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 Editorial

 Update on the role
of vitamin D
in the prevention
of osteoporosis

 Impact of Italian
Medicines Agency
Note 96 on the use
of vitamin D in Italy

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Up to 2019, a progressive increase in the consumption of vitamin D in Italy was noted, with a consequent rise in expenditures borne by the National Health Service (SSN) [Rapporto OsMed (Osservatorio Nazionale sull'impiego dei Medicinali – National Database on the Use of Medicines Report), Agenzia Italiana del Farmaco – Italian Medicines Agency (AIFA)]. The extent and growth in the consumption of Vitamin D led to speculation of possible inappropriate use. With the declared intention of reducing this consumption, in late October 2019 AIFA published Note 96 identifying reimbursement criteria for Vitamin D supplementation for the prevention and treatment of deficiency states in adults ¹.

In the first 20 months of application of the Note, compared to previous periods, there was a decrease in consumption and related expenditure for Vitamin D covered by the Note ² (Fig. 1). However, whether this was due to an improvement in the appropriateness of use is not known.

In this issue we are publishing two contributions that raise doubts and concerns as to whether Note 96 has led to a deterioration in appropriateness of use, at least in some respects, rather than an improvement.

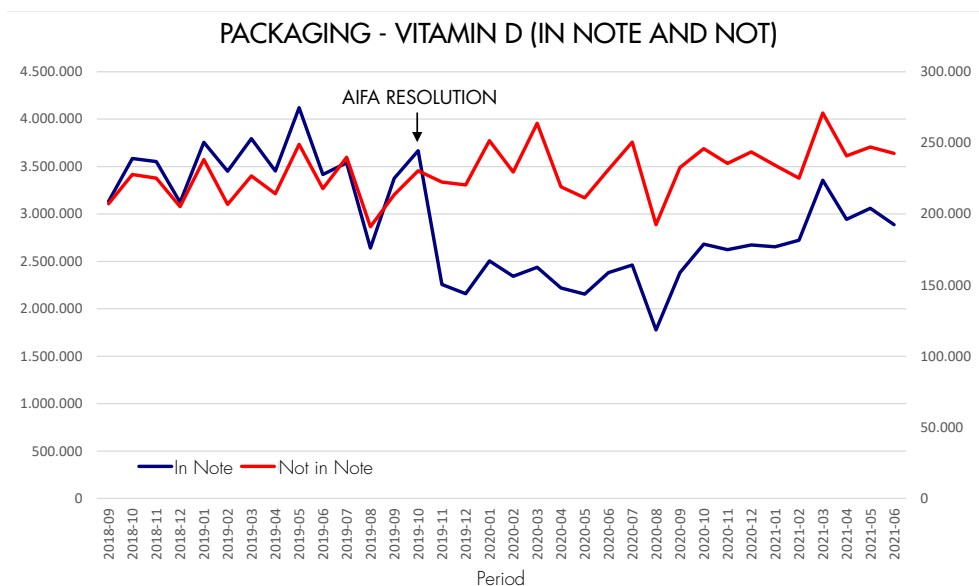


FIGURE 1.

(Source: https://www.aifa.gov.it/documents/20142/1030827/NOTA_96_20mesi_22.10.2021.pdf) ².

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The first article summarises the role of vitamin D in the prevention of osteoporosis, considering its physiological action, and updates the subject in light of some recent publications, sometimes critically highlighting its limitations, which might explain some inconsistencies or discrepancies. Furthermore, the article expresses concern that the fall in consumption among the elderly, which is at risk of vitamin D deficiency and osteoporosis, may have compromised appropriate and often necessary supplementation of this age group. Recall that immediately after the publication of Note 96, in April 2020, it was I, as President of the Italian Society of Osteoporosis, Mineral Metabolism and Skeletal Diseases (SIOMMMS), who reported this risk to AIFA, communicating my concern in view of the preliminary results of an AIFA monitoring report three months after the introduction of Note 96³. In particular, it was noted that the available data did not truly allow any assessment of whether the reduction in consumption and related expenditure on vitamin D could be attributable to improved appropriateness. We were particularly concerned about the significant reduction in the use of vitamin D in the elderly, who are known to be most at risk of deficiency. This is also because it has been known for some time⁴, though ignored by Note 96, that there is a reduced ability of the skin to produce adequate amounts of vitamin D despite exposure to sunlight, the main source for meeting requirements, in people over the

age of 60. Since Note 96 overlooks this aspect and specifically does not include advanced age as a risk condition for hypovitaminosis D, it does not adequately protect the elderly from the risk of vitamin D deficiency.

The second article analyses some very interesting aspects of the impact of Note 96 on the appropriate use of vitamin D in Italy. Specifically, using administrative flows for examinations and drug prescriptions at a ULSS (Local Health Service), an attempt was made to verify whether or not a reduction in the consumption of vitamin D was accompanied by greater appropriateness of use after Note 96 went into effect. Actually, after Note 96 was published, there was observed a reduction in the appropriate and recommended combination of vitamin D with drugs for the treatment of osteoporosis, which in my opinion was due to the lack of clarity in the text of Note 96 on this point and to its consequent often erroneous interpretation by doctors. Therefore, from this point of view, the observed drop in vitamin D consumption did not coincide with an improvement in appropriate prescription but rather with its worsening. Furthermore, the above analysis showed no improvement in the other indicator assessed, namely the proportion of patients treated with vitamin D without ascertained hypovitaminosis in the last 12 months. This, even though, in my opinion, those conditions for which the same Note does not provide for serum 25(OH)D dosage or for those patients for

whom the continuity of treatment or the persistence of well-known previous risk conditions of vitamin D deficiency should be considered. Frankly, to require said dosage to be entitled to supplementation covered by the National Health Service would be superfluous, inconvenient, inapplicable or even unethical.

The need to better assess the actual impact of Note 96 on the appropriateness of vitamin D use, is also further borne out among the conclusions of the foregoing AIFA 2 monitoring report by the following:

- “From the data presented, after 20 months the effects of the Note seem to begin to wane, if compared with the first months of its application...”
- “Assess an awareness campaign on proper prescription addressing primary care general practitioners”.

What are your thoughts?

Happy reading!

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Update on the role of vitamin D in the prevention of osteoporosis

VITAMIN D

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In recent years the possible multiple positive effects of vitamin D (antineoplastic, cardio-protective, immunomodulatory, etc.) have aroused growing interest and an increase in scientific (and non-scientific) publications on the subject. However, uncertainties about its usefulness in the prevention of osteoporosis have also been raised, following discordant results in the literature, beyond any reasonable doubt on extra-skeletal effects.

Osteoporosis has a burdensome impact on the healthcare system: in Italy approximately 3.5 million women and 1 million men are affected by the disease. Incidence increases with age (the steady ageing of the population leads to more cases). From age 50, the incidence of fragility fractures increases progressively, becoming comparable to that of stroke and breast cancer ¹. Annual costs attributable to such fractures (acute management and long-term disability) grow with the ageing of the population. What is needed is an acceptable prevention strategy that makes the best use of available resources.

NOTE 96

AIFA's recent Note 96 regulates the prescription of compounds with the indication "prevention and treatment of vitamin D deficiency" in adults, charged to the National Health Service (NHS), in an effort to reconcile the need to achieve sufficient vitamin D levels with the need to contain the cost of prescribing vitamin D based products.

AIFA's June 2021 update of the Note ² (20 months after its introduction), which monitors consumption trends, shows a 25% containment of the expenditure for drugs included in the Note incurred by the NHS compared to previous periods, with insignificant increases in the consumption of and expenditure for vitamin D analogues not in the Note. These are general and preliminary assessments. Considering the diversified "pre-Note" situation in the different Regions of Italy along with the equally disparate "post-Note" response, specific, long-term in-depth studies are clearly neces-

sary. In all age groups (except 0-10 years) there was a reduction in consumption (even among young adults, which was probably excessive). Nevertheless, the greatest reduction was in the 40-60 age group, especially among women, but also in the 60-80 age group (Table I). Both of these age groups are at risk of hypovitaminosis D and osteoporosis, for which correct supplementation is especially important, along with any anti-fracture therapies, whose clinical efficacy depends on the correction of hypovitaminosis D as a prerequisite, as specified in Note 96 and in the literature ³.

VITAMIN D AND BONE HOMOEOSTASIS

Vitamin D is a fat-soluble compound that acts as a steroid hormone. Its main source (with some coming from the diet) is the conversion of pro-vitamin D (7-dehydrocholesterol) in the deep layers of the epidermis, by exposure to UVB radiation, into vitamin D₃ (cholecalciferol), the inactive precursor. Cholecalciferol undergoes an obligatory two-step hydroxylation. The first is in the liver where it turns into 25(OH)D or calcifediol, the compound with the longest half-life, which is used for the dosage of serum vitamin D levels. The second, which is in the kidney, gives rise to the biologically active form, 1,25(OH)₂D or calcitriol (Fig. 1). By binding to the vitamin D receptor (VDR), calcitriol induces its biological effects, first of all on phosphocalcic metabolism [stimulation of calcium and phosphate absorption in the small intestine, inhibition of parathormone (PTH) synthesis and secretion, activation of the RANKL/RANK system and consequent osteoclastogenesis by induction of RANKL expression on osteoblasts], regulating serum calcium and phosphorus levels and bone mineralisation (Fig. 2) ⁴. It follows that subnormal levels of this nutrient can alter the balance described. Namely, 25(OH)D levels at < 30 ng/mL reduce intestinal calcium absorption (which increases in a linear manner with 25(OH)D levels reaching a plateau at 32 ng/mL) ⁵ and increases PTH secretion,

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The authors state that there are no conflicts of interest.

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TABLE I.

AIFA Note 96 monitoring of vitamin D consumption trends. Preliminary analysis of the 20 months after the introduction of the Note (November 2019 - June 2021). Data by age group - ATC in Note 96. Figures below the national average are in red.² NB Gender and age information was not available for 0.5% of packages (https://www.aifa.gov.it/documents/20142/1030827/NOTA_96_20mesi_22.10.2021.pdf).

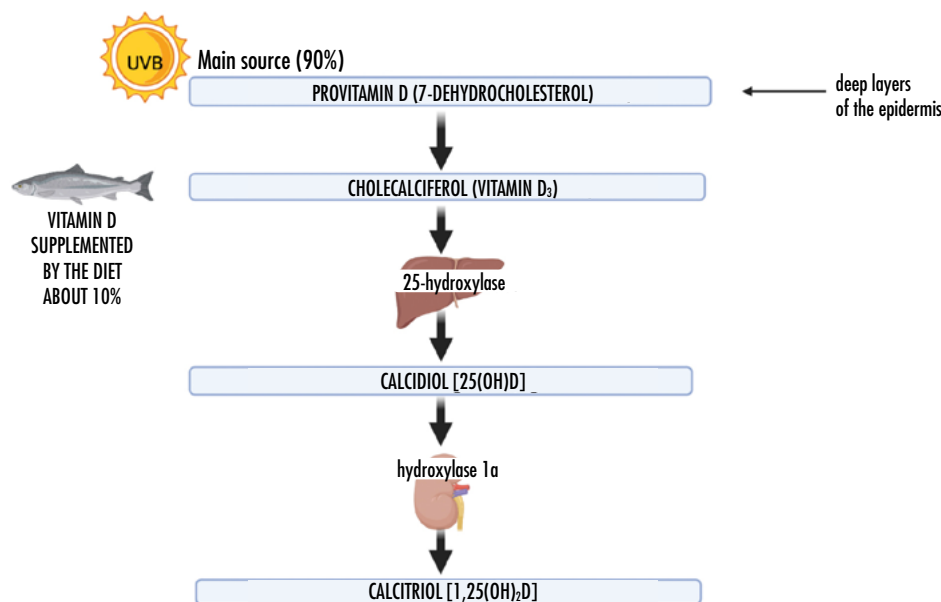
	Packages females	Delta % packages previous period	Gross females	Delta % packages previous period	Packages males	Delta % expenditure previous period	Gross males	Delta % expenditure previous period
Total Italy	42,295,282	-27.1	337,593,955	-24.7	8,230,373	-19.3	64,113,376	-17.5
Age groups								
0-10	400,521	1.7	2,070,124	1.4	431,335	1.6	2,220,819	1.4
10-20	269,051	-11.6	1,891,416	-14.3	198,484	-9.5	1,353,184	-11.9
20-30	427,089	-23.9	3,459,222	-23.0	186,544	-19.6	1,515,270	-18.1
30-40	787,504	-26.5	6,334,166	-25.7	232,703	-22.8	1,875,888	-20.9
40-50	2,298,338	-34.1	18,748,999	-32.7	470,127	-26.0	3,749,088	-24.2
50-60	6,839,559	-35.1	55,733,820	-33.2	981,648	-21.1	7,812,630	-19.3
60-70	10,043,108	-30.2	81,406,064	-27.5	1,572,989	-21.7	12,588,757	-19.7
70-80	11,762,214	-26.2	94,008,595	-23.1	2,251,209	-21.8	17,946,285	-19.3
> 80	9,467,898	-16.7	73,941,548	-13.3	1,905,334	-15.4	15,051,454	-12.5

stimulating tubular calcium reabsorption, renal hydroxylation of calcifediol to calcitriol, RANKL expression on osteoblasts and ultimately creating an imbalance in bone

homeostasis leading to dissolution of the mineralised bone matrix.⁴ There is no agreement on minimum 25(OH)D serum levels sufficient to prevent osteo-

porosis. According to the foregoing, levels > 30 ng/mL are optimal, as stated by the *International Osteoporosis Foundation* (IOF) and the *Endocrine Society* and the *National Osteoporosis Foundation* (NOF). Yet, the *World Health Organization* (WHO), the *European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis* (ESCEO) and the *National Osteoporosis Society* (NOS) have deemed 25(OH)D levels at ≥ 20 ng/mL, to be sufficient. Recommendations and guidelines based on findings from the literature mirror this controversy whilst also being open to criticism for their methodology. For example, a recent systematic review⁷ assessed the method of developing 47 Bone Health Guidelines published between 2009 and 2019 (which set out recommendations for serum 25(OH)D levels for the prevention of osteoporosis and fractures, ranging from 10 to 30~100 ng/mL) on the basis of 25 criteria adopted by WHO for the proper development of guidelines, whilst on average each guideline met only 10 out of the 25 methodological criteria.

A further disconcerting factor is the lack of standardisation of methods for measuring serum 25(OH)D levels, especially in studies prior to 2009 (the year when the first certified measurement procedures were im-

**FIGURE 1.**

Vitamin D metabolism. The main source (90%) is represented by the conversion of provitamin D in the deep layers of the epidermis, by exposure to solar UVB rays, into cholecalciferol, which will undergo a two-step hydroxylation (first hepatic, then renal) giving rise to the active metabolite, calcitriol.

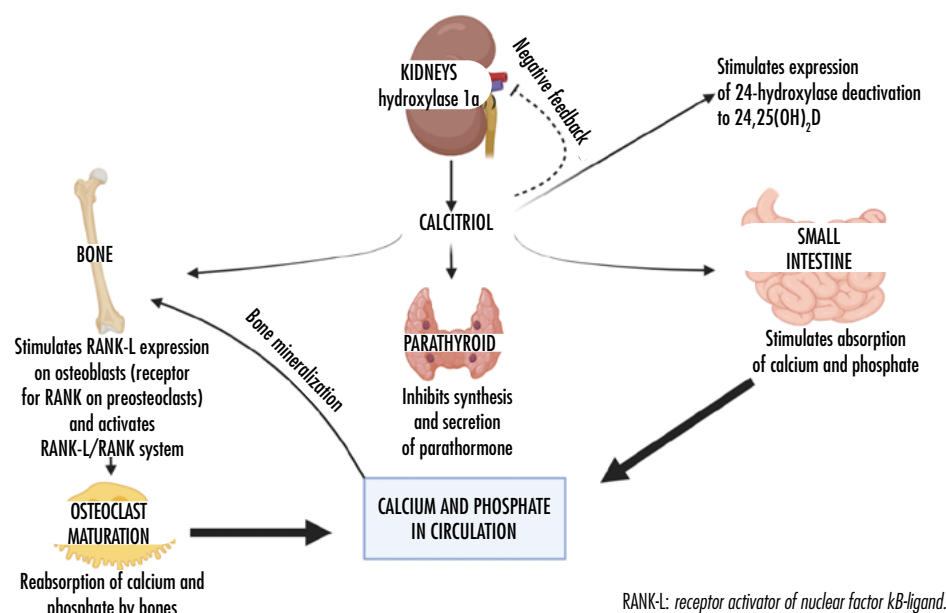


FIGURE 2. Effects of calcitriol [1,25(OH)₂D] on phosphocalcic metabolism.

plemented by the US National Institute of Standards and Technology, NIST), which were considered in several meta-analyses and inevitably coloured their results. The results of 25(OH)D dosage assays done with non-standardised methods showed significant variations when done retrospectively after standardisation.⁸

VITAMIN D AND OSTEOPOROSIS PREVENTION

If on the one hand, a great deal of evidence suggests that correction of hypovitaminosis D reduces the risk of osteoporosis, fragility fractures and falls, especially in the elderly (where hypovitaminosis D is more frequent due to reduced exposure to the sun, lowered capacity for synthesis by the skin and decreased dietary intake), all the more so in the case of medical treatment for osteoporosis,³ where results of some RCTs (randomised controlled trials) and related meta-analyses do not reveal these benefits, recommending their use only in rare conditions of rickets and osteomalacia.⁹ A number of critical issues make these latter conclusions poorly generalizable, starting with the recruitment of the sample, which 7 times out of 10 is characterised by individuals with normal serum 25(OH)D levels at baseline.¹⁰ Since vitamin D is a nutrient, the subjects who would benefit most from supplementation are those most deficient in the nutrient itself, who par-

adoxically are “scarcely considered” in the trials. This is even more compelling if these subjects are healthy and at low risk of osteoporosis and falls, since they are not likely to see an improvement in a risk that is already contained. Moreover, in some cases, sub-analyses referring to groups with vitamin D deficiency and osteoporosis risk showed positive effects after supplementation. A meta-analysis based on RCTs characterised by a population aged >65 years including administration of adequate vitamin D doses at close intervals (at least 800 IU/day, as suggested by the latest recommendations for the elderly population¹¹ and not in boluses, which might be counterproductive or ineffective¹²), in combination with calcium, showed a significant 15% reduction in total fractures (relative risk, RR = 0.85; 95% confidence interval, CI 0.73-0.98) and 30% fewer femur fractures (RR = 0.70; 95% CI 0.56-0.87) than placebo.¹³ Furthermore, the failure to dose 25(OH)D at the endpoint in several studies, considering the variability in dosage and frequency of administration used in the various trials, leaves the doubt that some of the deficient patients did not in any event reach a sufficient vitamin D level at the end of the study, which lessens the reliability of the results. Then again, several RCTs lasted no longer than 12 months, not guaranteeing an adequate observation period to assess long-term effects such as

fractures or significant changes in BMD.³ And we should not forget the already discussed issue of the methods used to measure 25(OH)D levels with no standardisation.⁸

CONCLUSIONS

Based on the foregoing considerations, for the prevention of osteoporosis and its complications, maintenance of 25(OH)D levels above 20 ng/mL (a range of 30-40 ng/mL is desirable, to provide maximum benefits, particularly important for the elderly and those at risk), together with adequate calcium intake, if deficient are required.¹⁴ Those who are vitamin D deficient or whose vitamin D intake is insufficient and those who are at risk of deficiency, benefit most from supplementation. Instead, those with adequate levels of vitamin D already enjoy the benefits of this natural condition. Maintenance dosing of the levels achieved should be provided for the elderly, those at risk of deficiency or who are undergoing treatment for osteoporosis. Needed are RCTs with standardised measurements of 25(OH)D, involving subjects with vitamin D deficiency and at risk of osteoporosis, with assessment of whether normal serum levels are actually achieved after supplementation. Finally, based on Note 96 monitoring, the uncertainty that perhaps reduced consumption in age groups that are at risk may lead to insufficient supplementation seems to emerge. It should be borne in mind that the costs incurred by supplementation are amply covered by the savings linked to avoiding the complications of osteoporosis. Clearly, prevention remains the winning formula, also from the standpoint of costs.

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Impact of Italian Medicines Agency Note 96 on the use of vitamin D in Italy

VITAMIN D

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Vitamin D plays a key role in maintaining serum calcium levels required for musculoskeletal health and bone metabolism within their natural physiological range.¹

Vitamin D ensures proper bone mineralisation. Vitamin D deficiency is a risk factor for skeletal fragility in the elderly and osteoporotic fractures.^{2,3} Moreover, scientific studies have shown that Vitamin D supplementation prevents systemic bone loss following a fracture and reduces the risk of multiple fractures.^{4,5} National and international guidelines on the management of osteoporosis recommend adequate calcium and vitamin D supplementation in addition to anti-osteoporotic therapies.^{6,7} ALFA Note 79, in defining which drugs for primary and secondary prevention of the risk of osteoporotic fractures are reimbursable, states that, before starting therapy with these drugs, an adequate intake of calcium and vitamin D is recommended, resorting, where diet and sun exposure are inadequate, to supplements with calcium salts and vitamin D3 (and not its hydroxylated metabolites).⁸

In recent years, a progressive increase in the consumption of vitamin D in Italy, has brought about a consequent increase in expenditure by the National Health Service (NHS).^{9,10} The growth in the consumption of Vitamin D led to speculation of possible inappropriate use. Consequently, in late October 2019, ALFA published Note 96 identifying the criteria for the reimbursement of Vitamin D supplementation for the prevention and treatment of vitamin deficiency in adults.¹¹

In the first 15 months of application of the Note, there was nearly a 30% decrease in the consumption of and expenditure for Vitamin D compared to previous periods.¹² However, whether this is due to an improvement in the appropriateness of use is not clear.

Recently, CliCon S.r.l. Benefit Corporation, in cooperation with Azienda ULSS Berica 8

Local Health Service, conducted an analysis to verify whether the reduction in vitamin D consumption observed after Note 96 became effective was accompanied by an increase in the appropriateness of the use of these supplements. The results were presented at the last edition of the ISPOR 2021 European Conference.¹³ The analysis was performed using the Local Health Service's administrative flows. All adult patients with at least one prescription for the pharmaceutical products in Note 96 (cholecalciferol, cholecalciferol/calcium salts, calcifediol) or in Note 79 (bisphosphonates, teriparatide, strontium ranelate, raloxifene, denosumab, bazedoxifene) in the 12 months before (1/10/2018 to 30/09/2019) and after (1/10/2019 to 30/09/2020) when Note 96 entered into force, were included. Improvement in the appropriateness of prescriptions, measured as a reduction in the deviation between clinical practice and therapeutic recommendations, was assessed using the following indicators:

- **indicator 1:** proportion of patients treated with drugs for osteoporosis combining Vitamin D (Vitamin D in Note 79, appropriate use);
- **indicator 2:** proportion of patients treated with Vitamin D without established hypovitaminosis in the last 12 months (Vitamin D out of Note 96, inappropriate use).

In the 12 months pre- and post-Note 96, the calculation of indicator 1, which measures adherence to the reimbursement criteria in Note 79, showed a reduction in the proportion of patients who combine Vitamin D with osteoporosis drugs, from 70.2% to 60.4% of the total number treated with osteoporosis drugs, as shown in Figure 1.

Conversely, no appreciable differences were found in the calculation of indicator 2, which measured the deviation from the reimburse-

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Conflict of interest

The authors state that there are no conflicts of interest.

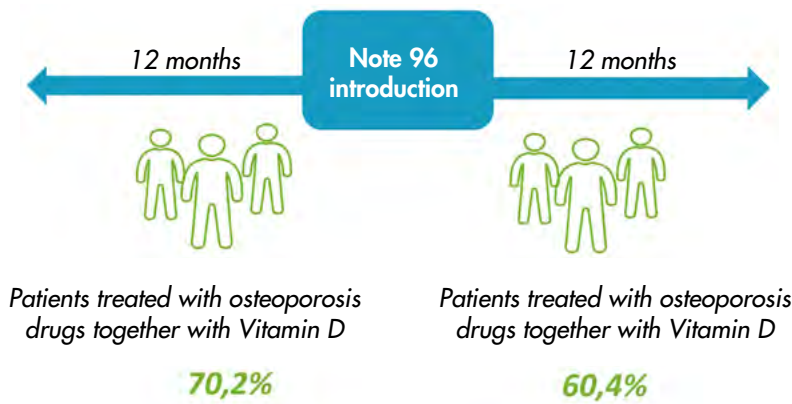
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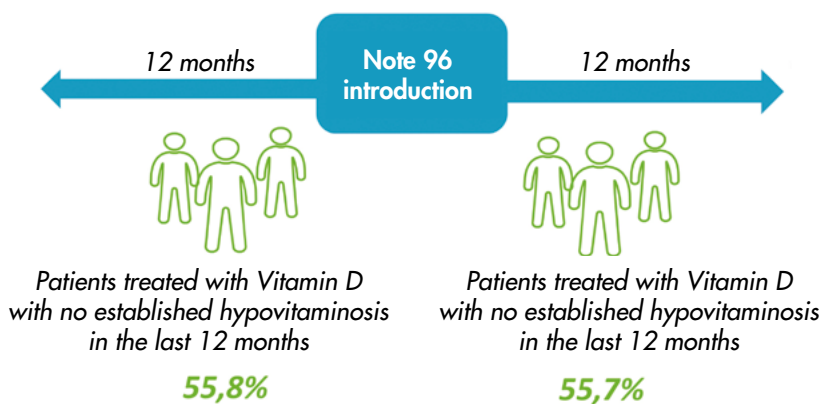


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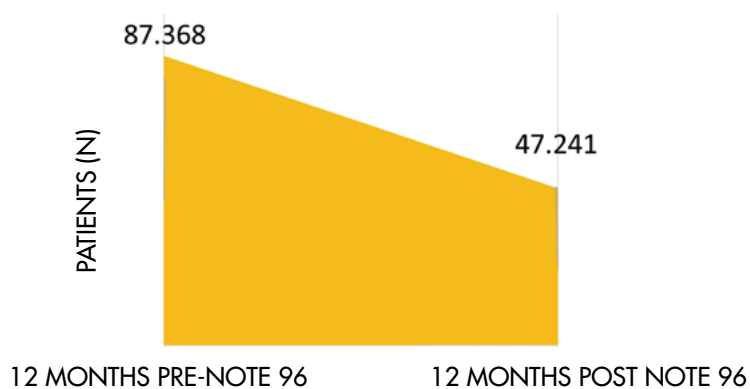
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**FIGURE 1.**

Proportion of patients treated with osteoporosis drugs together with Vitamin D in the 12 months before and after the introduction of Note 96.

**FIGURE 2.**

Proportion of patients in the 12 months before and after the introduction of Note 96 treated with Vitamin D with no established hypovitaminosis in the last 12 months (excluding patients in Note 79 for whom the determination of 25(OH)D levels is not envisaged).

**FIGURE 3.**

Total number of patients treated with Vitamin D in the 12 months before and after the introduction of Note 96.

ment criteria in Note 96: the proportion of patients treated with vitamin D without ascertained hypovitaminosis in the last 12 months, excluding patients in Note 79 for

whom the determination of 25(OH)D levels was not envisaged, remained unchanged (55.8% vs 55.7%), highlighting how, net of osteoporotic patients, more than half of

those treated with vitamin D did not have the indications for the drugs being reimbursed (Fig. 2).

Instead, the total number of patients treated with vitamin D was significantly reduced: as illustrated by figure 3, going from 87,368 to 47,041 subjects, with a resulting drop in expenditure (-€1.1 million: -44.8%).

On the whole, the results of the analysis showed a reduction on the use of Vitamin D, determined by a lower number of patients receiving these supplements on a reimbursable basis. Nevertheless, this decrease did not coincide with an improvement in the appropriateness of prescriptions, which, in contrast, declined, especially as regards to its use in combination with osteoporosis drugs. Indeed, while the proportion of patients treated with vitamin D without 25(OH)D detection remained equally high in the two periods, the proportion of patients who combined vitamin D with osteoporosis drugs fell by 10 percentage points. This suggests the need to implement clinical practice monitoring measures to promptly identify actions that will optimise the appropriateness of prescriptions.

The literature has widely acknowledged that inadequate vitamin D supplementation in combination with anti-osteoporotic treatments can reduce the effect of these therapies and lead to an increase in adverse outcomes.^{14,15} Several published studies have observed in Italian settings a greater increase in bone density and a significant decrease in fracture risk in post-menopausal women treated with osteoporosis drugs in combination with Vitamin D supplements compared to patients taking only anti-osteoporotic therapies.¹⁴ In addition, a previous retrospective observational study, based on administrative databases from a sample of Local Health Services, conducted on a cohort of osteoporotic patients with a previous fragility fracture, showed a lower incidence rate of re-fracture among patients on calcium/Vitamin D supplementation than among those receiving either osteoporosis medication alone or no treatment for the condition.¹⁶ Moreover, patients receiving calcium/vitamin D supplementation in addition to osteoporosis medication had a 64% reduced risk of developing a subsequent fracture and two times less risk of death compared to the group receiving osteoporosis medication alone.¹⁶ In line clinical outcomes, costs for clinical care for osteoporotic patients receiving calcium/Vitamin D supplementation

were also lower.¹⁷ On the other hand, supplemental vitamin D in situations other than osteoporotic fracture prevention is one of the most hotly debated issues in the medical field, being a source of controversy and beliefs that can also be strongly antithetical. Numerous observational studies of various pathological situations (heart disease, neoplasia, degenerative diseases, respiratory metabolic diseases etc.) have indicated that general health conditions in populations with low vitamin D levels are poor.¹⁸

However, the results of large-scale randomised clinical trials have not confirmed these hypotheses whilst revealing areas of documented ineffectiveness of vitamin D supplementation, especially in oncology and cardiology. The scientific literature considers a 25(OH)D value of 20 ng/mL (50 nmol/L) to be the limit beyond which adequate intestinal absorption of calcium and control of parathormone levels can be ensured in nearly the entire population. For this reason, it represents the level below which supplementation should be started.

Ultimately, as summarised by the two AIFA Notes, the literature has emphasised the importance of ensuring adequate vitamin D supplementation to prevent osteoporotic fragility fractures, to decrease the incidence of such events, as well as to limit the onerous economic burden associated with them, and that vitamin D should be supplemented in the presence of 25(OH)D values >20 ng/mL in osteoporotic patients.

On this basis, the analysis conducted clearly indicates the need for the appropriateness of vitamin D use to be optimised both for osteoporotic patients per Note 79, for whom vitamin D should be more widely prescribed, and in presumed deficient states, where more than 50% of patients receive supplementation without having had a 25(OH)D dosage, as provided for by Note 96.

The implementation and periodic monitoring of appropriateness indicators, designed to identify uses where there is no indication for use (vitamin D outside Note 96) and areas where there is a recommendation but no prescription (vitamin D in Note 79), offers an opportunity to organise and develop clinical governance and internal monitoring processes, to improve patient care, in the

form of clinical audits within the individual local health services. Finally, the involvement of primary care general practitioners would make it possible to identify off-target patients to audit, thus aiding in the reduction of inappropriate prescriptions, resulting in improved patient health and lower healthcare resource consumption.

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