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**Impact of forgoing care because of costs on the quality of diabetes care: a three-year cohort study**

***Running head: Forgoing care and quality of diabetes care***

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Forgoing care because of costs is a frequent situation in many countries, with estimated prevalences going from 4% to 30% [1-6]. It can be defined as a decision of not seeking care when needed because of financial reasons and the term is used interchangeably with unmet needs as both terms provide similar information [7]. Whereas most studies on the prevalence of forgoing care because of costs target the general populations, little is known of the prevalence of forgoing care for people with specific chronic conditions. The few studies exploring this issue reported a prevalence close to general population figures [5, 8-9]. As people with chronic conditions have a high demand of health care, such prevalence may either be lower, since they are being followed by a health practitioner and are already navigating the system, or on the contrary, may be similar or higher, since they might decide to prioritize some health issues at the expense of other conditions.

Our main objective was to assess the prevalence of forgoing care because of costs in Swiss patients with diabetes; a secondary objective was to explore whether forgoing care because of costs was related to a risk of worsening the quality of their care after three years of follow-up.

We used data from a prospective Swiss cohort study, the CoDiab-VD cohort, consisting of non-institutionalized adults with a diagnosis of diabetes of at least one-year duration and residing in the canton of Vaud ( $\approx$  750'000 inhabitants). Participants were recruited in 2011-2012 by community-based pharmacies and are followed-up yearly [10]. Study data were collected from paper-based questionnaires sent to participants' home. All variables, described in details elsewhere [10], are briefly presented thereafter. The primary exposure variable of the study was forgoing care because of costs at baseline,

measured using the following question: “During the last twelve months, did you forgo any type of care because of the costs you would have to pay?” Participants were considered to have forgone care during the past 12 months if they answered “yes” to that question. We considered eight diabetes-specific processes of care (e.g. HbA1c control, annual foot examination) and five outcomes of care (e.g. mean HbA1c, generic and disease-specific health-related quality of life) as dependent variables, and other covariates (e.g. age, gender, socio-demographics) [10]. The prevalence (and 95% confidence interval) of forgoing care and the type of care forgone were calculated. Then, bivariate analyses were conducted to compare participants forgoing vs not forgoing care. Finally, crude and adjusted mixed logistic and linear regression models were used to assess the over time effect of forgoing care on the dichotomous and continuous processes and outcomes of care indicators, respectively.

At baseline, results showed a prevalence of persons reporting having forgone care because of costs of 15.7% (95% CI 12.5%-18.9%), with dental (9.7%) and foot (5.2%) care most often reported to have been forgone (other types of care forgone being each reported by less than 2% of the participants). Table 1 summarizes characteristics of all 519 baseline participants, globally and according to their forgoing care status. People having forgone care were more likely to be women, non-Swiss, to receive health insurance subsidies, in poorer subjective health, report more co-morbidities, and be inactive; they also visited as many healthcare professionals and as often as the people not forgoing care, were more likely to have been hospitalized or have had emergency/non-scheduled visits during the past twelve months, yet more likely to have participated in education classes.

Primary and secondary baseline processes and outcomes of care results, according to the forgoing care status (Table 1) show that there were no statistically significant differences between the two groups, except for (health-related) quality of life which appeared significantly worse for persons forgoing care. Longitudinal analyses did not show a significant impact on the evolution of the quality of care patients with diabetes forgoing care, after three years (data not shown).

The prevalence of forgoing care among patients with diabetes was similar to that of the general Swiss population, situated at around 15% in 2013 for respondents declaring one or more chronic condition [1]. Moreover, the socio-demographics, household income and subjective health of this study's participants reporting forgoing care because of costs were similar to previous studies not targeting specifically persons with diabetes [6]. Whereas participants who declared forgoing care at baseline, reported suggestive evidence of high healthcare utilization and worse (health-related) quality of life, compared to participants not forgoing care, the three-year evolution over time did not seem to impact the medium-term quality of care of these persons, even when considering potential confounding variables. The somewhat paradoxical reports of forgoing care because of costs yet over-utilization of other types of care (emergency visits) could be explained by the reimbursement of certain care and not of others (i.e. dental and podiatric care) with the overall compensatory effect that the three-year quality of care had not worsened or that the power of the study was not enough to detect an effect.

This study showed that forgoing care because of costs concerned approximately one out of six persons living with diabetes. Although it did not show an impact on the quality of care of those patients in a three-year period, this should not lead to an underestimation of the potential risk to the health of people forgoing care. Healthcare practitioners should be aware of that issue and investigate what types of care are forgone and how to minimize them. Further examination of how health and care of people with chronic conditions, who declare forgoing care, evolves in the long run, should be carried out. It should also assess what the corresponding patient-reported unmet need is and whether it is recognized by the practitioner. People forgoing care because of costs are less well off than those not forgoing care and need stronger support to maintain stable overall health and quality of care. Healthcare systems, in Switzerland and elsewhere, should therefore strive to reduce the percentage of people forgoing care because of costs to a minimum.

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**Ethics approval and consent to participate:** The protocol of the CoDiab-VD cohort was approved by the Cantonal Ethics Committee of Research on Human Beings of the Canton of Vaud (Protocol N° 151/11). Written informed consent was obtained from all participants, and data were kept anonymous and confidential.

**Conflicts of interests:** none.

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**Table 1: Baseline characteristics, healthcare utilization and quality of care of persons with diabetes, according to forgoing care status**

		All participants *	Participants forgoing care	Participants not forgoing care	P-values
		(n=519)	(n=79)	(n=424)	
<b><u>Socio-demographics</u></b>					
<b>Age, mean (SD)</b>	(n=519)	64.5 (11.3)	61.8 (13.2)	64.9 (10.8)	0.02
<b>Women</b>	(n=519)	40.3%	50.6%	37.5%	0.03
<b>Living alone at home</b>	(n=516)	26.7%	36.7%	24.2%	0.02
<b>Education</b>	(n=504)				0.19
Primary		18.9%	24.7%	17.0%	
Secondary		56.2%	55.8%	56.6%	
Tertiary		25.0%	19.5%	26.5%	
<b>Health insurance subsidies</b>	(n=515)	16.3%	26.6%	14.0%	0.01
<b>Nationality</b>	(n=515)				
Swiss		88.2%	82%	89.3%	0.05
<b><u>Health status</u></b>					
<b>Subjective health</b>	(n=509)				0.00
Excellent/very good		14.2%	5.1%	16.4%	
Good		64.2%	56.4%	65.1%	
Mediocre/bad		21.6%	38.5%	18.5%	

<b>Screen-positive for depression</b>	(n=503)	30.6%	56.6%	26.1%	0.00
<b>Current smoking</b>	(n=509)	17.3%	19.5%	17.0%	0.62
<b>Physical inactivity</b>	(n=494)	29.8%	44.2%	26.2%	0.00

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**Diabetes characteristics**

<b>Type 2 diabetes</b>	(n=519)	84.6%	79.7%	85.6%	0.18
<b>Diabetes duration</b>	(n=511)				0.22
≤ 10 years		52.1%	46.2%	54.2%	
>10 years		47.9%	53.8%	45.8%	
<b>Diabetes treatment (oral-anti-diabetic drugs)</b>	(n=516)	50.8%	44.9%	52.2%	0.27
<b>Diabetes complications †, mean (SD)</b>	(n=504)	0.7 (1)	0.9 (1)	0.7 (0.9)	0.20

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**Healthcare utilization**

<b>GP visits (past 12 m)</b>	(n=473)				0.09
0		6.3%	8.8%	6.1%	
1		12.9%	8.8%	13.7%	
2-3		38.3%	27.9%	39.6%	
≥4		42.5%	54.4%	40.6%	
<b>Diabetologist visits (past 12m)</b>	(n=334)				0.28
0		35.6%	25.5%	38.4%	
1		12.3%	14.5%	12.2%	
2-3		28.7%	30.9%	28.0%	
≥4		23.4%	29.1%	21.4%	
<b>Hospitalization (past 12 m)</b>	(n=506)	26.5%	37.7%	24.2%	0.02

<b>Emergency/unscheduled visits (<math>\geq 1</math>, past 12m)</b>	(n=513)	28.7%	36.7%	27.3%	0.10
<b>Participation to education classes (at least once)</b>	(n=506)	32.8%	51.3%	29.2%	<0.001

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<b>Quality of care indicators</b>		<b>Participants forgoing care</b>	<b>Participants not forgoing care</b>	
				<b>OR (95%CI)</b>
<b>Processes-of-care</b>				
Annual HbA1c check **	(n=273)	98.0%	99.1%	0.4 (0.04;5.0)
Eye examination by ophthalmologist ††	(n=489)	81.8%	75.2%	1.5 (0.8;2.8)
Annual urine test for microalbuminuria	(n=425)	74.6%	73.4%	1.1 (0.6;1.9)
Annual foot examination	(n=494)	64.9%	68.1%	0.9 (0.5;1.4)
Annual lipid profile	(n=486)	96.1%	96.6%	0.9 (0.2;3.1)
Seasonal influenza immunization	(n=497)	70.1%	62.6%	1.4 (0.8;2.4)
Home glucose monitoring	(n=497)	86.8%	80.5%	1.6 (0.8;3.2)
HbA1c knowledge (yes)	(n=433)	70.4%	62.4%	1.4 (0.8;2.5)

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				<b>Difference (95%CI)</b>
<b>Outcomes of care</b>				
Mean HbA1c level, mean **	(n=172)	7.8	7.3	- 0.5 (- 1.1;0.03)
Quality of life (health-related):				
SF-12 PCS, mean (SD)	(n=484)	39.0	44.3	5.3 (2.6;7.9)

SF-12 MCS, mean (SD)	(n=483)	39.0	48.4	9.5 (6.9;12.1)
ADDQoL, mean (SD)	(n=497)	-2.3	-1.4	0.9 (0.5;1.3)
PACIC, mean (SD)	(n=489)	2.9	2.7	- 0.1 (- 0.4;0.1)
Care satisfaction (excellent-very good) ¶	(n=494)	55.1%	69.2%	0.5 (0.3;0.9)

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\*: Out of 519 CoDiab-VD cohort participants, 16 did not answer the forgoing care question

† sum of complications among the following: ischemic heart diseases, stroke, retinopathy, chronic kidney disease (CKD) without dialysis, CKD with dialysis or kidney transplant, neuropathies, foot ulcer, lower limb amputation, severe hypo- or hyperglycemia

\*\* among participants reporting knowing what HbA1c is; ††: within two years; ¶ odd ratio

Abbreviations: SF-12: Short Form-12; PCS: physical component score (mean 50 and SD 10 for American general population); MCS: mental component score (mean 50 and SD 10 for American general population); ADDQoL: Audit of Diabetes-Dependent Quality of Life 19 (score range: -9 (worse) to +3 (best)); PACIC: Patient Assessment of Chronic Illness Care (score 1 (never) to 5 (always))