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Cristina Ugolini
Matteo Lippi Bruni
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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

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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 2014-2015. Firstly, we test to see whether the monitoring activities prescribed for diabetics by regional diabetes guidelines, actually have a positive impact on patients' health outcomes and increase appropriateness in health care utilization. Secondly, we investigate whether GPs' participation in the local Diabetes Management Program (DMP) leads to improved patient compliance with regional guidelines. Our results show that such a program, which aims to increase GPs' involvement and cooperation in following regional guidelines for best practices, 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 the improved appropriateness of health care utilization.

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

JEL codes: C21, I10, I18, H51

NON-TECHNICAL SUMMARY

Long-run demographic and epidemiological trends have brought the treatment of chronic diseases to the forefront of the health policy agenda, with diabetes raising widespread concern due to its high prevalence among the elderly. Nowadays, diabetes management relies strongly on risk-reduction strategies, most of which are based on routine monitoring mainly based on periodic tests for haemoglobin A1c, lipid and microalbuminuria determination. The study of the association between patient surveillance and health outcomes has produced mixed findings, in particular for chronic patients affected by multiple morbidities. Despite that, the enhanced standardisation of patient supervision based on a designated set of activities is believed to improve the quality of diabetes care.

A large number of initiatives for disease management have been launched with the purpose of reducing heterogeneity in clinical decision making, and of aligning physician's behaviour with evidence-based best practices. They typically reward GPs for their involvement in cooperative activities, the compliance of their treatment methods to best practices, or their achievement of specific targets. In this paper, we address two key issues for the success of Diabetes Management Programs (DMPs). First, we examine the association between health outcomes and routine patient screening. When drafting DMPs, the benefits from regular monitoring are often posited in advance, whereas their ex-post measurement is a fundamental step to support the content of the guidelines. Hence, as a first step in our analysis, we test whether diabetics who enjoy regular monitoring in primary care, display better health outcomes regardless of whether they are enrolled in a structured program. The second goal of the paper is to study whether patients enrolled in a DMP have a higher probability of successfully meeting the guidelines' requirements. By doing so, we can establish the effectiveness of DMP as a policy tool for promoting compliance with best practices and thereby improving patient health. We use data from Bologna, the largest Local Health Authority (LHAs) within Italy's Emilia-Romagna Region, covering the period 2014-2015, consisting in a combination of patient and GP-level data taken from administrative sources and from the Diabetes Register containing clinical information.

The estimates show that, compared to patients who fail to follow the prescriptions, those who enjoy regular monitoring display better health outcomes. Moreover, we found that participation in the DMP program increases the probability of adherence to the surveillance standards established by the guidelines. Overall, such evidence supports the effectiveness of the disease-management program in promoting regular patient supervision, since enrolment in the program favours the likelihood of compliance with best practices, and, in turn, such actions are associated to beneficial effects on health. From a policy perspective, identifying an institutional arrangement like the DMP that encourages observance of diabetes guidelines, has implications for the design of policies that may be extended to other chronic conditions as well.

1. Introduction

Long-run demographic and epidemiological trends have brought the treatment of chronic diseases to the forefront of the health policy agenda, with diabetes raising widespread concern due to its high prevalence, especially among the elderly. Nowadays, diabetes management relies strongly on risk-reduction strategies, most of which are based on routine monitoring [WHO, 2016]. As unstructured care is often associated with greater mortality and other adverse outcomes, Diabetes Management Programs (DMPs) are deemed to reduce short- and long-term complications [Wagner et al. 2001]. Based on the consensus view that periodic tests for haemoglobin A1c, lipid and microalbuminuria determination and eye examination favour the timely identification and effective treatment of patients, clinical guidelines for best practices recommend the regular screening of diabetics [International Diabetes Federation 2017; De Micheli, 2008]. The study of the association between patient surveillance and health outcomes has produced mixed findings, in particular for chronic patients affected by multiple morbidities. Despite that, the enhanced standardisation of patient supervision based on a designated set of activities is believed to improve the quality of diabetes care [Tricco et al., 2012; Smith et al 2016; Simcoe, Catillon and Gertler, 2018].

A large number of initiatives for disease management have been launched with the purpose of reducing heterogeneity in clinical decision making, and of aligning physician's behaviour with evidence-based best practices. They typically reward GPs for their involvement in cooperative activities, the compliance of their treatment methods to best practices, or their achievement of specific targets. Despite this, compliance with the prescribed behaviour remains unsatisfactory in many cases [Oh et al. 2016; Kirkman et al., 2001; Beaulieu et al. 2006]. GPs' reluctance to comply with top-down directives is mainly attributed to the time and effort required to implement guidelines. However, it also results in some cases from GPs' opposition to audits and other monitoring schemes limiting their self-determination, together with scepticism in regard to the idea that standardised behaviour is always the best response to patients' needs [Zwolsman et al., 2012; Cook et al., 2018].

In this paper, we address two key issues for the success of Diabetes Management Programs (DMPs). First, we examine the association between health outcomes and routine patient screening. When drafting DMPs, the benefits from regular monitoring are often posited in advance, whereas their ex-post measurement is a fundamental step to support the content of the guidelines. Hence, as a first step in our analysis, we pursue this

aim by testing whether diabetics who enjoy regular monitoring in primary care, display better health outcomes regardless of whether they are enrolled in a structured program. The second goal of the paper is to study whether patients enrolled in a DMP have a higher probability of successfully meeting the guidelines' requirements. By doing so, we can establish the effectiveness of DMP as a policy tool for promoting compliance with best practices and thereby improving patient health.

Our study contributes to an increasingly rich economic literature on the role of primary care policies in treating chronic conditions, and diabetes in particular (e.g. Gil, Sicras-Mainar, Zucchelli 2018, Andrade, Rapp, Sevilla-Dedieu 2018, Iezzi, Lippi Bruni, Ugolini 2014, Dusheiko et al. 2011). We use data from the largest Local Health Authority (LHAs) within Italy's Emilia-Romagna Region, covering the period 2014-2015, consisting in a combination of patient and GP-level data taken from administrative sources and from the Diabetes Register containing clinical information. We show first that the successful completion of a cycle of screening activities during the course of the previous year, significantly improves patient outcomes as measured by a reduction in the probability of the onset of new diabetic complications (*Odds Ratio-OR 0.882*), of all-cause hospitalisations (*OR 0.832*) and of hospitalisations for Ambulatory Care Sensitive Conditions-ACSCs (*OR 0.826*); while no significant effect is found in terms of avoidable emergency admissions. We then show that enrolled patients display a significantly higher rate of compliance with monitoring prescriptions, and 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. From a policy perspective, identifying an institutional arrangement like the DMP that encourages observance of diabetes guidelines, has implications for the design of policies that may be extended to other chronic conditions as well.

The remainder of the paper is organised as follows: in the next section we discuss the related literature, while section 3 presents the institutional background; in section 4, we describe the data and the empirical strategy; our empirical findings are discussed in section 5; and finally, section 6 offers some conclusions.

2. Background literature

Diabetes management programs consist of multifaceted interventions aimed at promoting better quality standards through effective incentive schemes [Scott and Farrar, 2003; Sutton et al., 2010; Iversen and Luras, 2012]. This notwithstanding, the study of their impact often produces non-conclusive findings. The best-known European example is the UK's Quality and Outcomes Framework (QOF), which rewards high quality in primary care and promotes standardised medical practices. Sutton et al. (2011) find that this program has had positive effects, concluding that financial incentives have induced providers to increase targeted quality; while Kontopantelis et al. (2013) confirm the quality improvement (measured by achievement of the 17 diabetes process and outcome indicators from the QOF) after the introduction of the program specifically aimed at diabetes care. On the other hand, however, Roland and Guthrie (2016) point out that the QOF-related gains in quality, including those pertaining to diabetes, were in line with similar improvements recorded over the same period for conditions left out of the program. This signals the difficulty of isolating the effects of the program from those effects produced by general improvements in medical practice.

An important feature of these initiatives concerns their underlying incentives. Factors such as the broadness of the targets, the involvement of providers in drafting the program, and the rules for assigning the rewards, may all contribute towards successfully reorienting physicians' behaviour [Eijkenaar, 2013]. Proponents of the use of payments that are conditional on the achievement of pre-established health outcomes, have stressed their potential for enhancing the quality of care, whereas critics have raised doubts over their effectiveness. In this vein, and in keeping with a long line of research in psychology, the economic literature has highlighted the potential of flawed incentive schemes to undermine or "crowd out" intrinsic motivation [Promberger and Marteau, 2013; Irlenbusch and Sliwka, 2005; Gneezy et al., 2011]. When paying-for-performance curbs intrinsic motivation to perform the task for its own sake, physicians' responses may fail to meet the policy goals set by the health authority. If financial incentives belittle the non-financial motivations of providers (e.g. altruism), they could be harmful, especially in National Health Systems (NHS) where the public mission is expected to favour physicians' compliance with the system's societal objectives [Siciliani, 2009]. Conversely, low-powered incentives not directly linked to patient outcomes, can induce crowding-in effects, facilitate cooperation, and further the alignment of the objectives of clinicians with those of policy makers [Fiorentini

et al. 2011]. For example, the payment of a fixed additional amount per chronic patient included in the managed care programme, may help increase treatment adherence, reduce patient selection, enforce cooperation and preserve intrinsic motivations. Whether these factors ultimately improve patients' outcomes, even if they are not explicitly targeted, remains an empirical matter. The existing literature has pointed out that there are circumstances in which low-powered incentives based on process measures may have a significant impact on the quality of care [Dumont et al., 2008]. One example in the case of diabetes is provided by the experiences developed in Canada and Australia where physicians are rewarded for complying with guidelines when treating diabetes patients [Kantarevic and Kralj, 2013; Scott et al., 2009; Comino et al., 2013].

As regards Italy, earlier analyses have examined the impact of DMPs within the same institutional context considered in the present paper, where payments for diabetes-related initiatives are not contingent on health outcomes. Rather, they link financial reward to the GP's assumption of responsibility for diabetic patients. By exploiting heterogeneity in program implementation across practices, prior studies have shown that even if the achievement of health outcomes is not directly rewarded, DMPs reduce the probability of hyperglycaemic emergencies and hospital admissions for ACSCs in diabetics [Lippi Bruni et al., 2009, Iezzi et al., 2014].

One limitation of the contributions referred to above is that they rely exclusively on administrative data. By contrast, in this study we use richer, more recent sources of information consisting in a combination of administrative data with data reporting individual values for diabetes-related biomarkers. This enables us to control for diabetes severity at individual level, as the Register contains information on the HbA1c values recorded at each visit. A further advantage of the Diabetes Register is that it permits identification of those patients enrolled in the protocol for integrated diabetes care within each GP's list. Thanks to this additional information, we can exploit patient-level data in order to assess whether fulfilling monitoring standards has beneficial effects on health indicators that are not specifically rewarded by the program, and at the same time, whether participation in DMPs based on low-powered incentives increases compliance with clinical guidelines. Our findings are consistent with the view that promoting GPs' assumption of responsibility for diabetic patients, increases their involvement in the treatment of chronic diseases. In this way the policy reduces the probability of adverse events, and likely contributes towards slowing the deterioration in health generally associated with diabetes [Parsons et al., 2010].

3. The institutional framework

The Italian National Health Care System (NHS) is a decentralised public health service, mainly funded through general taxation, where regions autonomously manage and deliver 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 activities. Each patient is registered with a GP, who is a self-employed professional contracted to the NHS, mainly paid on a capitation basis under a contract negotiated between the central government and primary care organisations. Moreover, Regional Governments can introduce additional remuneration for selected activities, which results in substantial variability across the country.

In 2003, the Emilia-Romagna Department of Health issued its "Clinical Guidelines for Management of Diabetes Mellitus" prescribing the following actions: (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. The same document introduces a new organizational model based on integrated care management with a multidisciplinary team and the proactive approach to type-2 diabetes patients at LHA level through a Diabetes Management Program called "*Integrated Management*" (IM) involving GPs, nurses and other healthcare professionals [Emilia-Romagna Region, 2003, 2009]. Patients can be enrolled in the IM program if they do not exceed a given severity threshold (i.e. they are without complications or with minor complications, otherwise they have to be managed by the Diabetic Centre. Conditions to qualify for IM enrolment are: stable metabolic compensation and a limited number of mild complications (in particular no medium and severe micro-macro vascular complications). GPs are expected to play an active role in the management of enrolled patients, by planning access to the practice according to the IM protocol. Based on local agreements between the LHA and GPs, each district applies the criteria so as to reward GPs for performing those activities required by the regional guidelines. This is generally performed by setting a fixed additional fee per enrolled patient for whom the designated cycle of activities has been successfully completed.

In this study we benefit from information retrieved from the Administrative Databases and the Diabetes

Register of the Local Health Authority of Bologna that serves a population of almost 1 million inhabitants. GPs enrolled into the IM protocol receive an additional fixed payment that increases capitation for each diabetic patient taking part in the program; this payment is designed to remunerate the GP for the additional time and effort required to manage such patients.

4. Methods

4.1 The Data

Our primary data cover the year 2015. The study, based on routine administrative information and on the diabetes clinical 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 registers' data and anonymised by an ad hoc service located in the Regional Health Directorate. The Health and Social Regional Agency and the University of Bologna have no possibility to retrospectively identify individuals included. 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 completely anonymous nature of the data.

The baseline population for the present study comprises residents living within the Bologna LHA catchment area. The population within this area amounts to nearly 1 million people and represents almost one fourth of the Emilia-Romagna Region's total population. Moreover, Bologna LHA enjoys a prominent role in the regional health care system as a result of its technologically advanced hospital system and its well-established, comprehensive organisation of community care services. Data taken from the *Regional Healthcare Information System* are used to identify our study population, which 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, following the criteria established by the Regional Department of Health, we also include outpatients who attended a Diabetes Centre over the previous three years, together with inpatients diagnosed with diabetes.

Thanks to the records linking administrative and clinical datasets, we merge patient characteristics and information on pharmaceutical treatment, together with diabetes-related biomarkers and information about the

organisational setting for diabetes management. Three mutually exclusive organisational arrangements can be identified: that of low-severity patients enrolled in the IM program under the responsibility of their own GP; that of low-severity patients followed by a GP who does not enrol in the IM program; and that of medium or high-severity patients treated by the Diabetic Centre. As the paper focuses on the role of IM managed by GPs, we exclude from the estimating sample those individuals managed exclusively by Diabetes Centres, as they are complex patients for whom the responsibility for compliance rests on the Diabetes Centre rather than on the GP. Finally, in order to unambiguously assign the information on GP characteristics to each patient, we keep in our cohort only those diabetics who remained with the same GP over the entire year 2015. This led to the exclusion of 368 patients (1.2% of the initial sample). The resulting dataset includes 30,577 patients registered with 700 GPs located in 6 LHDs.

Table 1a presents the dependent variables employed in the analysis. We distinguish between dichotomous indicators of the *quality of diabetes care* shown in the upper panel of the table, and of *adherence to guidelines* shown in the lower panel of the table. The former set of variables is used in the first stage of our analysis, while the latter set is used in the second stage.

As measures for quality, we use the onset of new diabetes-related complications arising in 2015, together with indicators of the utilisation of hospital services, which are commonly used as indicators for poor surveillance in primary care. Given that effective disease management should avoid complications and rapid health deterioration, these measures were chosen based on medical evidence showing that the high-quality treatment of diabetes is associated with fewer hospital admissions. We focus first on admissions for ACSCs, conditions that should be prevented through timely monitoring and effective treatment in an ambulatory care setting [Billings et al., 1993, Caminal et al. 2004]. Alternatively, we consider all-cause hospitalisations, since non-adherence may reduce the effectiveness of treatment, making patients more vulnerable and exposed to the need for hospital assistance [Andrade, Rapp, Sevilla-Dedieu, 2018]. Finally, we include indicators for avoidable emergency visits [Lippi Bruni, Mammi, Ugolini, 2016]. In sum, the *quality of diabetes care* is measured using four dichotomous 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 ACSC; (3) had at least one inappropriate access to

the Emergency Department, based on the Italian four-level triage system (*white codes*); (4) were hospitalised at least once for any cause.

Table 1a shows the descriptive statistics for the quality indicators considered. 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. To give a sense of the degree of association among these dichotomous health outcomes, Table 1b shows conditional probabilities for pairwise associations between health outcomes. The data shows that 93.95% of patients with at least one new complication in 2015 were also hospitalised for any cause, 19.6% for an ACSC and only 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 a new complication in 2015. In all other cases, the degree of association ranges from 4% to 30%, suggesting that the set of outcomes covers a fairly broad range of conditions, capturing different kinds of failure in patient supervision.

We measure *adherence to guidelines* using two indicators: the first indicator is a dummy identifying patients who performed at least two HbA1c during 2015, which is the most important recommendation included in the guidelines. The second indicator is based on the more restrictive criterion requiring controls for blood cholesterol and urinary micro albumin in addition to the two HbA1c tests. When assessing patient compliance, we do not consider the other recommendations included in the official guidelines for different reasons. Electrocardiogram and ophthalmologic monitoring are not required on an annual basis, thus raising problems in properly identifying cases of non-compliance given the short timespan covered by our data. In addition, patients frequently receive ocular fundus examination privately during an ophthalmologic visit and consequently the total number of eye examinations is largely underestimated in the NHS administrative dataset, as this only records treatment provided by the public sector.

In our sample, the overall share of patients meeting the first compliance criterion is around one-third (34%). The share is 45.48% in the case of patients enrolled in an IM program, and 25.50% for those not enrolled in such. Diabetics undergoing two HbA1c tests and one microalbuminuria screening account for approximately

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 (Table 1a).

<div align="center">INSERT TABLE 1A AND TABLE 1B</div>

Table 2 provides the descriptive statistics for the covariates of our estimating sample. 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 (e.g. two HbA1c tests plus one blood cholesterol and one urinary micro albumin screening during 2014), enrolment in the Integrated Management program. In addition, given that glycaemic control is a key factor in reducing the risk of complications, we exploit the measure of blood glucose in the previous year to classify patients into three categories on the basis of the reported HbA1C 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. Conversely, patients are classified as decompensated if they display values that exceed the above thresholds. Finally, patients are classified as partially compensated if they present values both above and below the critical thresholds within the same year.

53% of our cohort are males, the average age of patients is 70, 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 in 2015, and nearly three-quarters have compensated diabetes (73%). Almost 42% of those in the sample are enrolled in the IM program.

GPs' characteristics include age and gender, practice type (individual practices are distinguished from group practices), together with a set of dummies for list size and share of diabetic patients in the list. About 65% of GPs are male, and their average age is 60, 77% of them work in a group practice, and an average 3% of their registered patients are diabetics. To account for unobserved heterogeneity at the local level, we include dummies for the six districts of the Bologna LHA in all our estimates.

<div align="center">INSERT TABLE 2</div>

4.2 Empirical strategy

In the light of the hierarchical structure of the data at hand, where patients are nested within GPs, we base our estimation strategy on multilevel regression models which consider the joint influence of characteristics measured at different levels. Clustered data of this kind are characterized by multilevel dependency, and by possible correlation among units, that must be accounted for since the independence assumption of the error terms is challenged by patients being nested into practices. Because of this, standard regression techniques can produce downward biased standard errors, whereas a multilevel regression approach overcomes this problem by assessing variability at each layer separately [O'Connell et al., 2008; Goldstein, 2010].

A two-level generalized linear multilevel model can be written as follow:

$$\pi_{ij} = f(X\beta)_{ij} \qquad [1]$$

where π_{ij} is the expected value of the response variable for the *i-th* patient and *j-th* GP, X is a vector of the independent variables, $\boldsymbol{\beta}$ is the associated vector of parameters, and *f* is a non-linear link function of the linear predictor $(X\beta)_{ij}$. Due to the dichotomous nature of all outcomes, we specify a Bernoulli distribution for the dependent variables and a logit link function. Therefore, the general model can be written as follows:

$$logit\ (\pi_{ij}) = (X\beta)_{ij} + v_j + \varepsilon_{ij} \qquad [2]$$

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

Following O'Connell et al. (2008), we estimate an unconditional model (i.e. with no covariates) and compute the intraclass correlation coefficient (ICC) in order to evaluate the basic partitioning of the variability of the outcomes at GP level. Larger values of *ICC* (0<*ICC*<1) are indicative of greater potential for each layer to influence the dependent variable.

$$ICC = \frac{population\ variance\ between\ GPs}{total\ population\ variance} \qquad [3]$$

We then perform regression analyses by estimating multilevel models for each dependent variable, and control for the set of explanatory variables previously presented. Multilevel modelling estimation is based on maximum likelihood procedure using Laplace approximation. Statistical analysis was performed using the SAS/STAT 9.4 software PROC GLIMMIX procedure, at a 95% confidence level. Statistical significance was

evaluated by means of the Wald test statistic, and goodness-of-fit was assessed using deviance [*-2Ln(L)*] [Goldstein, 2010].

Our empirical strategy is organised in two distinct steps, both based on the estimate of multilevel logit models as described in equation [2]. They include up to two levels, the first referring to the patient, the second to the GP's practice. Together with the estimated coefficients and p-values, we also compute the odds ratios (*OR*) in order to quantify the impact of each covariate on the outcomes of interest.

First, we test whether compliance with regional guidelines in the previous year has a positive impact on the quality of care, as measured by an array of dichotomous dependent variables that capture designed to account for poor patient supervision and low-quality care. The use of multiple outcomes is meant to accommodate the multidimensional nature of health, by covering a broad spectrum of potential effects. As already illustrated, our outcomes are dichotomous variables that take value 1 for the following: diabetics with a new diabetes-related complication; diabetics hospitalized for an ACSC; diabetics who have been hospitalised once; diabetics who have had at least one inappropriate access to the ED, respectively. We model each dummy indicator separately as depending upon a set of controls for patient and practice characteristics. The covariate we are mainly interested in is the dichotomous indicator of compliance with clinical guidelines during the previous year. We consider compliance with best practices to be satisfied if patients performed at least two HbA1c, blood cholesterol and microalbuminuria tests in 2014. This covariate allowed us to assess the impact of prior treatment adherence on health outcomes in diabetes patients. All other controls refer to the year 2015, but the degree of diabetes compensation is evaluated based on information for the year 2014.

Having established whether regular routine examinations are associated with better outcomes, irrespective of the patient's participation in a DMP, our second goal is to assess whether enrolment in a DMP increases compliance with the activities designated by the guidelines. 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. To account for different degrees of compliance, we consider patients who undertook at least two Hb1Ac tests per year in the first place. We then also established 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 representing the variable of main policy interest in this case. This allows us to test whether patients participating in a structured DMP based on Integrated Management protocols, are more likely to comply with regional guidelines than non-enrolled patients are.

5. Results

Table 3 reports the estimates for the variance components and for the *ICC* from the empty models. Such estimates of health outcomes are not always significant, suggesting that the hierarchical nature of the data affects the variability of our health indicators to a limited extent only. On the contrary, we get larger estimates for the *ICC* when we consider *adherence to guidelines* as a dependent variable. Using the compliance criterion based on blood glucose tests only, the intra-group correlation is equal to 13% at GP level, whereas including one cholesterolemia and one microalbuminuria in addition to the two HbA1C tests per year, the *ICC* for the GP layer increases to 18%. In these latter cases, the share of variability explained by the GP layer supports the choice of multilevel specification.

<center>INSERT TABLE 3</center>

Table 4 presents the estimates of the multilevel logit model discussed in Equation [2], where the dependent variables are the health indicators, and we focus on the impact of compliance with best practices during the previous year. Coefficients, standard errors, p-values and odds ratios are reported for each specification.

As for the covariate of main policy interest, we find a significant and negative association between adherence to the guidelines in the previous year and the probability of suffering a new diabetes-related complication, an ACSC and an all-cause hospitalisation; whereas no significant effect on inappropriate ED admissions was found. The difference in the odds between compliers with guidelines and non-compliers is of a similar magnitude for both measures of hospital admissions (ACSCs and all-cause hospitalisations), while a relatively smaller effect was found in terms of the probability of new complications. The estimated impact indicates that 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. Overall, these empirical

<center>14</center>

findings support the adoption of patient monitoring strategies based on the prescriptions set out in regional guidelines, as they seem to help slow down the onset of new complications and to prevent the unnecessary use of hospital services.

As expected, patients' characteristics emerge as good predictors of the probability of adverse health outcomes, although there is some heterogeneity across indicators. In particular, 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. Rather than better health conditions, the latter result likely reflects a lower propensity to classify ED admissions by elderly patients as inappropriate due to such patients' high vulnerability and exposure to complications. Female patients are significantly less likely to experience diabetes-related complications or to be hospitalized, whereas no significant gender difference is detected for ED admissions. Interestingly, natives display a higher probability of all-cause hospitalisations, but a lower probability of being inappropriately accessing hospital services in the form of either ED access or an ACSC admission. The smaller probability of hospitalisation in general in the case of foreigners is consistent with the healthy immigrant hypothesis (Moullan and Jusot, 2014). As for ED visits, the result is in line with prior evidence showing that in Italy, as in many other countries, foreigners display a relatively higher propensity to use emergency services than natives do (De Luca et al. 2013). The most interesting policy indication emerges from the different propensity to inappropriate hospital admissions of natives and foreigners. Since our data do not record the contacts between patients and GPs, at this stage 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) that weakens disease prevention among foreigners. Still, as long as foreigner status is a significant predictor of the avoidable use of hospital services, this helps identify an area of intervention with regard to primary care, and highlights the need for targeted initiatives in favour of foreign diabetic patients.

As expected, severity indicators such as insulin dependence or the presence of other chronic conditions are positively correlated with new complications and the extra-utilisation of health care services. These factors are by large those 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 in the case of all-cause hospitalisations and avoidable ED admissions. 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 [Gil, Li Donni, Zucchelli, 2018]. Most controls included at GP level do not affect the observed outcomes.

INSERT TABLE 4

Table 5 presents the estimates of the multilevel logit model described in Equation [2] using the two indicators of adherence to guidelines as dependent variables. Our empirical evidence shows that enrolment in an IM program leads to a significant increase in compliance with clinical guidelines, which suggests that patients with similar degree of diabetes severity, and treated by GPs with similar characteristics, are more likely to undergo regular blood glucose control and microalbuminuria tests when they are 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 HbA1C tests only, and almost four times larger (*OR 3.9*) when microalbuminuria is also considered. The main policy implication is that participation in a Diabetes Management Program that includes a structured clinical pathway identifying precise requirements for regular patient monitoring, proves effective in improving patient compliance.

In this case, the role of patients' characteristics appears relatively less important than in the previous case, in terms of both the significance of the coefficients and of the magnitude of the estimated effects. We find no significant difference in compliance across genders, and age also plays a minor role. Significant differences in compliance are found between natives and foreigners, with native patients showing 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*). These findings suggest that the more severe the patient's condition, the more effective are the GP's recommendations to follow the guidelines, because of the high exposure to possible complications. Practice level controls do not affect the observed outcomes, with the exception of being assisted by a female GP, which significantly increases the probability of guideline compliance.

INSERT TABLE 5

16

6. Conclusion

The design of disease management programs capable of improving the quality of outpatient care, is a challenging and highly debated policy issue; this is due to the widespread belief that when properly incentivised and implemented, such initiatives can lead to better health outcomes and can curb the unnecessary use of the health services. This topic is especially important in the case of chronic diseases, among which diabetes plays a prominent role. Despite the worldwide introduction of programs relying on guidelines for best practices, the evidence concerning the impact of actions promoting better diabetes surveillance remains inconclusive. Moreover, as the initiatives differ in a number of ways, empirical studies should try to account for the distinguishing features of the different experiences concerned. Therefore, new insights into the extent to which these programs improve health outcomes, and into the role of their specific characteristics are extremely helpful to policymakers wishing to improve the design of such schemes.

We have focused on DMPs, where targets refer to process measures based on the regular monitoring of patients, and not to health outcomes. The rationale behind such an approach is twofold: the prescribed actions are ultimately expected to have beneficial effects on patients' health; enrolment into the program is expected to steer the adoption of the recommended behaviour. Given this background, we tested the two hypotheses separately, thus providing a comprehensive assessment of the impact of the program. Using data from the Bologna Local Health Authority, we first investigated whether regular supervision of diabetic patients is associated with better health outcomes and with a reduced utilisation of hospital services. Secondly, we studied the effect that enrolment in a formal program has on the probability of meeting the guideline-recommended prescriptions requiring the regular testing of diabetes patients on a yearly basis.

Starting from a reference population of around 1,000,000 inhabitants, we extracted a cohort of around 30,000 diabetic patients using the criteria set by the Regional Department of Health. Given the purposes of the study, our estimating sample comprises patients with mildly and medium severe diabetes, since more complex cases come under the responsibility of the Diabetes Centre and not of the GP, and so are not eligible for the program. The cross-sectional data used for the analysis refer to the year 2015, and they contain both patient- and GP-level information, merging administrative and clinical sources, including a biomarker for glucose concentration (HbA1C level).

Our empirical strategy is organised in two separate steps, both of which are based on the estimate of multilevel logit models. In the first step, alternative indicators for health and hospital utilisation are regressed against patients' and GPs' characteristics. In the second step, the dependent variable is defined on the basis of various compliance criteria, and the same set of regressors was augmented by the inclusion of a variable accounting for individual enrolment in the program.

The estimates show that, compared to patients who fail to follow the prescriptions, those who enjoy regular monitoring display better health outcomes in terms of the lesser likelihood of new complications, and of more limited utilisation of hospital services (all-cause hospitalisations and ACSCs). On the contrary, no significant difference was recorded for avoidable ED admissions. Moreover, we found that participation in the IM program increases the probability of adherence to the surveillance standards established by the guidelines. Overall, such evidence supports the effectiveness of the disease-management program in promoting regular patient supervision, since enrolment in the program favours the likelihood of compliance with best practices, and, in turn, such actions are associated to beneficial effects on health. The results have therefore important implications also for health care financing, since, by containing the utilisation of health services, improved patient supervision seems to have the potential of reducing the economic burden of disease that for diabetes has been proven to be large (e.g. Mata-Cases et al. 2016, Baudot et al. 2019).

Nevertheless, the study also suffers from certain limitations that cannot be overlooked. In particular, the geographical and time dimensions of the data are not ideal, and as such they limit the extent of our conclusions. As with the first issue, our findings are restricted to a single LHA, and the possibility of extending the analysis to regional (or even national) level would reinforce its external validity. Secondly, and more importantly, the cross-sectional nature of the data does not allow to control for unobserved patient heterogeneity. Because of this, our findings, linking routine tests to health outcomes (first step) and DMP enrolment to treatment adherence (second step), should to be interpreted as statistical associations rather than causal relationships.

Despite these drawbacks, the internal consistency of the empirical evidence and its robustness across multiple health and compliance indicators, still deliver valuable policy insights into the role of disease management programs for the treatment of chronic conditions. Moreover, the analysis furthers our understanding of types of programs that have been little explored in the literature, as they rely on low-powered incentives. This is the

case of payments contingent on the GP's assumption of responsibility for the diabetic patient, through counselling and regular monitoring, rather than on the achievement of specific health outcomes.

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Table 1A. Outcome variables

Dependent variable	Number of cases	%
Quality of care		
At least one new diabetes-related complications	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
Adherence to guidelines		
At least 2 Hb1Ac	10,350	33.85
At least 2 Hb1Ac, 1 cholesterolemia and 1 microalbuminuria	7,828	25.60

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.

Table 1B. Association between outcome variables,

	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 complication	*1953* *(100%)*	*383* (19.61%)	*138* (92.93%)	*169* (9.53%)	1953 (100%)
At least 1 ACSC	*383* (46.20%)	*829* *(100%)*	*829* (100%)	*68* (8.89%)	829 (100%)
At least 1 hospitalisation	*1815* (31.56%)	*829* (14.41%)	*5751* *(100%)*	*472* (8.92%)	5751 (100%)
At least 1 inappropriate ER access	*169* (10.60%)	*68* (4.27%)	*472* (29.61%)	*1594* *(100%)*	1594 (100%)

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
GP list size	Low (<800)	%	7.14
	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. Variance components of models

	At least 1 complication			At least 1 ACSC		
	Coef	**S.E.**	**p-value**	**Coef**	**S.E.**	**p-value**
Level 2- $\sigma^2(v_k)$	0.024	0.019	0.101	0.018	0.045	0.347
Level 2-ICC	0.007			0.005		
-2ln(L)		14518.99			7615.77	
	At least 1 hospitalisation			At least 1 inappropriate ER access		
	Coef	**S.E.**	**p-value**	**Coef**	**S.E.**	**p-value**
Level 2- $\sigma^2(v_k)$	0.012	0.008	0.065	0.119	0.029	<.0001
Level 2-ICC	0.004			0.035		
-2ln(L)		29552.71			12338.30	
	At least 2 HB1Ac			At least 2 Hb1Ac, 1 cholesterolemia and 1 microalbuminuria		
	Coef	**S.E.**	**p-value**	**Coef**	**S.E.**	**p-value**
Level 2- $\sigma^2(v_k)$	0.488	0.037	<.0001	0.717	0.054	<.0001
Level 2-ICC	0.129			0.179		
-2ln(L)		35575.10			32248.84	

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	
Patient 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				Yes				Yes				Yes		
Variance 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.

Table 5. Adherence to guidelines

	At least 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	
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 level								
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	YES				YES			
Variance components								
Level 2-	0.493	0.040	<.0001		0.723	0.058	<.0001	
Level 2-ICC	0.130				0.180			
2ln(L)	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.

Alma Mater Studiorum - Università di Bologna
DEPARTMENT OF ECONOMICS

Strada Maggiore 45
40125 Bologna - Italy
Tel. +39 051 2092604
Fax +39 051 2092664
http://www.dse.unibo.it