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RESEARCH

Dispensing of vitamin products by retail pharmacies in South Africa: Implications for dietitians

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Objective: The objective of this study was to analyse the dispensing patterns of vitamins (Anatomical Therapeutic Chemical (ATC) group A11) over a one-year period in a group of community pharmacies in South Africa.
Design and setting: A retrospective drug utilisation study was conducted on community pharmacy electronic dispensing records in South Africa recorded in 2013.
Outcome measures: All products for ATC subgroup A11 were extracted and analysed.
Results: A total of 164 233 vitamin products were dispensed to 84 805 patients (62.64% female patients). Males received on average 2.09 (SD = 2.63) vitamin products per year, compared to 1.84 (SD = 2.13) products for females. Ergocalciferol (A11CC01) was the most often dispensed (37.48% of all vitamin products), followed by plain Vitamin B-complex products (A11EA00) accounting for 32.77%. Ergocalciferol (vitamin D2) is only available on prescription (50 000 IU tablets or 50 000 IU/ml oily drops) in South Africa. Tablets were the preferred dosage form (62.84% of products). Most injections were for Vitamin B1 or Vitamin B combination products.
Conclusion: Ergocalciferol and injectable vitamins have recently been rescheduled to prescription-only; it is probable that this has impacted on the usage of these products. It is important to monitor future vitamin supplementation behaviour in community pharmacies since pharmacies are selling many of these products and pharmacists can, by counselling patients, determine the reasons for the use of these products. Furthermore, should dietitians and nutritionists choose to work with this captive audience, supplementation patterns can be monitored to develop and implement appropriate awareness campaigns. Further studies to explore these baseline results are recommended.

Keywords: dispensing patterns, drug utilisation study, ergocalciferol, retail pharmacies, vitamins

Introduction

"Nutriceuticals/nutraceuticals" and "pharmaconutricals" are terms coined from "nutrition" and "pharmaceutical" to indicate a special therapeutic role for a food or food substance in the prevention and management of specific disease states.[1, 2] Nutraceuticals may include vitamins, minerals, amino acids and fatty acids, and differ from dietary supplements, as these not only supplement an individual's diet, but also aid in the prevention and/or treatment of a disease.[2] Vitamin D deficiency, for example, was reported in 2011 to be extremely common in black Africans living in Cape Town, and it was associated with susceptibility to tuberculosis (TB) infection.[3] It was concluded that vitamin D supplementation may be a highly cost-effective, safe and simple means to reduce TB incidence.[3] In a study recently reported by Busse *et al.*,[4] the negative impact of vitamin D deficiency on bone health, specifically the higher risk for bone fractures was demonstrated; however, its impact on other health areas is less clear. Vitamin D deficiency has been suggested, for example, to play a role in depression[5] and has also been associated with increased HIV-1 replication in HIV-infected individuals.[6]

It is well known that dietary supplement use in the United States of America (USA) is exceedingly high, with multivitamins and multiminerals the most frequently taken dietary supplement across all NHANES (National Health and Nutrition Examination Survey) years.[7] About 39% of US residents have used at least one multivitamin and multimineral during the 2003 to 2006 survey period, and use was more prevalent in females.[7] Further USA data suggest that adults and adolescents with suboptimal intakes of vitamins from food sources are less likely to be dietary supplement users.[8] It was also observed that some subgroups of the population may be at risk for excessive intakes.[8] Despite the high intake of multivitamins and multiminerals, tools to quantify intake and the potential public health impact of the use of dietary supplements were lacking. However, an integrated dietary supplement ingredient database was recently implemented in the USA.[9] The collection and analysis of data on dietary supplement provides important quantitative indicators regarding the exposure and potential public health impact of dietary supplements.

Vitamin A and iron deficiencies in South Africa are widespread, and inadequate dietary intakes have been attributed to be the most important cause of these deficiencies.[10] Micronutrient supplementation is routinely available to patients in the public health sector in South Africa, especially for pregnant and lactating women and vulnerable children at risk of developing malnutrition, as well as patients with infectious diseases.[11] However, there is little published data available regarding the use of vitamins and minerals acquired from community pharmacies, despite the prevalent dispensing thereof. Survey results are available regarding dietary supplement use in certain cohorts,[12] as well as the impact of marketing of nutritional or dietary supplements and resulting supplement choices by study participants in South Africa.[13] In addition, the schedules of some vitamin formulations have recently been changed, and it will be important to monitor the impact of these changes in follow-up studies. This study was therefore conducted to inform on current dispensing patterns of vitamins in community pharmacies and to establish a baseline for further research.

The primary aim of the study was to analyse the dispensing patterns of vitamins (specifically the Anatomical Therapeutic Chemical (ATC) group A11)[15] over a one-year period in a group of community pharmacies in South Africa. Secondary objectives included analysis of these patterns by age and gender.

Methodology

Study design and setting

A retrospective, cross-sectional drug utilisation study was conducted on a community pharmacy dispensing database of approximately 54 million records dispensed by 327 community pharmacies in 2013 in South Africa. The term "community pharmacy" (also known as "retail pharmacy") refers to a pharmacy wherein, or from which, some or all of the services as prescribed in terms of regulation 18 of the Regulations Relating to the Practice of Pharmacy in the Pharmacy Act are provided to the general public or any defined group of the general public, but excludes an institutional pharmacy (for example, a hospital pharmacy). According to the South African Pharmacy Council, there are 3 082 registered community pharmacies in South Africa.[14] The data therefore represented approximately 10% of all community pharmacy dispensing records in 2013. The database consisted of dispensing information from pharmacies in all nine provinces of South Africa. It included dispensing records from all the pharmacies participating in the database. Products included both medical aid claims and products that were purchased from the pharmacies' dispensaries. Thus, it included all vitamins prescribed by the clinicians, as well as those dispensed by pharmacists without a prescription, and that were recorded by the dispensing program of the pharmacy.

Approximately half of the supplements were claimed from 295 different medical aid scheme options (plans), 35.66% of the products were claimed as over-the-counter (OTC) products, and 13.47% were private purchases.

Data analysis

The Anatomical Therapeutic Chemical (ATC) Classification System,[15] Monthly Index of Medical Specialities (MIMS)[16] and the South African Medicines Formulary[1] were used to classify medicines. The ATC Classification system is recommended by the World Health Organisation as the standard medicine classification system for drug utilisation studies in the world in order to enable comparative studies to be conducted. All products in ATC subgroup A11 were extracted and analysed. This ATC classification system is acknowledged worldwide; products are screened by an expert panel before receiving an ATC code. It is recognised that some vitamins are also included in other ATC groups, such as Vitamin K under anti-haemorrhagics (ATC code B02B) and Vitamin B_{12} under anti-anaemic preparations (ATC code B03B). These products were not included in this study. This study focused exclusively on products classified under ATC group A11.

Each medication record contained information on the age and gender of the patient, with a unique number to identify each patient, the date of the prescription, detailed information on the dispensed drug (name, package size, formulation, strength and quantity) and gross sales value. Dosage instructions were given, but were not consistently recorded.

Microsoft Access® and Excel® (part of the Microsoft Office Professional Plus 2013® package) were used to analyse the data. Descriptive statistics were calculated. The results were described according to means and standard deviations for numerical data, and frequencies and percentages for categorical data. The Pearson's chi-squared test was used to determine statistical significant differences between sub-groups. A p-value < 0.05 was considered statistically significant.

Ethical approval

Ethical approval to conduct studies on prescription databases was obtained from the Research Ethics Committee (Human) of the Nelson Mandela Metropolitan University (ethics clearance number: H08-HEA-PHA-005). The dispensing records were de-identified, meaning that no patient nor prescriber could be identified. A patient identifier was added to enable the researchers to uniquely identify each patient in terms of age and gender, and to calculate the number and spectrum of products that a specific patient received, but it was a neutral code and not an identity or medical aid number.

Limitations of the study

A major limitation of the study was that only vitamins that were recorded by the dispensary were included in the study. Unscheduled vitamins that were purchased in the front-shop of the pharmacy and paid for at the cashier, were not included in the study. Further limitations of the study included: no clinical information was available in the database; and that the study only covered a one-year period (1 January 2013 to 31 December 2013). Other limitations included the exclusion of the analysis of vitamin K (ATC code B02B) and Vitamin B_{12} preparations (ATC code B03B) from this study. The analysis of the records for these vitamins would have provided important indicators of compliance in terms of only dispensing with a prescription, as well as the prevalence of the dispensing of these vitamins. Although dosage instructions were captured on the system, these were not consistently recorded, which potentially influenced or skewed the results.

Results

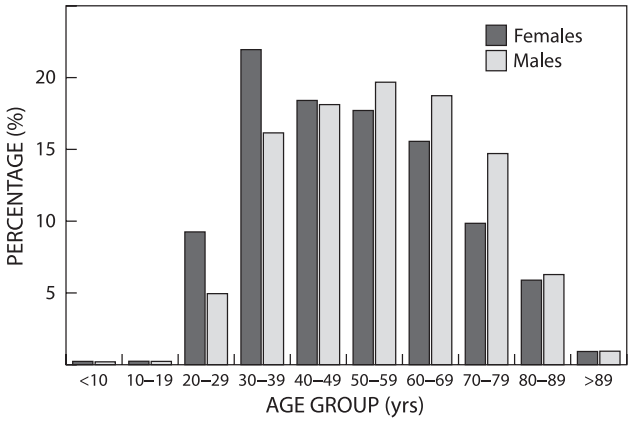
Demographic information

A total of 164 233 vitamin products were dispensed to 84 807 patients at a cost of ZAR7 689 306.34 in 2013. The majority of patients were females (n = 53 123; 62.64%). The average age of patients was 47.53 (SD = 16.17) years (females: 46.33 (SD = 16.12) years; males: 49.54 (SD = 16.06) years).

Number of products dispensed

The products were predominantly dispensed to patients between the ages of 30 and 59 years, as shown in Figure 1. Females in the 30 to 39-year age group were dispensed 21.95% of products compared with males (16.15%). The chi-square test was used to detect differences between female and male patients in the different age groups. Differences (χ^2 = 2513.0; d.f. = 5; p < 0.0001) were observed, after collapsing the small clusters below 30 years of age and above 70 years of age together.

Males received on average 2.09 (SD = 2.63) vitamin products over the year, compared to 1.84 (SD = 2.13) products for females. However, patients that were dispensed with ergocalciferol (vitamin D2) tablets received on average 3.38 (SD = 3.41) products per year, and those that were dispensed calcitriol



0.23	0.24	9.25	21.95	18.41	17.71	15.56	9.85	5.89	0.92
0.20	0.23	4.95	16.15	18.12	19.68	18.74	14.71	6.28	0.94

Figure 1: Percentage of products dispensed by gender in the different age groups (*N* = 164 233).

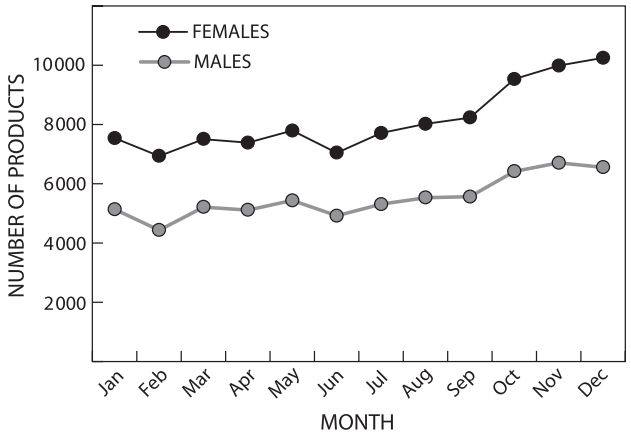


Figure 2: Frequency of vitamin products dispensed by gender over the 12 months (*N*=164 233).

(1,25-dihydroxyvitamin D3) received 4.84 (SD = 4.47) products per year. The number of vitamin products dispensed increased steadily over the year, as can be seen in Figure 2, with no seasonal peak during May to August, the winter season.

Prescribing of the different vitamin active ingredients

The percentage frequency distribution of the different vitamin active ingredients according to gender is given in Table 1. Ergocalciferol (vitamin D2) was the most frequently dispensed (37.48% of all vitamin products), followed by plain Vitamin B-complex products (A11EA00) accounting for 32.77% of products. Alphacalcidol (1-apha-hydroxyvitamin D3) reflected only 2.52% of the products and calcitriol (1,25-dihydroxyvitamin D3) only 0.49% of the dispensed products. In the Vitamin B-complex products category, vitamin B-complex tablets (56.88%) were more frequently dispensed, and 43.12% as Vitamin B-complex 10 mg/ml vials. Neurobion® injections, containing a combination of 100 mg of Vitamin B1, 100 mg of Vitamin B6 and 1 mg of Vitamin B12, reflected 9.69% of the products.

Table 1: Frequency distribution of the different vitamin active ingredients according to gender (*N* = 164 233)

ATC Groups		Percentage (%)		Both genders	
		Females	Males	Number	%
A11A	*Multivitamins, combinations*				
A11AA03	Multivitamins and other minerals, including combinations	6.88	4.58	9773	5.95
A11B	*Multivitamins, plain*				
A11BA01	Multivitamins, plain	1.04	1.06	1720	1.05
A11C	*Vitamin A and D, including combinations of the two*				
A11CC01	Ergocalciferol	36.15	39.44	61552	37.48
A11CC03	Alfacalcidol	1.58	3.92	4144	2.52
A11CC04	Calcitriol	0.37	0.67	808	0.49
A11D	*Vitamin B_1, plain and in combination with vitamin B6 and B12*				
A11DA01	Thiamine (Vit B1)	14.63	16.53	25291	15.40
A11E	*Vitamin B-Complex, including combinations*				
A11EA00	Vitamin B-Complex, plain	34.91	29.62	53822	32.77
A11EB00	Vitamin B-Complex with Vitamin C	0.00	0.00	5	0.00
A11EX00	Vitamin B-Complex, other combinations	0.20	0.29	387	0.24
A11G	*Ascorbic acid (vitamin C), including combinations*				
A11GA01	Ascorbic acid (Vitamin C)	0.004	0.01	12	0.01
A11GB00	Ascorbic acid (Vitamin C),combinations	0.001	0.00	1	0.00
A11H	*Oher plain vitamin preparations*				
A11HA02	Pyridoxine (Vitamin B6)	0.001	0.00	1	0.00
A11HA03	Tocopherol (Vitamin E)	0.004	0.003	6	0.00
A11HA07	Inositol	0.002	0.00	2	0.00
A11 J	*Other vitamin products, combinations*				
A11JB00	Vitamins with minerals	0.69	0.69	1135	0.69
A11JC00	Vitamins, other combinations	3.54	3.18	5574	3.39
TOTAL		**100.00**	**100.00**	**164 233**	**100.00**

The frequency distributions of products according to age and gender for the two most often dispensed groups are compared in Figures 3(a) and 3(b). Interestingly, most products for ergocalciferol (vitamin D2) were dispensed for patients older

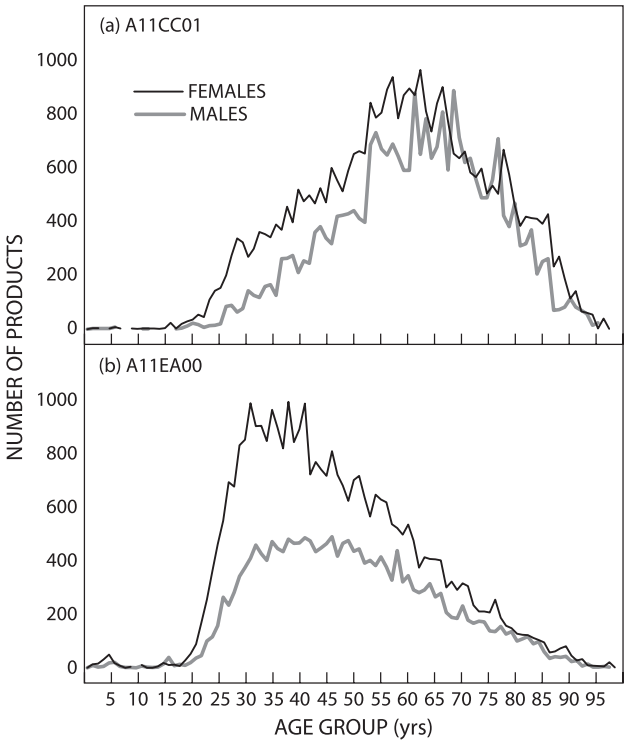


Figure 3: (a) & (b) Frequency distributions of products according to age and gender for the two most often dispensed vitamin subgroups

than 50 years, while vitamin B-complex products peaked at an earlier age (around 30 years).

Dosage forms and schedules dispensed

Vitamin tablets were the dosage form mostly dispensed (62.84%) compared with capsules (10.37%), vials (14.13%), injections (9.70%), followed by small amounts of chewable tables, drops and vitamin syrup. Most injections and vials were for vitamin B1 or vitamin B-complex products.

Vitamins are either unscheduled, Schedule 0, 1, 2, 3 or 4.[1] Approximately half (54.62%) of the products were prescription-only medicine (Figure 4). A total of 4 952 products were Schedule 4 prescriptions (alfacalcidol or calcitriol). A total of 84 760 products were classified as Schedule 3 (60 943 calciferol 50 000 IU

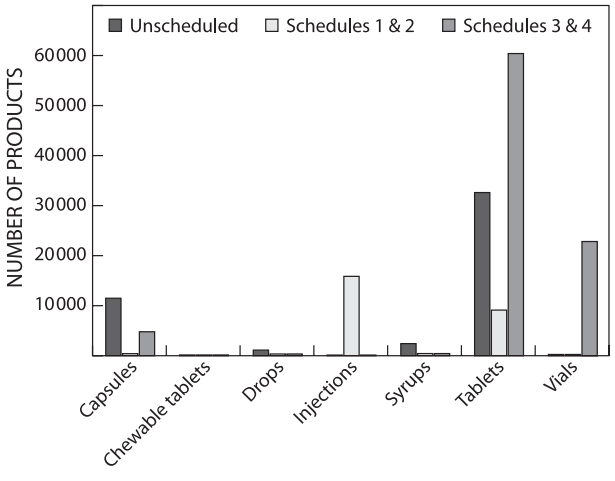


Figure 4: Vitamins dispensed by schedule

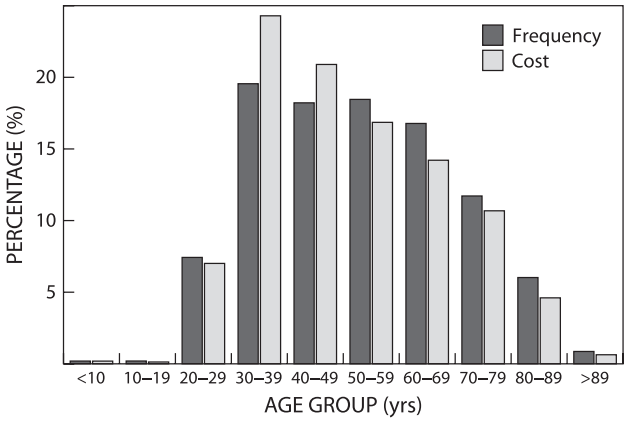


Figure 5: Percentage frequency versus cost of products in 10 year-age groups

tablets and 609 calciferol oil 5 000 IU/ml drops). A total of 23 208 vitamin B-complex (Vitamin B6) 10 mg/ml vials were dispensed (also Schedule 3).

Cost of vitamin products dispensed

The average cost per vitamin product was ZAR46.82 (SD = ZAR367.45). The average cost per product for females was ZAR43.74 and for males ZAR51.37. The percentage frequency versus the percentage cost of vitamin products in 10-year age groups are compared in Figure 5. The 30 to 39-year age group accounted for the largest percentage of cost (45.29%). Within that age group, 28.93% of the cost was due to the dispensing of a combination vitamin and mineral product marketed for pregnant female patients, or a vitamin and mineral syrup.

Discussion

Vitamin D has been described as "a nutraceutical that has exploded onto the prescription pad" in recent years[17], and is known to be widely deficient in Western populations.[18] Despite numerous observational studies on plasma vitamin D concentrations, as well as randomised controlled trials, no consensus exist on optimal vitamin D intake and supplementation.[19] In the umbrella review by Theodoratou *et al*.,[19] it was suggested that low plasma vitamin D is a marker of compromised health, but not necessarily a cause of disease.

In this study, it was evident that vitamin D supplements and specifically ergocalciferol (vitamin D2) are still widely used, since it was the product most often dispensed by participating pharmacies in the sample. It was probably due to the perceived benefits in relation to specifically bone health; however, the usage may be influenced by exposure to reports in the media which highlight the wide prevalence of vitamin D deficiency and associations with other health problems (for example, depression and rheumatoid arthritis).[20] Despite the documented benefits, the 2011 Daily Recommended Intakes for vitamin D only recommend levels of 400 IU/d for infants, 600 IU/d for children and adults through age 70 years, and 800 IU/d for ages 71 years and older.[21]

Owing to the prevalent dispensing of ergocalciferol to both genders, it may be of interest to investigate whether the use of vitamin D supplements is due to the perceived benefits of the vitamin by patients, clinicians or dietitians, hence further research is thus recommended. It would also be important to establish whether ergocalciferol is prescribed to treat low

25-hydroxyvitamin D levels, to prevent bone disease, or due to the perceived value as a nutraceutical. In the absence of vitamin D deficiency, ergocalciferol supplementation may result in intakes approaching upper limits of 4000 IU/d that may result in declining benefits. There is emerging evidence of a U-shaped curve associated with vitamin D supplementation for all-cause mortality, as well as morbidity.[21]

Although vitamin B-complex in tablet form was the product most often dispensed, vitamin B vials and injections accounted for more than 20% of products. It should be noted that vitamin B injections have recently been rescheduled in South Africa to prescription-only products, and consumers therefore can no longer buy these products directly from a pharmacy or ask the pharmacist to administer a vitamin B injection without a prescription.[22]

The vitamin and mineral supplementation market in South Africa in 2015 was worth approximately ZAR2.9 billion and growing annually at a rate of 7%.[23] It can be assumed that most consumers prefer to buy unscheduled vitamin and mineral supplements in retail stores or health shops rather than community pharmacies. We speculate consumers in South Africa are probably predominantly dependent on marketing from manufacturers and retailers to obtain accurate information about vitamin products they purchase. Since consumers normally do not seek professional advice prior to purchasing vitamin products,[24] it is important for dietitians to utilise all potential opportunities to educate vitamin product users about responsible supplementation. The results from this retrospective analysis predominantly reflect trends in relation to scheduled products. However, it was interesting to observe that a large number of patients still receive dispensed vitamin products which were either prescribed by a physician or dispensed by a pharmacist after consultation with a patient. This is especially true in relation to vitamin D supplementation and currently there is limited information about the reasons for vitamin D use in South Africa. Dietitians and nutritionists need to be aware of this captive audience and should work with pharmacists to interpret prescription and dispensing patterns and create referral systems for patients that may need additional nutrition counselling.

Conclusion and recommendations

Vitamins are important in treating nutritional deficiencies, yet few studies on vitamins have been conducted in pharmacies. Vitamin D2, vitamin B-complex (plain preparations) and vitamin B1 together, accounted for more than 85% of all vitamin products dispensed in ATC group A11.

It is expected that the restriction on the over-the-counter availability of vitamin B injections in South Africa will impact on the dispensing and usage patterns. It will be important to monitor the effect that this change in prescribing status will have on vitamin sales in pharmacies.

The study had various limitations, yet a baseline was established for further studies. It is important to monitor future vitamin supplementation behaviour in community pharmacies since pharmacies are selling many of these products and pharmacists can, by counselling patients, determine the reasons for the use of these products. There is also a need to develop a comprehensive vitamin database that includes clinical data (such as comprehensive diagnoses (the ICD10 code) and laboratory markers, where available). There is also a need for prospective studies to be conducted in this field. Furthermore, should dietitians choose to work with this captive audience, supplementation patterns can be monitored to develop and implement appropriate awareness campaigns. This may prevent an excessive micronutrient intake in individuals at risk of exceeding the upper tolerable limits. Further research to determine reasons behind these dispensing patters is recommended.

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