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EDITORIAL

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AIFA UPDATE OF NOTES 79 AND 96 IN RELATION TO VITAMIN D: CONFIRMATIONS AND DOUBTS

In this issue we would like to again sum up vitamin D's role in phosphorus and calcium metabolism and in bone health.

We are doing this by publishing a summary on the correct use of vitamin D supplementation according to the recent recommendations published by the Italian Society of Osteoporosis, Mineral Metabolism and Skeletal Diseases (SIOMMMS) [1].

Specifically, you will find here an update on the definition of vitamin D deficiency, on the identification of individuals at risk, on whether or not serum 25(OH)D screening is advisable, and on the conditions that indicate when supplementation would be suitable and the procedures for its application that are preferable in terms of dosage and timing, all based on the most recent understanding.

You will also find guidance on how to supplement with vitamin D in cases of kidney or liver insufficiency or when there are concomitant drug treatments that interfere with vitamin D metabolism in the liver.

Finally, you will find indications on when toxic effects such as hypercalcaemia and hypercalciuria should be of concern. All of this is substantiated by appropriate bibliographic references, which you may wish to supplement with the most recent articles, which can also be found in the rich bibliographic selection included in this issue. Although the recent updates of the Italian Medicines Agency (AIFA) Notes 79 [2] and 96 [3] did acknowledge the SIOMMMS recommendations, unfortunately the agency's acknowledgement was only partial.

NOTE 79

☺ In the new version of Note 79's "general considerations", the recommendation to make use of calcium and vitamin D supplements, where diet and exposure to sunlight are inadequate, were rightly reiterated because a vitamin D deficiency, in particular, can largely nullify the effects of drugs used for the treatment of osteoporosis.

☹ Compared with the Note's previous version, which recommended the use of cholecalciferol in particular and ruled out the use of hydroxy metabolites on the basis of the previous guidelines published in 2011 [3], calcifediol was added as an alternative to cholecalciferol, citing as alleged support, among other things, the same guidelines[3] which instead indicated the use of calcifediol, in addition to cholecalciferol, only under conditions of severe liver failure. Rightly so, in the "particular warnings" of Note 96's new version, it was acknowledged that the main evidence of vitamin D's efficacy against fractures was achieved through the use of cholecalciferol, which appears to be the reference molecule for this indication. On the other hand, the clinical documentation for hydroxy analogues was very limited whilst the risk of hypercalcaemia is not at all negligible.

☹ In the new version of Note 79's "Special Warnings" about patients with severe renal insufficiency, supplementation with vitamin D_3 was again recommended, as it was in the

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previous version. However, the possible use of 1-alpha-hydroxylated vitamin D metabolites for patients with this condition, which was supported by the old[3] and new guidelines[1], was surprisingly replaced with the use of 25-alpha-hydroxylated metabolites, yet with no bibliographic support.

NOTE 96

☺ The confirmation that screening extended to the general population would be inappropriate, is reasonable, considering that the determination of 25(OH)D levels should only be performed in the presence of risk factors for deficiency and when useful for patients' clinical management.

☺ Also appreciated was the new acknowledgement that supplemen-tation among people with severe vitamin D deficiency is appropriate, even when asymptomatic.

☺ AIFA's finding appropriate the raising of the minimum desirable threshold of serum 25(OH)D levels from 20 ng/mL (or 50 nmol/L) to 30 ng/mL (or 75 nmol/L) among patients with hyperparathyroidism (whether primary or secondary) and among those with osteoporosis or other established osteopathies was significant, recognising that correction of vitamin D deficiency remains, together with correction of deficient dietary calcium intake, one of the cornerstones of treatment for osteoporosis. Yet, vitamin D supplementation in healthy subjects without vitamin D deficiency understandably appears to be unnecessary, as shown by the far from surprising results of recent clinical studies.

☺ Also reasonable was the warning about using excessive doses of vitamin D, especially because of the potential negative effects on bone resorption as reported by our studies [5,6].

☺ Also, the new inclusion among recipients of vitamin D prescription covered by the National Health Service (NHS) without needing 25(OH)D screening, in addition to those who are institutionalised, those with severe motor deficits or who are bedridden living at home was also appreciated, given that exposure to sunlight, as rightly recognised, is the primary mechanism for meeting vitamin D requirements.

☹ Then there was still little acknowledgement of other conditions at risk of vitamin D deficiency such as those related to forced conditions of reduced sun exposure (for example, due to work or cultural reasons or conditions contraindicating exposure to UVB rays) or those related to an inability to produce adequate amounts of vitamin D despite exposure to sunlight, such as advanced age [7].

☹ Indications are unclear for patients already on mineralisation therapy combined with vitamin D supplementation, as recommended in Note 79. It is believed that continued vitamin D supplementation should be borne by the NHS regardless of any determination of 25(OH)D among these patients as well.

☹ With regard to vitamin D prescription guidelines, the doses of cholecalciferol given in Annex 1 to the Note have often been found to be insufficient under certain conditions: specifically, among the elderly, the obese, in cases of severe liver failure or chronic therapies interfering with vitamin D metabolism in the liver, or in conditions of poor absorption.[1]

☹ In that same annex, as an alternative treatment to cholecalciferol, calcifediol is indicated. In fact, however, this latter supplement should be indicated as the second choice, so that the Note's "Special Warnings" regarding the greater evidence of efficacy and safety of cholecalciferol are not contradicted, especially when administered daily. Even calcifediol's alleged faster normalisation of 25(OH)D levels was also refuted by our recent study, which showed that appropriate doses of cholecalciferol were able to offer equivalent rapidity [8].

☹ Finally, in view of the potential extra-skeletal benefits of vitamin D, based on what is currently known, though there is no firm scientific evidence that supplementation does indeed provide a cost-effective benefit, we feel that, at this time, such benefits cannot be ruled out with certainty either. See, for example, a critical analysis of the VITAL Study [9-11] with lights and shadows in this issue.

What do you think?

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VITAL Study: lights and shadows

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INTRODUCTION

Vitamin D is a fat-soluble hormone that plays a key role in regulating calcium absorption in the intestine. Cholecalciferol is converted into calcifediol by the liver enzyme 25-hydroxylase and subsequently, under the control of the parathormone (PTH), by the kidney enzyme 1-25-hydroxylase into the biologically active form, calcitriol. Because calcitriol directly regulates the absorption of elemental calcium from the gut, it is therefore essential to ensure an adequate substrate for bone formation.

Under conditions of low vitamin D levels, calcium absorption in the intestine is reduced and the calcium required for blood homoeostasis is drawn from the skeleton under the influence of PTH [1]. Therefore, as is well known in physiology, severe vitamin D deficiency leads to the development of osteomalacia (in adults) and rickets (in children) [2].

The earliest clinical/historical confirmation of vitamin D's fundamental role in the development of osteomalacia and in bone metabolism comes from ancient finds of skeletons of individuals with deformities and multiple bone fractures as well as from empirically garnered evidence.

It is also well known that populations living above the 37th parallel are at higher risk of developing rickets/osteomalacia. Humans are able to synthesise vitamin D_3 through photochemical conversion. Ultraviolet B radiation leads the conversion of 7-dehydrocholesterol into cholecalciferol by the skin. However, in the earth's northern and southern regions UVB radiation with the wavelength required for vitamin D synthesis does not reach the surface. It has also been found that when rachitic children are exposed to the sun their clinical picture improves until complete recovery.

Vitamin D, which is present in moderate amounts in animal fats, can also be absorbed from the diet. Among Scandinavian populations, it has been shown that the risk of vitamin D deficiency was particularly high for those who lived inland and therefore had a diet low in or even devoid of fish, which is the main animal source of dietary vitamin D. For centuries, cod liver, which is extremely rich in vitamin D, has protected Nordic populations from developing osteomalacia or rickets.

It has therefore been widely accepted that vitamin D is a fundamentally important nutrient/hormone for bone health. In recent years, evidence for this assertion has been further strengthened. There have been many studies published, especially observational but also interventional investigations, that confirm the importance of vitamin D and, in particular, that emphasise the marked deleterious effect of low levels of vitamin D or its deficiency on bone.

Interestingly, observational studies conducted on populations at risk of fracture are essentially all in agreement in pointing out the negative role of vitamin D deficiency in increased fracture risk. In contrast, the data from interventional studies has introduced a fair amount of uncertainty. Indeed, some clinical trials were unable to demonstrate a positive effect of vitamin D on the reduction of fracture risk. Nevertheless, although these studies were conducted with extreme scientific rigour and on large populations, their limitations should not be disregarded. Therefore, we cannot, we must not allow them to negatively influence our clinical choices [3]. Specifically, I will focus on the inherent weaknesses of the recent "Vitamin D and OmegA-3 TriaL (VITAL)" randomised clinical trial whose ancillary study results on fragility fractures [3], were recently published.

THE "VITAMIN D AND OMEGA-3 TRIAL (VITAL)"

The VITAL study was a pragmatic, randomised, blinded clinical trial in which vitamin D, omega-3 or placebo were administered according to a factorial design.

Summing up, participants (over 25,000 individuals residing in the United States of America) could receive either a tablet containing a combination of vitamin D and omega-3, vitamin D and placebo, omega-3 and placebo, or just placebo [4]. The main aim of the study, which was begun in 2010 at Harvard University, was to show a possible effect of vitamin D and omega-3 on the incidence of autoimmune diseases and cancer (Figs. 1, 2).

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Conflict of interest
The author states that there are no conflicts of interest.

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However, numerous other ancillary investigations were also planned, including studies targeting bone health and fractures. Serum, for biomarker analysis, was also collected from a proportion of the patients enrolled who were also given diagnostic examinations to assess bone density and fragility.

SUPPOSITIONS, CONTEXT AND THE VITAL-STUDY POPULATION

Before delving into the study details, one should recall the investigators' motivation to conduct this mega-trial. In the United States, it is extremely common for vitamin D to be administered together with so-called "over-the-counter" (OTC) preparations, which are by definition easy to find in ordinary supermarkets.

This widespread usage arose and was developed as a result of the strongly rooted belief in American society that regular multivitamin supplementation (often containing high doses of vitamin D) is essential for the health of people at all ages. The habit of taking OTC preparations is so ingrained that the market has shown continuous growth, having reached a staggering $30 billion/year in the US in 2023. This premise is crucial to understanding the context in which the VITAL study was conducted.

Specifically, understanding that the VITAL study's objectives were primarily to demonstrate that inappropriate vitamin D and omega-3 intake is, precisely, inappropriate.

To better understand the characteristics of the study population it would also be important to acknowledge the context in which the VITAL study was conducted.

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To better understand the characteristics of the study population it would also be important to acknowledge the context in which the VITAL study was conducted.

Middle-aged subjects with certain peculiar characteristics were enrolled in the VITAL study. The most important of these was certainly the subjects' high level of education. Enrolment was implemented through a letter, which included complex questionnaires that required suitable medical and scientific knowledge, which was sent to each subject's home address. This presupposition, together with informative brochures on vitamin D and omega-3 being mailed to the subjects, led to the enrolment of a considerable proportion of patients who were already taking vitamin D, before the study (42.6% of the patients enrolled had been taking vitamin D outside the study). In fact, before entering the study. this share of patients was found to have average 25-hydroxy-vitamin D [25(OH)D] levels of 34.9 ng/mL. Furthermore, subjects were also allowed to continue taking up to 800 IU of vitamin D supplements per day during

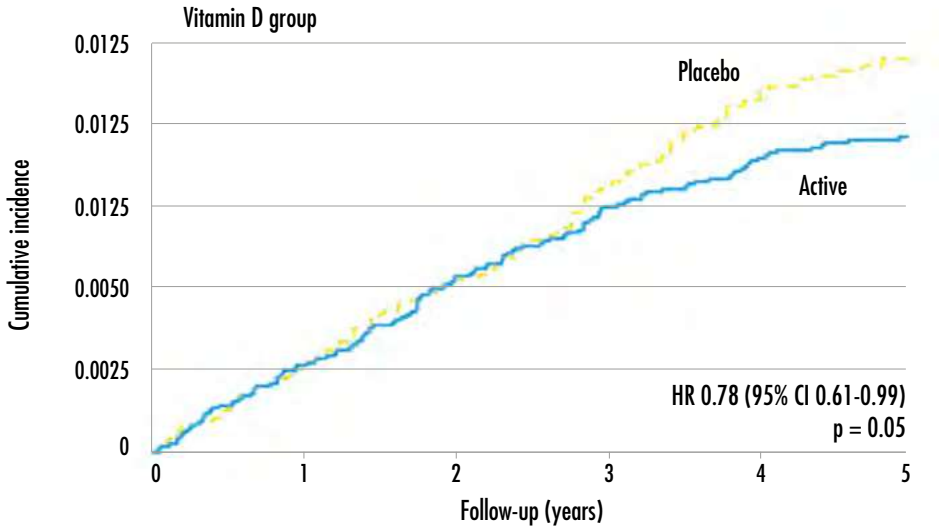

FIGURE 1.
Incidence of autoimmune diseases in the VITAL study (from Hahn et al., 2022, mod.) [6].

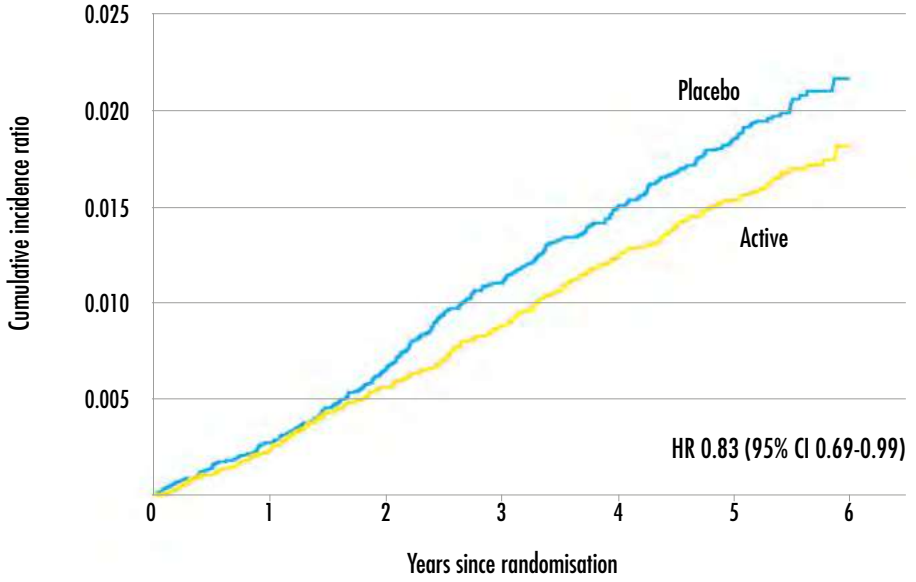

FIGURE 2.
Incidence of advanced cancer in the VITAL study (from Chandler et al., 2020, mod.) [7].

TABLE I.
Baseline characteristics of the population enrolled in the VITAL study (from LeBoff et al., 2022, mod.) [8].

Characteristic	Total (N = 25,871)	Vitamin D group (N = 12,927)	Placebo group (N = 12,944)
Women no. (%)	13,085 (50.6)	6,547 (50.6)	6,538 (50.5)
Age, years	67.1 ± 7.1	67.1 ± 7.0	67.1 ± 7.1
Body mass index (BMI)	28.1 ± 5.7	28.1 ± 5.7	28.1 ± 5.8
Diabetes no./total no. (%)	3,537/25,824 (13.7)	1,804/12,900 (14.0)	1,733/12,924 (13.4)
Family history of hip fracture, no./total no. (%)	3,704/23,979 (15.4)	1,809/11,970 (15.1)	1,895/12,009 (15.8)
Rheumatoid arthritis no./total no. (%)	1,118/25,512 (4.4)	556/12,749 (4.4)	562/12,763 (4.4)
Family history of fragility fracture no./total no. (%)	2,578/25,023 (10.3)	1,287/12,513 (10.3)	1,291/12,510 (10.3)
Falls in the last year no./total no. (%)	6,921/25,715 (26.9)	3,521/12,848 (27.4)	3,400/12,867 (26.4)
Use of anti-osteoporosis drugs no./total no. (%)	1,240/25,690 (4.8)	609/12,835 (4.7)	631/12,855 (4.9)
Smokers no./total no. (%)	1,835/25,488 (7.2)	921/12,732 (7.2)	914/12,756 (7.2)
Use of vitamin D supplements no./total no. (%)	11,030 (42.6)	5,497 (42.5)	5,533 (42.7)
Use of glucocorticoids no./total no. (%)	461/25,427 (1.8)	239/12,705 (1.9)	222/12,722 (1.7)
Milk intake (units)	0.71 ± 0.91	0.71 ± 0.89	0.72 ± 0.92
Basal 25(OH)D levels, ng/mL	30.7 ± 10.0	30.7 ± 10.0	30.7 ± 10.0
Basal calcaemia levels, mg/dL	9.00 ± 1.61	9.00 ± 1.61	9.00 ± 1.61

the VITAL trial. It was also surprising to note that subjects not taking vitamin D at the beginning of the study were found to have average blood 25(OH)D levels measuring 27.4 ng/mL, which is more than adequate for bone health maintenance.
Summing up, on average, patients who would never have been treated with additional doses of vitamin D in clinical practice were enrolled in the VITAL trial. Moreover, this population was already at low risk of fracture at baseline. Only 1 in 10 patients had a history of fragility fracture and only 1 in 20 were treated with osteoporosis drugs. Table I shows the baseline characteristics of the VITAL study population [8].

VITAL STUDY RESULTS, *PRIMARY* ENDPOINTS, AND INCIDENCE OF FRACTURES

After being randomised, the VITAL study subjects enrolled were followed up with annual questionnaires for more than 5 years, whilst several outcomes were evaluated each year and at the end of the study.
The primary endpoint (incidence of fragility fractures in the two randomisation groups) was not achieved: the fracture incidence rates overlapped in the two groups.
Before going into the detail on the results of the ancillary study on fractures it is important to establish the observed fracture rate, i.e., the number of fractures the patients had during the follow-up. once again, this will allow us to better understand the characteristics of the individuals enrolled in the study. A total of 865 fragility fractures (excluding pathological, traumatic, periprosthetic fractures, etc.) were observed during a median follow-up period of 5.3 years. This rate corresponds to a fracture risk of 3.3% at 5 years, coming to, approximately, a 6.6% risk at 10 years, which is well below the pharmacological treatment threshold for osteoporosis. Similarly, the 0.8% 10-year femoral fracture incidence rate that was observed was still well below the treatment threshold, which is usually set at 3%. Clearly, the enrolled population was already at a low risk of fracture even before entering the study and remained so throughout the duration of the investigation.

VITAMIN D *SAFETY*

The incidence of hypercalcaemia, kidney stones and adverse events in general was similar among all the patients. Nevertheless, there was a reduction in gastrointestinal bleeding events and skin rash among the patients treated with vitamin D.
The safety profile was therefore found to be favourable in the active vitamin D treatment arm.

SUBGROUP ANALYSIS AND VITAMIN D LEVELS

In one of the subgroups of the study population, 25(OH) D values were analysed after 2 years (besides at baseline). As expected, 25(OH)D levels increased significantly (statistically but not clinically) in the subgroup treated with vitamin D (29.2 ng/mL→ 41.2 ng/ mL). Still, not very surprisingly, patients in the placebo arm also maintained adequate vitamin D levels, achieving values of 29.4 ng/mL at year 2. Once again, this indicates how the patients enrolled were largely already on supplementation and how they continued using it during follow-up. Therefore, though several sub-analyses were conducted on the basis of the baseline 25(OH)D levels, still again no (significant) reduction in fracture risk was found. Nonetheless, laboratory data were available from only a small portion of the cohort. Of these, only a minority had insufficient vitamin D

TABLE II
Hazard Ratio in subgroups of patients in the VITAL study (from LeBoff et al., 2022, mod.) [3].

Subgroup	Total	Vitamin D group	Placebo group	Hazard Ratio (95% CI)	Hazard Ratio if patients are doubled & equal fracture incidence
Anti-osteoporosis drugs					
Yes	1,240	62	79	0.74 (0.53-1.03)	**0.74 (0.62- 0.97)**
No	24,450	704	697	1.01 (0.91-1.12)	1.01 (0.96-1.11)
History of fragility fractures					
Yes	2,578	146	161	0.87 (0.69-1.09)	**0.87 (0.74-0.99)**
No	22,445	598	595	1.01 (0.90-1.14)	1.01 (0.93-1.08)

levels. Furthermore, among the 401 subjects whohad 25(OH)D levels below 12 ng/mL, the incidence of fractures was 3.7% at 5 years, which was extremely similar to the entire cohort. Even so, this apparently counter-intuitive finding can be explained by the admission of up to 800 IU/day of vitamin therapy outside the study. Whilst 25(OH)D dosages were also allowed outside the study according to current clinical practice, it cannot be ruled out that a major bias (exclusion of patients from the analysis or increased vitamin D levels even in the placebo group) may have been caused once patients with very low levels started vitamin D supplementation. Also, to be noted was that PTH and calcaemia levels in the study population were found to be normal as they were also in the subgroup with vitamin D deficiency (the presence of hyperparathyroidism of any nature was one of the exclusion criteria). This implies that the vitamin D deficient patients had most likely been so for just a short time and/or that their homeostatic compensation mechanisms of their PTH/calcaemia/25(OH)D axis had not yet been established or were not yet fully evident. No stratified analyses were conducted on the basis of 25(OH)D values at the end of the study. Sub-analyses were conducted in subgroups at particular risk of fracture, such as those patients with previous fractures or those treated with osteoporosis drugs. In these subgroups (in any event in the minority) the risk of fracture was no different between the placebo and the vitamin D groups. Yet, a numerically lower fracture incidence rate was shown in the active treatment group (Tab. II). It is interesting to note that among these many subgroups there was insufficient proof to show any reduction in fracture risk.

In addition, the fracture incidence rate was not especially high. This rate was 11.3% at 5 years (about 22% at 10 years) for those patients being treated for osteoporosis, whilst it was 11.9% at 5 years (about 23-24% at 10 years) among those subjects with previous fractures. For comparison, in the 10-year extension of the FREEDOM study (clinical trial with denosumab), which was very similar to the VITAL study, the 10-year cumulative overall incidence rate for fragility fractures among patients treated with denosumab was 16.3% *vs* 26% in the "virtual" placebo arm. It would therefore be difficult to believe that vitamin D alone could have a clear anti-fracture effect among so few patients who were at such low risk. Nonetheless, it would be sufficient to assume that a doubling of the number of cases (keeping the fracture incidence rates the same) in these subgroups could achieve statistical significance in favour of vitamin D (Table II). Indeed, it is a well-known fact that it is even more crucial to achieve and maintain adequate vitamin D levels (probably above the threshold of 20-30 ng/mL) among patients being treated with anti-osteoporosis drugs in order to maximise the anti-fracture effect of the drugs [5]. This finding is further confirmed by evidence from another sub-analysis still from the VITAL trial that showed a significant reduction in the risk of major osteoporotic fracture (MOF) among patients being treated with anti-osteoporosis drugs [HR 0.54 (95% CI 0.29-0.99)].

CONCLUSIONS

Regardless of its limitations, VITAL is a crucially important study. The trial was conducted meticulously, on a very large population, who were studied over an extended period of time. Additionally, the study brought to light an important confirmation of vitamin D's potential extra-skeletal effects. Nevertheless, in the ancillary study on fragility fractures, the group treated with vitamin D showed no reduction in the incidence of fractures. This result was largely to be expected considering the study's significant limitations as well as the low-risk population enrolled. Among selected patients, such as those with osteoporosis, vitamin D treatment is and remains essential to preserve bone health. Moreover, this important observation was also reiterated by the same VITAL study authors, who suggested that thresholds of 25(OH)D ≥30 ng/mL [8] should be achieved and maintained in all patients with osteoporosis.

In conclusion, the effects of vitamin D on bones appear to be more pronounced in vitamin-D deficient individuals at risk of fracture or of osteomalacia.

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Summary of the new 2022 recommendations of the Italian Society for Osteoporosis, Mineral Metabolism and Skeletal Diseases (SIOMMMS) for the management of vitamin D deficiency

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INTRODUCTION

In light of new scientific findings, the Italian Society of Mineral Metabolism and Skeletal Diseases (SIOMMMS) believed that there was a need to revise and update its original 2011 recommendations on the definition, prevention, and treatment of vitamin D deficiency in adults using a GRADE/PICO 1 system approach [1].

In recent years, there has been a steady increase in prescriptions for 25(OH)D serum level screening and for the use of vitamin D supplements.

In 2019, AIFA (Italian Medicines Agency), in Note 96, set out to regulate the reimbursement of these prescriptions, in an attempt to curb their consumption and costs, with no appropriate grounds [2,3]. A multidisciplinary task force was set up to provide clinical guidelines with the following main objectives: a) to make the management of vitamin D deficiency appropriate by improving and standardising "clinical practice"; b) to provide patients with indications for the most appropriate treatment, to be followed uniformly at national level; and finally c) to ensure an evidence-based reference for national and regional institutions and agencies. Several key points were addressed. Some of these suggested a marked change in behaviour in clinical practice, including a new definition of vitamin D status with deficiency and optimal values varying depending on the population involved [4]. For methodological aspects related to the search for corroboration and the drafting of levels of evidence and recommendations please see the original publication [4].

QUESTION 1. VITAMIN D STATUS DEFINITION: DEFICIENCY AND OPTIMAL VALUES

Serum levels of 25(OH)D vary widely throughout life, depending on the season, the latitude, the degree of exposure to sunlight, phototype and body mass index (BMI). In addition, one should always consider the high variability linked to chemiluminescent immunoassay screening, which can vary between 10-20% intra-screening and inter-laboratory. On the other hand, there is unanimous agreement that 25(OH)D values < 10 ng/mL are a condition of severe deficiency, which, if prolonged over time, leads to rickets and osteomalacia, whilst consensus on what can be considered "normal" simply does not exist. SIOMMMS recommends a level that can be deemed "optimal" or "desirable", which has been defined as the value that has been shown to be effective in preventing or correcting diseases of the bone such as fragility. A distinction should also be made between the recommendations for the general population and the guidance given to those who are at risk of vitamin D deficiency or who need anti-fracture drug therapy. There is consensus on the association between serum 25(OH)D values <20 ng/mL and increased fracture risk [5] among the general population. Recent meta-analyses have revealed that for values < 20 ng/mL (50 nmol/L) there is a 40 per cent increase in femoral fracture risk for each standard deviation decrease in 25(OH)D levels, whilst for values above 20 ng/mL, supplementation does provide additional benefit [6]. Therefore, among the general population the following definitions for 25(OH) levels have been set out: "defi-

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TABLE I.

a. Definition of vitamin D status in the healthy general population

	Deficient	Insufficient	Optimal
General population	< 10 ng/mL	< 20 ng/mL	Between 20 and 50 ng/mL

b. Definition of vitamin D status in the population at risk of vitamin D deficiency or who are on medication for osteoporosis

	Deficient	Insufficient	Optimal
Population at risk of low vitamin D* or requiring osteoporosis medication	< 10 ng/mL	< 30 ng/mL	Bet 30 & 50 ng/mL

The reported cut-off values must be considered with a margin of variability of ±10%, considering the variability analysis of the 25(OH)D dosage.
Furthermore, due to the seasonal variability of 25(OH)D levels, the value determined in late winter/early spring is indicative. From ng/mL to nmol/L: ng/mL x 2.5. * The population at risk of vitamin D deficiency is shown in Table II.

TABLE II.
Population/condition at risk of vitamin D deficiency.

- Elderly (≥ 75 years)
- Institutionalised subjects or conditions associated with inadequate exposure to sunlight
- Obesity
- Pregnancy and breastfeeding
- Metabolic bone diseases and other skeletal disorders
- Vegan diet
- Anorexia nervosa
- Chronic renal insufficiency
- Cancer (especially breast, prostate and colon)
- Diabetes mellitus type 2
- Intestinal malabsorption and bariatric surgery
- Drugs that interfere with the absorption or liver metabolism of vitamin D (antiepileptics, glucocorticoids, AIDS antivirals, anti-fungal agents, cholestyramine)
- Cystic Fibrosis

cient" <10 ng/mL, "insufficient" if < 20 ng/mL and "optimal" if between 20-50 ng/mL [4] (Tab. Ia). Conversely, among patients with osteoporosis, especially those treated with drugs for osteoporosis therapy, as well as among individuals at risk of vitamin D deficiency (shown in Table II), a value of at least 30 ng/mL is indicated as being "optimal" This value has been associated with significant reductions in femoral fracture risk among women who are institutionalised and a 4.5-fold improved response among subjects treated with bisphosphonates [7] (Tab. Ib).

QUESTION 2. WHO ARE THE SUBJECTS AT RISK OF VITAMIN D DEFICIENCY?

There are many clinical and lifestyle conditions that expose individuals to much higher risks of vitamin D deficiency than are found in the general population. These are listed in Table II. With respect to the classic risk conditions indicated in other international guidelines, SIOMMMS has updated its list to include subjects who maintain a vegan diet or those with anorexia nervosa. Whilst those patients with cancer of the breast, prostate or colon, and those with diabetes [4] are especially at risk. The categories of subjects included in this list should all have "optimal" levels of 25(OH)D that are at least 30 ng/mL.

QUESTION 3. IS IT APPROPRIATE TO GIVE THE GENERAL POPULATION 25(OH)D ASSAYS?

Assays of serum levels of 25(OH)D have shown a dramatic increase over the last decade worldwide. Clearly, this has increased healthcare expenditures inappropriately. Currently, there is no evidence that "universal" vitamin D level screening is useful, nor has it been shown to be helpful in ensuring greater success in vitamin D supplementation [8,9]. Therefore, at this stage, it is being recommended that extensive screening of 25(OH)D levels in the general population not be implemented, since there is, as yet no evidence that this represents any benefit,4 which is in agreement with most of the guidelines in this field.

QUESTION 4. ARE 25(OH)D LEVEL ASSAYS APPROPRIATE AMONG POPULATIONS AT RISK FOR VITAMIN D DEFICIENCY OR WHO ARE TO BEGIN OSTEOPOROSIS DRUG THERAPY?

Although most guidelines highly recommended serum 25(OH)D level screening among individuals who have been defined as being at risk for vitamin D deficiency, there is no direct evidence to support this recommendation [4]. Furthermore, there is no evidence that basal assessment of 25(OH)D levels is a predictor of the risk of toxicity during supplementation or that it can be used to determine the dosage of vitamin D to be administered [10]. At the same time, many studies have shown that supplementation with high doses of vitamin D is safe even in subjects with 25(OH)D levels > 20 ng/mL. Therefore, it has been suggested that among patients with conditions or diseases at risk of vitamin D deficiency, 25(OH)D levels should not be measured indiscriminately. It has also been proposed that basal 25(OH)D levels should not be measured routinely in patients who are candidates for bone fragility drug treatment, since this is mandatory regardless of basal values. If anything, it would be useful to check whether "optimal" 25(OH)D levels have been achieved once supplementation has begun [4].

QUESTION 5. HOW SHOULD VITAMIN D BE SUPPLEMENTED?

There is no single fixed supplementation dose for everyone who needs vitamin D. For supplementation, an oral dose between 800 IU and 2,000 IU/day of cholecalciferol is recommended [11].
A supplementation programme is suggested, which may be daily, weekly, or monthly, adjusting the dose to be administered to the time interval of the schedule adopted.
It is recommended that divided doses not be used beyond 30 days. The bolus dose of 100,000 IU of cholecalciferol in one day (in a monthly schedule) should not be exceeded. The dose of cholecalciferol administered to obese subjects should be increased by about 30 per cent compared to the dose administered to individuals with a normal BMI.
An adequate intake of calcium (800-1,000 mg/day) through the diet or supplements

TABLE III.
Synopsis of recommendations, degree of evidence and strength of recommendation.

Question and Recommendation	Level of evidence
1. Should biochemical assessment of serum 25(OH)D levels be conducted in the general population?	
It is recommended that the 25(OH)D screening in the general population not be done	⊕
2. Should serum 25(OH)D levels be determined in the population at risk of vitamin D deficiency?	
It is suggested that 25(OH)D levels not be indiscriminately measured in patients with conditions or diseases at risk of vitamin D deficiency	⊕⊕
It is recommended that 25(OH)D levels be measured only when it has been deemed necessary for the patient's clinical management (i.e., when osteomalacia is suspected)	⊕⊕
3. Should a determination of serum 25(OH)D levels be made in specific categories of subjects/patients at risk (Table II)?	
It is suggested that baseline 25(OH)D levels should not be routinely assessed in patients who are candidates for pharmacological treatment for osteoporosis or other metabolic bone disorders (which are perforce associated with vitamin D supplementation), unless osteomalacia is suspected	⊕⊕
4. How should vitamin D be supplemented in individuals with vitamin D deficiency or candidates for pharmacological treatment with anti-fracture drugs?	
A supplementation dose of cholecalciferol between 800 IU/day and 2,000 IU/day is suggested. There is no single fixed dose for all subjects to be supplemented	⊕
A daily, weekly, or monthly schedule based on the dose administered is suggested. The maximum single daily dose to be administered must not exceed 100,000 IU.	
An adequate intake of calcium (800-1,000 mg/day) should always be ensured	⊕
An initial loading dose followed by a maintenance dose is suggested in patients with symptomatic osteomalacia and/or 25(OH)D levels < 10 ng/mL or in patients starting intravenous bisphosphonate therapy or denosumab with 25(OH)D < 20 ng/mL	⊕⊕⊕
We suggest, as a loading dose, cholecalciferol 3,000-10,000 IU/day (average 5,000 IU/day) for 1-2 months, or cholecalciferol in a single dose of 60,000 to 150,000 IU followed by the maintenance dose (2,000 IU/day)	⊕⊕⊕
Alternatively, calcifediol 20-40 mcg/day (4-8 drops/day) for 20-30 days is suggested, before switching to the maintenance dose with cholecalciferol**	
5. Should vitamin D be supplemented in the general population?	
It is recommended that vitamin D supplements not be administered to the general population, as there is no definite evidence of favourable cost-effectiveness, either on mortality or on skeletal and extra-skeletal effects	⊕⊕⊕
6. How should vitamin D be supplemented in patients with impaired renal function?	
It is recommended that patients with CKD-MBD correct vitamin D deficiency with cholecalciferol in the same manner as in the general population with normal renal function	⊕⊕⊕⊕
It is recommended that the use of active vitamin D compounds (calcitriol or synthetic analogues) be limited to individuals on dialysis or to patients with CKD stages G4 and G5 with severe and progressive hyperparathyroidism	
7. How should vitamin D be supplemented in subjects suffering from severe liver failure or therapies that interfere with vitamin D metabolism in the liver?	
Supplementation with at least 2,000 IU/day of cholecalciferol is suggested patients with severe liver failure or in the case of chronic therapies that interfere with vitamin D metabolism in the liver. The use of calcifediol is a possible alternative	⊕

* The recommendation is restricted to achieving a more rapid normalisation of serum 25(OH)D levels.
Strength of the recommendation: suggested/not recommended: positive/negative weak; recommended/not recommended: positive/negative strong.
Level of evidence: ⊕ very low, ⊕⊕ low, ⊕⊕⊕ moderate, ⊕⊕⊕⊕ high.

should always be ensured. An initial loading dose followed by a maintenance dose is recommended for patients requiring rapid normalisation of vitamin D levels (symptomatic osteomalacia or in those who are to start using zoledronic acid or denosumab). As a loading dose, we recommend 3,000-10,000 IU/day (mean 5,000 IU/day) of cholecalciferol for 1-2 months or a single dose of 60,000 to 150,000 IU of cholecalciferol followed by a maintenance dose (2,000 IU/day) [4,12]. Alternatively, calcifediol 20-40 mcg/day (4-8 drops/day) for 20-30 days may be considered before switching to the maintenance dose with cholecalciferol.

QUESTION 6. SHOULD THE GENERAL POPULATION BE SUPPLEMENTED?

The rationale for potential supplementation of all subjects with cholecalciferol is based on considering subjects with values < 30 ng/mL as "deficient", over the potential extra-skeletal effects, the safety profile, and the low cost.

However, based on recent evidence sufficient conclusions for an advantage in supplementation among the general population cannot currently be drawn (among subjects excluded from Table II) [13]. Therefore, it is recommended that the general population not at risk of vitamin D deficiency not receive supplements.

QUESTION 7. SHOULD SUBJECTS WITH RENAL IMPAIRMENT BE SUPPLEMENTED WITH VITAMIN D AND HOW?

In renal impairment, reduced 25(OH)D levels limit the availability of the substrate for renal hydroxylation to calcitriol, thus exacerbating the effects of reduced hydroxylation to $1,25(OH)_2D$. This results in secondary hyperparathyroidism. Vitamin D supplementation can normalise 25(OH)D levels and reduce PTH levels whilst improving bone mineralisation in renal impairment. The same supplementation indications suggested for the general population [14] are suggested for these cases.

The use of cholecalciferol is recommended, whereas the evidence is limited for calcifediol. [14] It is recommended that the use of active vitamin D compounds (calcitriol or synthetic analogues) be limited to individuals on dialysis or for patients with CKD stages G4 and G5 with severe and progressive hyperparathyroidism [14].

QUESTION 8. HOW TO SUPPLEMENT PATIENTS WITH LIVER FAILURE OR THOSE IN THERAPY WITH DRUGS THAT INTERFERE WITH VITAMIN D METABOLISM IN THE LIVER?

Reduced 25(OH)D levels are common in patients with chronic liver disease (CLD) not only due to a deficiency in 25-hydroxylation or to increased catabolism of calcifediol, but due to multiple conditions, including malnutrition, reduced sun exposure, malabsorption, and reduced D-Binding Protein synthesis [4].

The importance of reduced 25-hydroxylation seems to be limited to the more advanced stages of liver failure [15]. Vitamin D supplementation is also necessary in the case of the administration of many drugs that interact with vitamin D metabolism in the liver, such as antiepileptics (carbamazepine, phenobarbital, dintoin), but also glucocorticoids, anti-neoplastic agents, antiretrovirals, and anti-tubercular antibiotics. Supplementation with at least 2,000 IU/day of cholecalciferol is recommended for patients with severe liver failure or in the case of chronic therapies that interfere with vitamin D metabolism in the liver. The use of calcifediol is a possible alternative although evidence of any advantage is limited [4].

QUESTION 9. WHAT IS ITS SAFETY PROFILE AND LEVEL OF TOXICITY?

The "classic" manifestations of vitamin D intoxication, such as hypercalcaemia and hypercalciuria, are to be considered exceptional with the administration of cholecalciferol and may only occur with 25(OH)D levels around or above 150-200 ng/mL [16]. Toxicity may occur more frequently, even with recommended dosages, with calcitriol or alfacalcidiol (per SPC). Among the "non-classical" toxicity effects, the risk of falling has been indicated in some studies. Though the data are contradictory and limited to high bolus doses and in institutionalised subjects, in those subjects deficient in vitamin D, the effect of normalisation (to 30 ng/mL) appears to be protective against falls [17].

CONCLUSIONS

These recommendations on how to manage vitamin D deficiency in Italy have been based on the most solid scientific findings currently available. This advice, which was generated through the use of rigorous methodology, is mainly directed at physicians so that they can address this widespread issue with evidence-based appropriateness, whilst perhaps being able to offer some improvement on the standard of approach to the problem. Though some of these recommendations are consistent with other guidelines there are some points that offer a new approach, such as the personalisation of optimal levels. These recommendations have focused on the skeletal effects of vitamin D in at-risk populations. Extra-skeletal effects were deliberately not addressed, whilst the lack of clear benefits in supplementation of healthy populations can, for now, be confirmed.

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