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Claudio Lucifora
Università Cattolica del Sacro Cuore

Antonio Russo
ATS Città Metropolitana di Milano

Daria Vigani
Università Cattolica del Sacro Cuore

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Dipartimento di Economia e Finanza
Università Cattolica del Sacro Cuore
Largo Gemelli 1 - 20123 Milano – Italy
tel: +39.02.7234.2976 - fax: +39.02.7234.2781
e-mail: dip.economiaefinanza@unicatt.it

Does prescribing appropriateness reduce health expenditures? Main effects and unintended outcomes

Claudio Lucifora*[1], Antonio Russo†[2], and Daria Vigani‡[3]

[1]Epidemiology Unit, Agency for Health Protection of Milan
[2]Catholic University of Milan,IZA and CNEL
[3]Catholic University of Milan

Abstract [1]

We evaluate the effectiveness of a reform to contain health-care costs by restraining general practitioners' (GP) ability to prescribe outpatient treatments, on the basis of strict appropriateness criteria. Using register data for a large Metropolitan area in Italy, we find a significant contraction in both outpatient expenditures (-24%) and volumes (-12%) after the reform. The effects on expenditures are found to be heterogeneous across GPs' characteristics, pointing out the mediating role of GPs' prescribing behavior. The reform also affected the composition of outpatient spending and produced unintended consequences on the demand for medical services of vulnerable groups, who were originally excluded from its application, as well as on access to emergency care.

JEL classification: H51 I38 I18

Keywords: Prescribing appropriateness, Health-care expenditures, Primary care

*Corresponding author: Department of Economics and Finance, Università Cattolica, Largo Gemelli, 1 (20123) Milan. e-mail: claudio.lucifora@unicatt.it

†ATS Città Metropolitana di Milano, Corso Italia, 19 (20122) Milan
e-mail: agrusso@ats-milano.it

‡Department of Economics and Finance, Università Cattolica, Largo Gemelli, 1 (20123) Milan.
e-mail: daria.vigani@unicatt.it

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1 Introduction

Over the last decades health-care spending has increased dramatically in most industrialized countries. From 1980 to 2009 the annual growth of per-capita health expenditure in real terms has been around 3% on average across OECD countries (OECD, 2005-2017), with an upsurge in public expenditure in the early 2000s that outpaced GDP growth in all countries. As the aging of populations has proven to be a long-lasting trend characterizing most countries, concerns have grown about the financial sustainability of health-care spending and the quality and cost of health care provision have come under increasing scrutiny. In response to growing health expenditure and over-consumption of medical services, several cost-containment policies have been implemented over the years in a number of countries, targeting three main dimensions of the health-care systems: financing, service provision, and regulation.

Overall, cost-sharing and deductibles have been identified as one main tool to reduce moral hazard in medical consumption and excess spending (Pauly and Blavin, 2008; van Kleef et al., 2009). Available empirical evidence suggests that cost-sharing at the point of consumption does lead to a reduction in health-care utilization (Baicker and Goldman, 2011; Goodell and Swartz, 2010; Ziebarth, 2014), even though with significant heterogeneity across type of plans (Schreyögg and Grabka, 2010) and across patients with different price-sensitivity. On top of cost-sharing options, health systems that share the physician 'gatekeeper' feature are provided with additional means that can be used for cost-containment purposes. As the gatekeeper simultaneously acts as a clinical expert that steers patients to proper services and as a rationing agent, it represents a valuable resource in cutting relatively ineffective or unnecessary health-care services. Recent evidence on regional variations in health-care utilization and spending in the US also suggests that physician organizational factors and beliefs about medical treatments are among the most important sources of heterogeneity, with a significant share of spending associated with physician beliefs unsupported by clinical evidence (Cutler et al., 2019).

Pay-for-performance programs and financial incentive schemes on gate-keeping doctors have been designed worldwide, but empirical evidence on the effect of different plans on quality and costs of health care is still rather controversial (Dusheiko et al., 2006; Fiorentini et al., 2013).

Regardless of the chosen strategy, a central concern for policy-makers in most publicly-funded health-care systems is to achieve budgetary goals while retaining the necessary and desirable demand of vulnerable groups.

In this context, policies aimed at both containing health-care spending and improving the efficiency of resource allocation are guided by the concept of *appropriateness*, being defined principally in terms of achieving efficiency while minimizing costs. While there is no universal definition, typically an appropriate service is delivered according to clinical indications with proven efficacy, precise timing and within a technically correct and least expensive setting (Lavis and Anderson, 1996). Hence, the concept of appropriateness in health-care delivery requires appropriate measurement, which, unfortunately, by being context-specific and varying by medical service, is not matched by firm consensus on how to evaluate its application (Buetow et al., 1997; Robertson-Preidler et al., 2017). Moreover, when considering prescribing appropriateness, that combines evidence-based medicine with professional opinion, physicians' discretion represents an additional element of variability. In other words, while cutting health-care spending has been on the agenda of policymakers for years, doing it without harming patients' health or well-being has proved much more difficult.

In this paper, we evaluate the effects of a reform aimed at regulating general practitioners' prescribing appropriateness, on outpatient expenditures (and volumes). The idea that a substantial proportion of provided care was inappropriate and leading to excess spending set the ground for this reform. On December 9^{th} 2015, the Italian Ministry of Health issued a Decree (the so-called "appropriateness" Decree) [2], establishing appropriateness requirements and introducing prescribing constraints on 203 procedures and diagnostic tests. Using register data from the Agency for Health Protection of Milan, we show that this reform had a substantial effect in reducing outpatient expenditures on the regulated treatments, but also affected the composition of GPs' outpatient spending, shifting GPs' prescriptions away from the treatments subject to appropriateness criteria, toward other less expensive unconstrained procedures. Moreover, our findings point to a substantial heterogeneity in prescribing behaviors of GPs in response to the policy shift. The reform, in fact, faced intense opposition by the latter, who claimed that appropriateness restrictions were compromising their role in secondary care, and was partially repealed in July 2016. Finally, heterogeneous effects across categories of patients suggest that the reform also produced unintended consequences on the demand for medical services of vulnerable groups, as well as increased access to emergency care.

Our contribution to the literature is twofold. First, we contribute to the policy debate on

[2] D.M. 9 dicembre 2015, *Condizioni di erogabilità e indicazioni di appropriatezza prescrittiva delle prestazioni di assistenza ambulatoriale erogabili nell'ambito del Servizio sanitario nazionale.*

value-based health-care systems investigating the effects of introducing appropriateness constraints to GPs' prescribing behavior on expenditures and volumes of outpatient treatments. In particular, using detailed information on individual outpatients, we are able to assess the impact on specific procedures and diagnostic tests, as well as investigate composition effects across different diagnostic categories. Second, we contribute to the analysis of the effectiveness of policies aimed at regulating primary care, and in particular of how the gate-keeping role of GPs in delivering health-care services can be regulated when cost-containment policies have to be designed/implemented. We explore the differential impact of the reform on outpatient spending and volumes according with several GPs' attributes, to understand how the reform was mediated by GPs' prescribing behaviors. More experienced doctors are found more reluctant to change their prescribing behavior in response to the reform, showing milder reductions in outpatient expenditures. Conversely, unionized GPs and those associated to a group practice, having better access to information concerning the provisions of the reform and the associated sanctions, are found to be more resilient. We are, however, unable to assess whether the contraction in outpatient expenditures is related to a change in GPs' prescribing behavior, or is due to the complexity of appropriateness criteria and the introduction of sanctions for GPs who refuse to comply with the regulations. The latter mechanisms might indeed increase uncertainty, favoring a more restrictive interpretation of appropriateness criteria or a more frequent use of defensive medicine practices.

Overall, we expect our results to be informative about the effects of adopting stringent rules and sanctions, compared to incentivizing GPs' appropriate prescribing behavior. Indeed, the complexity in the application of appropriateness criteria, combined with the introduction of sanctions may have increased uncertainty and the use of defensive medicine practices. Also, the strong opposition of GPs, which eventually led to the partial repeal of the Decree, point to the importance of engaging service providers when implementing new reforms.

The rest of the paper is structured as follows. In Section 2 we provide a brief overview of the Italian health-care system and a description of the institutional setting. Section 3 describes the data and the empirical strategy, also providing some descriptive evidence. Section 4 presents the results and Section 5 concludes.

2 Institutional Background

2.1 The Italian health-care system

The Italian National Health Service (NHS) is organized around the regional level, with a central government responsible for general legislation and financing, and regional governments in charge of management and provision of care. The NHS provides universal coverage to all citizens and residents largely free of charge and it is funded through national and regional taxes, supplemented by co-payments for pharmaceuticals and outpatient care. As a matter of fact, while there are no user charges for GPs' consultations and hospitalizations, patients pay a co-payment for outpatient treatments, specialist visits and pharmaceuticals, up to a ceiling. There is also a co-payment for the "unwarranted" use of emergency care (ER), defined as any access to ER with non-critical or non-urgent conditions.

Each individual is assigned to a GP (or pediatrician for children under 14) who provides family medicine free of charge and acts as a gatekeeper to higher levels of care and pharmaceuticals. GPs and pediatricians are independent professionals, paid *via* a combination of capitation and fee-for-services for some interventions, and often associated to group practices. The level of cost-sharing for pharmaceuticals and outpatient care ranges from total exemption (i.e. free access) to a coverage of part of the costs. Total exemptions are applied to people aged 65 and over, children below 6, unemployed individuals or those with a gross family income below a given threshold, and to patients with severe disabilities. Moreover, exemptions also apply to individuals with chronic or rare diseases, HIV-positive and to pregnant women as far as the needed treatments are related with their condition. Finally, all individuals with out-of-pocket payments above a set amount (currently 129 euros) in a given year are eligible for a tax credit equal to roughly one-fifth of their spending.

2.2 The reform: D.M. *Lorenzin* 9^{th} December, 2015

On December 9th, 2015 the Italian Ministry of Health issued the so-called "appropriateness" Decree (D.M. *Lorenzin* 9^{th} December, 2015), from the name of the then Minister of Health), that came into force on January 21^{st}, 2016. The reform introduced appropriateness requirements and prescribing constraints for 203 procedures and diagnostic tests, with the aim of putting a filter to the increasing over-consumption of health services driven by aging and health awareness of the population, as well as limiting the so-called 'defensive medicine' (i.e. over-prescription of

exams and medications as a safeguard from malpractice litigation). The latter phenomenon is in fact plaguing many health-care systems, with an estimated cost about 10 billion euros a year for Italy (around 0,75% of GDP and 10% of total NHS expenditure[3]).

In practice, the above reform introduced a constraint on the ability of physicians and GPs to prescribe a selected number of medical treatments - such as laboratory analyses, diagnostic imaging and genetic exams[4] -, unless predetermined conditions were met[5]. For example, Magnetic Resonance Imaging (MRI) ought to be restricted to cancer patients or those suffering traumas, while total cholesterol tests should only be prescribed to individuals over 40 years of age or with certified chronic illnesses. In other words, following the guidelines of the reform, any doctor could refuse to prescribe a specific treatment for lack of appropriateness: either because the patient is below a critical age, because too little time elapsed since the last check-up, or because, at doctor's discretion, the treatment was not necessary or appropriate. Conversely, when the appropriateness criteria were satisfied, the doctor could prescribe each treatment within the NHS (i.e. free of charge or with a co-payment). The reform also envisaged penalties for doctors who (repeatedly) refused to comply with the regulations, prescribing inappropriate medical treatments to their patients. In such way, the gatekeeper role of GPs was tightened by adding a filter to the growing medicalization.

The approval of the reform followed a long dispute with associations representing physicians and general practitioners, as the latter are highly unionized. The arguments for opposing the implementation by the medical associations were that it would compromise the relationship between patients and doctors, demean the role of health professionals and, more importantly, expose patients' health at risk for not receiving adequate treatments and therapies. Also, the new rules were expected to introduce ambiguities in the allocation of responsibilities and discretion, as far as the limitations on deliverability are concerned. Doctors also opposed the reform saying that it would transfer national health responsibilities to the private sector and increase patients' costs for treatments. It was questioned whether adherence to appropriateness criteria in doctors' prescriptions would not increase resort to emergencies and patients' hospitalization rates.

After a long dispute, in mid-July 2016, the Decree was repealed and replaced by simpler

[3]Source: Defensive Medicine Report from the Ministry of Health and Panella et al. (2017).

[4]The 203 procedures and diagnostic tests belong to 7 specialties: laboratory analyses, diagnostic imaging, dentistry and maxillo-facial surgery, physical therapy and rehabilitation, dermatology, nuclear medicine and genetic tests.

[5]Exemption rules based on income and chronic disease status were defined to avoid a deterrent effect on vulnerable subjects.

rules concerning standard/minimum health care provision (*D.P.C.M. LEA - Livelli Essenziali di Assistenza*), both reducing to 40 the number of medical treatments subordinated to appropriateness criteria (i.e. mainly radiotherapy, genetic testing and a few other tests) also softening the sanctions for doctors.

3 Data and Methods

3.1 Data and descriptive statistics

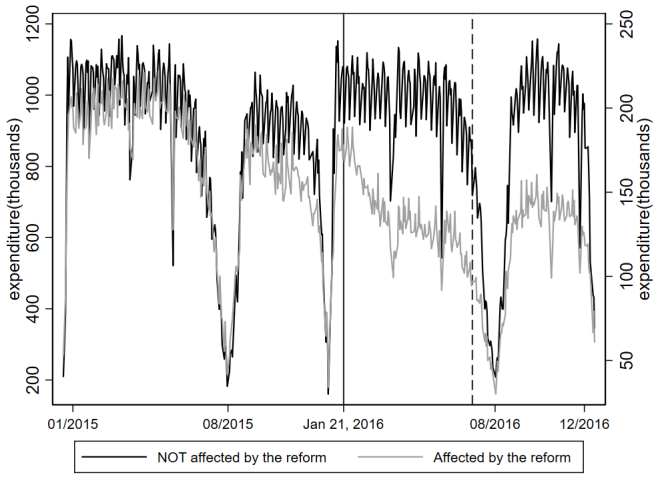
We use register data from the Agency for Health Protection (*Agenzia di Tutela della Salute*) of the Milan Metropolitan Area (MA), with information on the universe of health-care services for the whole population of the largest MA of Northern Italy (approximately 3.2 million inhabitants).

In the empirical analysis, we combine information on both expenditures and volumes for outpatient treatments, prescribed by GPs over the period of the reform (from January 1^{st}, 2015 to December 31^{st}, 2016), along with patients' demographic characteristics, access to health services (such as hospital admissions and emergency care), as well as GPs' characteristics. Using a unique anonymous personal identifier, we match different data sources drawn from the Regional Health Roster: *Outpatient Records* (covering over 46 million medical treatments and 2,3 million patients), *Hospital Discharges* and *Emergency Room Access*. In particular, personal characteristics include patients' age, any diagnosed chronic disease[6] and cost-sharing exemptions (based on income, chronic disease and severe disability), while GPs' characteristics include age, years of practice, number of patients, union membership and association to a group practice within the Chronic Related Group (CReG) project[7]. Overall, our working sample consists of 2,255,326 individuals and 2,723 GPs, 37% living in the municipality of Milan, 7% in the municipality of Lodi, and the remaining 56% in neighboring municipalities. Italian citizens represent 90% of the individuals' sample. Patients' average age is around 49, more than half of them meet at least one criterion for cost-sharing exemptions within the NHS regulations (48% are income-exempt, 38% have access to a disease-related exemption and 8% have severe disability). Patients with chronic diseases account for 40% of the sample, most of which suffer from cardiopathies (27%). Figure 1 shows the evolution of outpatient treatments, both in terms of daily expenditures (panel

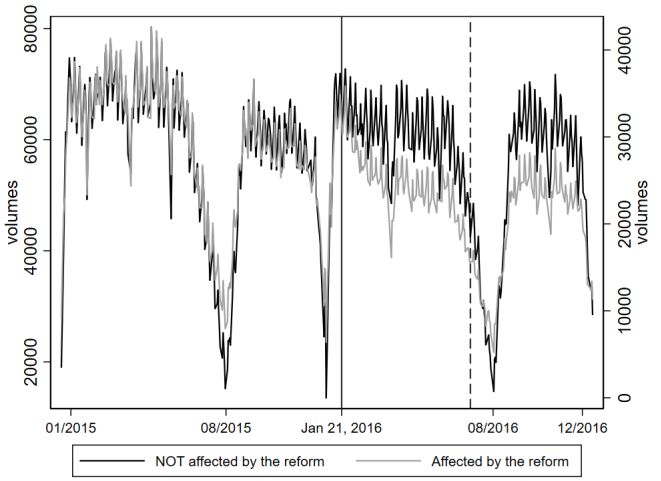
[6] We focus on Cardiopathies, Chronic Obstructive Pulmonary Diseases (COPD), Diabetes and Cancer that are mostly diffused.

[7] CReG is a new model of practice organization promoting continuity of care for chronic patients *Chronic Related Groups*. The CReG organizational model identifies a group practice – the so-called "provider" – for the provision of established treatment plans to chronic patients outside hospitals.

Fig. 1 Evolution of expenditures and volumes of outpatient treatments



(a) Expenditure(thousands)



(b) Volumes

a) and volumes (panel *b*), prescribed by GPs over the period under consideration. The grey line identifies the 203 treatments affected by the appropriateness criteria regulated by the Reform, while the black line indicates all the remaining treatments [8]. The vertical solid line indicates the introduction of the reform (January 21^{st},2016), while the dashed line shows the partial repealing, occurred in mid-July 2016.

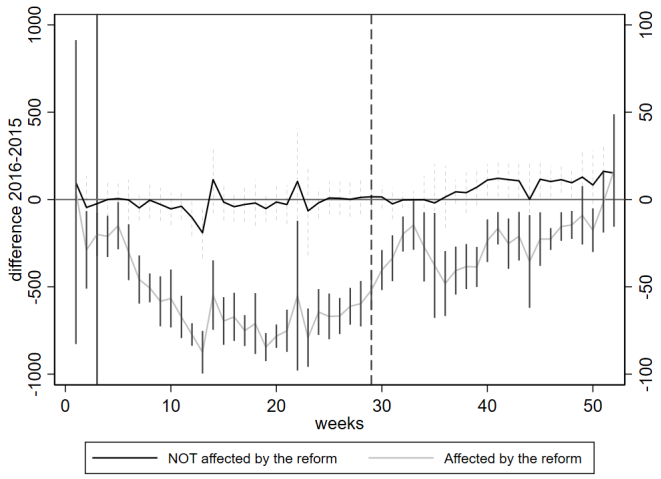
Overall, health-care utilization and related expenses exhibit a marked seasonal patterns, with downturns during summer time and around Christmas holidays. Both outpatient expenditures and, to some extent, volumes of treatments regulated by appropriateness criteria show a sizable drop after January 21^{st} 2016 up until mid-July (i.e. when the repeal of the Decree was announced). The reduction in outpatient expenditures and volumes is particularly pronounced for treatments belonging to*Diagnostic Imaging* and *Laboratory analyses* diagnostic categories, while spending and volumes for treatments in other diagnostic categories (i.e. also affected by the reform, such as dentistry and maxillo-facial surgery, physical therapy and rehabilitation, dermatology, nuclear medicine and genetic tests) exhibit a smaller change (see Figure A1 in the Appendix). In the second semester of 2016, both expenditures and volumes of regulated treatments appear to have stabilized, albeit at a much lower level compared with the same semester of 2015. Conversely, we do not observe any significant change in expenditures and volumes of outpatient treatments in the group excluded from the application of the reform, both before and after its introduction (i.e the black line, net of seasonal patterns, is relatively flat).

In Figure 2, we also directly compare the weekly difference – 2016 vs (same week in) 2015 – in the levels of expenditures (panel *a*) and volumes (panel *b*) between the two groups of outpatient treatments: those affected (black line) and those unaffected (gray line) by the reform.
Panel *a* shows a relatively flat black line around zero, suggesting no difference in (week-by-week) outpatient spending between 2016 and 2015 for unregulated treatments after the introduction of the reform. Conversely, the gray line shows a growing gap in (week-by-week) outpatient spending, between regulated and unregulated treatments, following the introduction of the reform (solid vertical line). This gap, following the partial repeal of the Decree (dashed vertical line), progressively disappears in the second semester as expenditures of the two groups slowly converge. Interestingly, the weekly differences in total volumes (panel *b*) exhibit a decreasing pattern also for unregulated treatments (black line), although with a smaller reduction com-

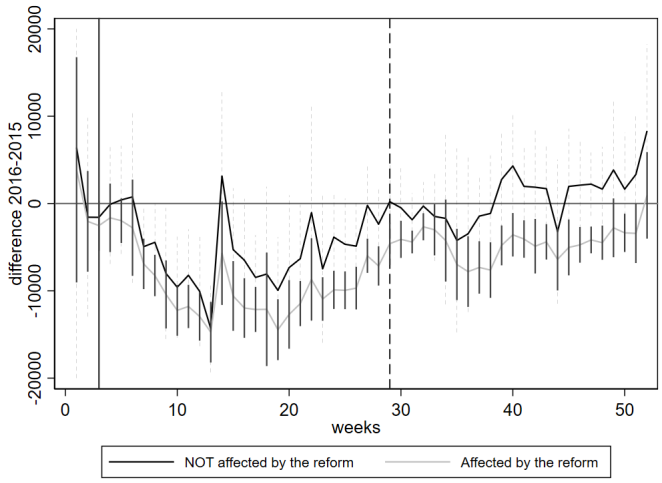
[8] Outpatient treatments provided on Saturdays, Sundays and holidays are excluded from the following descriptive analysis. The *y-axis* on the left refers to the group of treatments not covered by the reform, while the *y-axis* on the right refers to the 203 selected treatments.

pared with regulated services. In other words, this evidence, taken at face value, seems to suggest that GPs' response to prescribing appropriateness was a generalized 'restraint' effect on outpatient services (i.e. volumes), along with a 'substitution' effect shifting prescribing behavior away from expensive medical services subject to appropriateness criteria towards unconstrained less-expensive ones (i.e. expenditures)[9].

Fig. 2 Weekly difference in expenditures and volumes of outpatient treatments (2016-2015)



(a) Expenditures(thousands)



(b) Volumes

[9]One can speculate that GPs, rather than refusing to prescribe an expensive medical treatment affected by appropriateness restrictions to their patients, would prescribe the closest alternative from the group of treatments unaffected by the reform.

3.2 Empirical strategy

In the empirical analysis, we focus on total outpatient expenditures (and volumes) for each treatment prescribed by a GP, in each month (and year), over the period considered – i.e. 1^{st} January 2015 to 31^{st} December 2016, excluding January 2016. In practice, we estimate a Difference-in-Difference model of the form:

$$logY_{ijt} = \alpha + \beta DM_i + \delta DM_i \times Post_t + Time_t + \phi_j + \epsilon_{ijt} \qquad (1)$$

where $logY_{ijt}$ is our outcome of interest, which represents either total outpatient expenditures or volumes (in logs) for each medical treatment i prescribed by GP j in month $t = 1, ..., 23$[10]. DM_i is a binary variable that takes value one for any of the 203 medical treatments affected by the reform. $DM_i \times Post_t$ is the interaction term for the medical treatments affected by the reform in the *Post*-reform period. $Time_t$ are monthly dummies, capturing common factors affecting the evolution of outpatient expenditures and volumes over the time period considered. Hence, δ is our coefficient of interest, measuring the impact on outpatient expenditures and volumes of the introduction of the reform as $\delta = [Y_{DM,1} - Y_{DM,0}] - [Y_{\text{noDM},1} - Y_{\text{noDM},0}]$[11]. Finally, ϕ_j are the GPs' fixed-effects controlling for time-invariant unobserved characteristics of GPs and ϵ_{ijt} is the error term.[12]

Notice that since the Decree was partially repealed in July 2016, in equation (2) we re-specify our model adding an additional term and allowing for the effect of the repeal on health-care expenditures – i.e. to see whether it had any reversal effect on GPs' behavior in terms of outpatient expenditures and volumes. Specifically, we estimate a model of the form:

$$logY_{ijt} = \alpha + \beta DM_i + \delta_1 \underbrace{DM_i \times Post_t}_{\text{Decree (Jan '16)}} + \delta_2 \underbrace{DM_i \times Repeal_t}_{\text{Repeal (Jul '16)}} + Time_t + \phi_j + \epsilon_{ijt} \qquad (2)$$

where δ_1 measures the effect of the introduction of the reform as in equation (1), while δ_2

[10] In the empirical analysis we exclude January 2016 as the reform entered into force on the 21^{st}.

[11] $Y_{DM,1}$ ($Y_{DM,0}$) represents the outcome of interest for outpatient treatments affected by the reform after (before) the introduction of the latter, while $Y_{\text{noDM},1}$ and $Y_{\text{noDM},0}$ refer to outpatient treatments not affected by the reform, respectively after and before its introduction.

[12] As an additional exercise, we also set up a dynamic event-study specification (Autor, 2003) at the prescription level, to test whether the parallel-trend assumption (PTA) is satisfied. In practice, we estimate a semi-parametric model specification allowing for leads and lags of the effects of medical treatments affected by the reform (DM_i) interacted with the time dummies ($Time_t$) over the period of interest. If the PTA holds, no statistically significant coefficient should be associated with any of the pre-reform interaction terms. Results from this estimation procedure, plotted in Figure A2 of the Appendix, show that outcomes for both groups in the pre-reform months follow a common trend, while after the introduction of the reform we observe a decrease in expenditures and volumes of outpatient treatments.

refers to its repeal.

Finally, we explore the heterogeneous effects of the reform on outpatient expenditures and volumes according to the Major Diagnostic Category (MDC) of medical treatments, as well as across different groups of vulnerable patients. Namely, we estimate equation (1) separately for patients of different age groups and by different migrant status, as well as for patients with (and without) cost-sharing exemptions, and with certified chronic conditions.

4 Results

4.1 Baseline results

In Table 1 we report the main set of estimates of the effect of the reform on overall outpatients expenditures and volumes, as well as by MDC (Diagnostic Imaging, Laboratory Analyses and a residual category)[13].

Tab. 1 Estimated impact of the reform on outpatient treatments (expenditures and volumes)

	Pooled Sample	***Category***		
		DI	*LA*	*OT*
	(1)	(2)	(3)	(4)
Expenditures (log)				
$DM \times Post$	-0.239***	-0.113***	-0.215***	-0.075**
	(0.0254)	(0.0356)	(0.0261)	(0.0351)
Volumes (log)				
$DM \times Post$	-0.118***	-0.0970*	-0.118***	-0.114***
	(0.0232)	(0.0520)	(0.0278)	(0.0322)
Time dummies	✓	✓	✓	✓
GPs fixed-effects	✓	✓	✓	✓
N	7,787,261			

Significance: * p<.1, ** p<.05, *** p<.01. Robust standard errors in parentheses, clustered at the prescription level.

Results suggest an overall negative impact of the reform on both expenditures and volumes of outpatients. The introduction of appropriateness criteria reduced the number of provided medical treatments prescribed by GPs by almost 12%, with a 24% contraction in spending. The largest drop in outpatient expenditures (volumes) is associated with Laboratory analyses (LA),

[13] The residual category includes dentistry and maxillo-facial surgery, physical therapy and rehabilitation, dermatology, nuclear medicine and genetic tests, that are the other 5 specialties whose treatments were affected by the reform. We choose to group the above specialties into a residual category as the level of spending for this group only represents 8% of total expenditures (DI and Laboratory analyses represent 30% each) and the volume of prescriptions accounts for 5% (80% of total treatments prescribed are laboratory analyses).

showing a 21% reduction in expenditures (12% volumes), while for Diagnostic imaging (DI) and Other treatments (OT) the estimated impact on expenditures is smaller (-11% and -7.5%, respectively). The larger effect detected on specific categories of outpatients, and on expenditures compared to volumes, suggests that the reform also affected the composition of GPs' outpatient spending. In particular, we argue that by regulating prescribing appropriateness, the reform may have shifted GPs' prescriptions behavior away from the 203 treatments subject to appropriateness criteria, towards other less expensive treatments that were not regulated. Such reallocation effect is particularly pronounced among laboratory analyses, that account for over 80% of outpatients volumes and are characterized by a wider dispersion in prices.

Since after the repeal of the Decree the stringency of prescribing appropriateness was slightly relaxed, we estimate equation (2) exploiting the different timing of the reform – i.e. its introduction and successive partial repeal – to assess the effects on GPs' behavior. In other words, if prescribing appropriateness mandated by the reform was effective in reducing inappropriate spending and over-prescription by GPs, one would expect a strong reduction of outpatient expenditures and volumes immediately after the reform (post January 2016). Conversely, the lower stringency of regulations and the withdrawal of sanctions implied by the repeal of the Decree (in July 2016) suggest a partial reversal of the effects of the reform on GPs' outpatient expenditures and volumes. The main set of results, reported in Table 2, confirm the expected effects, showing a 21% (10%) reduction in outpatient expenditures (volumes) after the introduction of the reform, while the reduction in expenditures (volumes) becomes milder (-5% expenditures and -4% volumes) after its partial repeal.

Tab. 2 Estimated impact of the reform on outpatients (expenditures and volumes) and repeal of the Decree

	Expenditures (log)	***Volumes (log)***
	(1)	(2)
$DM \times Post$	-0.216***	-0.0994***
	(0.0262)	(0.0219)
$DM \times Repeal$	-0.0512***	-0.0414**
	(0.0170)	(0.0174)
Time dummies	✓	✓
GPs fixed-effects	✓	✓
N	7,787,261	7,787,261

Significance: * p<.1, ** p<.05, *** p<.01. Robust standard errors in parentheses, clustered at the prescription level.

These numbers, compared with those obtained from our baseline estimates (Table 1), suggest that the overall impact of the reform on expenditures (-24%) and volumes (-12%) of outpatient

treatments can be decomposed into a strong short-run reaction – -21% expenditures and -10% volumes – immediately after its introduction, and a milder effect in the medium-run after its partial repeal.

The empirical analysis presented so far indicates that the reform did achieve its primary goal of health-care cost containment, even if after its partial repeal the overall impact was mitigated. One question, however, is whether the reduction in spending was also accompanied by some unintended effects on the health and well-being of more vulnerable patients. In the remainder of this section, we explore the heterogeneous effects of the reform focusing, in particular, on the effects on more vulnerable patients, who *de facto* were excluded from the application of the appropriateness criteria.

Replicating our analysis on different groups of patients, we find a persistent negative effect also on the elderly, on migrants and on patients suffering from chronic diseases (see Tables A1, A2 and A3). The reduction in spending and volumes of outpatient treatments after the reform is statistically different from zero for both patients older than 65 and for those with cost-sharing exemptions, albeit smaller in magnitude compared to younger patients and those with no exemptions. As for specific chronic diseases, the impact of the reform on outpatient expenditures and volumes is largest among subjects suffering from cardiopathies and cancer patients - slightly lower for COPD and diabetic patients -, with the 13% to 19% contraction in outpatient spending mainly driven by fewer prescriptions on laboratory analyses. The extent of the reduction of expenditures and volumes of outpatients among subjects who were intentionally excluded from the application of the reform points to some unintended effects on the provision of health care. However, we are unable to assess whether the contraction in outpatients relates with an actual change in prescribing behavior of GPs or is due to the complexity of the application of appropriateness criteria and to the introduction of sanctions for GPs who repeatedly refuse to comply. The latter mechanisms might indeed increase uncertainty, favoring a more restrictive interpretation of appropriateness criteria or a more frequent use of defensive medicine practices.

4.2 The Role of GPs

The main channel introduced by the reform to reduce excess health spending is expected to work through the restrictions imposed on GPs' ability to prescribe outpatient treatments, as well as by further regulating their gate-keeping role. Indeed, the reform intended to discipline doctors' over-treatment behavior, often triggered by the desire to satisfy patients' requests for medical care

(even when not deemed to be medically appropriate), as well as to offset indirect costs implied by potential malpractice litigation. In this context, one may expect that if GPs are characterized by different ethical norms *vis-à-vis* health-care spending, or if they hold different beliefs about what is to be considered an appropriate prescribing behavior, the effects of the reform might exhibit a significant heterogeneity in the levels of health-care spending (Cutler et al., 2019; Tsugawa et al., 2017). The complexity of appropriateness criteria defined by the reform and the unpredictability of sanctions for non-compliant doctors, may also have introduced further uncertainty in GPs' attitudes, differentiating their behavior. In this context, doctors who are affiliated with a trade union or work in a group practice, by having better access to information about the aims and implications of the reform, might adopt a more adherent interpretation of the regulations. To better understand how the effect of the reform was mediated by GPs' behavior, in this section we further explore the different patterns according to various GPs' attributes. In practice, we investigate whether older, more experienced or more unionized GPs adopted a different prescribing behavior in response to the reform, compared with other GPs. To do this, we focus our analysis on the population of GPs (i.e. 2,545) that induced at least one outpatient treatment each month in the period under consideration[14]. In Table 3, we report the main results for outpatient expenditures according to the selected GPs' attributes[15].

The selected characteristics show that the average GP is 58 years-old, has 23 years of work practice and approximately 1,340 patients (see Table A4 in the Appendix). More than half of GPs are member of a doctors' union, while only 7% are associated to a group practice[16].

To evaluate the differential effect of the reform according to GPs' characteristics, we specify our baseline model (equation (1)) as a triple Difference-in-Difference analysis interacting the reform dummy with k selected GPs' characteristics – i.e. $DM \times Post \times GP^k$. We recoded continuous variables as age and years of practice in dummy variables assuming value one for older (age above 63) and more experienced GPs (more than 31 years of practice). Additional characteristics considered are a dummy for being member of a doctors' union and working in a group practice.

We find that older and more experienced GPs are associated with milder effects on outpatient expenditures. The reduction in spending is 5% (1%) lower for older (experienced) GPs compared

[14]Due to missing observations 178 doctors were excluded from our working sample. Since the average per-capita number of patients for each GP is above 1,300 it is very unlikely that a GP does not figure in the Outpatient Record in any given month.

[15]Results on volumes of outpatients are available in the Appendix

[16]Doctors associated to group practice in the sample were also involved in the CReG program.

Tab. 3 Estimated impact of the reform on outpatients (expenditures and volumes) - by GPs' characteristics

Expenditures (log)	*Years of Practice*	*Age*	*Group practice*	*Union member*
	(1)	(2)	(3)	(4)
$DM \times Post \times GP^k$	0.0134**	0.0488***	0.00550	-0.0171***
	(0.00658)	(0.00910)	(0.00971)	(0.00601)
Time dummies	✓	✓	✓	✓
GPs fixed-effects	✓	✓	✓	✓
N	7,732,045	7,732,045	7,732,045	7,732,045

Significance: * p<.1, ** p<.05, *** p<.01. Robust standard errors in parentheses, clustered at the prescription level.

with their younger (less experienced) counterpart, suggesting a lower compliance of more experienced GPs with the reform's provisions in terms of prescribing appropriateness. The results are also consistent with previous evidence from the U.S. on the variation in physicians' spending, which indicates that higher-spending doctors are slightly older (Tsugawa et al., 2017).

Conversely, unionized GPs show a stronger resilience to prescribing appropriateness requirements (-25% in expenditures) compared with non-unionized GPs. No behavioral differences are detected for GPs associated to group practices. We interpret the above findings as evidence that GPs with more years of practice were more reluctant to change their behavior in response to the reform, while those unionized by having better information on both the provisions and sanctions of the reform exhibited more resilience.

4.3 Emergency Room and Hospital Admissions

As a final step, we investigate whether the application of prescribing appropriateness and the associated reduction in outpatient spending did effectively target unnecessary health spending or, in some cases, led to inappropriate care. In particular, we focus attention on the group of GPs who, after the introduction of the reform, changed their prescribing behavior by reducing outpatient treatments and explore whether their patients reacted by seeking substitute treatments or experience a higher likelihood of hospitalization. To do this we proceed as follows. First, we estimate our baseline Difference-in-Difference model separately by GP, and retrieve a GP-specific coefficient for the impact of the reform (as $\hat{\delta}_i$ in equation 1). Second, focusing on the subset of GPs that after the reform reduced their outpatient spending (i.e. with a negative estimated coefficient), we regress the estimated coefficients (in absolute value) on the GP-specific 2016-2015 percentage change in access to Emergency Room (ER) and hospital

admissions. In other words, we test whether the reform triggered some unintended response of patients, who, after receiving a refusal for an outpatient treatment from their GP, may have resorted to emergency care as a substitute for outpatient, or, due to inappropriate care, were in need of hospitalization. In case of significant reductions in outpatient spending, we expect larger estimated $\hat{\delta}_i$ to be associated with higher probability (percentage change) of ER access and hospital admission. We also explore whether this effect is heterogeneous across groups of patients, such as those more likely to be exposed and the most vulnerable. Table 4 presents the main results obtained estimating different specifications. In column 1 (column 4), we use as dependent variable a simple binary indicator taking value one if access to ER (hospital admissions) increased after the reform (i.e. $\mathbf{1}\{\Delta > 0\}$), and as explanatory variable the estimated change (in absolute value) of GPs' outpatient expenditures[17]. In column 2 (column 5), we replicate the same specification but define the dependent variable as the percentage change (Δ) in access to ER (hospital admissions). Finally, in column 3 (column 6), using the same definition for the dependent variable, we regress different quartiles of the estimated change in outpatient expenditures ($\hat{\delta}(Q_{1-4})$). In this setting, as previously discussed, a positive correlation indicates that larger reductions in outpatient spending – either in percentage terms or according to higher quartiles of the distribution – are associated with a higher use of emergency care or hospitals admissions.

Tab. 4 Estimated impact of the reform on ER and hospital admissions

	2016-2015 % Variation (Δ)					
	ER services			***Hospital Admissions***		
Expenditures	$\mathbf{1}\{\Delta > 0\}$	Δ	Δ	$\mathbf{1}\{\Delta > 0\}$	Δ	Δ
	(1)	(2)	(3)	(4)	(5)	(6)
$\lvert\hat{\delta}\rvert$	0.145*	0.0363**		-0.207**	0.0235	
	(0.0864)	(0.0180)		(0.0864)	(0.0273)	
2^{nd} quartile of $\lvert\hat{\delta}\rvert$			0.00441			-0.00356
			(0.00779)			(0.0108)
3^{rd} quartile of $\lvert\hat{\delta}\rvert$			0.00347			0.0193*
			(0.00766)			(0.0110)
4^{th} quartile of $\lvert\hat{\delta}\rvert$			0.0178**			0.00501
			(0.00767)			(0.0111)

Significance: * p<.1, ** p<.05, *** p<.01.

The estimated coefficient of interest, in Table 4 column 1, indicates that GPs who reduced outpatient spending more are also more likely to record an increase in access to ER among their patients. This finding is consistent with a substitution mechanism, where patients address

[17] Results on volumes of outpatients are available in the Appendix.

emergency care to receive the missed outpatient treatment. Additional evidence of substitution effects also comes from the fact that the increasing resort to emergency care is essentially driven by non-urgent cases (white and green triage codes), while there is no statistically significant correlation with urgent emergency care (yellow and red triage codes)[18]. Moving to hospital admissions (column 4), we find an opposite result, as reductions in outpatient spending are negatively associated with the likelihood of an hospital admission. However, when the percentage change in hospital admission is considered (columns 5 and 6), the negative correlations turns positive and it is not statistically significant. While, on average, we find no strong evidence that the reform led to inappropriate care and higher hospitalization rates, pooling all patients together may conceal a different effect on more vulnerable patients.

As a final exercise, we replicate the above analysis across different groups of patients. In the upper panel of Table 5 we report estimates of the probability that large reductions in outpatient spending led to an increase in the use of ER services for patients with/without a cost-sharing exemption for chronic conditions, and older/younger than 65. The lower panel repeats the same exercise on the likelihood of a hospital admission.

Tab. 5 Estimated impact of the reform on outpatients (expenditures and volumes) - Vulnerable patients

	Patient's type			
Expenditures	*w/Exemption*	*wo/Exemption*	*over 65yo*	*up to 65yo*
	(1)	(2)	(3)	(4)
$\mathbf{1}\{\Delta > 0\}$ - ER services				
$\lvert\hat{\delta}\rvert$	0.211**	-0.0307	0.0947	0.231***
	(0.0863)	(0.0886)	(0.0905)	(0.0858)
$\mathbf{1}\{\Delta > 0\}$ - Hospital admissions				
$\lvert\hat{\delta}\rvert$	-0.0688	-0.000300	-0.105	-0.0884
	(0.0864)	(0.0905)	(0.0921)	(0.0860)

Significance: * p<.1, ** p<.05, *** p<.01.

Results show that for those GPs who considerably reduced outpatient spending, access to ER increased particularly among patients without cost-sharing exemptions, thus reinforcing previous results on substitution effects. Patients with cost-sharing exemption for chronic condition, conversely seem to be unaffected. Similarly, considering different age groups, we find that the increase in the likelihood of ER access is mainly driven by younger patients (up to 65 years old). In other words, a more rigid prescribing behavior by their GPs after the reform may have induced many patients to bypass the gatekeeper for a direct use of emergency care. While

[18] Results on triage codes are not reported for space concerns, but are available upon request with the authors.

previous evidence suggested that also older patients faced a reduction in outpatient spending after the reform, we do not find for them any evidence of substitution effect towards higher use of ER services. Finally, no heterogeneous effects are found on hospital admissions, suggesting no health-damaging effects of outpatient cost containment in the short run, also considering vulnerable patients.

5 Conclusions

This paper evaluates a reform regulating GPs' prescribing appropriateness with the objective of reducing over-consumption of medical treatments and excess spending in the Italian National Health Service. The reform intended to discipline GPs' ability to prescribe a selected number of medical treatments, introducing strict appropriateness criteria. More vulnerable patients, however, were excluded from the application of such criteria.

Overall, we find that the introduction of the reform was followed by a 12% reduction in the volumes of outpatient treatments, and a 24% associated contraction in expenditures. The reform also affected the composition of outpatient spending, shifting GPs' prescribing behavior away from expensive medical services subject to appropriateness criteria towards other less expensive procedures that were not regulated by the reform.

When we exploit the different timing of the reform, we find that the overall effect can be decomposed into a short-run reaction, observed immediately after its introduction, and a medium-run mitigated effect after the partial repeal of reform.

While the reform achieved its primary target of reducing health-care expenditures, we also find that specific groups of vulnerable patients (i.e. the elderly, patients with cost-sharing exemptions or suffering from chronic diseases) were affected by the reduction in outpatient expenditures, despite being originally excluded from the application of appropriateness regulations. As the main channel for the reform to reduce excess spending concerned regulating GPs' discretionary power by limiting their prescribing behavior, we investigate the mediating role of GPs on health-care spending according to some specific observable individual attributes and work practice. We find that age and seniority are associated with lower compliance and a smaller reduction in spending, suggesting that more experienced doctors are less resilient to changing prescribing behavior. Conversely, membership to a trade union or a group practice – that we consider proxies for better information on both the provisions and sanctions of the reform –

favor a more restrictive interpretation of the regulations, with a stronger reduction in outpatient spending.

Finally, considering the relationship between health-care spending and patients' outcomes, we find that GPs with larger reductions in outpatient expenditures are associated with increasing access to emergency care for their patients, but lower hospital admissions. This evidence supports the view that the reform may also have triggered some substitution effects between outpatient and emergency care.

Overall, our results suggest that, in a context where GPs' remuneration schemes follow a combination of capitation and fee-for-services and medical care is largely free-of-charge, policies limiting GPs' discretionary power over prescribing behavior may prove particularly effective in reducing health-care utilization and spending. At the same time, additional evidence on the effect of the reform across different groups of patients shows that some forms of inappropriate care – either under-use of health-care services among vulnerable patients or misuse of emergency care – may still emerge as unintended outcomes. We find that different GPs' characteristics, as well as their beliefs about the appropriateness of treatments may translate into differential prescribing behaviors and compliance rates. Finally, the strong opposition of doctors towards the reform, should inform policymakers about the costs of adopting stringent rules and sanctions compared to the benefits of engaging service providers in the design of policies and incentivizing their behavior.

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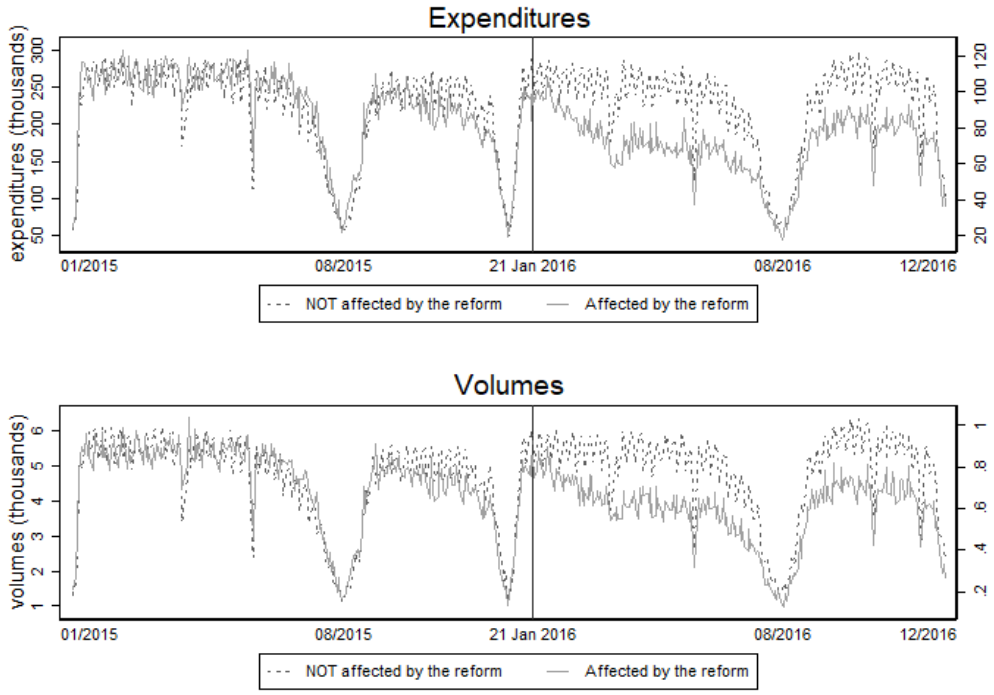
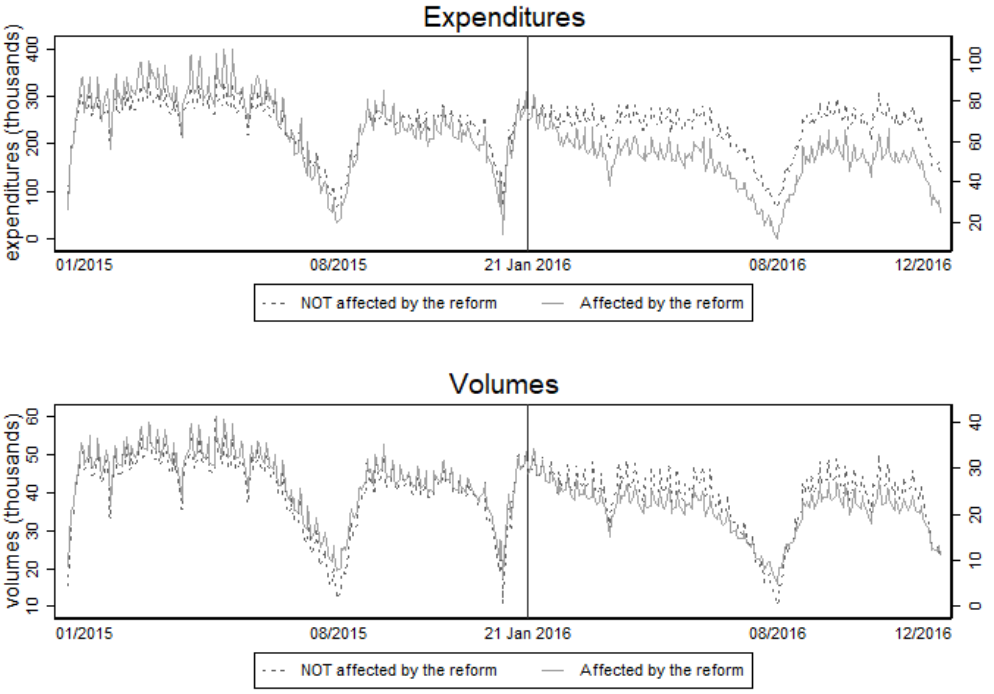
6 Appendix

Fig. A1 Evolution of expenditures and volumes of outpatients across categories of medical services

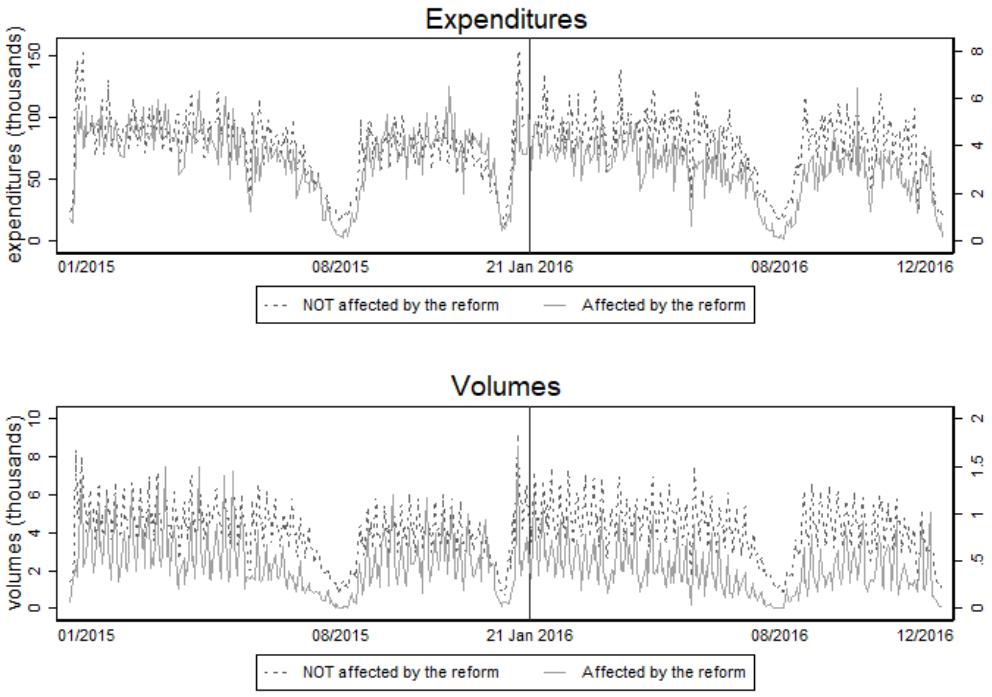


(a) Diagnostic Imaging



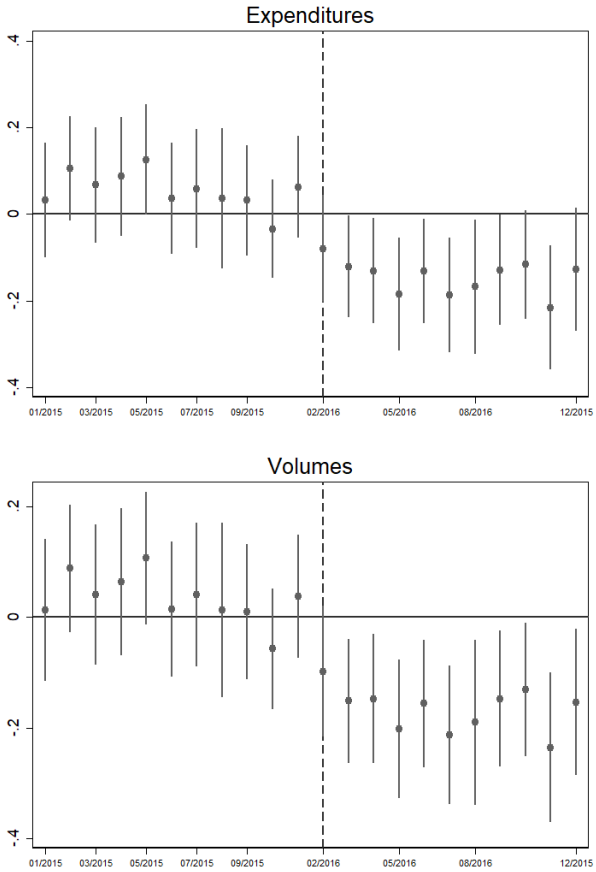
(b) Laboratory Analyses

Fig. A1 Evolution of expenditures and volumes of outpatients across categories of medical services (cont.)



(c) Other health services affected by the reform

Fig. A2 Estimated impact of the reform on expenditures and volumes of outpatients for months before, during, and after the introduction



Tab. A1 Estimates impact of the reform on outpatients (expenditures and volumes) - by age classes and citizenship

	Age classes			*Citizenship*	
	0-44	*45-64*	*65+*	*Migrants*	*Italians*
	(1)	(2)	(3)	(4)	(5)
Expenditures (log)					
$DM \times Post$	-0.268***	-0.248***	-0.209***	-0.147***	-0.237***
	(0.0313)	(0.0291)	(0.0269)	(0.0164)	(0.0254)
Volumes (log)					
$DM \times Post$	-0.172***	-0.120***	-0.0874***	-0.0722***	-0.113***
	(0.0308)	(0.0297)	(0.0258)	(0.0112)	(0.0232)
Time dummies	✓	✓	✓	✓	✓
GPs fixed-effects	✓	✓	✓	✓	✓

Significance: * p<.1, ** p<.05, *** p<.01. Robust standard errors in parentheses, clustered at the prescription level.

Tab. A2 Estimated impact of the reform on outpatients (expenditures and volumes) - by exemption status

	Exemption			**No exemption**
	Income	*Illness*	*Invalidity*	
	(1)	(2)	(3)	(4)
Expenditures (log)				
$DM \times Post$	-0.222***	-0.210***	-0.172***	-0.275***
	(0.0270)	(0.0258)	(0.0218)	(0.0296)
Volumes (log)				
$DM \times Post$	-0.0937***	-0.0862***	-0.0881***	-0.146***
	(0.0251)	(0.0238)	(0.0192)	(0.0322)
Time dummies	✓	✓	✓	✓
GPs fixed-effects	✓	✓	✓	✓

Significance: * p<.1, ** p<.05, *** p<.01. Robust standard errors in parentheses, clustered at the prescription level.

Tab. A3 Estimated impact of the reform on outpatients (expenditures and volumes) - by chronic disease

	Chronic diseases			
	Cardiopathies	*COPD*	*Diabetes*	*Cancer*
	(1)	(2)	(3)	(4)
Expenditures (log)				
All services	-0.195***	-0.126***	-0.140***	-0.157***
	(0.0257)	(0.0168)	(0.0185)	(0.0194)
DI	-0.0504**	-0.0226	-0.0138	-0.0317
	(0.0213)	(0.0219)	(0.0324)	(0.0256)
Lab	-0.160***	-0.0974***	-0.111***	-0.131***
	(0.0257)	(0.0166)	(0.0175)	(0.0192)
Other	-0.0692*	-0.0468	-0.0423	-0.109**
	(0.0403)	(0.0362)	(0.0920)	(0.0540)
Volumes (log)				
All services	-0.0726***	-0.0432***	-0.0528***	-0.0659***
	(0.0262)	(0.00995)	(0.0155)	(0.0124)
DI	-0.0142	0.0227	0.0124	0.0122
	(0.0273)	(0.0155)	(0.0149)	(0.0144)
Lab	-0.0900***	-0.0479***	-0.0631***	-0.0760***
	(0.0291)	(0.0109)	(0.0171)	(0.0137)
Other	-0.108**	-0.0538	-0.143	-0.131*
	(0.0441)	(0.0456)	(0.116)	(0.0778)
Time dummies	✓	✓	✓	✓
GPs fixed-effects	✓	✓	✓	✓

Significance: * p<.1, ** p<.05, *** p<.01. Robust standard errors in parentheses, clustered at the prescription level.

Tab. A4 GPs' descriptive statistics

	Statistics					
Variable	*Mean*	*p1*	*p25*	*p50*	*p75*	*p99*
N. patients	1,340	251	1,111	1,511	1,579	1,754
Age	58	37	54	59	63	68
Years of practice	23	1	18	24	31	38
Union member	.53					
CReG member	.072					
Total expenditure - 2015	101,894	5,739	55,974	110,695	142,863	214,319
Total expenditure - 2016	99,009	6,193	58,623	106,869	137,684	207,508
ER services - 2015	370	57	308	377	440	616
ER services - 2016	375	54	314	383	442	640
Hosp. admissions - 2015	149	27	119	157	182	238
Hosp. admissions - 2016	149	23	117	158	183	238

Note: Total spending, ER and Hospital admissions do not include 01/2015, to make figures for 2015 comparable with 2016.

Tab. A5 Estimated impact of the reform on volumes of outpatients - by GPs' characteristics

Volumes (log)	*Years of Practice*	*Age*	*Creg ass.*	*Union member*
	(1)	(2)	(3)	(4)
$DM \times Post \times GP^k$	0.0153***	0.0416***	0.0203**	-0.00893*
	(0.00521)	(0.00854)	(0.00882)	(0.00463)
Time dummies	✓	✓	✓	✓
GPs fixed-effects	✓	✓	✓	✓
N	7,732,045	7,732,045	7,732,045	7,732,045

Significance: * p<.1, ** p<.05, *** p<.01. Robust standard errors in parentheses, clustered at the prescription level.

Tab. A6 GP's response to the reform (volumes of prescriptions) and patients' admission to Hospital and ER

	2016-2015 % Variation (Δ)					
	ER services			***Hospital admissions***		
Volumes	$\mathbf{1}\{\Delta > 0\}$	Δ	Δ	$\mathbf{1}\{\Delta > 0\}$	Δ	Δ
	(1)	(2)	(3)	(4)	(5)	(6)
$\lvert\hat{\delta}\rvert$	-0.0415	0.0292		0.313**	-0.0336	
	(0.156)	(0.0339)		(0.156)	(0.0450)	
2^{nd} quartile of $\lvert\hat{\delta}\rvert$			0.0105			-0.00210
			(0.00940)			(0.0134)
3^{rd} quartile of $\lvert\hat{\delta}\rvert$			0.00454			0.0102
			(0.00947)			(0.0135)
4^{th} quartile of $\lvert\hat{\delta}\rvert$			0.0167*			-0.0111
			(0.00964)			(0.0131)

Significance: * p<.1, ** p<.05, *** p<.01.

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