



RESEARCH ARTICLE

Underestimating the Diagnosis of Diabetes

Inmaculada Sauri^{1,2}, Alba Maria Oltra^{1,2}, Javier Diaz^{1,2}, Carlos Baeza^{1,2}, Maria Jose Forner^{2,3} and Josep Redon^{1,2*}

¹INTEGRACLOUD Project

²Big-Data and AI Research Group. INCLIVA, Spain

³Internal Medicine, Hospital Clinico of Valencia, Spain

Abstract

Objective: The implications of undiagnosed diabetes are significant. The objective was to identify the prevalence of subjects with elevated parameters of glucose and/or HbA1c and its consequences

Patients and methods: A cohort of subjects in 2018 were recorded for the presence of a diabetes diagnosis based on CIE9 and 10 (CIE9 codes 250.0 and 250.2 and CIE10 code E11) or with active treatment for diabetes (ATC code A10). Subjects with abnormal laboratory test results with HbA1c >6.5% or serum glucose >126 mg/dL, in the absence of a diabetes diagnosis or treatment with glucose-lowering drugs on more than two occasions, were also included. During the following five years, the number of subjects who initially were non-diabetic and subsequently developed diabetes was recorded. Likewise, the mortality rates of both diagnosed and undiagnosed diabetic were also evaluated.

Results: Out of a total of 40.786 patients, 26.843 have been diagnosed with diabetes, while 13.943 have not. Whereas before age 50, the prevalence is higher for people who have not been diagnosed with diabetes; after that age the prevalence for people who have been diagnosed with diabetes is higher. In terms of sex, undiagnosed cases were more frequent in women than in men. During the follow-up, 2.588 subjects were diagnosed with diabetes. Among those diagnosed with diabetes, mortality tend to be lower than among those not diagnosed.

Conclusion: Many patients with abnormal pf metabolism glucose parameters remain undiagnosed, and most of them are not diagnosed with diabetes. A trend to be lower risk of mortality is observed in those in whom the diagnosis was established.

*Corresponding author(s)

Josep Redon, Emeritus Researcher, INCLIVA Research Institute, Valencia, Spain

Email: josep.redon@uv.es

DOI: 10.37871/EODA115

Submitted: 13 March 2026

Accepted: 25 March 2026

Published: 26 March 2026

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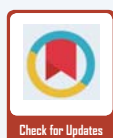
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Introduction

Type 2 Diabetes Mellitus (T2DM) is widely recognised as a significant public health concern. It is a chronic disease with a high prevalence, associated with an increased risk of complications,

VOLUME: 5 ISSUE: 1 - 2026



How to cite this article: Sauri I, Oltra AM, Diaz J, Baeza C, Forner MJ, Redon J. Underestimating the Diagnosis of Diabetes. Endocrinol Diabet Open Access. 2026 Mar 26; 5(1): 7. DOI: <https://www.dx.doi.org/10.37871/EODA115>

as well as a significant rise in the utilisation of and costs associated with healthcare resources. An accurate diagnosis of diabetes mellitus is important for effective treatment, preventing complications, improving patient outcomes, and reducing the public health and economic burden of the disease [1,2]. Identifying individuals with analytical parameters suggestive of diabetes who have not received a formal diagnosis or are not undergoing treatment is a common clinical scenario [3]. This phenomenon is observed across multiple healthcare settings, particularly in primary care and during hospital admissions, where hyperglycaemia may be detected incidentally. Several factors may contribute to this discrepancy, including pre-analytical and analytical laboratory errors, transient hyperglycaemia related to acute illness or stress, and the influence of medications that alter glucose metabolism (notably glucocorticoids and certain psychotropic agents). Inadequate patient preparation prior to testing may also be a factor. Regardless of the cause, underestimating the burden of diabetes is a significant issue in healthcare [4–7].

Significantly underestimating the burden of diabetes leads to systemic gaps in prevention, treatment and long-term management. Not only is diabetes a chronic condition requiring continuous clinical attention, it is also a driver of serious complications such as cardiovascular disease, kidney failure, vision loss and neuropathy, each of which greatly increases healthcare utilisation and costs [6]. When policymakers and healthcare systems fail to account for the diseases full clinical and economic impact, they may underfund screening programmes, delay investment in education and lifestyle support initiatives, and overlook the need for comprehensive, multidisciplinary care [8,9]. This results in higher rates of undiagnosed cases, preventable complications, and a reduced quality of life for patients and escalating financial strain on individuals and healthcare infrastructures.

Therefore, accurately recognising and addressing the true burden of diabetes is

essential for creating effective public health strategies and improving long-term outcomes. The present study aims to assess the prevalence of false negative patients and their impact by taking advantage of a data lake integrating all hospital and primary care information within a Department of Health.

Material and Methods

Study design and participants

The sample was recruited from a Department of Health programme including Primary Care and Hospitals, with a total of 330,000 subjects. Each patient has a unique personal identification number within the health system, meaning each patient has a unique, centralised electronic clinical record. Population data were extracted using the health information exchange platform for the period between 2015 and 2024. Of the total population, 40,786 individuals met the inclusion criteria for the present study. The platform includes information on patient demographics, medications, vital status, past medical history, and laboratory data, among other things. The patient data collected from the system during the study were pseudo-anonymised, meaning it was impossible to identify patients as the only link between the data and the patient was a code unavailable to researchers. The Ethics Committee waived patient consent because the EHR used was pseudo-anonymised and researchers did not have access to the code.

Ethical considerations

Based on the seventeenth additional provision of Spanish Organic Law 3/2018, dated 5 December, which relates to the protection of personal data and the guarantee of digital rights, informed consent was not required. This provision legalises the use of pseudonymised personal data for health-related purposes, particularly in biomedical research. Data collection and analysis were carried out with patients' privacy in mind, using a two-layered pseudonymisation method, and the information was managed as aggregated data.

The research was conducted in full compliance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, as well as with the Seventeenth Additional Provision on the Processing of Health Data of Organic Law 3/2018 of 5 December on the Protection of Personal Data and the Guarantee of Digital Rights, and the applicable sectoral legislation. The information was made available for research purposes and was pseudo-anonymised in accordance with the Spanish Data Protection Act. The study was approved by the Ethics and Clinical Trials Committee of INCLIVA. Spanish legislation in force at the time — specifically Law 3/2018 on Data Protection and Guarantee of Digital Rights — was also followed, in conjunction with the European Union's General Data Protection Regulation (GDPR).

Subjects and procedures

In 2018, 26,843 individuals were selected from a cohort of 330,000 subjects in the department who met the inclusion criteria for a diabetes diagnosis based on ICD-9 and ICD-10 codes (ICD-9 codes 250.0 and 250.2, and ICD-10 code E11), or who were receiving active treatment for diabetes (ATC code A10). Additionally, 13,943 individuals with abnormal laboratory test results (HbA1c >6.5% or serum glucose >126 mg/dL) in the absence of a diabetes diagnosis or treatment with glucose-lowering drugs on more than two occasions were included in the study. All subjects in the two groups were monitored for five years using data from the Electronic Health Record.

Therefore, an annual record was kept of the number of subjects who were not initially diagnosed with diabetes but were subsequently diagnosed with the condition. Likewise, mortality rates among subjects with and without a diabetes diagnosis were evaluated.

Statistical analysis

Data obtained from Electronic Health Records is presented as absolute numbers and

percentages where applicable. This study aimed to assess differences in the prevalence and incidence of new diagnoses among individuals with a confirmed diabetes diagnosis compared to those with abnormal laboratory test results and no diabetes diagnosis. Mortality rates were compared using a chi-squared test of homogeneity to ascertain whether the proportions differed across the three subpopulations within each year. For each annual cross-section, the test was conducted under the null hypothesis that all classes share the same underlying probability. This framework provides a non-parametric test of equality of proportions across groups, making no assumptions about the distribution beyond multinomial sampling. All statistical analyses were conducted using Python version 3.12.1.

Results

Study population

Of a total of 40,786 patients, 26,843 were diagnosed with diabetes, and 13,943 had elevated HbA1c and/or elevated baseline glucose on two or more occasions in the absence of a diabetes diagnosis or active treatment. The age and sex distribution of the two groups of subjects are shown in table 1. While the prevalence was higher in those without a diabetes diagnosis under 50 years old, it was higher in those with a diabetes diagnosis over 50 years old. Regarding sex, the undiagnosed group was more prevalent in women than in men. The clinical characteristics of the study population are shown in table 2. The most frequent comorbidities in both groups of patients were hypertension and dyslipidaemia, while the prevalence of heart failure, coronary heart disease, peripheral vascular disease, and stroke was lower. Although the undiagnosed diabetes group is smaller in number, these subjects were represented across all comorbidity categories.

Follow-up

Table 3a shows patient follow-up over the five-year period starting from 2018. During this period, 2,588 patients were diagnosed with

Table 1: Age and sex distribution of the patients included in the study.

Age years	Diabetes			No diabetes		
	Number	Men	Women	Number	Men	Woman
18 - 29	192	93	99	491	260	231
30 - 39	464	197	267	844	439	405
40 - 49	1510	901	609	1439	828	611
50 - 59	4224	2632	1592	2339	1314	1025
60 - 69	7048	4070	2978	2857	1503	1354
70 - 79	7649	3886	3763	2915	1421	1494
80 - 89	4939	2047	2892	2442	939	1503
89+	817	244	573	616	158	458
Total	26843	14070	12773	13943	6862	7081

Table 2: Risk factors and comorbidities in the study population.

Patients	Diabetes		No diabetes	
	Number	Percentage	Number	Percentage
Hypertension	17848	66.49%	6626	47.52%
Heart failure	2044	7.61%	1069	7.67%
Dyslipidaemia	20210	75.29%	7412	53.16%
Coronary heart disease	3043	11.34%	1228	8.81%
Peripheral vascular disease	2245	8.36%	934	6.70%
Cerebrovascular disease	1989	7.41%	928	6.66%

diabetes for the first time, with 750, 593, 349, 516 and 380 cases recorded annually.

Table 3b also shows the mortality rates of the cohort. The mortality rate among those diagnosed with diabetes at the beginning of the study was around 4%, which is similar to the rate in the undiagnosed group. Among those diagnosed with diabetes, there was an overall downward trend in mortality. Significant differences were observed when comparing groups across the years. The greatest differences were found between undiagnosed individuals and those who were newly diagnosed. In most cases, the highest rates were observed in the undiagnosed population. The year 2020 showed the smallest statistical differences.

Discussion

The present study, which was conducted within a regional Department of Health in a

Western country, found that a large number of subjects were not identified as having diabetes or being at risk, despite having elevated HbA1c or fasting plasma glucose levels on at least two occasions. Delayed diagnosis of diabetes appears to be associated with increased mortality in subsequent years.

To ensure an accurate diagnosis and optimal patient care, it is essential to carefully interpret laboratory findings in the appropriate clinical context and perform confirmatory testing when necessary [10–12]. Failure to identify underlying dysglycaemia may result in delayed diagnosis and management, thereby increasing the risk of microvascular and macrovascular complications. Conversely, misinterpreting transient or spurious glucose elevations may lead to overdiagnosis, inappropriate therapy initiation and unnecessary follow-up investigations.

Table 3a: Trends in the diagnosis of diabetes and mortality in the study population.

Year	Diabetes	No diabetes	New diagnostic	Mortality of total population of diabetics	%	CI%		
2018	26843	13943	750	1006	3.75	3.52	3.97	
2019	26559	12613	593	882	3.32	3.11	3.54	
2020	26249	11511	349	1040	3.96	3.73	4.20	
2021	25544	10676	516	1102	4.31	4.06	4.56	
2022	24948	9727	380	1029	4.12	3.88	4.37	
	Mortality without diagnostic	%	CI%		Mortality with diagnostic	%	CI%	
2018	608	4.36	4.02	4.70	28	3.73	2.38	5.09
2019	530	4.2	3.85	4.55	21	3.54	2.05	5.03
2020	500	4.34	3.97	4.72	14	4.01	1.95	6.07
2021	443	4.15	3.77	4.53	10	1.94	0.75	3.13
2022	448	4.61	4.19	5.02	19	5	2.81	7.19

The implications of undiagnosed diabetes are significant. Early detection and appropriate therapeutic intervention can slow disease progression, reduce complications and improve quality of life [13]. However, by the time a formal diagnosis is made, individuals with undetected diabetes may have already developed advanced complications, including retinopathy, nephropathy, cardiovascular events and lower-extremity amputations [14,15]. This emphasises the importance of accurate laboratory interpretation, repeat or confirmatory testing, and systematic screening of high-risk groups [8].

If diagnosed early, lifestyle changes and medication can be started promptly if necessary. In many cases, particularly with type 2 diabetes and prediabetes, these measures can slow or even halt the progression of the disease. However, the prevalence of complications appears to vary considerably depending on the definition of undiagnosed diabetes used. Individuals with confirmed undiagnosed diabetes (i.e. elevated HbA_{1c} and Fasting Plasma Glucose (FPG) levels) have a higher prevalence of microvascular complications (e.g. retinopathy and albuminuria) than those with

Table 3b: Statistical analysis.

Year	Diabetes vs No diabetes	No diabetes vs New diagnosis	Diabetes vs New diagnosis
2018	< 0.01*	0.01*	0.08
2019	< 0.01*	< 0.01*	0.01*
2020	0.08	0.15	0.34
2021	0.44	0.01*	0.01*
2022	0.05	0.07	0.19

unconfirmed undiagnosed diabetes [3]. Prompt treatment can help individuals with diabetes to lead healthier and longer lives. Early diagnosis and treatment can also reduce the healthcare costs associated with diabetes.

The long-term mortality rate is higher among hospitalised patients with undetected prediabetes and type 2 diabetes who have worsening heart failure and a reduced ejection fraction [14]. Electronic clinical documentation appears to help prevent diagnostic errors [16]. In the present study, which used an electronic data lake, the mortality rate of the cohort was found to be one percentage point lower among those with a diabetes diagnosis than among those who remained undiagnosed, similar to the rate in the overall diabetic cohort. This is a

noteworthy finding, given that mortality in the diabetic group is below 4%.

This study should be considered in light of its limitations and strengths. The criteria for selecting patients with elevated HbA1c or glucose levels at baseline are partly arbitrary. Despite the requirement for abnormal values to be confirmed on at least two occasions, there is still potential for error, even with careful follow-up. All data were obtained from a data lake at our institution, which contains information from the Department of Health covering primary and hospital care services.

In conclusion, the study draws attention to the important issue of underestimating the impact of diabetes on healthcare. The present study observed a potential reduction in mortality when diabetes was diagnosed. Leveraging electronic health records to facilitate earlier diagnosis could help reduce diagnostic delays and enable earlier intervention to improve patient outcomes.

Declarations

Ethical approval

The study was approved by the Ethics and Clinical Trials Committee of INCLIVA data September 27, number 2024/322.

The Ethics Committee waived patient consent because the EHR used was pseudo-anonymised, meaning the researchers did not have access to the code.

Acknowledgements

This work has been supported by the INTEGRACLOUD project, funded by the Ministry of Economic Affairs and Digital Transformation (Spain) and the European Union – NextGenerationEU through the Recovery and Resilience Facility, under the UNICO I+D Cloud Programme (Royal Decree 959/2022).

Conflict of interest

No conflict of interest to declare

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