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#### **Short Communication**

## A study of the differences in the request of glycated hemoglobin in primary care in Spain: A global, significant, and potentially dangerous under-request

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#### ABSTRACT

**Objectives:** The study was performed to compare the variability and appropriateness in the request of glycated hemoglobin (HbA1c) in primary care in Spain.

**Design and methods:** 76 Spanish laboratories from diverse regions across Spain filled out the number of HbA1c tests requested by general practitioners (GPs) during the year 2012. Every patient seen at the different primary care centers was included in the study. Each participating laboratory was required to provide organizational data. The number of HbA1c requests per 1000 inhabitants was calculated and compared between regions. To investigate whether HbA1c was appropriately requested to manage and to diagnose Diabetes Mellitus (DM), the number of necessary HbA1c was calculated, according to the disease prevalence in Spain (6.9%) and the guidelines regarding DM management and diagnosis.

**Results:** 17 679 195 patients were included in the study. A total of 1544551 HbA1c tests were ordered. No significant difference in the number of HbA1c requests per 1000 inhabitants was seen according to hospital setting (rural, urban or rural–urban). No significant differences were noticed between 3 Spanish regions, except the Valencian Community that presented higher values. Regarding the request appropriateness, 3 280 183 additional tests would have been necessary to manage diabetic patients and to diagnose new patients with the disease.

**Conclusion:** There was a high variability regarding the request of HbA1c; the test was under-requested in all the participating health departments. This emphasizes the need to accomplish interventions to improve an appropriate use.

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#### Introduction

Diabetes Mellitus (DM) is the most common endocrine disease and its incidence is increasing [1]. It is crucial to detect this high prevalent disorder early in its clinical course, as timely treatment delays progression and prevents its devastating complications, thus improving prognosis [2,3].

Traditionally, glycated hemoglobin (HbA1c) has been used for the management of patients with DM [4]. Besides its pivotal role in the management of the disease, HbA1c has been recently shown to be a valid test

Abbreviations: DM, Diabetes Mellitus; HbA1c, glycated hemoglobin; GPs, general practitioners; PCC, primary care center patients.

\* Corresponding author at: Hospital Universitario de San Juan, Carretera Alicante-Valencia, s/n, 03550 San Juan de Alicante, Alicante, Spain. Fax: +34 965938383. E-mail address: salinas\_mar@gva.es (M. Salinas). in the initial diagnosis [5]. This renders it in one of the most powerful laboratory parameters, a screening tool that has begun to being used in adults above 45 years old, independently of their risk factors [6]. Great efforts should be accomplished in order to use this test appropriately in this new scenario to improve DM diagnosis and prognosis.

Prior studies have shown a high variability in the request pattern of HbA1c [7], and demonstrated that the test may be under-requested in some regions [8]. Other investigations suggest that HbA1c may be over-used in non-diabetic patients [9] although this was, however, performed prior to the recommendation of HbA1c as a tool to diagnose DM. Other authors demonstrated that although HbA1c over-requesting was common, under-requesting was more prevalent, potentially affecting longer-term health outcomes [10]. In all, new strategies and recommendations regarding the use of HbA1c are needed [11]. A first step will be to investigate the real variability in the test request, trying to identify the root causes of inappropriateness.

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The aim of this study was, first, to compare and analyze the interpractice and inter-regional variability in HbA1c requested by general practitioners (GPs) in Spain and second to identify a potential requesting inappropriateness, by comparing the prior data with the prevalence of DM and the current guidelines regarding the role of HbA1c in the diagnosis and management of the disease.

#### Methods and materials

#### Data collection

Encouraged by previous pilot studies in the Valencian Community [12] and all around Spain [7] a call for data was posted via email. Spanish laboratories willing to participate in the study were invited to fill out an enrollment form and submit their results online. We obtained production statistics (number of tests requested by GPs) for the year 2012 from laboratories at different hospitals from diverse regions across Spain. Every patient seen in any primary care center (PCC) of any of these health departments, regardless of the reason for consultation, gender or age, was included in the study. Each participating laboratory was required to be able to obtain patient data from local databases and to provide organizational data (i.e. population served, public/private management, location). HbA1c test requesting was examined in a cross-sectional study.

#### Data processing

After collecting the data, we calculated the number of test requests per 1000 inhabitants. In order to explore the inter-practice variability, a second indicator, the "index of variability", was calculated as follows: top decile divided by bottom decile (90th percentile / 10th percentile).

The indicator results obtained in the laboratories in the three regions with the highest numbers of departments participating in the study (Valencia, 23 laboratories and 4848 900 patients; Andalucía, 12 laboratories and 3849 485 patients; and Castilla y León, 9 laboratories and 1695 916 patients) were compared with each other and to the pooled results of the remaining regions in order to establish whether there were regional differences in the requesting patterns.

To investigate whether HbA1c was appropriately requested to manage patients with DM, we compared the theoretically ideal number of HbA1c requests that should have been ordered to the number of real HbA1c requests. The former was calculated according to the disease prevalence in Spain (6.9%) [13] and to the current guideline recommendations regarding the glucose monitoring (HbA1c test at least two times a year) and testing for diabetes in asymptomatic patients (HbA1c every 3 years in patients older than 45 years) [6].

Finally, we calculated if the rate of test requests was different according to the setting (rural, urban, or rural–urban) of the hospital and whether the institution had a public or private management.

#### Statistical methods

The statistical treatment of the calculated data included: the distribution, mean, 95% confidence level for the mean, standard deviation, median and interquartile range. The analysis of the distribution of the number of test requests per 1000 inhabitants was conducted by way of the Kolmogorov–Smirnov test.

The differences in the number of test requests per 1000 inhabitants according to the hospital characteristics and per region were calculated by way of the Mann–Whitney U test analysis.

A two-sided p  $\leq$  0.05 rule was utilized as the criterion for rejecting the null hypothesis of no difference.

#### Results

We obtained production statistics from 76 laboratories at different hospitals from diverse regions across Spain. 17679195 patients were included in the study, from 13 communities throughout Spain. 1544551 HbA1c tests were ordered. Table 1 displays a summary of the organizational data of the different laboratories that participated in the study.

There was no significant difference in the number of HbA1c requests per 1000 inhabitants according to hospital setting. The number of HbA1c requests was significantly higher in hospitals with private management than in institutions with public management (p = 0.009) (Table 2).

No significant differences were noticed between 3 Spanish regions, except when compared the Valencian Community to the Castilla y Leon community (p=0.045) and with the rest of regions (p=0.001), the Valencian Community presenting higher values.

Regarding the appropriateness analysis, 2439729 HbA1c requests would have been necessary to appropriately manage the existing patients with DM. 2384408 tests would have been needed to diagnose new subjects, according to the current guidelines. Taking into account the real number of tests performed, a total of 3280183 additional tests would have been necessary for both purposes. Not a single health care area reached those theoretical figures.

#### Discussion

This study highlights the high regional variability in HbA1c requesting in primary care in Spain. This variability was not explained by geographic characteristics, and was only influenced by the type of hospital management. Hospitals with private management showed a higher number of HbA1c requests. This may be explained by the fact that those hospitals are newer compared to those with public management, and physicians working in such centers with new management models may be more prone to apply recommendations and guidelines.

Interestingly enough, despite the high variability observed in our study, HbA1c was under-requested in each and every of the 76 health care departments, compared to what would be ideal to control the existing diabetic patients and diagnose new subjects with the disease.

Inappropriate test over-requesting is harmful [10], taking into account the noxious consequences of false positive results [14] and the economic costs generated from unnecessary tests. Inappropriate test under requesting has also significant drawbacks. In this particular case, given the high prevalence of the disease and the fact that the course of DM is highly influenced by early detection and correct monitoring, a significant number of subjects are not being promptly diagnosed with DM, besides the already existing diagnosed patients are not getting proper monitoring and are at risk of complications.

**Table 1**Descriptive characteristics of the hospitals/health care departments that participated in the study.

Hospitals/health departments (n)		76
Patients (n)		17679195
Beds/hospital [mean (95%CI)]		442.97 (371.68-514.26)
Population/hospital [mean (95%CI)]		232 621 (200 099.8-265 142.2)
Location [n (%)]	Valencia	23 (30.3%)
	Andalucía	12 (15.8%)
	Castilla y León	9 (11.8%)
	Rest	32 (42.1%)
Management [n (%)]	Public	70 (92.1%)
	Private	6 (7.9%)
Setting [n (%)]	Urban	15 (19.7%)
	Rural	3 (3.9%)
	Urban-rural	58 (76.3%)

CI: confidence interval of the mean.

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