

BACKGROUND

In October 2019, the reimbursement criteria of vitamin D (vit-D) analogs for the prevention and treatment of vit-D-deficiency in adults were refined by Agenzia Italiana del Farmaco (AIFA) through the publication of Note-96.

In the first 15 months from Note's adoption, a 30% of decrease in drug-related consumptions and expenditures compared to previous periods was observed.

The study aimed to verify whether this reduction was related to greater appropriateness in vit-D analogs use.

METHODS

A retrospective analysis of a Local Health Unit's administrative databases with **around 491,000 inhabitants** was conducted. All adult patients with ≥ 1 prescription of drugs included in **Note-96** (such as cholecalciferol, cholecalciferol/calcium, calcifediol) or in **Note-79** (such as bisphosphonates, teriparatide, strontium ranelate, raloxifene, denosumab, and bazedoxifene, whose reimbursements are for primary and secondary prevention of osteoporotic fractures), during 12 months before and after the establishment of **Note-96** (31/10/2019), were included.

According to **HEALTH-DB** monitoring system, two indicators of prescription appropriateness, designed to measure the difference between clinical practice and recommendations, were proposed:

1. % of patients treated with osteoporosis drugs plus vit-D;
2. % of patients treated with vit-D without hypovitaminosis tested in the last 12 months (excluding patients defined by Note-79).

DATA PRIVACY STATEMENT. The integration of administrative datasets makes it possible to represent the patient's entire clinical history and not just individual prescriptions. The analyses were conducted on exclusively anonymous data in full compliance with privacy regulations. CliCon s.r.l. has obtained the approval as per legislation by all the Ethics Committees to analyse these data. The results are exclusively in aggregated form and never attributable to a single institution, department, doctor, individual, or individual prescribing behaviours. The study was conducted in full compliance with current legislation for retrospective studies.

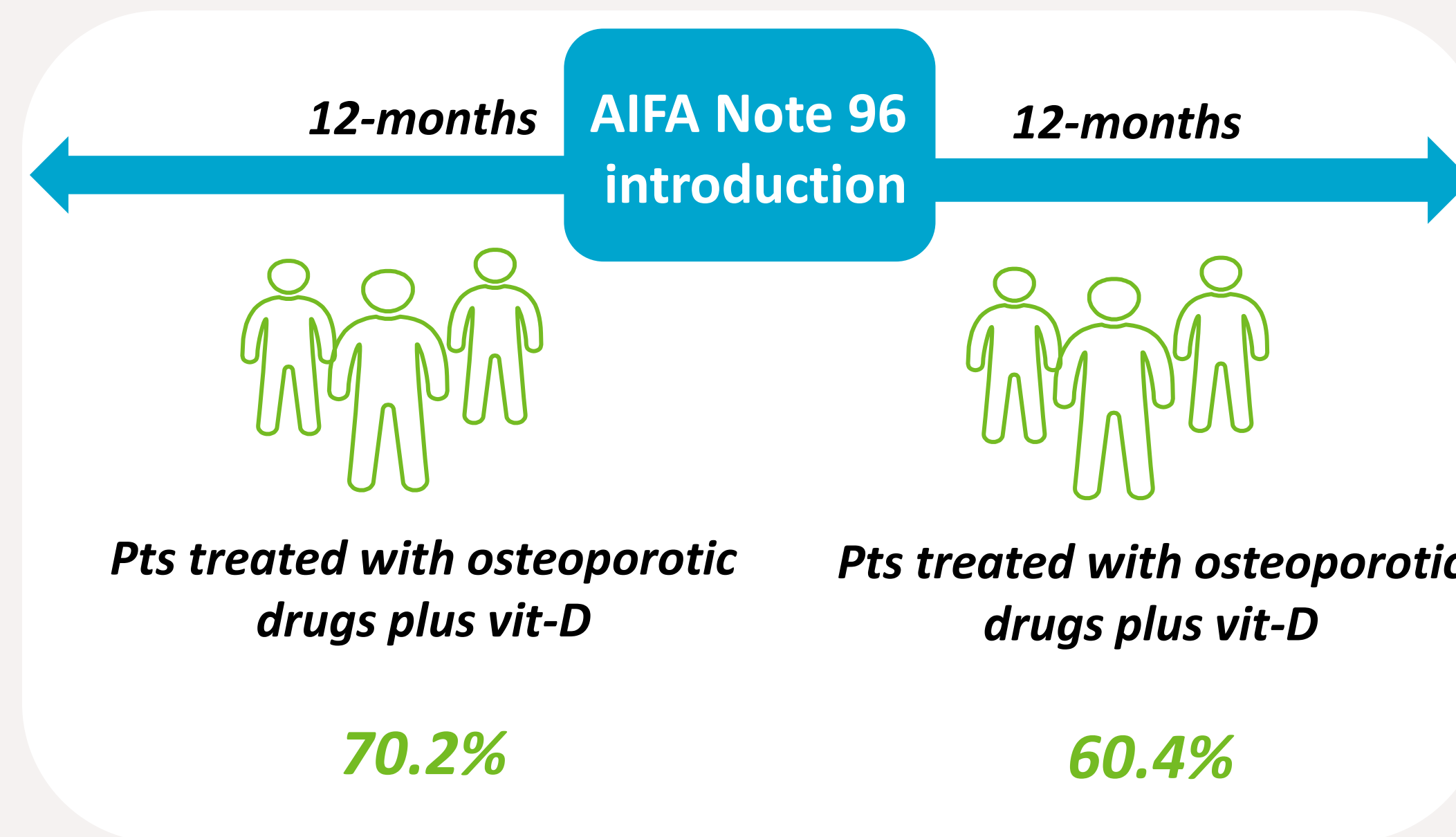
IMPACT OF AIFA NOTE 96 ON VITAMIN D ANALOGS' PRESCRIPTIVE APPROPRIATENESS

POSA239

RESULTS

Considering the **12 months before and the 12 months after** the introduction of the AIFA Note 96, patients treated with osteoporotic drugs plus vit-D, in accordance with the AIFA Note 79, decrease from **70.2%** (before the AIFA Note 96) to **60.4%** (after the AIFA Note 96) with respect to the total amount of patients treated with osteoporotic drugs (Fig. 1).

Fig. 1 – Vit-D users before and after Note 96 adoption



AUTHORS

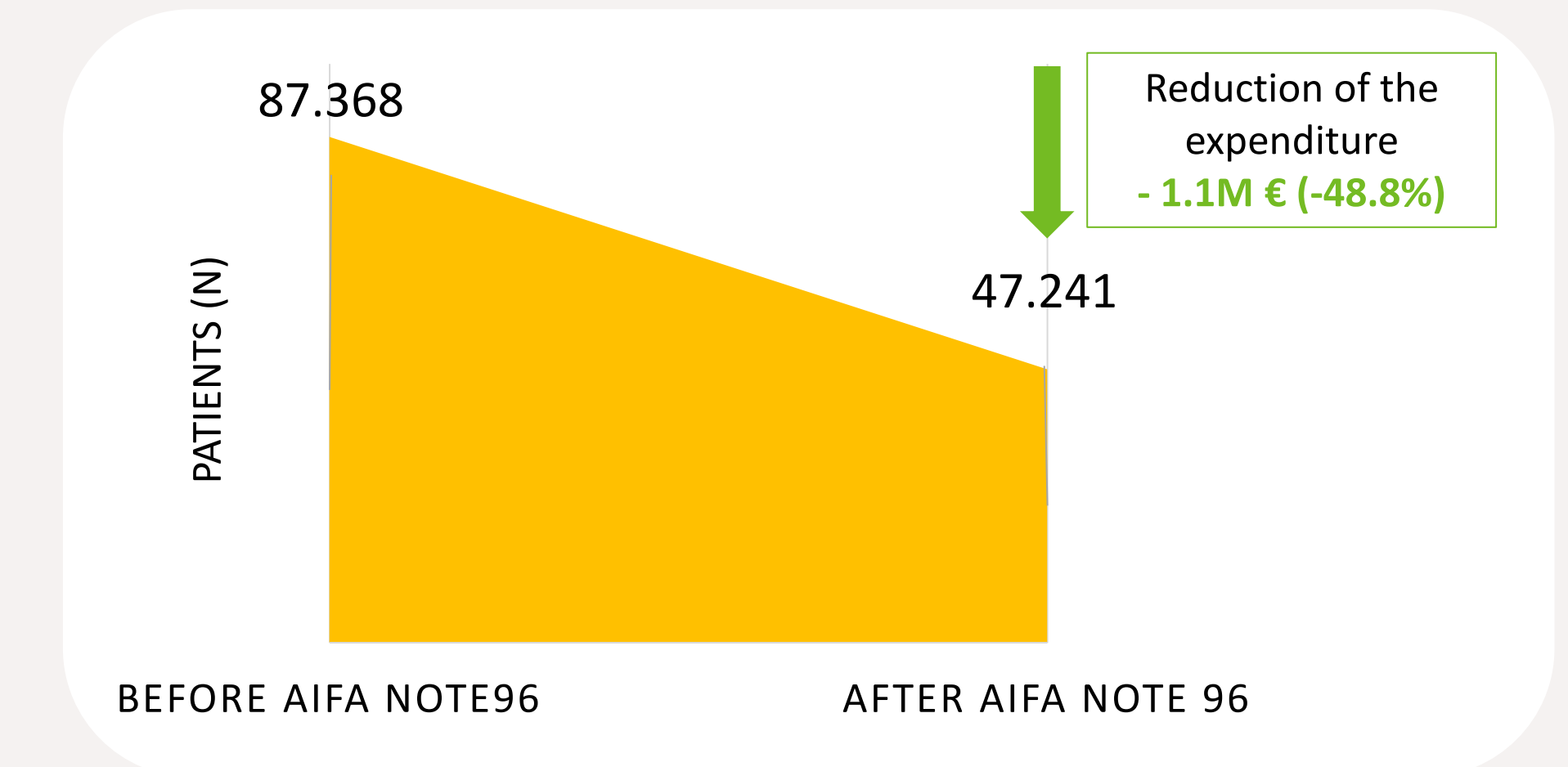
Degli Esposti Luca¹, Ghigi Alessandro¹, Nappi Carmela¹, Tonello Iva², Andretta Margherita²

¹ CliCon S.r.l. Health, Economics & Outcomes Research, Bologna, Italy; ² Assistenza Farmaceutica Territoriale Azienda ULSS 8 Berica, Vicenza, Italy

Patients **treated with vit-D analogs** without testing its level during the last 12 months remained unchanged: 55.8% pre- and 55.7% post-Note-96 establishment.

The **total number of subjects treated with vit-D** decreased significantly from 87,368 to 47,241 with a consequent reduction of expenditure (-1.1 million €: -44.8%).

Fig. 2 – Number of Vit-D treated patients and expenditure reduction before and after AIFA note 96



CONCLUSIONS

The introduction of Note-96 led to vit-D consumption and expenditure reduction, but not to an improvement of its prescription appropriateness, which decreased, especially in association with osteoporosis drugs. The periodic monitoring of prescription appropriateness indicators allows improving the prescription adequacy, the patient's health, and healthcare resources consumption.