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THE CHANGE OF THE VITAMIN D TEST REQUEST NUMBER AFTER THE REGULATION BY THE MINISTRY OF HEALTH

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Abstract

Objectives: There has been an increase in 25-hydroxy vitamin D (25(OH)D) test requests and laboratory costs in recent years. At the end of 2019, the General Directorate of Health Information Systems issued a regulation calling for restricting vitamin D requests in primary care. We aimed to investigate the effect of this regulation on the requested numbers of 25(OH)D tests with the big data obtained from the national information health system of the Turkish Ministry of Health.

Materials and Methods: Between 2016-2022, all inpatient and outpatient tests and 25(OH)D tests in all medical biochemistry laboratories in Turkey were determined based on department and institution type. Distribution among health institutions and test request rates were calculated.

Results: The total number of 25(OH)D tests requested was increased from 2016 to 2022, except for 2020 and 2021, probably related to the COVID-19 pandemic. The yearly increase rate in 2017, 2018, 2019, and 2022 was 137%, 56%, 16%, and 5%, respectively. The number of 25(OH)D tests requested in primary care institutions decreased after the regulation. The total number of 25(OH)D tests requested in 2nd and 3rd Stage Public Health Facilities and private hospitals increased in 2022 compared to 2019.

Conclusion: Our findings showed that the request for 25(OH)D testing decreased in primary care and increased in 2nd and 3rd Stage Public Health Facilities and private hospitals after the regulation was released. Despite the decrease in the yearly increase rate in the number of test requests, the annual number of tests requested is still high, suggesting that different measures should be taken.

Keywords: 25-hydroxyvitamin D, medical biochemistry laboratory, big data, laboratory tests, national health data, ministry of health.



Introduction

Vitamin D is a hormone known to be vital for bone development and strength. Vitamin D is found to be associated with multiple conditions such as autoimmune diseases, cardiovascular disorders, multiple sclerosis, diabetes, cancer, and infection risk without a proven causal relationship.¹ Moreover, a very large proportion of the population has low vitamin D levels, which may be due to a normal variation in vitamin D metabolism.²

On the other hand, the role of vitamin D in the pathogenesis of many diseases has prompted doctors and patients to request more vitamin D tests, increasing the number of tests exponentially.³ Who should be tested for vitamin D deficiency is still a matter of debate. Although vitamin D deficiency is common, universal testing is not recommended because due to the high cost of the test materials. Additionally, extensive studies demonstrated that vitamin D supplementation in vitamin D-replete individuals did not improve overall health status.⁴ National and international guidelines suggest vitamin D testing only in certain risk groups.^{5,6}

The use of laboratory tests is vital in diagnostic decision-making, and approximately 70% of these decisions are based on the results of diagnostic tests.⁷ As a result of the increased use of laboratory testing, the associated costs have increased considerably.⁸ Several studies have been done in recent years to find a better solution to improve the appropriate use of laboratory tests in hospital and primary care settings.⁹ The impact of different interventions to decrease laboratory test requests was evaluated in these studies. These modifications are classified as weak, moderate, or strong based on the strength of their effect on decreasing inappropriate testing.¹⁰ Educational approaches, such as reference to evidence-based guidelines, are considered weak tools; however, various restrictions in the ordering process, such as limiting or completely eliminating test availability, test ordering algorithms, and reflex testing, as well as the design of the ordering process, including decision support and the use of pop-ups, are considered to \$39,662,184,539 in 2016 while spending on medical laboratory services in 2002 was approximately \$100 million (0.802% of the entire budget), 2016 it increased by about 3.5-fold, exceeding \$350 million (approx. 0.882% of the overall budget) and the 25-hydroxyvitamin D (25(OH)D) test was one of the most striking tests of recent years.¹¹

At the end of 2019, the Turkish Ministry of Health imposed a regulation that prevented the request for vitamin D testing by primary care physicians. The present study aims to describe the effect of this circular on vitamin D test request numbers among different health facilities and specialties.



Materials and Methods

The health records of individuals who were admitted to public, private, and university health institutions were collected via the Turkish Ministry of Health National electronic database. E-Health uses information and communication technologies for health and includes the data of health information systems, including electronic health records, telemedicine, mobile devices, e-learning tools, and decision support system.¹² This retrospective study included 25(OH)D measurements from 2016 to 2022. Laboratory results were presented to the author group under the supervision of the Ministry of Health to encourage data sharing and scientific research with the scientific community. The National Health Database provided information about laboratory services and testing processes. The test name, test result, test unit, and reference range were all included in the test process information. Demographic information of individuals was included in laboratory service information. Chromatographic methods, especially the immunoassay method, were generally used for vitamin D testing in Turkey (approximately 95%). All of the test measurements were presented as mg/L.¹³

At the end of 2019, the Turkish Ministry of Health imposed a regulation regarding vitamin D testing, preventing the request for vitamin D testing by primary care physicians. At the beginning of 2020, this Regulation was launched. Although by the regulation, every physician could order a free vitamin D test for inpatients and intensive care patients, only certain specialists were allowed to order vitamin D tests in the outpatient and emergency departments. Family physicians working in primary care could no longer request vitamin D testing. Additionally, the vitamin D test ordering interval has been established as 90 days, and it has been made mandatory for the Hospital Information System (HIS) to send a message to remind of this interval. A restriction was also imposed on requesting more than two tests per year.

Statistical analysis

Study data were analyzed by the SPSS program (version 20). Statistics output was presented as numbers and percentages.



Results

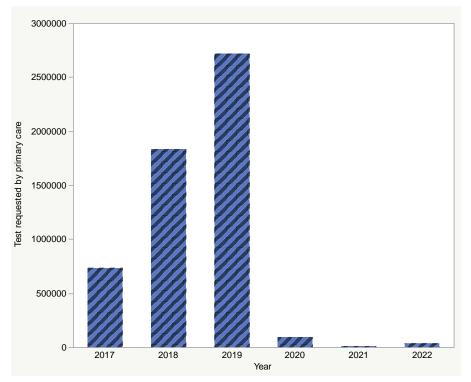
The total number of 25(OH)D tests requested between 2016 and 2022 were 2,826,997, 6,722,430, 10,506,144, 12,216,974, 5,477,206, 9,704,615 and 12,823,842 for consecutive years respectively. The total number of 25(OH)D tests requested in primary care institutions increased from 732,246 in 2017 to 2,714,443 in 2019, decreasing to 36,130 in 2022. The total number of 25(OH)D tests requested in 2nd and 3rd Stage Public Health Facilities and private hospitals increased in 2022 compared to 2019. There is a decrease in 25(OH)D testing in 2020 and 2021 compared to 2019 among all institutions (Table 1 and Figure 1). The yearly distribution of the number of Vitamin D requests by primary care institutions is shown in Figure 1. We excluded the year 2020 and 2021 because of the COVID-19 pandemic and calculated the yearly increase rate in the test requests. The yearly increase rate in 2017, 2018, 2019, and 2022 were 137%, 56%, 16%, and 5%, respectively. Despite the restriction on vitamin D requests with the regulation, the fact that the number of test requests has not decreased to zero in primary care institutions shows that the restriction could not be applied in some centers. However, it should be underlined that there is a substantial decrease in test request numbers.

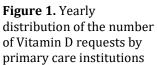
Year	Primary care institutions	2nd and 3rd Stage Public Health Facilities	Private Institutions	University Hospitals	Total	
2016	9,219	2,127,364	380,031	310,383	2,826,997	
2017	732,246	4,489,953	723,596	776,635	6,722,430	
2018	1,830,337	6,492,303	1,097,516	1,085,988	10,506,144	
2019	2,714,443	6,758,801	1,420,031	1,323,699	12,216,974	
2020	89,738	3,246,971	1,478,096	662,401	5,477,206	
2021	8,752	6,314,894	2,371,408	1,009,561	9,704,615	
2022	36,130	8,935,703	2,464,049	1,387,960	12,823,842	

Table 1. Distribution of the number of Vitamin D requests by institutions and by years

The total number of individuals who had three or more tests per year is shown in Figure 2. There was an increase in the number of individuals who had three or more tests per year from 2016 to 2019. By the regulation, a decrease was observed in the number of individuals who had three or more tests per year (Table 2 and Figure 2).







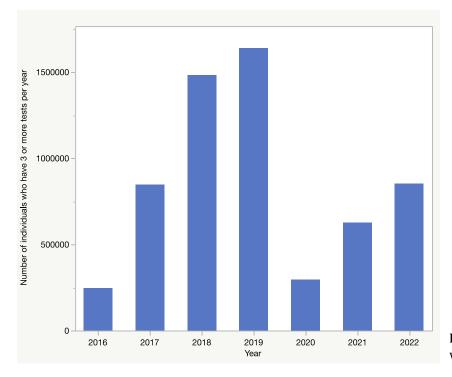


Figure 2. Number of individuals who had \geq 3 tests per year

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	Number of patients who were given a test only once a year	%	Number of patients for whom testing was requested twice a year	%	Number of patients who were asked to be tested ≥3 times a year	%	Total
2016	2,008,551	71	576,252	20	242,194	9	2,826,997
2017	4,281,303	64	1,600,384	24	840,743	13	6,722,430
2018	6,431,140	61	2,604,705	25	1,470,299	14	10,506,144
2019	7,502,170	61	3,089,549	25	1,625,255	13	12,216,974
2020	4,180,491	76	1,005,494	18	291,221	5	5,477,206
2021	6,933,119	71	2,151,595	22	619,901	6	9,704,615
2022	8,926,439	70	3,049,329	24	848,074	7	12,823,842

Table 2. Distribution of test request numbers by year

The distribution of the top 10 branches with the highest demand for vitamin D tests by year is shown in Table 3. In general, most of the 25(OH)D tests were requested by internal medicine, pediatrics, and their subspecialties. Family medicine was in the top 10 list before the regulation, and family medicine was not in the top 10 list after the regulation.

Table 3. Distribution of the top 10 branches with the highest demand for vitamin D tests by years

	2016	2017	2018	2019	2020	2021	2022
1.	Internal Medicine						
2.	Subspecialties of Medicine	Family Medicine	Family Medicine	Family Medicine	Pediatrics	Pediatrics	Pediatrics
3.	PTR	Subspecialties of Medicine	Subspecialties of Medicine	Pediatrics	Subspecialties of Medicine	Subspecialties of Medicine	Subspecialties of Medicine
4.	Pediatrics	PTR	Pediatrics	Subspecialties of Medicine	PTR	PTR	PTR
5.	Medical Biochemistry	Pediatrics	PTR	PTR	Neurology	Neurology	Neurology
6.	Neurology	Neurology	Neurology	Neurology	Subspecialties of Pediatrics	Subspecialties of Pediatrics	Subspecialties of Pediatrics
7.	Family Medicine	Subspecialties of Pediatrics	Subspecialties of Pediatrics	Subspecialties of Pediatrics	Obstetrics and Gynecology	Obstetrics and Gynecology	Obstetrics and Gynecology
8.	Subspecialties of Pediatrics	General Surgery	Dermatology	Dermatology	Family Medicine	Medical Biochemistry	Medical Biochemistry
9.	General Surgery	Dermatology	Obstetrics and Gynecology	Obstetrics and Gynecology	Orthopedics	Orthopedics	Orthopedics
10.	Dermatology	Obstetrics and Gynecology	General Surgery	General Surgery	Cardiology	Cardiology	Cardiology

(PTR: physical therapy and rehabilitation)



Discussion

This study showed that the regulation of vitamin test requests led to a substantial reduction in vitamin D requests among primary care physicians. The decrease in vitamin D requests may be related to the change in the request screens of the medical software used by primary care physicians. This link between change in requesting behavior and laboratory request forms has been previously demonstrated in the literature.^{14–16} The number of vitamin D tests ordered in general practice has increased substantially in developed countries in recent years, possibly due to its relationship with diseases, increasing scientific publications, and the influence of the media.¹⁷ Vitamin D testing is an expensive test and imposes a significant financial burden, especially due to inappropriate testing and retesting. Clear and precise guidance for evaluating vitamin D status in primary care settings is needed. It is known that a substantial proportion of vitamin D tests are retested unnecessarily. Although guidelines suggest retesting after 3-6 months, 20% of retests were performed within three months.¹⁸ The regulation restricted requesting more than two tests per year in our country. The total number of individuals who had three or more tests per year decreased after the regulation.

Many studies observed that the 25(OH)D test is unnecessarily requested by primary care physicians worldwide as a screening test, regardless of clinical diagnosis or pre-diagnosis. Bastemur et al. investigated 25(OH)D levels of 772.525 of healthy children requested by family physicians from 2000-2014, and they reported an increase in both test demand and prescriptions. Additionally, this increase was more pronounced, especially after 2008, and increased by 15 times from 2008 to 2013.¹⁹ Rodd et al. compared the numbers of 25(OH)D tests in 2006/2007 and 2012/2013 and reported an increase in test numbers from 4,854 to 20,089. Additionally, they stated that family physicians were responsible for this increasing trend.²⁰ Another study conducted in the UK demonstrated that the demand for 25(OH)D tests in primary care increased by 11 times.¹⁸ Bilinski et al. also reported that the need for 25(OH)D tests increased by 94 times from 2000 to 2010, and they stated that family physicians are responsible for this increase.²¹ Our study observed a yearly increase in demand for the 25(OH)D test from 2016 to 2019, which is much more pronounced in primary care facilities. At the beginning of 2020, this Regulation by the Turkish Ministry of Health was launched. There was a decrease in demand for the 25(OH)D test between 2020 and 2021. The decreases in test demands during 2020-2021 were probably due to the Covid-19 pandemic, but not the regulation. In 2022, the effect of the Regulation became more evident, there was a significant decrease in the increase rate of 25(OH)D test demand compared to 2019. We think that the main factor as a reason for this decrease in tests was the restriction imposed on primary care physicians by the regulation released at the end of 2019.

Wong et al. observed that the combination of educational courses and the removal of laboratory tests on request forms could lead to a decrease in the use of thyroid function tests by 60%.²² Shalev et al. showed that physician test ordering practices could be influenced by changes in laboratory order forms, either by adding or



deleting tests.¹⁶ Patel et al. showed that a simple, pragmatic redesign of the electronic request form for vitamin D tests significantly decreased vitamin D requests without affecting the quality of care in primary care settings.²³ Munk JK et al. observed that a compulsory pop-up form decreased the number of vitamin D requests from general practitioners by 25%.⁹

Hofstede H et al. aimed to investigate the barriers and facilitators for reducing the number of unnecessary orders of vitamin D and B12 laboratory tests. They suggested that updating GPs' knowledge with guidelines with clear and uniform recommendations on evidence-based indications for vitamin testing, combined with regular (individual) feedback on test-ordering behavior, was necessary to facilitate a sustainable decrease in vitamin testing. Furthermore, the education of the general public to access clear and reliable information on vitamin testing is also necessary.²⁴

One limitation of this study was that we could not have information on patient's medications, including vitamin D supplementation. Moreover, the database does not contain any information related to measurement methods. Therefore, we were not able to compare the vitamin D measurement methods used in various laboratories. Finally, patients with chronic diseases (e.g., cardiovascular disorders, diabetes mellitus, and cancer) could not be excluded.

Unnecessary, inadequate, and uncontrolled test requests may lead to harmful treatments that may have an adverse impact on healthy individuals.^{25,26} With the regulation issued to reduce the number of tests, although a decrease in the yearly increase rate in test request number was provided, it did not provide a decrease in the total number of test requests.

Our findings showed that the request for 25(OH)D testing decreased in primary care and increased in 2nd and 3rd Stage Public Health Facilities and private hospitals after the regulation letter released at the end of 2019. The regulation allowed the follow-up of vitamin D deficiency in secondary and tertiary health institutions. Despite the decrease in the rate of increase in the number of test requests, the annual number of tests requested is still high, suggesting that different measures should be taken. The possible negative effects on costs of performing vitamin D tests in more expensive 2nd and 3rd stage health facilities instead of primary care facilities, which are inherently much cheaper, should be investigated. We think that all physicians should know that the 25(OH)D test should not be used as a screening test and that this test will be requested only in suitable patients, which will reduce the demand for 25(OH)D tests in the future. It is clear that there are different interventions to decrease laboratory test requests, such as educational-based approaches (evidence-based guidelines), various restrictions in the requesting process, and using of pop-ups; however, the general public needs access to clear and reliable information on vitamin testing. Additionally, all physicians, not just family



physicians, should be aware that the 25(OH)D test is not a screening test, which will reduce the demand for 25(OH)D tests in the future.

Ethical Considerations: This study conforms to the ethical norms and standards in the Declaration of Helsinki. The Ministry of Health's Ethical Board Committee approved the study protocol (IRB number: 95741342020/27112019).

Conflict of Interest: The authors declare no conflict of interest.



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