

# Alma Mater Studiorum Università di Bologna Archivio istituzionale della ricerca

Disease management in diabetes care: When involving GPs improves patient compliance and health outcomes

This is the final peer-reviewed author's accepted manuscript (postprint) of the following publication:

Published Version:

Disease management in diabetes care: When involving GPs improves patient compliance and health outcomes / Cristina Ugolini; Matteo Lippi Bruni, Gianluca Fiorentini, Anna Caterina Leucci, Maria Luisa Moro, Elena Berti, Lucia Nobilio. - In: HEALTH POLICY. - ISSN 0168-8510. - STAMPA. - 123:10(2019), pp. 955-962. [10.1016/j.healthpol.2019.08.014]

Availability:

This version is available at: https://hdl.handle.net/11585/700146 since: 2022-02-23

Published:

DOI: http://doi.org/10.1016/j.healthpol.2019.08.014

Terms of use:

Some rights reserved. The terms and conditions for the reuse of this version of the manuscript are specified in the publishing policy. For all terms of use and more information see the publisher's website.

This item was downloaded from IRIS Università di Bologna (https://cris.unibo.it/). When citing, please refer to the published version. This is the final peer-reviewed accepted manuscript of:

Ugolini, C., Lippi Bruni, M., Leucci, A. C., Fiorentini, G., Berti, E., Nobilio, L., & Moro, M. L. (2019). Disease management in diabetes care: when involving GPs improves patient compliance and health outcomes. *Health Policy*, *123*(10), 955-962.

The final published version is available online at:

https://doi.org/10.1016/j.healthpol.2019.08.014

Rights / License:

The terms and conditions for the reuse of this version of the manuscript are specified in the publishing policy. For all terms of use and more information see the publisher's website.

This item was downloaded from IRIS Università di Bologna (<u>https://cris.unibo.it/</u>)

When citing, please refer to the published version.

# Disease management in diabetes care: when involving GPs improves patient compliance and health outcomes

Cristina Ugolini\*, Matteo Lippi Bruni\*, Anna Caterina Leucci\*\*, Gianluca Fiorentini\*,

Elena Berti \*\*\*, Lucia Nobilio\*\*\*, Maria Luisa Moro\*\*\*

\*Department of Economics and CRIFSP-School of Advanced Studies in Health Policy, University of Bologna, Italy

\*\*CRIFSP-School of Advanced Studies in Health Policy, University of Bologna, Italy

\*\*\* Regional Agency for Health and Social Care, Emilia-Romagna Region - ASSR, Italy

### **Corresponding author:**

Cristina Ugolini Department of Economics, Alma Mater Studiorum University of Bologna Piazza Scaravilli 1, 40128, Bologna, Italy <u>cristina.ugolini@unibo.it</u> +39 333 4982021 +39 051 2098139 <u>https://orcid.org/0000-0001-8453-674X</u>

### Highlights

- We study the association between supervision of diabetics and health outcomes
- Participation in a disease management program increases patients' adherence
- Stricter adherence to guidelines is associated with better health outcomes

#### Abstract

Although the study of the association between interventions in primary care and health outcomes continues to produce mixed findings, programs designed to promote the greater compliance of General Practitioners and their diabetic patients with treatment guidelines have been increasingly introduced worldwide, in an attempt to achieve better quality diabetes care through the enhanced standardisation of patient supervision. In this study, we use clinical data taken from the Diabetes Register of one Local Health Authority (LHAs) in Italy's Emilia-Romagna Region for the period 2012-2015. Firstly, we investigate whether GPs' participation in the local Diabetes Management Program (DMP) leads to

improved patient compliance with regional guidelines. Secondly, we test to see whether the monitoring activities prescribed for diabetics by the Regional diabetes guidelines have a positive impact on patients' health outcomes and increase appropriateness in health care utilization. Our results show that such a Program, which aims to increase GPs' involvement and cooperation in following the Regional guidelines, achieves its goal of improved patient compliance with the prescribed actions. In turn, through the implementation of the DMP and the greater involvement of physicians, Regional policies have succeeded in promoting better health outcomes and improved appropriateness of health care utilization.

Keywords: diabetes care; clinical guidelines; primary care; Diabetes Management Programs.

**JEL codes:** C21, I10, I18, H51

#### 1. Introduction

The treatment of diabetes is at the forefront of the health policy agenda and the adoption of Diabetes Management Programs (DMPs) is deemed to reduce short- and long-term complications, thanks to periodic tests for haemoglobin A1c, lipid and microalbuminuria determination and eye examination [1-5]. Increased patient supervision based on a designated set of activities is believed to improve the quality of treatment compared to unstructured care [6-8]. The main purpose of these initiatives is to reduce heterogeneity in clinical decision-making, and to align physician's behaviour with evidence-based best practices. Despite the rewards GPs typically receive for complying, adherence with best practices remains unsatisfactory in many cases [9-11]. GPs' reluctance to comply with top-down directives is mainly attributed to the effort required to implement the guidelines and to resistance to monitoring schemes that limit GPs' self-determination [12-13].

In this paper, we study the influence of DMPs on health outcomes, and we address two key issues for the success of the former. First, we aim to establish whether DMPs effectively promote compliance with guidelines that recommend regular screening. Our second goal is to examine the association between patient screening and health outcomes, by testing whether diabetics who enjoy regular monitoring display better outcomes.

We use data from the largest Local Health Authority (LHA) within Italy's Emilia-Romagna Region, covering the period 2012-2015. Our information consists of patient and GP-level data taken from administrative sources and from the

Diabetes Register. We find that enrolled patients display a probability of compliance that is nearly four (two and half) times as large as that of non-enrolled ones, depending on whether more (less) restrictive criteria for adherence are considered. Such evidence has implications also for extensions of similar policies to other chronic conditions [14-17]. We also show that the successful completion of the set of actions recommended by the regional guidelines during the course of the previous year significantly improves patient outcomes. Health outcomes are measured by the reduction in the probability of new diabetic complications (*Odds Ratio-OR 0.882*), in all-cause hospitalisations (*OR 0.832*) and in hospitalisations for Ambulatory Care Sensitive Conditions-ACSCs (*OR 0.826*). No significant effect is found for avoidable emergency admissions.

### 1.1. Background

The study of diabetes management programs has produced non-conclusive findings, so far [18-19]. The UK's Quality and Outcomes Framework (QOF) has been found to have positive effects on targeted quality [18] and specifically for diabetes care [20]. Nevertheless, the QOF-related gains, including those pertaining to diabetes, were in line with improvements recorded for conditions left out of the program [21], signalling the difficulty of isolating the effects of the program from those effects produced by general medical improvements.

Proponents of the use of payments conditional on the achievement of outcome targets have stressed their quality enhancing potential, whereas critics have raised doubts over their effectiveness. In keeping with a long line of research in psychology, the economic literature has highlighted that flawed incentive schemes may "crowd out" intrinsic motivation [22-23] and they could even be harmful, especially in National Health Systems (NHS) where the public mission is expected to favour compliance with societal objectives [24]. Conversely, incentives not directly linked to patient outcomes, can induce crowding-in effects and facilitate cooperation between clinicians and policymakers. For example, the payment of an additional amount per chronic patient included in the managed care programme, may help increase treatment adherence, reduce patient selection, and preserve intrinsic motivations [25]. Whether these initiatives ultimately improve patients' outcomes, even if the latter are not explicitly targeted, remains an empirical matter. The literature has pointed out that incentives based on process measures can have a significant impact on health outcomes [26], as in the Canadian and Australian experiences where physicians are rewarded for complying with guidelines when treating diabetes patients [27-29].

As regards Italy, earlier analyses show a positive impact of DMPs when payments target the assumption of responsibility for diabetic patients and not health outcomes such as hyperglycaemic emergencies and/or hospital admissions for ACSCs [30, 16]. One limitation of these contributions is to rely exclusively on administrative data. By

contrast, in this study we combine administrative data with diabetes-related biomarkers. This enables us to control for individual-specific severity using information on HbA1c values, i.e. glycated haemoglobin. A further advantage is that we can identify those patients enrolled in the protocol for managed diabetes care in each list. We exploit patient-level data to assess whether DMPs increase compliance with clinical guidelines and whether fulfilling the monitoring standards set by the guidelines has beneficial effects on health indicators not explicitly rewarded by the DMP. Taking a different perspective, other insightful contributions have investigated how institutional features affect diabetes management in the Italian context. However, they are relatively more focused on the role of multidisciplinary teams in disease-specific management plans, rather than on the impact of incentives for GPs to assume a pivotal role in such plans [31, 32].

Our findings support the view that promoting GPs' assumption of responsibility by means of formally established DMPs increases the accuracy of patients supervision in the treatment of chronic diseases and, in turn, this reduces the probability of adverse events.

#### 1.2 Institutional framework

The Italian NHS is mainly funded through general taxation and the Regions autonomously manage health services via Local Health Authorities (LHAs). Each LHA is organised into Local Health Districts (LHDs) that provide community and hospital services and coordinate primary care. Each patient is registered with a GP, who is a self-employed contracted to the NHS, mainly paid on a capitation basis. On top of that, Regional Governments and LHAs can introduce additional GP remuneration for selected activities.

In 2003, the Emilia-Romagna Department of Health introduced a new DMP called "*Integrated Management*" (IM), based on a proactive integrated approach to type-2 diabetes patients involving GPs [33, 34]. Type-2 patients are divided into two groups: medium or high-severity patients that are followed by specialists operating in hospital-based clinics (Diabetic Centres); low-severity patients - with stable metabolic compensation and a limited number of mild complications (in particular no medium and severe micro-macro vascular complications) - that are followed by their GPs.

Within such a framework, GPs have the option to enrol in the IM program the low severity patients registered with them who agree to do so. Upon enrolment, GPs are responsible for the enforcement of the regional Guidelines for the Management of Diabetes Mellitus. The Guidelines prescribe the following main monitoring activities: (1) the measurement of Hb1Ac twice a year; (2) blood cholesterol and urinary micro albumin tests once a year; (3) an

electrocardiogram and/or visit to a cardiologist every 1-2 years; (4) ophthalmologic monitoring by means of an ocular fundus examination every 1-2 years.

To implement the IM program locally, each LHA lays down a specific agreement with the local board of GPs, defining the incentives - additional to the capitation fees - for the enforcement of the Clinical Guidelines. The Bologna LHA set a fixed fee per-visit (with a maximum of 4 visits per year) conditional on a half-yearly GP certification of the satisfactory adherence to the Guidelines. In 2015, on average, each GP obtained a yearly integration of about 100 euro per patient enrolled in the DMP, while the base capitation fee was 40 euro per patient enrolled (59 for those above 75 years).

### 2. Materials and method

#### $2.1 Data^1$

Our primary data cover the year 2015. Our baseline population comprises residents of the Bologna LHA, that amount to nearly 1 million people and comprise almost one fourth of the regional population. Following the criteria of the Regional Department of Health, our study population consists of all residents over the age of 18 years who have received at least two diabetes drug prescriptions (oral agents or insulin) over the previous three years (2012-14). As this criterion fails to detect patients treated through diet and exercise, also outpatients who attended a Diabetes Centre at least once over the previous three years and inpatients diagnosed with diabetes are included.

We merge patient characteristics and pharmaceutical treatments, together with diabetes-related biomarkers and information about the organisation of diabetes management. As the paper focuses on IM programs managed by GPs, we exclude (more severe) patients managed exclusively by Diabetes Centres. Finally, we excluded those diabetics who changed GP during the year 2015 (368 patients). The resulting dataset includes 30,577 patients registered with 700 GPs located in 6 LHDs.

Table 1 presents the dependent variables. We distinguish between indicators of the *adherence to guidelines* in the upper panel of the table, and of *quality of diabetes care* shown in the lower panel.

<sup>&</sup>lt;sup>1</sup> The study, based on routine administrative information and on the Diabetes Register, was carried out in conformity with the regulations on data management of the Emilia-Romagna Region and with Italian privacy law. Administrative data were linked to the Diabetes Register's data and anonymised by an ad-hoc service of the Regional Health Directorate. The Health and Social Regional Agency and the University of Bologna have no possibility to retrospectively identify individuals included in the study. When informed consent cannot be obtained, the Italian law requires ethical approval for retrospective studies for non-anonymous data only, hence such approval was not required given the anonymous nature of the data.

We measure *adherence to guidelines* using two indicators: the first is a dummy for patients who performed at least two glycated emoglobin tests during 2015: the main recommendation included in the guidelines. The second is based on the more restrictive criterion requiring controls for blood cholesterol and urinary micro albumin in addition to the two glycated emoglobin tests. We do not consider the other recommendations for different reasons. Electrocardiogram and ophthalmologic monitoring are not required on an annual basis, thus raising problems in identifying non-compliance given the short span of our data. In addition, patients frequently receive ocular fundus examination during private ophthalmologic visits, leading to a likely underestimation of the procedure in our dataset that covers public sector treatments.

Around one third of the patients meets the first compliance criterion, with the share varying from 45.48% in the case of patients enrolled in the IM program, to 25.50% for those not enrolled. Diabetics undergoing two glycated emoglobin tests and one microalbuminuria test account for one quarter of the total (26%), with shares of 39.26% for patients enrolled in an IM program and of 15.79% for non-enrolled ones.

The *quality of diabetes care* is measured using four variables. For the year 2015, we consider patients who: (1) had at least one new diabetes-related complication; (2) were hospitalised for at least one admission for ACSCs preventable through effective ambulatory treatment [35, 36]; (3) had at least one inappropriate access to the Emergency Department, based on the Italian four-level triage system [37]; (4) were hospitalised at least once for any cause, since non-adherence may reduce the effectiveness of treatment, making patients more vulnerable and exposed to the need for hospital assistance [17].

All-cause hospitalisation involves nearly one fifth of the diabetics (18.8%), followed by patients for whom at least one new complication was recorded in 2015 (6.4%), and by those who experienced at least one avoidable admission to the ED (5.5%). Only 2.7% of diabetes patients were hospitalised for ACSCs in 2015. The second part of Table 1 shows conditional probabilities for pairwise associations between health outcomes: 93.95% of patients with at least one new complication in 2015 were also hospitalised for any cause, 19.6% for an ACSC and 9.53% were admitted to the ED for a non-urgent episode. A high degree of association is recorded also for patients with at least one ACSC hospitalisation, nearly half of whom experienced new complications in 2015. In all other cases, the degree of association ranges from 4% to 30%, suggesting that the set of outcomes covers a broad range of conditions, capturing different kinds of failure in patient supervision.

### TABLE 1

Table 2 provides the descriptive statistics for the covariates. Patients' characteristics include gender, age, foreign citizenship, regular insulin use, the presence of at least one chronic disease, the adherence to clinical guidelines in the previous year, the enrolment in the IM program. We exploit the measure of blood glucose in the previous year to classify patients on the basis of the glycated haemoglobin value. To be classified as compensated, patients must report glycated haemoglobin levels of less than 7% before the age of 60, below 7.5% when aged between 60 and 75, and below 8% when aged 75 or more. Patients are decompensated if their glucose values exceed the thresholds. Finally, patients are classified as partially compensated if they present values both above and below the age-specific threshold within the same year. 53% of our patients are males, the average age is 70 (ranging from a minimum of 18 to a maximum of 104), and 76% of them have at least one chronic disease. Foreigners account for 5% of the total, while 7% of the sample received at least one insulin prescription, and nearly three-quarters have compensated diabetes (73%). Almost 42% of patients are enrolled in the IM program.

GPs' characteristics include age and gender, practice type (individual vs. group practices), together with dummies for list size and share of diabetics in the list. About 65% of GPs are male, their average age is 60 (ranging from a minimum of 37 to a maximum of 68), 77% of them work in a group practice, an average 3% of their registered patients are diabetics (ranging from a minimum of 0,5% to a maximum of 10%). To account for unobserved heterogeneity at the local level, we include Health District fixed effects.

#### TABLE 2

### 2.2. Empirical strategy

Since patients are nested into practices, the independence assumption of the error term is challenged, and standard regression techniques can produce downward biased standard errors. On the contrary, a multilevel approach overcomes this problem by assessing variability at each layer separately [38-39]. In the light of the hierarchical structure of the data, we consider a two-level generalized linear multilevel model:

$$\pi_{ij} = f(X\boldsymbol{\beta})_{ij} \tag{1}$$

where  $\pi_{ij}$  is the expected value of the response variable for the *i*-th patient and *j*-th GP, X is a vector of independent variables,  $\beta$  is the associated parameter vector, and f is a non-linear link function of the predictor  $(X\beta)_{ij}$ . Due to the dichotomous nature of all outcome variables, we specify a Bernoulli distribution for the dependent variables and a logit link function. Therefore, the model becomes:

$$logit (\pi_{ij}) = (X\boldsymbol{\beta})_{ij} + v_j + \varepsilon_{ij}$$
<sup>(2)</sup>

 $v_j \sim N(0, \sigma_v^2)$  is a Gaussian-distributed random-effect term specific for the *j*-th GP, and  $\varepsilon_{ij} \sim N(0, \sigma_{\varepsilon}^2)$  is a gaussiandistributed error term specific for the *i*-th patient and the *j*-th GP.

We estimate an unconditional model and compute the Intraclass Correlation Coefficient (*ICC*) as estimate of the share of the total variance that potentially refers to the GP level and in order to evaluate the basic partitioning of the outcome variability at GP level [38]. Larger values of *ICC* (0 < ICC < 1) are indicative of greater potential for each layer to influence the dependent variable.

$$ICC = \frac{population \ variance \ between \ GPs}{total \ population \ variance}$$
(3)

We perform regression analyses by estimating separate multilevel models for each dependent variable and controlling for relevant explanatory variables. We adopt a maximum likelihood procedure with Laplace approximation, using the SAS/STAT 9.4 software PROC GLIMMIX procedure, at a 95% confidence level. Statistical significance is evaluated by means of the Wald test statistic, and goodness-of-fit is assessed using deviance [39].

Our empirical strategy is organised in two distinct steps, both based on multilevel logit models as described in equation (2) that include up to two levels, the first referring to the patient, the second to the GP. First, we assess whether DMP enrolment increases compliance with the activities recommended by the guidelines. To do so, we test if patients enrolled in an IM program are more likely to perform the prescribed tests than are patients not part of such a program. Compliance requires undertaking at least two Hb1Ac tests per-year in the first place. We then introduce a more restrictive criterion whereby, in addition to blood glucose control, compliant patients are also required to have one blood cholesterol test and one urinary micro albumin test. The compliance indicators are regressed against the same set of covariates from the previous specification, augmented by a dummy for patient enrolment in the IM program. This allows us to test whether enrolment in a structured DMP based on IM protocols increases the probability to comply with best-practice guidelines.

Our second goal is to establish whether compliance with the recommended activities in the previous year has a positive impact on health outcomes that cover a broad spectrum of potential effects and accommodate the multidimensional nature of health. Our dependent variables take value 1 for: diabetics experiencing a new diabetes-related complication; diabetics hospitalized for an ACSC; diabetics who have been hospitalised at least once; diabetics who have had at least one inappropriate access to the ED, respectively. We model each dummy as depending upon patient and practice characteristics. The covariate of main interest is the dichotomous indicator of compliance with guidelines during the previous year. We consider compliance to be satisfied if patients performed at least two glycated emoglobin tests, blood

cholesterol and microalbuminuria tests in 2014. Diabetes compensation is evaluated based on information for the year 2014, while all other variables refer to the year 2015.

#### 3. Results

The appendix reports the estimates for the variance components and for the *ICC* from the empty models. Such estimates are not always significant, suggesting that the hierarchical nature of the data affects the variability of our *health indicators* to a limited extent. Conversely, we get larger *ICCs* for *adherence to guidelines*. Using the compliance criterion based on blood glucose tests only, the *ICC* is equal to 13% at GP level, whereas adding cholesterolemia and microalbuminuria, the *ICC* for the GP layer increases to 18%. The share of variability explained by the GP layer supports the choice of the multilevel specification.

Table 3 presents the estimates for the determinants of adherence to guidelines. Enrolment in the IM program leads to a significant increase in compliance with guidelines, which suggests that patients with similar disease severity and treated by GPs with similar characteristics are more likely to undergo regular blood glucose controls and microalbuminuria tests when enrolled in the IM program. The odds ratio for enrolled patients is more than twice as large (OR 2.5) than for non-enrolled diabetics in the specification accounting for glycated emoglobin tests only, and almost four times larger (OR 3.9) when microalbuminuria is also considered. The main policy implication is that participation in a DMP that includes a structured clinical pathway identifying requirements for regular patient monitoring, is positively associated to patient compliance.

The role of patients' characteristics appears of minor relevance. We find no difference in compliance across genders, and age plays a minor role, while natives show greater compliance with clinical guidelines than foreign patients do. Not surprisingly, insulin users and patients with other chronic diseases are more likely to comply with the routine tests (OR 1,3). The more severe the patient's condition, the more effective are the GP's recommendations to follow the guidelines, because of the exposure to possible complications. Practice level controls do not affect the outcomes, with the exception of being assisted by a female GP, which increases the probability of compliance.

#### TABLE 3

In Table 4 we present the results for the health outcome indicators. We find a significant and negative association between adherence to the guidelines in the previous year and the probability of experiencing a new diabetes-related complication, an ACSC and an all-cause hospitalisation; no significant effect on inappropriate ED admissions emerges. The difference in the odds between compliers with guidelines and non-compliers is of a similar magnitude for ACSCs

and all-cause hospitalisations, while a smaller effect is found for new complications. Non-compliers have 20% greater odds than compliers do when the adverse outcome is measured in terms of either type of hospital admission, and 13% greater odds in terms of new complications. These findings support the adoption of patient monitoring strategies based on the Regional guidelines, as they slow down the onset of new complications and prevent the unnecessary use of hospital services.

Patients' characteristics are good predictors of adverse health outcomes. Three out of the four outcomes are significant and positively correlated with patient age. The only exception is inappropriate ED admissions, which occur more frequently among younger patients. The result likely reflects a lower propensity to classify ED admissions by elderly patients as inappropriate due to such patients' high vulnerability. Females are less likely to experience diabetes-related complications or to be hospitalized, whereas we find no gender difference for ED admissions. Natives display a higher probability of all-cause hospitalisations, but a lower probability of being inappropriately accessing hospital services with ED access or ACSC admission. The smaller probability of hospitalisation in general in the case of foreigners is consistent with the healthy immigrant hypothesis [40]. As for ED visits, the result is in line with prior evidence showing that in Italy foreigners display a relatively higher propensity to use emergency services than natives do [41]. The most interesting policy indication emerges from the higher propensity to inappropriate hospital admissions of foreigners. We cannot establish whether the aforesaid result is due to a lower propensity to attend primary care practices, or to other problems in the patient-physician relationship (e.g. communication). Still, this highlights the need for targeted initiatives in favour of a more appropriate use of hospital services by foreign diabetic patients.

Insulin dependence and chronic conditions are positively correlated with new complications and the extra-utilisation of health services, leading to the greatest increase in the probability of adverse outcomes. For both severity measures, the odds-ratios range from 3.7 to 4.5 in the case of new complications and ACSC admissions, and from 1.2 to 3.2 for all-cause hospitalisations and avoidable ED admissions. Having a compensated diabetes in 2014 does not affect the probability of experiencing a new complication in the following year. On the contrary, compensated patients are more likely to be hospitalised, which is in keeping with recent findings in Spain [42]. Most controls included at GP level do not affect the outcomes.

#### TABLE 4

### 4. Conclusion

The design of disease management programs for chronic diseases aimed at improving the quality of outpatient care is a challenging issue that bears high policy relevance. We have focused on a DMP where targets refer to process measures

based on the regular monitoring of diabetic patients, and we have tested two key hypotheses to provide a comprehensive assessment of its potential impact. Using data from a large Italian Local Health Authority, we first investigated whether the probability of meeting the guideline recommendations is related to DMP enrolment; second, we assess whether regular supervision of diabetic patients is associated with better health outcomes and reduced utilisation of hospital services.

From a reference population of around 1,000,000 inhabitants, a cohort of around 30,000 patients was extracted. Our estimating sample comprises patients with mildly and medium severe diabetes, since more complex cases are not eligible for the GP-run DMP. The data refer to the year 2015, containing both patient- and GP-level information, including a biomarker for glucose concentration (HbA1C or glycated haemoglobin level).

We show that participation in the DMP is associated to a higher probability of adherence to the surveillance regime established by the guidelines. Moreover, we find that, compared to patients who fail to follow the prescriptions, those who enjoy regular monitoring display better health outcomes in terms of lesser likelihood of new complications, and of more limited utilisation of hospital services (all-cause hospitalisations and ACSCs). No significant difference was recorded for avoidable ED admissions. Such evidence supports the effectiveness of the program in promoting regular patient supervision, since enrolment favours compliance with best practices, and, in turn, such actions are associated to improved outcomes. As for the financial implications, by limiting the utilisation of health services, improved patient supervision possibly reduces the economic burden of diabetes.

The internal consistency of the empirical evidence and its robustness across multiple health and compliance indicators deliver valuable policy insights into the role of chronic care models. In particular, the analysis furthers our understanding of the types of programs where payments are contingent on the GP's overall assumption of responsibility for the diabetic patient, through counselling and regular monitoring, rather than on the achievement of specific health outcomes.

### **Ethical approval**

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

#### **Conflict of interest statement**

The authors are employees of their institutions, University of Bologna (Ugolini, Fiorentini, Lippi Bruni) and the ASSR-RER (Moro, Nobilio, Berti). The two institutions have jointly concurred to the project with their own resources and the ASSR-RER has assured the financial resources necessary for the research assistant contract of Anna Caterina Leucci. The opinions expressed here are the sole responsibility of the authors and do not represent the views of the University of Bologna and the ASSR-RER.

### Acknowledgments

The project is the result of a partnership entitled "Economic evaluation of clinical pathways and prescribing appropriateness" between the School of Health Policies-University of Bologna and the Regional Agency for Health and Social Care of the Emilia-Romagna Region (ASSR-RER), with the cooperation of the Local Health Authority of Parma. The three institutions have jointly concurred to the project with their own resources with the ASSR-RER assuring the financial resources necessary for research assistant contracts. The ASSR-RER and the Local Health Authority of Bologna provided the databases used in this study. The opinions expressed here are the sole responsibility of the authors and do not represent the views of the University of Bologna and the ASSR-RER. The usual disclaimers apply.

#### References

[1] World Health Organization (2016). Global report on diabetes. Geneva: World Health Organization.

[2] International Diabetes Federation (2017) Recommendations for Managing Type 2 Diabetes in primary care. www.idf.org/mantain-type2-diabetes.

[3] Gil J., Sicras-Mainar A., Zucchelli E. (2018). Uncontrolled diabetes and health care utilisation: panel data evidence from Spain, The European Journal of Health Economics, 19:785-795.

[4] Bansal, M., Shah, M., Reilly, B. et al. (2018) Impact of Reducing Glycated Hemoglobin on Healthcare Costs Among a Population with Uncontrolled Diabetes. Appl Health Econ Health Policy 16:675.

[5] De Micheli A. (2008) Italian standards for diabetes mellitus 2007: executive summary Diabete Italia, AMD Associazione Medici Diabetologi, SID Società Italiana di Diabetologia, Acta Diabetol 45: 107-127

[6] Tricco, A. C., Ivers, N. M., Grimshaw, J. M., Moher, D. et al. (2012). Effectiveness of quality improvement strategies on the management of diabetes: A systematic review and meta-analysis. The Lancet, 379: 2252–2261.

[7] Smith, S.M., Wallace E., O'Dowd T., Fortin M. (2016). Interventions for improving outcomes in patients with multimorbidity in primary care and community settings. Cochrane Database of Systematic Review.

[8] Simcoe T, Catillon M, Gertler P. (2019) Who benefits most in disease management programs: Improving target efficiency. Health Economics, 28 (2): 189-203.

[9] Oh S.W., Lee H.J., Chin H.J., Hwang J.I. (2011), Adherence to clinical practice guidelines and outcomes in diabetic patients, International Journal for Quality in Health Care, 23(4): 413–419.

[10] Kirkman M., Williams S., Caffrey H.H., Marreo D.G (2002) Impact of a program to improve adherence to diabetes guidelines by primary care physicians, Diabetes Care; 25:1946-51.

[11] Fattore G., Frosini F., Salvatore D., Tozzi V. (2009) Social network analysis in primary care: The impact of interactions on prescribing behaviour, Health Policy, 92(2-3): 141-148.

[12] Zwolsman, S., te Pas, E., Hooft, L., Wieringa-de Waard, M., & van Dijk, N. (2012). Barriers to GPs' use of evidence-based medicine: a systematic review. The British journal of general practice: the journal of the Royal College of General Practitioners, 62(600), e511-21.

[13] Cook, D. A., Pencille, L. J., Dupras, D. M., Linderbaum, J. A., Pankratz, V. S., & Wilkinson, J. M. (2018). Practice variation and practice guidelines: Attitudes of generalist and specialist physicians, nurse practitioners, and physician assistants. PloS one, 13(1), e0191943. doi:10.1371/journal.pone.0191943

[14] Rudkjøbing A., Vrangbaek K., Birk H.O., Andersen J.S., Krasnik A. (2015) Evaluation of a policy to strengthen case management and quality of diabetes care in general practice in Denmark. Health Policy 119(8):1023-30.

[15] Harris M.F., Jayasinghe U.W., Chan B.C., Proudfoot J., Crookes P., Zwar N., Powell Davies G. (2011) Patient and practice characteristics predict the frequency of general practice multidisciplinary referrals of patients with chronic diseases: A multilevel study, Health Policy 101(2): 140-145.

[16] Iezzi E., Lippi Bruni M., Ugolini C. (2014) The role of GP's compensation schemes in diabetes care: Evidence from panel data, Journal of Health Economics, 34: 104–120.

[17] Dusheiko M., Doran T., Gravelle H., Fullwood C., Roland M. (2011), Does higher quality of diabetes management in family practice reduce unplanned hospital admissions? Health Services Research, 46: 27-46.

[18] Sutton, M., Elder, R., Guthrie, B., Watt, G. (2010) Record rewards: the effects of targeted quality incentives on the recording of risk factors by primary care providers. Health Economics 19: 1–13.

[19] Iversen T., Luras H. (2012) Capitation and incentives in primary care. In: Jones AM, editor. The Elgar companion to health economics. 2<sup>nd</sup> Edition, Cheltenham, UK: Edward Elgar; 280–88.

[20] Kontopantelis, E., Reeves D., Valderas J.M., Campbell S., Doran T. (2013) Recorded quality of primary care for patients with diabetes in England before and after the introduction of a financial incentive scheme: a longitudinal observational study. BMJ Quality and Safety 22(1): 53–54.

[21] Roland M., Guthrie B. (2016) Quality and Outcomes Framework: what have we learnt? BMJ, 354: i4060.

[22] Promberger, M., & Marteau, T. M. (2013) When do financial incentives reduce intrinsic motivation? Comparing behaviors studied in psychological and economic literatures. Health Psychology, 32(9): 950-957.

[23] Gneezy, U., Meier, S., Rey-Biel, P. (2011) When and why incentives (don't) work to modify behavior. Journal of Economic Perspectives 25(4): 1–21.

[24] Siciliani L. (2009) Paying for performance and motivation crowding out. Economic Letters 103: 8-71.

[25] Fiorentini G., Iezzi E., Lippi Bruni M., Ugolini C. (2011) Incentives in primary care and their impact on potentially avoidable hospital admissions, The European Journal of Health Economics 12: 297–309.

[26] Dumont, E., Fortin, B., Jacquemet, N., Shearer, B. (2008) Physicians' multitasking and incentives: empirical evidence from a natural experiment. Journal of Health Economics 27: 1436–1450.

[27] Kantarevic, J., Kralj, B. (2013) Link between pay for performance incentives and physician payment mechanisms: evidence form the Diabetes Management Incentive in Ontario. Health Economics, 22(12):1417-39.

[28] Scott, A., Schurer, S., Jensen, P.H., Sivey, P. (2009) The effects of an incentive program on quality of care in diabetes management. Health Economics 18 (9): 1091–1108.

[29] Comino, E.J., Tran, D.T., Taggart, J.R., Liaw S.T., Ruscoe, W., Snow, J.M., (2013) A preliminary study of the relationship between general practice care and hospitalisation using a Diabetes Register, Australian Health Review 37(2): 210-217.

[30] Lippi Bruni, M., Nobilio, L., Ugolini, C. (2009) Economic incentives in general practice: the impact of pay-forparticipation and pay-for-compliance programs on diabetes care. Health Policy, 90: 140–148.

[31] Armeni, P., Compagni, A., & Longo, F. (2014). Multiprofessional primary care units: What affects the clinical performance of Italian General Practitioners?. Medical Care Research and Review, 71(4), 315-336.

[32] Compagni, A., Armeni P., Tasselli, S. (2019) When peers count: The effects on integrated type II diabetes care of communication within general practitioner-only subgroups in interprofessional primary care teams. Health care management review 44.: 67-78.

[33] Regione Emilia-Romagna (2003) Linee guida clinico-organizzative per il management del diabete mellito, (in Italian) http://salute.regione.emilia-romagna.it/@@search?Subject%3Alist=Diabete

[34] Regione Emilia-Romagna (2009) Linee guida regionali per la gestione integrata del diabete mellito tipo 2aggiornamento dell'implementazione, (in Italian). http://salute.regione.emiliaromagna.it/documentazione/leggi/regionali/linee-guida/linee-guida-regionali-per-la-gestione-integrata-del-diabetemellito-tipo-2-aggiornamento-dellimplementazione/view

[35] Caminal J., Starfield B., Sanchez E., Casanova, C., Morales, M. (2004) The role of primary care in preventing ambulatory care sensitive conditions. European Journal of Public Health 14: 246–251.

[36] Kim H., Cheng S.H. (2018). Assessing quality of primary diabetes care in South Korea and Taiwan using avoidable hospitalizations, Health Policy, 122(11): 1222-1231.

[37] Lippi Bruni M., Mammi I., Ugolini C. (2016) Does the extension of primary care practice opening hours reduce the use of emergency services? Journal of Health Economics, 50: 144 – 155.

[38] O'Connell, A.A., Goldstein, J., Rogers, H.J., & Peng, C.Y.J. (2008). Multilevel logistic models for dichotomous and ordinal data. In A.A. O'Connell & D.B. McCoach (Eds.), *Multilevel modeling of educational data*. Charlotte, NC: Information Age Publishing, Inc.: 199-242.

[39] Goldstein H. (2010) Multilevel statistical models. 4rd ed. Wiley.

[40] Moullan Y., Jusot F. (2014). Why is the 'healthy immigrant effect' different between European countries? European Journal of Public Health, 24 (S1): 80-86.

[41] De Luca G., Ponzo M., Andrés A.R. (2013) Health care utilization by immigrants in Italy. International Journal of Health Care Finance Economics, 13: 1-31.

[421] Gil J., Li Donni P., Zucchelli E. (2018a). Uncontrolled diabetes and health care utilisation: a bivariate Latent Markov model approach, Health, Econometrics and Data Group (HEDG) Working Paper 18/28.

#### Table 1. Outcome variables and association between outcome variables

Dependent variable			Number of case	%	
Adherence to guidelines					
At least 2 Hb1Ac			10,350	33.85	
At least 2 Hb1Ac, 1 cholesterolemia ar	d 1 microalbuminuria		7,828	25.60	
Quality of care					
At least one new diabetes-related comp	olications		1,954		6.39
At least 1 ACSC			828	2.71	
At least 1 inappropriate ED access			1,675	5.47	
At least 1 hospitalisation			5,754	18.82	
	At least 1 new diabetes- related complication	At least 1 ACSC	At least 1 hospitalisation	At least 1 inappropriate ED access	Totals
At least 1 new diabetes- related	1953	383	138	169	1953
complication	(100%)	(19.61%)	(92.93%)	(9.53%)	(100%)
At least 1 ACSC	383	829	829	68	829
	(46.20%)	(100%)	(100%)	(8.89%)	(100%)
At least 1 hospitalisation	1815	829	5751	472	5751
-	(31.56%)	(14.41%)	(100%)	(8.92%)	(100%)
At least 1 inappropriate ER access	169	68	472	1594	1594
•	(10.60%)	(4.27%)	(29.61%)	(100%)	(100%)

All variables are dummy indicators. Shares are computed using the total number of patients as denominator (N=30,577). All data refers to year 2015. Each cell displays the number of patients jointly experiencing the row and column outcome. The probability of the column outcome conditional on the row outcome is reported in parenthesis. Year 2015.

### Table 2. Control variables

Explanatory variable	Coding		Values
Patient Level (n=30577)			
Patient Female	Female=1	%	47.07
Patient age	Years	Mean	70.11
Patient Native	Native=1	%	94.88
Insulin user	User=1	%	6.86
Chronic Disease	At least one=1	%	85.91
Adherence to guidelines 2014	Yes=1	%	33.71
IM (Integrated management)	IM=1	%	41.80
Compensated diabetes	Compensated		72.88
Decompensated diabetes	Decompensated	%	17,90
Partially compensated diabetes	Partially compensated		9.22
$GP \ Level \ (n=700)$			
GP gender	Female=1	%	35.02
GP age	Years	Mean	59.91
	Low (<800)	%	7.14
GP list size	Medium (800-1500)	%	44.86
	High (>1500)	%	48.00
Diabetic patients in list	Percentage	Mean	3.44
Associated Practice	Associated=1	%	77.29

Patient and GP characteristics, year 2015. All variables expressed as shares except for Patient age and GP age expressed in years.

### Table 3. Adherence to guidelines

9		At least 2	2 Hb1Ac	At least 2 Hb1Ac, 1 cholesterolemia and 1 microalbuminuria						
	Coef	S.E.	p-value	OR	Coef	S.E.	p-value	OR		
Intercept	-0.306	0.4955	0.5372		-0.492	0.5879	0.4031			
<b>B</b> 41 4 4	[		Patient	level						
Patient Age	-0.001	0.001	0.357	0.999	-0.008	0.001	<.0001	0.992		
Patient Female	0.039	0.031	0.204	1.040	-0.058	0.033	0.081	0.944		
Patient Native	0.273	0.080	0.001	1.313	0.284	0.087	0.001	1.328		
Insulin user	0.634	0.060	<.0001	1.885	0.601	0.064	<.0001	1.82		
Compensated Diabetes	0.001	0.044	0.988	1.001	-0.134	0.047	0.005	0.875		
Partially compensated Diabetes	0.689	0.062	<.0001	1.992	0.466	0.065	<.0001	1.593		
Chronic Disease	0.345	0.051	<.0001	1.412	0.309	0.056	<.0001	1.361		
Integrated Management (IM)	0.913	0.036	<.0001	2.493	1.352	0.040	<.0001	3.864		
			GP le	evel						
Age GP	-0.004	0.008	0.588	0.996	-0.005	0.009	0.563	0.995		
Female GP	0.215	0.075	0.004	1.240	0.238	0.089	0.008	1.269		
Associated Practice	-0.042	0.093	0.654	0.959	-0.056	0.111	0.616	0.946		
% Diabetics in list	-1.519	2.904	0.601	0.219	2.060	3.457	0.551	7.844		
Small GP List	-0.011	0.174	0.948	0.989	0.228	0.203	0.262	1.255		
Medium GP List	-0.042	0.073	0.566	0.959	-0.081	0.087	0.349	0.922		
Districts		YE	ES		YES					
			Variance co	mponents						
Level 2-	0.493	0.040	<.0001		0.723	0.058	<.0001			
Level 2-ICC	0.130				0.180					
<b>2ln(L)</b>	25736.91				22518.80					

All specification based on *multilevel logit* models (GP and patient layer). *Coefficients, standard errors, p-values* and *odd-ratios* reported for each specification. Year 2015.

#### Table 4. Health outcomes

Table 4. Health outcomes	New complications			ACSCs				All-cause hospitalisation				Avoidable ED access				
	Coef	S.E.	p-value	OR	Coef	S.E.	p-value	OR	Coef	S.E.	p-value	OR	Coef	S.E.	p-value	OR
Intercept	-4.209	-4.209	0.504		-6.508	0.7695	<.0001		-2.0468	0.3101	<.0001		-1.1823	0.5152	0.0221	
							Patier	nt level								
Patient Age	0.041	0.003	<.0001	1.041	0.072	0.005	<.0001	1.075	0.017	0.002	<.0001	1.017	-0.008	0.003	0.004	0.992
Patient Female	-0.531	0.059	<.0001	0.588	-0.159	0.089	0.075	0.853	-0.130	0.036	0.000	0.878	0.063	0.061	0.305	1.065
Patient Native	-0.242	0.174	0.163	0.785	-0.634	0.279	0.023	0.531	0.203	0.108	0.060	1.225	-0.470	0.128	0.000	0.625
Insulin user	1.401	0.080	<.0001	4.058	1.384	0.119	<.0001	3.989	1.171	0.061	<.0001	3.226	0.272	0.113	0.016	1.313
Compensated Diabetes	-0.100	0.081	0.219	0.905	-0.130	0.129	0.312	0.878	0.187	0.054	0.001	1.205	0.133	0.088	0.128	1.142
Partially compensated Diabetes	0.070	0.113	0.536	1.072	0.083	0.177	0.640	1.086	0.378	0.075	<.0001	1.460	-0.058	0.131	0.658	0.943
Chronic Disease	1.324	0.171	<.0001	3.757	1.507	0.340	<.0001	4.515	0.744	0.075	<.0001	2.104	0.253	0.104	0.015	1.287
Guidelines 2014	-0.126	0.061	0.038	0.882	-0.191	0.096	0.046	0.826	-0.184	0.038	<.0001	0.832	0.048	0.064	0.456	1.049
							GP	level								
Age GP	0.003	0.007	0.627	1.003	-0.015	0.010	0.133	0.985	0.000	0.004	0.993	1.000	-0.004	0.007	0.600	0.996
Female GP	-0.012	0.067	0.863	0.989	-0.051	0.101	0.613	0.950	0.054	0.041	0.185	1.056	0.008	0.071	0.907	1.008
Associated Practice	0.016	0.087	0.859	1.016	-0.1331	0.128	0.300	0.875	0.036	0.054	0.506	1.037	0.056	0.092	0.546	1.057
% Diabetics in list	1.867	2.540	0.463	6.466	1.5381	3.694	0.020	4.656	0.578	1.578	0.714	1.782	-2.604	2.724	0.339	0.074
Small GP List	0.144	0.192	0.454	1.155	0.113	0.280	0.687	1.119	0.015	0.128	0.906	1.015	0.365	0.191	0.055	1.441
Medium GP List	-0.013	0.065	0.844	0.987	-0.123	0.099	0.2167	0.884	0.054	0.040	0.180	1.055	0.017	0.071	0.815	1.017
Districts			Yes			Y				Y	es			Y	es	
								components								
Level 2-	0.028	0.027	0.159		0.003	0.066	0.482		0.007	0.010	0.247		0.049	0.033	0.071	
Level 2-ICC	0.008				0.001				0.002				0.015			
2ln(L)	9631.37					4635.10			20000.17				8895.09			

All specification based on *multilevel logit* models (GP and patient layer). Coefficients, standard errors, p-values and odd-ratios reported for each specification. Year 2015.