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Reference:

Boogaerts Tim, De Swert Chanel, Covaci Adrian, van Nuijs Alexander, Hamelinck Wouter, Saevels Jan, De Loof Hans.- Out of pocket expenses : effect of fee-waivers on opioid prescribing and dispensing
International journal on drug policy - ISSN 1873-4758 - 98(2021)4 p.
Full text (Publisher's DOI): <https://doi.org/10.1016/J.DRUGPO.2021.103423>
To cite this reference: <https://hdl.handle.net/10067/1803350151162165141>

Out of pocket expenses: effect of fee-waivers on opioid prescribing and dispensing

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Abstract

Introduction: Pharmaceutical reimbursement policies should aim for satisfactory health care at reasonable prices and assure treatment adherence while avoiding wasteful pharmaceutical spending. In Belgium, the maximum billing system, also called “Maximum Amount Fixed” system (MAF), ensures that out-of-pocket payments beyond a ceiling are fully reimbursed to guarantee pharmaceutical treatment in vulnerable population groups (e.g. low-income people and chronic patients). Starting from 2015, a policy change occurred and these expenses were waived during the same calendar year once this ceiling was reached instead of reimbursing these expenses in the next fiscal year. Each subsequent fiscal year, out-of-pocket payments were reintroduced in January.

Methods: Longitudinal dispensing trends, from early 2013 to mid-2020, for 13 prevalent reimbursed opioids were investigated.

Results: For MAF patients, significant seasonal increases in opioid dispensing reoccurred towards the end of the year. This pattern was absent for non-MAF patients and was only observed after the 2015 policy change. Periodic changes in out-of-pocket expenses, a characteristic of the reimbursement policy in Belgium, clearly influences opioid availability in an already at-risk group.

Conclusions: Out-of-pocket reimbursement policies should be urgently re-evaluated to minimize unnecessary opioid exposure, while preserving the affordability of pain treatment for vulnerable patients.

1. Introduction

Pharmaceutical policies should ideally ensure affordable, sustainable and equitable access to essential and quality-assured medicines. As a part of these policies, reimbursement systems should aim to make these pharmaceuticals affordable to vulnerable citizens (World Health Organization (WHO), 2018). These social policies should strive for satisfactory health care at reasonable prices to ensure treatment adherence while avoiding wasteful pharmaceutical spending (Eaddy, Cook, O'Day, Burch, & Cantrell, 2012; Luiza et al., 2015). Previous studies have shown that co-payment reduction for statins and antiplatelet drugs preferentially improved treatment adherence (Pallares et al., 2009; Watanabe, Kazerooni, & Bounthavong, 2014) and especially vulnerable patient groups (e.g. older individuals, low income groups,...) may be susceptible to pharmaceutical non-adherence as a result of high out-of-pocket payments (Eaddy et al., 2012; Sinnott, Buckley, O'Riordan, Bradley, & Whelton, 2013). Multiple studies clearly highlight the adverse effects of high co-payment shares on pharmaceutical treatment (Eaddy et al., 2012; Goldman, Joyce, & Karaca-Mandic, 2006; Goldman, Joyce, & Zheng, 2007; Sinnott et al., 2013). There is also ample evidence that increasing co-payments impact the use of pharmaceuticals especially among more vulnerable populations (Goldman et al., 2007) and in certain circumstances may increase other medical expenditure such as emergency medical use or hospitalizations (Gibson, Ozminkowski, & Goetzel, 2005; Hsu et al., 2006). This is however a complex issue and not all observational studies (Mohan & Nolan, 2020; Puig-Junoy & Pinilla, 2020), in a changing context, have confirmed these trends as other interrelated economic aspects (e.g. unemployment, etc.) are also involved (Gellad, Grenard, & Marcum, 2011; Ridley, Rao, Schilbach, & Patel, 2020).

In Belgium, compulsory health insurance ensures that medical costs are in large part reimbursed by a governmentally organized system in which fee-for-service financing is combined with out-of-pocket expenses (Schokkaert et al., 2008). These payments, including drug expenses, can however become substantial and led to the introduction of the "Maximum Amount Fixed" (MAF) system in 2002. Out-of-pocket expenses, beyond a ceiling, were reimbursed in a subsequent fiscal year. Each year, the MAF went into effect once a collective out-of-pocket payment ceiling of a household was reached. Aiming to protect the most vulnerable, this ceiling was based on a patient's family income, family composition and disease complexity (Schokkaert et al., 2008). Subsequently, personalized tracking enabled real-time decision-making on the need to pre-finance these out-of-pocket payments. In January 2015, the system was therefore changed and these expenses were no longer reimbursed afterwards, but were instead waived during the calendar year for patients becoming eligible for this MAF benefit. Each January however, out-of-pocket payments for the subsequent fiscal year always resume for MAF patients until the ceiling is reached again (National Institute for Health and Disability Insurance, 2020). Thus, the biggest change in the post-intervention period is the timing of the reimbursement with out-of-pocket payments being waived immediately for MAF patients. Out-of-pocket expenses for non-MAF patients remain unaffected by this policy change.

Proper treatment of pain remains an important public health concern with 20% of adult Europeans suffering from chronic pain (Padfield & Zakrzewska, 2017). Although opioids are widely considered as the most effective

pharmaceuticals for the treatment of many types of acute pain, there is little evidence for their use for the management of chronic pain (Krebs et al., 2018; Murphy et al., 2018; Yaster, Benzon, & Anderson, 2017; Ziegler, 2015). The opioid epidemic in the US exposed the complex interplay between a socio-economic context and the overprescribing of opioids for chronic pain and clearly illustrated the need for social policies to protect vulnerable patient groups (Dasgupta, Beletsky, & Ciccarone, 2018).

This study investigates whether the changes of the MAF affected dispensing of opioids in community pharmacies in Belgium. Unlike any other previous research, the differences in fee-waiving as observed in this study, may bring new insights into this complex issue (García-Gómez, Mora, & Puig-Junoy, 2018; Gibson et al., 2005).

2. Materials and methods

Setting and data

Longitudinal trends in monthly defined daily doses (DDD), from January 2013 to May 2020 were obtained from the Belgian Institute for Pharmaco-epidemiology (IPHEB) and the Association of Pharmacists in Belgium (APB). The IFSTAT-IPHEB database compiles drug utilization data on dispensed pharmaceuticals in public pharmacies that are reimbursed by the National Institute for Health and Disability Insurance (NIHDI). Dispensing data was extracted for the 13 most prevalent reimbursed opioids: buprenorphine, codeine combinations, fentanyl, hydromorphone, morphine, oxycodone, oxycodone combinations, pentazocine, pethidine, piritramide, tramadol and tramadol combinations. This dataset allows the differentiation between opioids dispensed to non-MAF and MAF patients and covers 93% of all dispensed pharmaceuticals.

Analysis

GraphPad Prism version 9.0.0 (GraphPad Software Inc., California, USA) was employed for data visualization and statistical analysis. To evaluate whether dispensing of prescription opioids differs significantly after the periodic changes to the MAF, the area under the curve (AUC) was calculated pre- and post-intervention for each individual year. The 95% confidence interval was used to investigate whether the AUC was significantly different in the pre- and post-intervention years.

3. Results & Discussion

Figure 1 illustrates the monthly variations in the dispensing of opioids to MAF and non-MAF patients. The DDDs of the 13 abovementioned prescription opioids were combined and plotted for both patient groups. Medical expenditures of the non-MAF patients are still below the out-of-pocket payment ceiling and these patients still need to contribute a co-payment share when their prescription drug is delivered. All 13 prescriptions opioids share the same reimbursement category and are fully refunded once the patient's out-of-pocket payment ceiling is reached. Prescriptions of opioids to non-MAF patients clearly outnumber those for MAF-patients. The monthly opioids for MAF patients remained stable throughout 2013 and 2014, but there were clear seasonal increases since 2015, when real-time tracking of out-of-pocket expenses started. These increases were consistently followed by a steep decline in a subsequent January when out-of-pocket payments resumed. These seasonal

variations were absent in opioid dispensing to non-MAF patients. The AUC of the years in the pre-intervention period were significantly lower compared to the years in the post-intervention period, further evidencing that the seasonality of the total opioids dispensed changed after the implementation of 2015's addendum to the MAF. Although a substantial number of MAF patients belong to vulnerable patient groups with low socio-economic status, the NIHDI reports that the majority of MAF patients consists of middle-class families with a ceiling on their out-of-pocket payments based on their family income (National Institute for Health and Disability Insurance (NIHDI), 2019).

Figure 1 Seasonal plot of the total dispensing of the 13 most prevalent prescription opioids (expressed in defined daily doses) in community pharmacies to MAF patients (bottom half) and non-MAF patients (top half, using another Y-scale).

Together these observations potentially indicate that patients quickly become self-aware of their MAF status and started stockpiling opioids by the end of the year. There is some parallel with the one-time introduction of co-payments Spain in 2011 (García-Gómez et al., 2018) and the Medicare Part D insurance coverage in the US aimed to improve access to essential medicine through reduced cost-sharing (Fu, Tang, Wang, Du, & Jiang, 2010; Polinski, Donohue, Kilabuk, & Shrank, 2011). The data show that stockpiling may be a reality and is not counterbalanced by restrictive prescribing practices. Based on this dispensing data alone it is not possible to determine if these prescription opioids are actually consumed by the patients. However, increased availability of opioids increases the risk of adverse effects such as opioid use disorder, diversion and (un)intentional overdose (Bohnert & Ilgen, 2019; Chiu et al., 2018; Hulme, Bright, & Nielsen, 2018). Additionally, multiple reports show that opioid overdose rates are higher in patients with low socio-economic status (Altekruse, Cosgrove, Altekruse, Jenkins, & Blanco, 2020; Friedman et al., 2019). This raises the concern that a substantial proportion of MAF patients might be susceptible to opioid-related harms.

The original implementation of the reimbursement of out-of-pocket payments in Belgium was designed to protect low-income groups, and was found in 2008 to not induce medical spending (Schokkaert et al., 2008). However, changes in the way these expenses are handled clearly have an influence on dispensing. These policy changes therefore may unwittingly endanger vulnerable groups, as unnecessary opioid exposure should be minimized at all times (Fink, Uyttebrouck, & Larson, 2020). The system of real-time tracking of out-of-pocket payments should be re-evaluated urgently to limit the availability of prescription opioids, especially in the absence of stringent control systems preventing doctor shopping (De Mooter, Maebe, Willems, Lys, & Hans, 2019). Although overdispensing of opioids as a by-product of this social policy may increase diversion and misuse (Hulme et al., 2018), additional financial barriers might result in denying patients their legitimate pain treatment (Knaut et al., 2018). Re-engineering of these reimbursement policies should eliminate the imbalance between out-of-pocket expenses throughout the year and needs to ensure affordable treatment options for vulnerable pain patients. A moving average or any other adaptive system based on recent medical expenditure through which these payments are reduced, but not fully eliminated, could be implemented if medical costs in prior months become substantial, thereby safeguarding social protection but diminishing the incentives for stockpiling

medication. Another approach is to differentiate these out-of-pocket expenses in light of the risks of stockpiling or diversion as this risk is much smaller for medication used in the treatment of diabetes or hypertension as compared to opioids or other psychoactive substances. These initiatives should ideally be combined with efforts to limit doctor shopping and limit inappropriate opioid prescriptions (Fink et al., 2020).

Conclusions

Although repeated seasonal changes in out-of-pocket expenses are a local phenomenon in Belgium and cannot directly conclude overuse of opioids, it clearly demonstrates the impact of these payments on opioid availability. The hazards of the well-intentioned re-engineering of out-of-pocket expenses therefore should lead to a rebalancing of the current policies without unduly impacting those in real need. In addition, these findings further document an additional area of urgent concern: the prescribing habits of physicians. Although these national figures are generalizable for the general population, future research could also benefit from investigating the socio-demographic features and motivators for opioid use of individual MAF patients.

Acknowledgements

The authors would like to thank the Belgian Institute for Pharmaco-epidemiology (IPHEB) and the Association of Pharmacists in Belgium (APB) for providing the data for this study.

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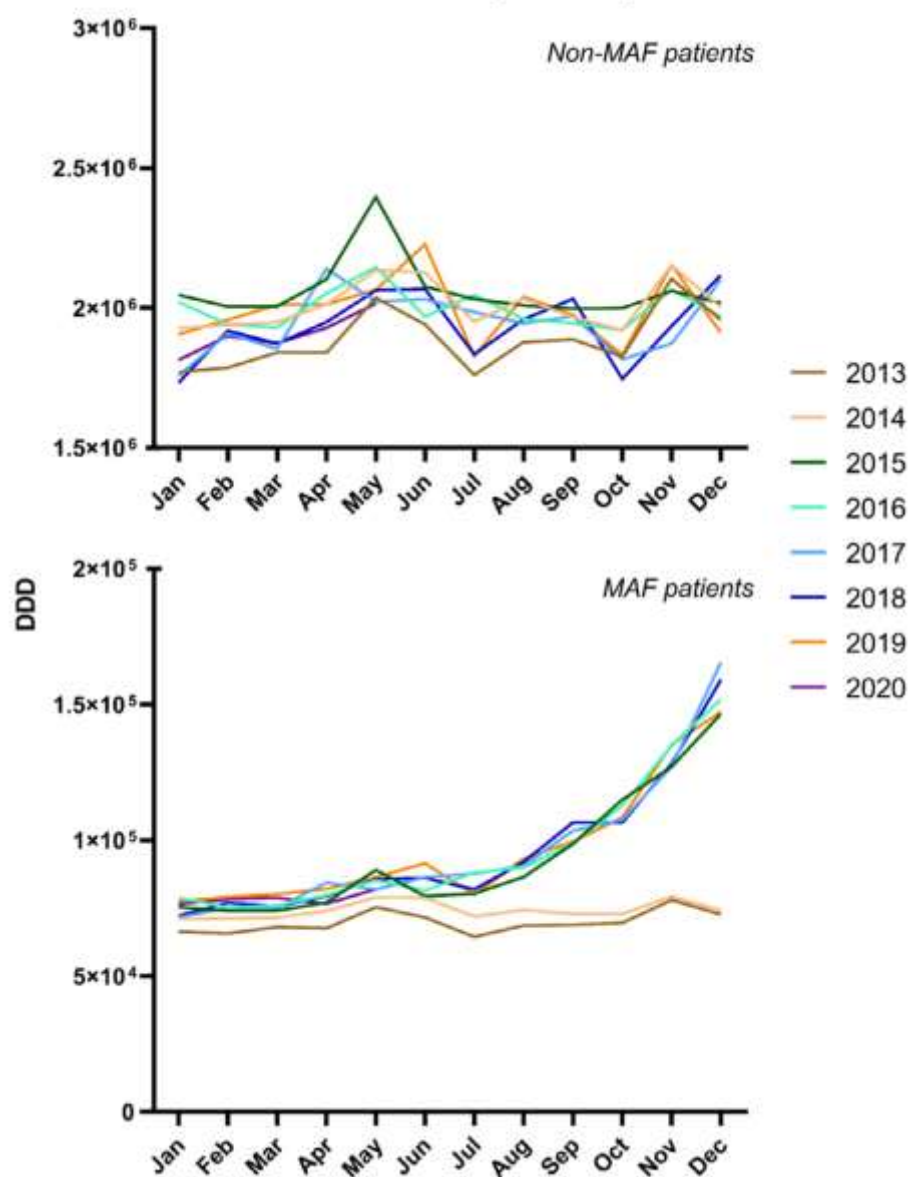


Fig. 1. Seasonal plot of the total dispensing of the 13 most prevalent prescription opioids (expressed in defined daily doses) in community pharmacies to MAF patients (bottom half) and non-MAF patients (top half, using another Y-scale).