



## Effectiveness of pro-active organizational models in primary care for diabetes patients



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### ABSTRACT

**Background:** Demographic changes and chronicity are posing new challenges to health care systems. Our study aimed to examine how effectively the three different types of proactive primary care models adopted by three different regional health care systems in Italy were improving the quality of diabetes management by general practitioners.

**Methods:** A coordinated Italian nationwide project to compare systematically the new proactive organizational models implemented at regional and local level (the MEDINA Project) involved several regions and their local health units (LHUs). A quasi-experimental study was conducted on a large dataset obtained by processing administrative databases. A combined indicator was developed to assess the quality of care delivered by primary care physicians, based on adherence to recommendations concerning patient monitoring and treatment.

**Result:** The study concerned 602 Italian general practitioners (GPs), 174 of them female, who were caring for a total of 753,366 patients (47,575 of them diabetic). Analyzing a total score, representing global adherence to a quality management of patients with diabetes, confirmed that GPs who had adopted the new model of care for their diabetic patients obtained better results than those who had not, so the new policy was generally effective.

**Conclusion:** Our study showed that introducing new, proactive primary care models could sustain efforts made around the world to guarantee good-quality chronic disease management in the primary care setting.

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## 1. Introduction

Chronic diseases are posing new challenges to health care systems and their organization all over the world. In 2016 epidemiological estimates calculated that more than 60% of morbidity and 72% of mortality were attributable to chronic diseases [1].

The Alma-Ata Declaration, and more recent epidemiological evidence have reinforced the role of primary care for facing the burden of chronic disease, underscoring such distinctive features as person-centeredness, care comprehensiveness and integration, continuity of care, and trust in a regular health care provider [2–5]. Conceptual healthcare delivery frameworks have been developed to redesign primary care models capable of responding effectively to this challenge. Some have proved remarkably effective, such as the Chronic Care Model (CCM) [6], the expanded Chronic Care Model (eCCM) [7] and the Kaiser Permanente Model [8].

In Italy, the implementation of new organizational models has followed the institutional architecture of the Italian National Health System, with the Regional Authorities taking responsibility for their organization and planning. Experimental primary care models have consequently been adopted in some regions, with differing degrees of adherence on the part of patients and primary care providers [9]. In particular one region adopted the jet experimented CCM (6), other two regions experimented new organizational models one a new proactive a bundle payment model and the other an integrated ambulatory care model. Hence the need for a nationally coordinated project (called MEDINA) to conduct a systematic comparison of the models adopted at regional and local levels, involving seven different regions and their local health units (LHUs). Diabetes management has been widely considered as a model for assessing the quality of chronic disease management programs and primary care models. Quality indicators for this condition have been developed and used in various countries to validate the quality of care delivered by primary care organizations [10]. These indicators were consequently judged appropriate for the purposes of our analysis.

Our study aimed to examine how effectively the three different types of proactive primary care models adopted by three different regional health care systems in Italy were improving the quality of diabetes management by general practitioners (GPs), measured in terms of their adherence to internationally established indicators for the primary care setting.

## 2. Methods

### 2.1. Context

Italy is divided administratively into 20 regions, whose governments have the important role of fulfilling the objectives of the National Health Plan at regional level. They are responsible for planning and organizing health care facilities and related activities through regional health departments. They also coordinate and control LHUs, which are geographically distributed public organizations that deliver public health and community health services, primary care and hospital care. They may provide these services either directly with their own structures and personnel, or outsource the work to other service providers [9]. LHUs are organized into districts that coordinate all NHS and publicly-funded facilities providing services outside the hospital for a portion of the community. The main primary care providers in Italy are GPs, who are self-employed, independent physicians. GPs also serve as system gatekeepers, playing a pivotal part in managing care for chronic diseases, such as diabetes, by defining care programs and treatment pathways for each patient.

This was a quasi-experimental study conducted on data obtained for the MEDINA project. Seven Italian regions, three in

northern Italy (Lombardy, Veneto and Emilia Romagna), two in central Italy (Tuscany and Marche), and two in southern Italy (Sicily and Puglia) took part in the MEDINA project. One LHU for each region was involved in the change organization of primary care toward proactive solution, but for the purposes of the present study the data analysis was only conducted on the LHUs with a sample size of GPs large enough to guarantee an adequate statistical power of 80% (Tuscany, Lombardy and Sicily Region).

The new proactive models for organizing primary care are described in Table 1, in particular:

- Northern Italy – Lombardy: the Bergamo LHU has an interesting model involving risk stratification, patient identification, and resource allocation [11]. Starting from a historical dataset, tariffs have been set for 155 categories, grouping together clinical and therapeutic profiles absorbing similar amounts of resources. This a priori risk stratification enables resource allocation to single GPs to be adjusted according to their patients' case-mix. Clinical pathways and guidelines have been identified and represent the framework on which individualized health care plans are built. A bundle payment scheme covers outpatient and specialist visits, individualized health care plans, prosthetics, drugs, home-based care, and intermediate hospital-based care that complies with the expected clinical pathway. It excludes the standard salary paid to GPs for acute care hospitalizations.
- Central Italy – Tuscany: the Arezzo LHU has implemented a Chronic Care Model, in which modules serving an average population of 10,000 are composed of multi-professional teams of GPs, nurses and healthcare workers [12]. The principles of the Chronic Care Model judged to have been implemented by the Regional Authority were: define roles and distribute tasks among team members; emphasize the patient's central role by means of effective strategies to support their self-management, including assessments, goal-setting, action planning, problem-solving, and follow-up; embed evidence-based guidelines in daily clinical practice, and share guidelines and information with patients; and introduce a clinical database (electronic medical records) to collect the critical information needed to generate a disease registry.
- Southern Italy – Sicily: the Ragusa LHU implemented an integrated ambulatory care model, in which GPs recruit chronic patients and refer them to an integrated office, which plans their chronic care in the light of specialists' visits. For the "moderate-to high-risk" patients, a more proactive approach is undertaken to drive patients' empowerment, with follow-up contacts, health education and health promotion activities.

### 2.2. Data analysis

The study considered GPs as a statistical unit, recording their age, gender, adherence or non-adherence to a new organizational model, average number of patients seen during the study period, average number of diabetic patients seen during the study period, LHU membership, average age of diabetic patients, and their performance score before and after the intervention (i.e. the introduction of the new primary care models).

Each GP's performance was assessed on the grounds of quality of care standards, based on their adherence to recommendations concerning patient monitoring and treatment, and internationally validated indicators [13], including:

- I1 = Proportion of diabetic patients that had at least two glycosylated hemoglobin (HbA1c) tests annually;
- I2 = Proportion of diabetic patients that had at least one test for microalbuminuria annually;

**Table 1**  
Description of new proactive models for organizing primary care.

Local Primary Care Model	Tuscany Region Chronic Care Model – LHU Arezzo	Lombardy Region The Chronic Related Groups (CReG) model – LHU Bergamo	Sicily Region Integrated Ambulatory Care model – LHU Ragusa
Year of implementation	2010	2012	2011
Years studied before and after implementation	2009–2011	2011–2013	2010–2012
Patient recruitment	Preplanned)	Preplanned	On demand Proactive management is activated after enrollment
Person responsible for patient management	General Practitioner (GP)	Subject Manager (GP cooperative, House of Health, etc.)	General Practitioner (GP)
Team	District nurse, social health worker, specialist	Nurse	District nurse, specialist
Integration between GP and specialists	The specialist is an integral part of the model	GP refers the patient to a specialist	The specialist is an integral part of the model
Payment schemes	Per capita	Bundle payment scheme	Fee for service

- c) I3 = Proportion of diabetic patients that had at least one creatinine level measurement annually;  
d) I4 = Proportion of diabetic patients that had at least one lipid profile measurement annually;  
e) I5 = proportion of diabetic patients treated with cholesterol-lowering drugs.

Adherence to these requirements was estimated from the administrative databases recording drug prescriptions and diagnostic service usage in 2014, as described in detail elsewhere [14]. The reliability of the extraction algorithms applied to these databases was assessed in recently-published papers [14].

Each indicator takes a value from 0 to 100 (e.g. 0 if none of a GP's diabetic patients were positive for a given process indicator, and 100% if all of a GP's diabetic patients were positive for the process indicator). The indicators were calculated for each GP, before and after the introduction of the new proactive strategy for handling diabetic patients. A total score, given by the arithmetic mean of the five indicators, was calculated for each GP, before and after the introduction of the new strategy, to obtain their average performance in the previously-listed five indicators (range 0–100%), representing their global adherence to a quality management of patients with diabetes (measure of effectiveness):

$$TSB_i = \frac{\sum_{k=1}^5 I_k^b}{5} \text{ is the total score before the treatment for GP } i$$

$$TSA_i = \frac{\sum_{k=1}^5 I_k^a}{5} \text{ is the total score after the treatment for GP } i$$

Overall, 602 GPs were involved in the study: 102 in Arezzo, 414 in Bergamo and 86 in Ragusa. The sample was chosen by including all the GPs taking part in the MEDINA project (who had decided to adopt new models of care) and matched controls (GPs who had not adopted new models of care) selected using a Propensity Score (PS) approach. The variables considered in the matching (implemented with nearest neighbor method) were gender, age, number of diabetic patients, and performance score before the intervention. The balance obtained by the PS was verified in the following ways: a) the means of the variables before and after the matching were compared by the paired t-test, and we verified that after the matching all results are not significant. b) A logistic model, where the “treatment” (adherence to the new model) is the dependent variable and the matching variables are the explanatory ones has been fitted on the matched sample. If the matching was successful, pseudo R2 should be negligible, because explanatory variables have the same distribution in treated and untreated. This is confirmed by our results (see Appendix 1 for details).

A descriptive analysis was carried out and Wald confidence intervals were calculated.

An indicator was calculated as the difference between the variations in the total scores obtained before and after the intervention by the GPs who were exposed to the intervention and the matched GPs who were not. This indicator was obtained by means of the following calculations:

- first we obtained the variation in the total score between and after the intervention for the exposed GPs as  $D_{Ei} = TSA_{ie} - TSB_{ie}$ , where  $TSA_{ie}$  is the total score after the intervention in the  $i$ -th exposed GP, and  $TSB_{ie}$  is the total score before the intervention in the same  $i$ -th exposed GP.  $D_E$  is the arithmetic mean of the variations measured on exposed GPs
- second, we obtained the corresponding variation in the total score for the GPs not exposed to the intervention as  $D_{NEi} = TSA_{ine} - TSB_{ine}$ , where  $TSA_{ine}$  is the total score after the intervention in the  $i$ -th not exposed GP, and  $TSB_{ine}$  is the total score before the intervention in the same  $i$ -th not exposed GP.  $D_{NE}$  is the arithmetic mean of the variations measured on not exposed GPs

The final indicator of effectiveness is simply given by:  $EFFEC-TIVENESS = D_E - D_{NE}$ . Using the Shapiro-Wilk normality test, it was verified that the assumption of a normal distribution of the differences was not satisfied, so a non-parametric Wilcoxon test was used to test whether the median of the indicator differed from 0, and thus establish whether the policy was effective.

Then, to take into account the variable degree of difficulty of achieving the performance improvement goals starting from different baseline performance levels, a further analysis was run using different count for different range of increment in total score. First, 5 different right closed classes for the total score were created and a weight was given to every class. Then every single increment of the total score from TSB and TSA was weighted as follows:

- for every single increment of the total score in 1–50 class, 0.1 points were given to the GP
- for every single increment of the total score in 50–60, 0.5 points were given
- in 60–70, was given 1 point
- in 70–80, were given 2 points
- in 80–100, were given 2.5 points.

As an example, a GP who has  $TSB = 50$  and  $TSA = 65$  would have achieved 10 points, as a result of the sum of an increment of 10 percentage points in the 50–60 score class, weighted 0.5 for every single increment, and an increment of 5 percentage points in the

**Table 2**  
Sample characteristics by LHU and exposure to the new method for matched GPs.

LHU		GP's Average Age	%GP Female	Average No. of patients	Average No. of diabetic patients
Arezzo	Exposed	55.57	22%	1182.25	70.06
	Not Exposed	55.96	10%	1234.59	72.82
	Total	55.76	16%	1208.41	71.44
Bergamo	Exposed	55.21	33%	1316.49	79.17
	Not Exposed	54.84	32%	1285.06	78.78
	Total	55.02	33%	1300.78	78.98
Ragusa	Exposed	54.19	30%	1043.69	89.02
	Not Exposed	53.86	23%	1086.27	87.53
	<b>Total</b>	54.02	27%	1064.98	88.28

**Table 3a**  
Scores related to the five indicators composing the total score, computed pre and post intervention, by LHU and exposure to new proactive models for matched GPs.

		Arezzo				Bergamo				Ragusa			
		Exposed		Not exposed		Exposed		Not exposed		Exposed		Not exposed	
		Mean	Std. Dev.	Mean	Std. Dev.	Mean	Std. Dev.	Mean	Std. Dev.	Mean	Std. Dev.	Mean	Std. Dev.
Before	Creatinine	77.28	8.65	79.09	7.09	67.89	11.38	67.71	9.94	12.68	9.54	10.30	7.50
	Microalbuminuria	41.50	22.53	39.79	17.03	48.26	13.30	47.93	14.24	4.47	5.23	3.82	4.27
	HbA1c	41.04	12.45	42.41	11.24	71.72	9.59	71.86	9.32	5.83	5.96	3.90	4.12
	Statin	40.05	10.09	40.00	9.18	42.77	10.72	43.83	9.48	36.70	9.95	37.94	10.50
	Lipid profile	62.25	13.18	62.98	10.83	67.17	9.64	66.01	9.49	9.23	7.94	7.49	6.83
After	Creatinine	83.88	6.99	80.10	5.90	73.40	8.49	70.90	8.27	16.43	10.65	8.18	7.15
	Microalbuminuria	53.43	20.29	37.29	16.06	49.58	11.88	48.31	10.81	13.04	9.30	5.58	5.48
	HbA1c	49.11	11.85	41.30	9.02	71.66	8.60	69.78	9.56	9.83	7.96	4.27	4.30
	Statin	43.29	8.66	40.04	9.22	46.10	9.84	44.95	8.82	38.96	7.42	37.60	9.54
	Lipid profile	71.11	11.32	66.51	8.97	66.13	9.55	65.30	8.47	16.24	10.93	7.62	6.99

**Table 3b**  
Difference between the scores post and pre intervention related to the five indicators composing the total score, by LHU and exposure to new proactive models for matched GPs, and difference between exposed and not exposed.

		Arezzo			Bergamo			Ragusa		
		Exposed	Not Exposed	Diff	Exposed	Not Exposed	Diff	Exposed	Not Exposed	Diff
After-Before	Creatinine	6.60	1.01	5.59	5.50	3.19	2.31	3.75	-2.12	5.87
	Microalbuminuria	11.94	-2.50	14.44	1.33	0.38	0.95	8.57	1.76	6.81
	HbA1c	8.08	-1.11	9.18	-0.07	-2.07	2.01	4.00	0.37	3.63
	Statin	3.24	0.04	3.20	3.33	1.11	2.22	2.26	-0.34	2.60
	Lipid profile	8.86	3.53	5.33	-1.04	-0.71	-0.32	7.00	0.13	6.87

**Table 4**  
Total performance scores pre and post intervention (with 95% Wald confidence interval) by LHU and exposure to new proactive models for matched GPs, and difference between the score post and the score pre (Score Δ).

LHU	N	Score pre (TSB)	Confidence interval	Score post (TSA)	Confidence interval	Score Δ D = TSA-TSB	Confidence interval	
Arezzo	Exposed	51	52.42	49.75–55.10	60.17	57.65–62.68	7.75	5.77–9.71
	Not Exposed	51	52.86	50.97–54.74	53.05	51.34–54.76	0.19	-1.67 to 2.06
	Total	102	52.64	51.00–54.27	56.61	54.94–58.27	3.97	2.43–5.51
Bergamo	Exposed	207	59.56	58.54–60.59	61.37	60.43–62.32	1.81	1.13–2.49
	Not Exposed	207	59.47	58.46–60.47	59.85	58.92–60.77	0.38	-0.36 to 1.12
	Total	414	59.52	58.80–60.23	60.61	59.95–61.27	1.09	0.59–1.60
Ragusa	Exposed	43	13.78	12.17–15.40	18.90	16.74–21.06	5.12	3.27–6.96
	Not Exposed	43	12.69	11.25–14.13	12.65	11.25–14.05	-0.04	-0.9 to 0.83
	Total	86	13.24	12.16–14.32	15.78	14.33–17.22	2.54	1.39–3.69

60–70 score class, weighted 1 for every single increment, so his achieving follows from  $10 \times 0.5 + 5 \times 1 = 10$ .

This calculation, as stated before, was carried out for every exposed GP and then the mean for every LHU was calculated and used as an indicator of the new organizational model efficacy in the LHU.

### 2.3. Ethical considerations

The data analysis was performed on anonymized aggregate data with no chance of individuals being identifiable. The study complied with the Declaration of Helsinki and with Italian Law n. 196/2003 on the protection of personal data. The recent resolution

n. 85/2012 of the Italian Guarantor for the Protection of Personal Data also confirmed the allowability of processing personal data for medical, biomedical and epidemiological research, and that data concerning health status may be used in aggregate form in scientific studies. Permission to use unidentifiable individual data extracted from administrative databases for the MEDINA project was granted by the ASP 7 Ragusa, and the Bergamo LHU, which are responsible for the use of the data concerning their respective populations. The Agenzia Regionale di Sanità della Toscana is allowed by a regional law to use Tuscan data for research purposes. Approval for use of encrypted and aggregate data from the HSD was also obtained from the Italian College of General Practitioners.

**Table 5a**

Differences of Score  $\Delta$  (total performance score post – total performance score pre, Table 4), with Wald 95% confidence interval, between GPs exposed and not exposed to new organizational models, by LHU.

LHU	Increased effect on global score Effectiveness = $D_E - D_{NE}$	Wald CI 95%
Arezzo	7.55	6.12–8.97
Bergamo	1.43	0.94–1.93
Ragusa	5.15	4.13–6.18

**Table 5b**

Weighted<sup>a</sup> differences of Score  $\Delta$  (total performance score post – total performance score pre, Table 4), with Wald 95% confidence interval, between GPs exposed and not exposed to new organizational models, by LHU.

LHU	Score	Wald CI 95%
Arezzo	6.45	4.26–8.65
Bergamo	2.57	1.46–3.67
Ragusa	0.51	0.33–0.70

<sup>a</sup> Weights computation and an example are given in paragraph “Data Analysis”.

### 3. Results

Our study was performed on a population-based database of 602 Italian GPs, 174 females and 428 males, with a mean age of 55 years. They cared for a total of 753,366 patients, with an average of 1252 patients each, and a consistent prevalence of 6.32% of patients with diabetes.

Table 2 shows the physicians' characteristics by LHU and exposure to the new models of primary care.

Table 3a shows the value of the five indicators composing the total performance score before and after the intervention, stratified by LHU and exposure to the new models. Table 3b shows the difference after-before.

Table 4 shows the GPs' performance scores before and after the intervention, stratified by LHU and exposure to the new models, with the corresponding confidence intervals. Tables 5a and 5b shows the effectiveness of the policy intervention, stratified by LHU.

The adoption of the new models of care resulted in significant differences in performance scores between GPs who were or were not exposed to the intervention, reaching 7.55 points in Arezzo, 1.43 in Bergamo, and 5.15 in Ragusa. When the analysis was run again using the scores adjusted for the different baseline performance levels, the difference (between GPs who were or were not exposed to the intervention) was 6.45 in Arezzo, 2.56 in Bergamo, and 0.51 in Ragusa.

### 4. Discussion

This study showed that different models for proactively addressing chronic diseases early in their cycle, with a view to preventing their progression and containing potential related complications, can improve diabetes management by GPs.

The study also showed, however, that almost half of the diabetic population sampled at Northern and Central Italian LHUs, and as many as 80% in the South of the country were not being monitored annually in terms of HbA1c, LDL or creatinine levels at the start of our study. Only a few cross-sectional studies conducted in Europe provide details of the care process at population level. In a UK population of patients with diabetes, an HbA1c test had been done within the previous year in 93.5% of cases, a serum cholesterol test in 93.1%, and a creatinine test in 93.8% [15,16]. A study performed in Israel found that the care delivered by the health services ensured that almost 85% of patients had annual HbA1c and serum cholesterol tests [17]. Our results are very similar to those reported in the USA for Medicare beneficiaries as regards two quality measures (annual

HbA1c and lipid profile tests) [18], and to the findings of a previous survey conducted in the Italian city of Turin [19]. Such differences in performance from one country to another may stem from the way in which primary care has been organized and motivated, such as a different reliance on multidisciplinary primary healthcare teams (which are important in empowering patients and supporting their day-to-day self-management), or different methods for training diabetics and their key carers to ensure effective self-management and monitoring. Other issues may help to explain the differences too, since better results are observed in countries where ‘pay for performance’ in primary care schemes are in place, as in the UK. Once a quarter of the income of family practitioners in the UK had been tied to measures of their performance, the Quality and Outcomes Framework showed that previously-identified quality improvement trends for major chronic conditions were maintained or bettered, but the effect plateaued as soon as physicians gained the maximum available reward. For major chronic conditions like diabetes, financial incentives could be seen as a part of a broader quality improvement strategy [20], within the framework of a chronic disease model. Be that as it may, the differences in performance identified in different countries should drive the exchange of good practices for the purpose of controlling diabetes, with a benchmarking process and efforts to improve poor performance [21]. In fact, Italy has taken action to introduce new models of proactive primary care. Its federalized, regional healthcare system is now well developed, however, and each region plans and organizes its own health care services, and consequently choose which proactive configuration to adopt as a model for its primary care services.

The present study revealed a small, but significant improvement in performance in Lombardy after it adopted a bundle payment scheme associated with a proactive, new, disease management approach. Bundling care that rightly belongs to the same care pathway is a common-sense approach to optimizing care, costs and outcomes. Payment for bundles of care at a preset rate has implications for accountability and performance management. A previous study ran an initial assessment of the program and found that it improved the organization and coordination of care, the collaboration among health care providers, and adherence to care protocols. The negative consequences included an extra administrative burden, due to outdated IT systems [22]. Another study found the bundle payment model associated with rising costs, in the start-up phase at least [23].

Tuscany adopted a chronic care model (CCM) [24] to adapt its primary health care system to the needs of chronic patients and, judging from the present findings, this model was more effective in ameliorating performances scores. A recent review [25] showed that half of the studies conducted to date found the CCM effective for type 2 diabetes management in primary care, with significant improvements in clinical outcomes. The other half of the studies found no such improvements in clinical outcomes, however. A study conducted in the same region of Tuscany [12] nonetheless showed that CCM implementation had a significant impact on the diabetes care indicators.

Sicily implemented an integrated ambulatory care model, which involves GPs recruiting chronic patients with a view to ensuring a service delivery designed to create connectivity, alignment and collaboration within and between the cure and care sectors (between primary and specialist physicians in this case) in order to enhance quality of care for chronic patients [26]. In fact, the plans for implementing the model were produced in the light of shared contributions from primary and specialist physicians. For “moderate- to high-risk” patients, a more proactive approach is taken to ensure patient empowerment, with follow-up, health education and health promotion activities. An article written some time ago demonstrated that this model of integrated care for diabetes

was at least as effective as conventional exclusive second-level clinical care [27]. An Italian study also found it safe, subject to a first specialist assessment at a diabetes service, for low-risk diabetic patients to be managed by family physicians as part of a coordinated care approach, based on the specialist's clinical recommendations. GPs could subsequently refer patients to a specialist whenever warranted by their clinical condition [28]. In the present study, however, although the new organizational model contributed to improving the Sicilian LHM's performance (which was comparatively poor at the baseline), the difference between its unadjusted and adjusted performance scores shows that the efficacy of the new model was still unable to make up for the region's low performance in terms of the process indicators considered.

The shared management strategies among three new primary care organizational models which could have contributed to reach positive results of the regional projects depend on new integrated care pathways (ICPs) for diabetes with varying definitions and components of care. ICPs enhance the quality of care by improving patient outcomes and suggesting good practices for doctors and nurses. Proactive organizational models provide a sort of multidisciplinary template of the plan leading each patient through the system of care to a desired outcome. They identify considerable potential for nurses to take a lead role in patient education, improving the monitoring of patients' health status.

This study has some limitations. For a start, it focused primarily on the underuse of diabetes management services in primary care, but not their overuse, but providing unnecessary care and making unnecessary use of health care services is not just a cost issue but also a patient safety problem. Further studies should also investigate whether the implementation of new proactive models could affect the overuse of health care services too, even though proactive models favoring the adoption of clinical guidelines (which cover the appropriate use of services in various clinical scenarios) could be an impediment to the routine assessment of overuse [29]. In addition, our study method prevents us from concluding whether one model is better than others. Different regional health systems will implicitly have differences in unmeasured contextual variables, which may have acted as confounders, or even effect modifiers in the relationship between the organizational model and the performance scores. This means that our study did not compare the different models, it examined the effectiveness of each of them. Finally, we did not adopt a randomized controlled trial with non-participants as a control group, which would have enabled us to control for potential selection bias, given also by the voluntary adherence of GPs to the organizational innovation; those who adhere could have a stronger motivation in improving their practice, thus producing the Hawthorne effect.

In conclusion, our study showed that introducing new, proactive primary care models can sustain efforts being made around the world to guarantee good-quality chronic disease management in the primary care setting. These efforts need to be intensified because the vast majority of chronic patients (e.g. more than 90% of diabetic patients in the United States) [30] receive the bulk of their care at primary care practices, and are likely to do so for the foreseeable future.

## Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.healthpol.2019.05.014>.

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