Assessment of a screening protocol for type 2 diabetes in community pharmacy. The DiabNow Study

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ABSTRACT

The aim of this study was to assess the performance and feasibility of a protocol for screening type 2 diabetes in community pharmacy. Performance was primarily assessed by measuring stakeholders' adherence (pharmacists, patients and physicians) to the protocol's components.

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1. Introduction

Several organizations have developed diabetes screening protocols for various clinical settings [1–7]. Some support the use of glycated haemoglobin (HbA1c), which can be measured anytime, as a screening test [2,6,7]. To our knowledge, no protocols for type 2 diabetes screening including HbA1c capillary measurement have been proposed for the community pharmacy setting. Ideally, protocols should be evidence-based and their feasibility and functioning/performance tested in real-world scenarios to enable optimization [8]. Thus, the aim of this study was to assess a type 2 diabetes screening protocol that included HbA1c measurement, in the community pharmacy setting.

2. Methods

The study involved 70 community pharmacists. The process of patient recruitment involved the pharmacists offering the service to all patients over 45 years of age that entered the

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pharmacy, regardless of the patients' reason for visiting. The pharmacists identified consecutive patients until they had each recruited 10 subjects without a previous diagnosis of diabetes. The screening protocol consisted of: (1) identification of high-risk individuals using the American Diabetes Association (ADA) questionnaire, (2) measurement of capillary HbA1c with the A1cNow+® device (Bayer Health Care LLC, Diabetes Care, Tarrytown, NY, provided by Pharmaceutical Laboratories Almirall S.A) in those patients with a score ≥10 on the ADA (ADA+), (3) referral of patients with a capillary HbA1c ≥ 5.7% (≥39 mmol/mol) to the general practitioner (GP) by means of a written report. Diabetes diagnosis was confirmed by the GP based on an additional plasma test: fasting plasma glucose, oral glucose tolerance, and/or HbA1c plasma levels. Referred patients were offered a follow-up appointment at the pharmacy to discuss the GP's decisions.

The functioning/performance of the screening protocol was assessed by measuring the adherence of the stakeholders (i.e. pharmacists, patients and GP) to the protocol. Moreover, the pharmacists' opinions about both the training and feasibility of the protocol were collected.

Statistical analyses were performed with SPSS v18.0. To summarize the quantitative variables, mean and standard deviation (SD) were calculated; qualitative variables were described using frequencies and percentages. To assess accuracy of detecting people with undiagnosed diabetes Lin's concordance correlation coefficient (CCC) was used to compare the results of HbA1c capillary tests performed by the pharmacist with laboratory measured plasma HbA1c.

3.　　Results

The study included 663 subjects. Participants' characteristics are summarized in Table 1. All subjects completed the ADA

Table 1 – General characteristics of the sample (n = 663).	
Male; n (%)	244 (36.8)
Age (years); mean (SD)	59.4 (9.6)
BMI (kg/m^2); mean (SD)	29.5 (4.8)
Current smoker; n (%)	119 (19.9)
Physical activity[*] (none); n (%)	389 (58.8)
Hypertension; n (%)[**]	253 (38.2)
Dyslipidemia; n (%)[**]	222 (33.5)
Caucasians; n (%)	663 (100.0)
Marital status (with partner); n (%)	515 (77.7)
Level of education	
No education; n (%)	108 (16.3)
Primary; n (%)	361 (54.5)
Vocational education/University; n (%)	193 (29.2)
Employment status	
Paid worker; n (%)	285 (43.0)
Housewife; n (%)	203 (30.6)
Retired person; n (%)	145 (22.5)
Unemployed; n (%)	25 (3.8)
Student; n (%)	1 (0.2)

[*] Physical exercise was defined as walking or any form of aerobic exercise for an average of half an hour a day, three times a week.
[**] The patients confirmed the diagnosis of primary hypertension and dyslipidemia.

questionnaire. Pharmacists miscalculated the ADA score in 46 cases (6.9%). These subjects were excluded from further analysis to avoid misinterpretations of the results. Out of 617 individuals, with correctly calculated ADA scores, 563 (91.2%) showed a positive ADA score (ADA+) and 54 (7.8%) a negative ADA score (ADA−).

HbA1c levels were obtained in 559 cases (99.3%): 326 (58.3%) obtained HbA1c < 5.7% (<39 mmol/mol), 189 (33.8%) with 5.7 ≤ HbA1c < 6.5% (39 ≤ HbA1c < 48 mmol/mol) and 44 (7.9%) ≥6.5% (≥48 mmol/mol). 140 out of the 145 subjects (96.5%) who visited the GP, returned to the pharmacy for their

Table 2 – General practitioner interventions for patients with elevated HbA1c.			
	5.7 ≤ HbA1c < 6.5% (39 ≤ HbA1c < 48 mmol/mol) (n = 109)	HbA1c ≥ 6.5% (HbA1c ≥ 48 mmol/mol) (n = 31)	Total (n = 140)
Non-pharmacological advice provided			
None; n (%)	87 (79.8)	19 (61.3)	108 (77.1)
Diet; n (%)	12 (11.0)	8 (25.8)	19 (13.7)
Exercise; n (%)	3 (2.8)	0 (0.0)	3 (2.2)
Diet and exercise; n (%)	7 (6.4)	4 (12.9)	10 (7.2)
New pharmacological treatments			
Number of patients with new medication(s); n (%)[*]	8 (7.3)	15 (48.4)	23 (16.5)
Number of pharmacological treatments			
Without pharmacologic treatment; n (%)	101 (88.6)	16 (51.6)	116 (83.5)
One medicine; n (%)	8 (7.0)	11 (35.5)	19 (13.7)
Two medicines; n (%)	0 (0.0)	4 (12.9)	4 (2.9)
Type of pharmacological treatments			
Metformin; n (%)	8 (7.3)	15 (48.4)	23 (16.5)
Glicliazide; n (%)		1 (3.2)	1 (0.7)
Vildagliptine; n (%)		1 (3.2)	1 (0.7)
Insulin; n (%)		2 (6.5)	2 (1.4)

HbA1c: glycated haemoglobin.
[*] In the two cases in which the patient was diagnosed but not pharmacologically treated, diet and exercise were suggested.