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Impact of Chronic Care Model on diabetes care in Tuscany: a controlled before-after study

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Background: In 2010, Tuscany (Italy) implemented the Chronic Care Model (CCM), to improve general practitioner (GP) management of chronic diseases. **Aim**: assessing how the introduction of CCM affected GPs' compliance with standards of care for diabetes patients. **Methods**: A controlled before-after study was performed. Two exposed groups of GPs, one entering the study in 2010 and one in 2011, were considered. Patients with diabetes assisted by GPs of the groups were identified through the healthcare administrative data of the Regional Healthcare System and followed up from 2009 to 2012. A diabetes care indicator called Guideline Composite Indicator (GCI: annual assessment of glycated haemoglobin and at least two assessment among eye examinations, total serum cholesterol, and microalbuminuria) and an indicator of adherence to statin therapy were computed per year and by group. Impact of intervention was estimated by difference in differences analysis for panel data, stratified by GP performance level at baseline. **Results**: 483 GPs constituting the first group entered the study in 2010, 258 GPs of the second group entered it in 2011, and 1,820 GPs constituted the control group. After 1 year, the diabetes care indicator increased of 8.1%. During the second year, it showed a further increase of 1.6%. The mean impact on the adherence to statin therapy was smaller (+1%), yet statistically significant. **Conclusion**: The first year of the CCM implementation had a significant impact on the diabetes care indicator, and performance was stabilized after the first year. Impact on therapy indicator was smaller.

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Introduction

Tuscany is an Italian region with 3.7 million inhabitants, almost 900 000 of them are over 65 years.[1] For the last decades this region has been facing population ageing. Therefore, a further increase in chronic diseases, and diabetes in particular, is expected together with an increase in the related economical burden and worsening of the individuals' quality of life.

Diabetes is a major cause of heart disease and stroke among adults and is the leading cause of non-traumatic lower-extremity amputations, new cases of blindness and kidney failure.[2] Besides, diabetes still places an enormous burden on hospitalization, despite the availability of effective treatments to prevent or delay major complications.[3]

Many health care decision-makers have been seeking methods to more efficiently and effectively treating chronic diseases; frequently, these methods include the development and implementation of disease management programmes.[4]

The Chronic Care Model (CCM) is a specific model aimed at switching care for patients with chronic diseases (e.g. type 2 diabetes, heart failure, stroke and Chronic Obstructive Pulmonary Disease) from an acute and reactive intervention to a planned and proactive intervention,[5,6] and at providing patients with self-management skills. It comprises six components meant to improve functional and clinical outcomes associated with disease management[5] (appendix 1).

Many studies have reported positive outcomes of CCM, such as reduction of average glycated haemoglobin (HbA1c) and cholesterol levels, blood pressure, improved foot care, better compliance with standards of care, patient knowledge and empowerment levels.[7–9]

Tuscan Regional Health Ministry launched the 'Project for proactive health care implementation at community level' as one of the major items of the 2008–10 Regional Health Planning. The project started in 2010 and was based on the six components of CCM.

This study tries to assess how the introduction of the CCM in Tuscany affected general practitioners' (GPs) compliance with standards of care for patients with diabetes.

Methods

Setting

Italy has a tax-based universal health system organized on three levels. National level provides funding and dictates the fundamental services that must be provided to every inhabitant. Tuscan regional level receives the national funding and organizes its health system through a network of 12 Local Health Authorities (LHAs). Every inhabitant is entitled to choose a GP, who has a gatekeeping function and might have in charge a maximum of 1500 inhabitants. Copayment of some health services might be requested, according to national or regional regulations.[10,11] LHAs are further subdivided into health districts which are homogeneous with respect to a number of characteristics (e.g. rural vs. urban vs. mountain areas) and primary care is organized at the health district level.

Even though each GP is personally responsible for healthcare of his/her patients, GPs may decide to work in groups.[12]

The CCM implemented in Tuscany

The project started on the 1 June 2010. The six components of CCM were implemented in Tuscany as follows:

(i) Health system organization of health care: GPs were organized in teams supported by personnel of the corresponding LHA, such as nurses, physiotherapists, dieticians, and medical specialists. Roles, tasks and responsibilities were explicitly stated. Each team comprised 5–15 GPs and at least one nurse per 10 000 patients. Nurses were responsible for updating the chronic disease registry, contacting patients for routine services, scheduling specialist visits, managing patient counselling,

providing self-management support and recording patient weight, waist circumference, blood pressure, blood glucose (http://www.usl8.toscana.it/images/stories/pdt_diabete_7_ago sto_09.pdf).

(ii) Self management support: nurses were trained to provide self-management support and health education through individual or group counselling, aimed at inviting patients to take an active part in the improvement of their own health. Moreover, in some LHAs only, active education programmes, such as the 'Expert Patient' programme from the Stanford University, were activated.[13]

(iii) Decision support: In each LA, multidisciplinary teams identified diagnostic and therapeutic pathways using international guidelines, and explicit recommendations that were compatible with the resources available were provided to the GPs.

(iv) Delivery system design: regular follow-up visits in the GP practice were proactively scheduled for each patient with diabetes and recalls were set up for patients who failed to attend.

(v) Clinical information systems: teams were asked to set up an electronic diabetes registry, used to support care planning, internal audit and computation of pay-for-performance indicators (see below).

(vi) Community resources and policies: patients involved in the programme were invited to follow a physical training called Adapted Physical Activity, which is a set of non-medical exercise programmes, carried out in a group, especially designed for people suffering from chronic diseases and aimed at lifestyle changes in order to prevent disability (http://www.usl3.toscana.it/allegati/PROGETTOCHRONICDI ABETEPRIMAREVISIONE1_100615011939.pdf).

After the first year a second wave of GPs joined the CCM project during 2011. GP adherence was voluntary throughout the implementation period, although GPs participating in groups followed their group's decision.

A pay-for-performance scheme was set up. A panel of GPs and regional policymakers established a target for each performance indicator, and GPs were paid if minimum four out of the six following indicators reached their target. Performance indicators for diabetes were percent of patient who (i) had an HbA1c test, where the target was 70%, (ii) attended individual or group counselling, (iii) were trained in the use of blood glucose reflectometer, (iv) waist circumference measured, (v) were not on treatment for diabetes at the beginning of the follow-up, (vi) had good glycemic control, where the target was HbA1c < 7%.

Study design

A controlled before-after study was chosen to evaluate the effects of the programme. Two indicators of compliance with standards of care for diabetes were chosen as end points: adherence to statin therapy and Guideline Composite Indicator (GCI), a measure including annual assessment of Hb1Ac and at least two assessments among eye examinations, total serum cholesterol, and microalbuminuria. GCI can be considered a proxy of fair adherence to screening guidelines.[14]

Since one LHA entered the programme only in 2013, we considered 11 of 12 LHAs. Two exposed groups were considered: GPs entering the CCM programme in 2010 and GPs entering it in 2011.

In both groups, performance during the first calendar year after adherence was compared with performance during the calendar year before adherence (2009 for the first group, 2010 for the second). The comparison was both pooled and stratified by year of entrance.

In GPs who entered CCM in 2010, performance during the second year after adherence (year 2012) was compared with performance in 2009 as well. GPs who never joined the CCM programme during the study period were the control group for all analyses. Only those

patients who already had diabetes at the beginning of 2009, were still alive in 2012, and were assisted by the same GP during the whole period 2009–12, entered the analysis.

Data sources

The Regional Health Agency (ARS) hosts an anonymized copy of the Regional Healthcare System administrative data. Such data include hospital discharge records, records of exemptions from copayment for specific chronic diseases, records of drug dispensation and diagnostic procedures reimbursed by the Regional Healthcare System. Moreover, they include a registry that records the gender, birth date and GP of all inhabitants.

LHAs transmitted to ARS the list of those GPs who joined CCM, including their entering date and the health district which they belonged to.

Study variables

Patients in charge to each GP were identified at the beginning of 2009, and those who had changed GP or died during the study period were excluded.

Patients with diabetes were identified as those who matched at least one of the following rules before 1 January 2009: hospital discharge with primary or secondary diagnosis of diabetes, exemption from copayment due to a diabetes diagnosis, at least two dispensations of antiglycemic drugs in a same calendar year. The detailed algorithm is described elsewhere.[15] Adherence to statin therapy was estimated by measuring whether the patient had at least two dispensing records of statins during the year of observation, and at least 6 months between the first and the last. The GCI target was met if the patient had an assessment of glycated haemoglobin and at least two assessments among eye examination, total serum cholesterol and microalbuminuria during the year of observation.

Charlson index was computed for each patient by feeding the enhanced ICD9-CM algorithm of Quan *et al.*[16] with primary and secondary hospital discharge diagnosis recorded during the 3 years before 1 January 2009. Charlson index for comorbidity was then categorized as 0 (no comorbidity), 1 (1 comorbid condition) or 2 (2+ comorbid conditions).

Statistical analyses

Age and sex distribution of the patients in the three groups were computed.

Patient-level characteristics were aggregated per GP. Percentages of patients with diabetes in statin therapy and the GCI were computed. Average Charlson index, percentage of patients over 85 years, percentage of patients under 45 years, and percentage of women entered the analysis, as well as number of patients with diabetes. Moreover GPs were classified as low, middle or high performers at baseline in each indicator (GCI in 2009, adherence to statin therapy in 2009, average number of patients), according to the tertile of the overall distribution of their performance during 2009. The baseline performance was determined separately for GCI and adherence to statin therapy. Characteristics of the three groups of GPs at baseline were compared by ANOVA analysis.

Crude mean of adherence to statin therapy indicator and GCI were computed in the patients of the three groups of GPs in 2009–12.

For both indicators the impact of the first year and the further impact of the second year of policy implementation were estimated by means of a difference in difference (DID) model.[15] The model equation is:

$$y_{it} = \beta' \mathbf{X}_{it} + \gamma G_i + \gamma D_t + \delta(G_i \times D_t) + \alpha_i + \varepsilon_{it} \qquad (1)$$

Table 1 Characteristics of patients with diabetes in the practices of GPs participating in the Tuscan CCM from 2010 to 2012 and from 2011 to 2012 and of non-participating GPs

	Control group	2010 group	2011 group	*P*-values[a]
No of GPs	1820	483	258	
Total diabetic patients	93 553	27 772	14 137	
Average no of diabetic patients per GP	34.8	41.3	39.7	<0.001
	(SD18.4)	(SD 15.6)	(SD 15.5)	
average % of diabetic women	51	50.9	51.1	0.996
	(SD 14.7)	(SD 9.2)	(SD9.1)	
average % of diabetic patients under 45	2.6	2.3	2.2	0.248
	(SD 4.6)	(SD 2.8)	(SD 3.1)	
average % of diabetic patients over 85	6.1	6	6.9	0.130
	(SD 5.9)	(SD 4.4)	(SD 7.6)	
average Charlson index	0.4	0.4	0.4	0.907
	(SD 0.3)	(SD 0.2)	(SD 0.2)	
average baseline in GCI	32.9	34.7	36.7	0.001
	(SD 19)	(SD 16.6)	(SD 15.1)	
average baseline in adherence to statin therapy	30.1	30.5	29.1	0.429
	(SD 15)	(SD 11.3)	(SD 11.8)	

a: The 'p' column is the *P* values for the difference between the two CCM groups.

where y_{it} is the response for the *i*th GP at time *t*, $t = 0,1$, α_i are the specific GPs unobserved characteristics, constant over time and uncorrelated with the mean zero error term ε_{it}, *G* is the exposure indicator (equal to 1 for exposed, i.e. GPs of 2010 and 2011 groups), D_t is the indicator variable of the after-policy implementation period. The inclusion of the GPs observed characteristics **X** in Model (1) allows for differences in the time trend across groups based on observable characteristics. Included covariates were health district, average Charlson index, number of patients with diabetes, percentage of patients aged 85+, percentage of patients aged 45 years or less, percentage of women, baseline performance.

The analysis was repeated by stratifying GPs as low, middle and high performers.

The model was fitted with the xtreg procedure of Stata.[17]

Results

Table 1 shows the baseline distribution in the three groups of GPs of the demographic and comorbidity characteristics of their patients, and of the GCI and the adherence to statin therapy indicator. The ANOVA analysis showed no difference, except for the average number of patients with diabetes, which was significantly lower in the control group, and for the baseline level of GCI, which was significantly better in GPs adhering to the programme. On the contrary, the baseline level of adherence to statin therapy was not significantly different across groups.

Figure 1 shows the crude mean of the GCI and Figure 2 shows the crude mean of adherence to statin therapy indicator in the patients of the three groups of GPs in 2009–12.

For the control group the GCI increased from 29.4% in 2009 to 31.9% in 2012, while in the same 3 years the group of GPs joining the programme in 2010 increased much more, from 31.3 to 42.4%, and the group of GPs joining the programme in 2011 increased more as well, from 33.8 to 41.5%. In both intervention groups a steep increase was observed in the first year after policy implementation, although bigger in the 2010 group (from 31.3 in 2009 to 41.7% in 2011) than in the 2011 group (from 34.9 in 2010 to 41.5% in 2012). The 2010 group did not increase further during the second year (42.4% in 2012).

Adherence to statin therapy was similar for the three groups of GPs in 2009 (27.8, 27.8 and 26.5 for 2010, 2011 and control groups respectively) and increased in all groups to 35.0, 33.3 and 33.4, respectively during the next 3 years.

Panel model

The introduction of the CCM led to an increase in the GCI of 8.1% after 1 year (Table 2). This improvement was mostly among those GPs classified as high performers at baseline, who showed an increase of 9.8%. During the second year of exposure middle and high-performers improved slightly while low performers had a further increase of 3.4%. The policy implementation had a smaller, though statistically significant, impact on the percent of diabetic patients per GP who were treated with statins (overall increase of 1% from 2010 to 2012, see Table 2). This improvement was again mostly among GPs classified as high performers at baseline, who had an increase of 1.6%.

There was no statistically significant difference between the GPs entering CCM in 2009 and those entering in 2010 regarding the GCI and patient adherence to statin therapy.

Discussion

The introduction of a proactive healthcare model in Tuscany had a significant impact on the GCI in the first year, although it was most evident on high performers, and a significant, although small, impact on the adherence to statin therapy. The second year did not have any further impact, although the results of the first year were confirmed.

More than 100 studies have been published about the implementation of CCM on diabetes management and its efficacy.[7–9,18–32] Nutting *et al.*[21] showed that the implementation of CCM improved clinical parameters as well as process parameters.

We focused on two process indicators to summarize the achievement of a standard in monitoring the progression of the disease and therapeutical follow-up: the GCI and the adherence to statin therapy. Both of them were computed from administrative data since they collect drug dispensing records as well as records of diagnostic tests reimbursed by the Regional Healthcare System. Process parameters are part of a set of quality indicators for diabetes identified by the American National Diabetes Quality Improvement Alliance. This set, which gained widespread acceptance internationally, consists of six indicators for care processes and three care outcomes.[32] So, even though the administrative database available to ARS lacks in results from diagnostic tests, such as levels of HbA1c, LDL cholesterol and blood pressure, as well as patients smoking status or foot examination, we are confident to monitor adequate follow-up in diabetes care.

It must be noted that the pay-for-performance scheme focused only on the main test included in the GCI, that is the HbA1c test, but
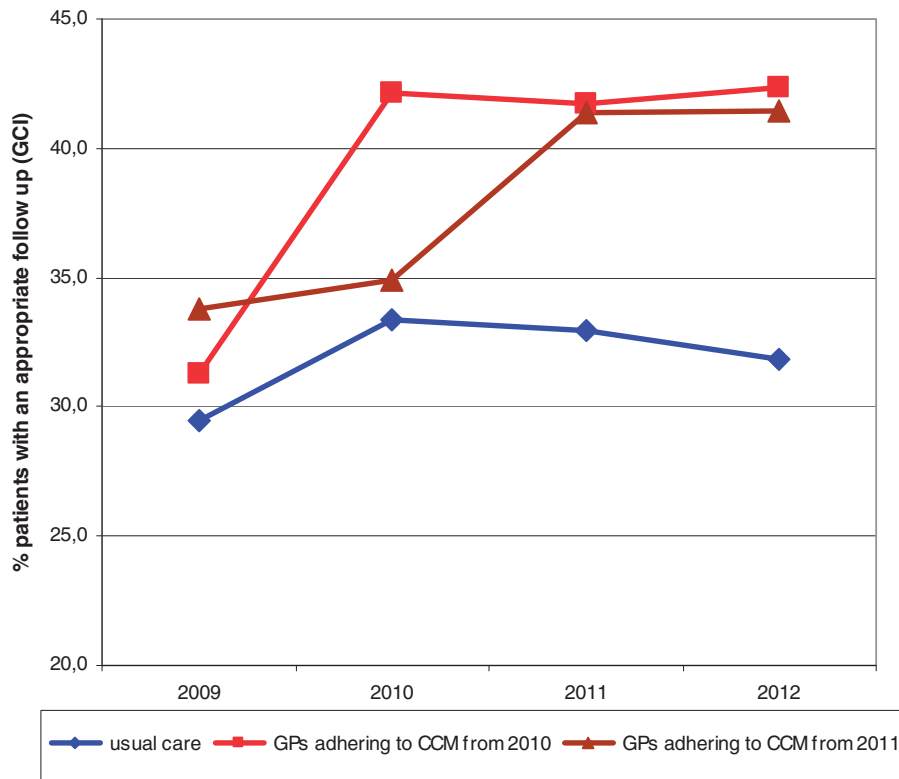
Figure 1 Percentage of diabetic patients with an appropriate follow up in the two interventions and in the control groups, from 2009 to 2012
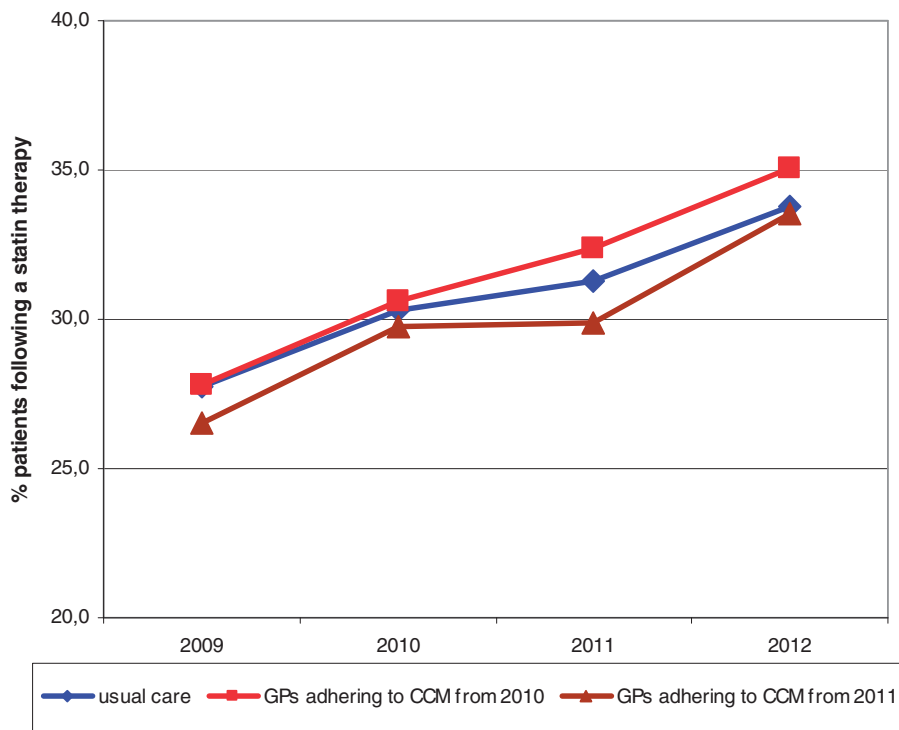
Figure 2 Percentage of diabetic patients in therapy with statin drugs in the two interventions and in the control groups, from 2009 to 2012

this triggered an improvement in the monitoring of the whole composition, as it was confirmed by the increase of the 8% of the GCI.

As reported in the American Diabetes Association guidelines for statin use in primary prevention of cardiovascular disease (CVD), it is recommended that all individuals with diabetes should be treated with a statin unless they apply to very specific exclusion criteria.

These criteria include a patient with type 2 diabetes under the age of 32 years (or 38 years in women), short duration of disease (<10 years), and no apparent CVD risk factors (including a baseline LDL > 100 mg %).[33] Hence, a better ATS should be promoted, especially for diabetic patients with high CVD risk factors. Therefore, we considered adherence to statin therapy as a proxy of therapeutical follow-up.

Table 2 The impact of proactive care implementation, stratified for GPs performance at baseline, after 1 year of the policy implementation for the two groups of GPs participating the Tuscan CCM from 2010 to 2012 and from 2011 to 2012 and the further increase in the second year for the group of GPs joining the Tuscan CCM in 2010

Impact stratifying for GP performance in 2009[a]				
indicator	GPs performance in 2009	Start of intervention	Impact after 1 year of intervention (year after–year before)	Impact of the second year of intervention (2 year after–1 year before)
GCI	Low	2010 group	+6.1***	+3.4*
		2011 group	+11.5***	
		overall	+7.6***	
	Medium	2010 group	+7.5***	+2
		2011 group	+8***	
		overall	+7.7***	
	high	2010 group	+10.8***	−0.7
		2011 group	+8.3***	
		overall	+9.8***	
	overall	2010 group	+7.6***	+1.6*
		2011 group	+8.9***	
		overall	+8.1***	
ATS	low	2010 group	+0.4	+0.1
		2011 group	−0.2	
		overall	+0.2	
	medium	2010 group	+0.7	−0.14
		2011 group	+0.7	
		overall	+0.7	
	high	2010 group	+2.1**	+1.03
		2011 group	+0.5	
		overall	+1.6**	
	overall	2010 group	+1.2**	+0.36
		2011 group	+0.7	
		overall	+1***	

a: The stars are indicating the statistical significance level: $*: P < 0.05$; $**: P < 0.01$; $***: P < 0.001$. GPs performance, year 2009: low if $y_{i,2009} \leq y_{0.33\ 2009}$, medium if $y_{0.33\ 2009} < y_{i,2009} \leq y_{0.66\ 2009}$, and high if $y_{i,2009} \leq y_{0.33\ 2009}$, where $y_{p,2009} : pr(y_{i,2009} \leq y_{p,2009}) = p$.

According to our results, CCM improved the adherence to recommended monitoring of diabetes progression in high, medium and low-performers at baseline. It is noteworthy that the policy implementation had an early impact on high and middle performers, and was effective on low performers during the second year.

The lower impact of the CCM on the adherence to statin therapy, especially in low- and middle-performers is difficult to explain. A possible explanation is the so-called 'therapeutic inertia', that is the failure to change or uptitrate treatment strategy when a disease is uncontrolled. In patients with type 2 diabetes this may occur with antidiabetic treatments and/or treatment for various cardiovascular risk factors.[34]

We used the Charlson index in an attempt to rule out the possibility that lower impact of CCM in terms of compliance with standards of care for chronic patients was due to an average worse condition of patients overall. Charlson index, although developed to predict mortality, has been often used to summarize morbidity burden.[35]

Limitations to the study

A limitation to our analysis comes from the fact that we identified patients from administrative data, and that patients actually exposed to the programme could not be identified. On the one hand, this protected the analysis from selection bias in terms of case-mix and other relevant characteristics. On the other hand, the impact we measured could be underestimated.

A selection bias due to non-random assignment to the CCM groups may have played a role in our results: GPs who were more motivated towards innovation in chronic disease management might have adhered more frequently to the programme. However, we do not expect that this limitation greatly influenced our results. First of all, initial motivation is likely to be associated to baseline performance, and our model was adjusted for this characteristic. Secondly,

Gp involvement in CCM was in many cases determined at the group level, meaning that some GPs may not have been willing volunteers for the programme. Finally, DID, a statistical technique widely used in economics to evaluate the impact of a policy,[36–38] is useful to overcome this limitation. Indeed, under the assumption that the differences between exposed and non-exposed are time-independent, although unobserved, DID can be attributed to the intervention groups only.

Conclusions

The first year of the CCM implementation for patients with diabetes in Tuscany had a significant impact on the diabetes care indicator, showing a better monitoring of the disease, and a smaller impact on the statin therapy indicator. This was due especially to GPs who were already achieving good standards of care. After the first year, their performance was stabilized, and also low performers showed a further increase, uniforming GPs' overall performance.

Conflict of interests: One author belongs to the Regional Health Ministry of Tuscany, which is performing the programme object of the study. The other authors belong to the ARS of Tuscany, which is funded by Regional Health Authority of Tuscany.

Key points

- Evaluating the Chronic Care Model for diabetes management using administrative data revealed an improvement in care processes in the first 2 years of the programme implemented in Tuscany.

- GPs were stratified into three levels of performance, verifying that after the first year of policy implementation positive results in terms of a better monitoring of the disease was confirmed in high- and middle performers. After the first year, their performance was stabilized, and also low performers showed a further increase, uniforming GPs' overall performance.
- The statistical analysis performed (difference in differences analysis for panel data) allowed us to exclusively attribute the improvement in diabetes management to the policy adopted, as shown by the increase of the diabetes care indicator and the indicator of adherence to statin therapy.

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