring clothing, dietary intake, and supplement usage. Additional parameters such as latitude and BMI were calculated from the responses. These data were statistically correlated with serum vitamin D levels to determine the impact of each factor on vitamin D status.

Since self-reporting is subject to inaccuracies, 90 subjects were contacted directly by phone to verify survey responses. Forty were chosen at random, and 50 due to perceived errors on their survey. The follow-up responses chosen at random were not significantly different from the original online survey responses (p>0.05). The 50 follow-up responses identified as potentially erroneous, were corrected if an error was identified by the phone screener.

RESULTS

- **USANA Associates/Customers who regularly use USANA nutritionals have a significant 64% higher serum vitamin D level than their Guests (p<0.001; Figure 2).**
- **There were nearly 6 times as many USANA Associates/Customers with vitamin D levels in the healthy target range (40-60ng/mL) compared to Guests (Figure 3).**
- **The most significant predictors of vitamin D status were found to be Supplementation and Body Mass Index (BMI) or Weight (p<0.001; Table 2). Dietary Intake and Skin Color were also significant (P<0.05; Table 2).**
- **During the winter, a healthy serum vitamin D concentration of 40-60ng/mL could theoretically be achieved and maintained by supplementing with approximately 5000 IU's of vitamin D per day (Figure 1).**

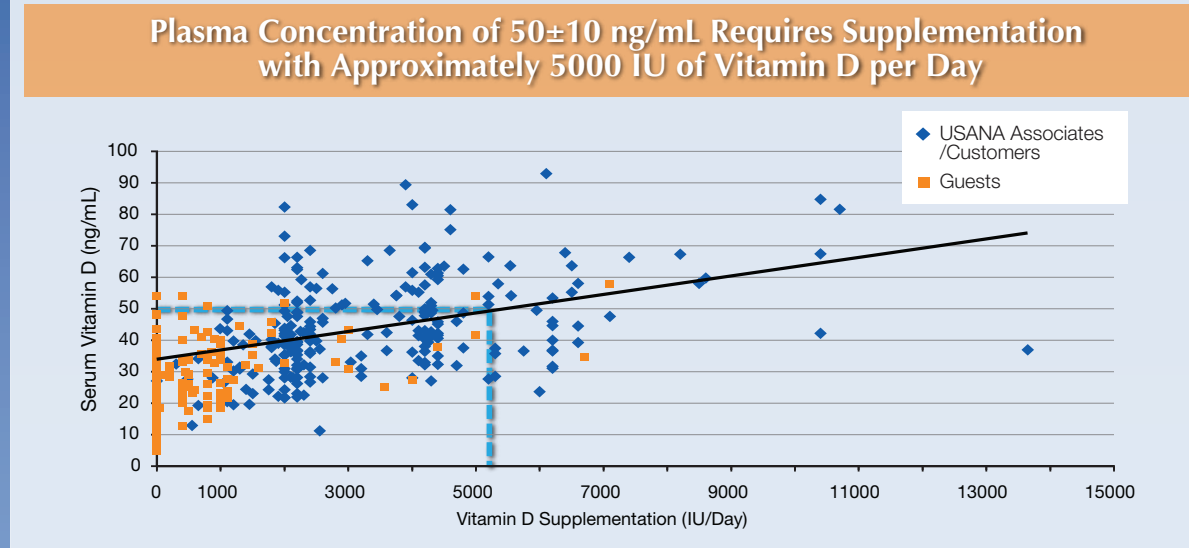


Figure 1. Linear regression analysis of supplemental vitamin D intake versus serum concentration (solid line). On average, supplementation with 5000IU/day results in a serum concentration of 50±10 ng/mL (40-60 ng/mL).

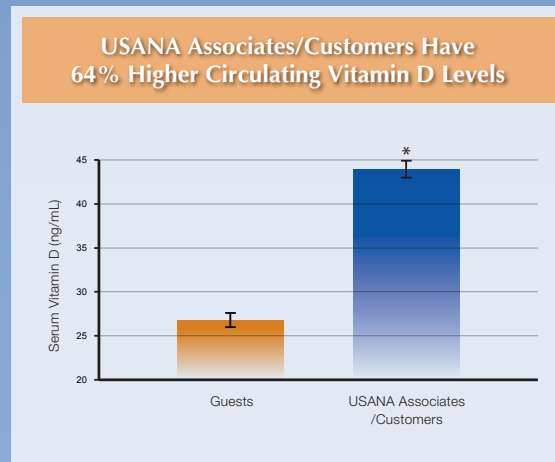


Figure 2. Average serum vitamin D concentrations in USANA Associates / Customers (44.0 ng/mL) versus Guests (26.8 ng/mL). Data represents mean +/- SEM. Asterisks (*) denotes statistical significance (p<0.001).

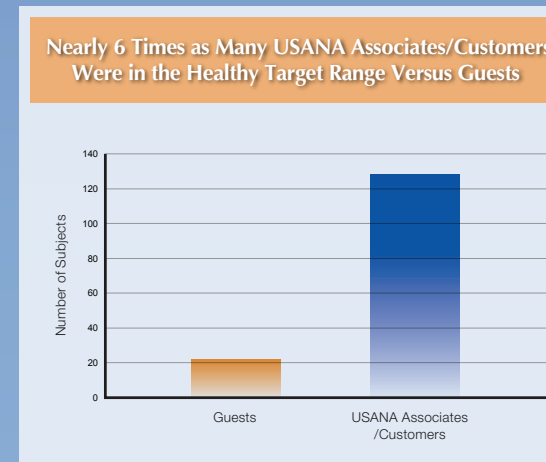


Figure 3. Total number of subjects with serum vitamin D levels >40ng/mL.

TABLE 1. SUBJECT CHARACTERISTICS

	# of Subjects	Gender M/F	Mean Age (Years)	Skin Color*	Ethnicity**	BMI	Average Serum Vitamin D Concentration (ng/mL)	Average Vitamin D Intake (IU/Day)
USANA Associates \ Customers	231	69/162	40-49	(70 F) (5 D) (124 L) (32 O/B)	(5 Af) (8 As) (208 Ca) (7 Hi) (3 O)	25.7 ± 6	44.0 ± 15	3408.4 ± 2020
Guests	180	45/135	40-49	(54 F) (5 D) (88 L) (33 O/B)	(5 Af) (5 As) (154 Ca) (13 Hi) (3 O)	26.3 ± 6	26.8 ± 11	555.4 ± 1126

* F= Fair Skinned, L= Light Skinned, O/B= Olive / Brown Skinned, D= Dark Skinned ** Af= African American, As= Asian, Ca= Caucasian, Hi= Hispanic, O= Other

CONCLUSIONS/DISCUSSION

The purpose of this study was three-fold: 1. To determine if USANA Associates/Customers have, on average, higher serum vitamin D levels than the general public. 2. To correlate serum vitamin D levels to factors known to influence vitamin D status. 3. To determine optimal supplemental dose at the end of winter when vitamin D levels are traditionally the lowest. Our results show supplementation to be one of the most significant affectors of serum vitamin D levels, (p<0.001; Table 2) indicating that supplementation with advanced levels of vitamin D is necessary to ensure optimal vitamin D levels are achieved. BMI and Weight were also found to have a highly significant correlation with vitamin D levels (p<0.001; Table 2). This data shows that the larger the individual, as measured by either BMI or Weight, the lower their vitamin D status. This is likely because vitamin D is a fat soluble nutrient, and has been shown to be absorbed and sequestered in fat deposits thereby removing it from circulation. These data indicate that larger individuals may need to supplement with higher doses of vitamin D to achieve desired serum levels. Dietary Intake and Skin Color also had a significant effect on serum vitamin D levels (p<0.05; Table 2). Thus, individuals with high melanin content in their skin or that eat a diet lacking vitamin D-rich, or fortified foods, may also need to consider supplementation to achieve optimal vitamin D levels. A linear regression analysis of the entire data set is shown in Figure 1. On average, it was found that supplementation with 5000IU/Day results in a serum concentration between 40-60ng/mL. However, the relatively high standard deviation of the population as a whole highlights the need for individuals to have their vitamin D levels monitored to ensure that between their lifestyle and supplementation regime, one achieves their desired serum vitamin D level. Sunlight exposure during the winter was found to be an insignificant contributor to serum vitamin D levels (p=0.11; Table 2). This was expected considering the decrease in sunlight intensity during the so-called "Vitamin D Winter". Surprisingly, this trend was also seen when the data was further analyzed excluding the northern most latitudes and only examining the most southern latitudes (<37°N; data not shown). The analysis showed that even though people have the potential to synthesize vitamin D during the winter, lifestyle characteristics (sun exposure, time of day outside, use of sunscreen or sun-obscuring clothing) significantly limit serum vitamin D levels. These data taken together show that supplementation with doses of vitamin D much higher than the RDA are required to obtain optimal vitamin D status during the winter, even in southern latitudes of the United States. This explains why individuals using USANA nutritional products containing advanced levels of vitamin D are more likely to have an optimal vitamin D status.*

TABLE 2. EFFECT OF LIFESTYLE FACTORS ON SERUM VITAMIN D LEVELS

Supplementation and BMI \ Weight are the Most Significant Determinants of Serum Vitamin D Levels		
Influencing Factor	Significant? (p<0.05)	P-Value
Supplemental Intake	Highly	<0.001
BMI \ Weight	Highly	<0.001
Dietary Intake	Yes	0.015
Skin Color	Yes	0.023
Time Outside	No	0.110
Gender	No	0.313

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*USANA was one of the first major nutritional companies to provide advanced levels of vitamin D in a multivitamin. In August of 2009 USANA reformulated and launched the Essentials with 1800 IU of vitamin D per daily dose (2000 IU for a HealthPak). This was followed in October with the introduction of USANA's Vitamin D product providing an additional 2000 IU of vitamin D. Thus, between the advanced doses of vitamin D found in USANA's core products, in tandem with the stand-alone vitamin D tablet, USANA makes it easy for individuals to customize a vitamin D supplementation regime to achieve one's desired, optimal vitamin D status.

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

