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Health Policy Analysis

Real-World Impact of Transferring the Dispensing of Hospital-Only Medicines to Community Pharmacies During the COVID-19 Pandemic

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ABSTRACT

Objectives: In Portugal, the dispensing of most outpatient specialty medicines is performed exclusively through hospital pharmacies and totally financed by the National Health Service. During the COVID-19 first wave, the government allowed the transfer of the dispensing of hospital-only medicines (HOMs) to community pharmacies (CPs). This study aimed to measure the value generated by the intervention of CP in the dispensing of HOM.

Methods: A single-arm, before-and-after study with 3-month follow-up was conducted enrolling a randomly selected sample of patients or caregivers with at least 1 dispensation of HOM through CP. Data were collected by telephone interview. Main outcomes were patients' self-reported adherence (Measure Treatment Adherence), health-related quality of life (EQ-5D 3-Level), satisfaction with the service, and costs related to HOM access.

Results: Overall 603 subjects were recruited to participate in the study (males 50.6%) with mean 55 years old (SD = 16). The already high mean adherence score to therapy improved significantly ($P < .0001$), and no statistically significant change ($P > .5757$) was found in the mean EQ-5D score between baseline (0.7 ± 0.3) and 3-month follow-up (0.8 ± 0.3). Annual savings account for €262.1/person, arising from travel expenses and absenteeism reduction. Participants reported a significant increase in satisfaction levels in all evaluated domains—pharmacist's availability, opening hours, waiting time, privacy conditions, and overall experience.

Conclusions: Changing the dispense setting to CP may promote better access and satisfaction. Moreover, it ensures the persistence of treatments, promotes savings for citizens, and reduces the burden of healthcare services, representing a crucial public health measure.

Keywords: community pharmacies, COVID-19, health services research, hospital-only medicines, patient satisfaction, public health

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Introduction

The COVID-19 pandemic deeply challenged health systems capacity to handle current and emerging threats worldwide. In Portugal, several measures were adopted to contain the transmission of the virus and the spread of the disease, starting on March 18, 2020, when the state of emergency was first time declared. The law imposed unprecedented measures, with stricter restrictions over domestic and international movements and social distancing rules, reducing the number and proximity of contacts.[1] In this context, a decrease in the delivery of healthcare, through a lower number of diagnosis,[2-4] emergency visits,[5-7] and medical appointments,[8,9] was alarming, given the risk of increased severe and long-term health problems. This scenario emphasized the need of public health measures that ensure the continuation of care, including strategies to promote continuous access to medication.[10]

In Portugal, the dispensing of outpatient high-cost medicines for oncology, multiple sclerosis, and human immunodeficiency virus (HIV), among other pathologies, is performed exclusively through hospital pharmacies (HPs) and totally financed by the Portuguese National Health Service. Nevertheless, in response to this pandemic crisis, national authorities took several transitional emergency measures, such as allowing patients to receive their hospital-only medicines (HOMs) in community pharmacies (CPs).[11] This policy measure aimed to ensure the proximity and safety of the dispensing act in a period of extreme workload in hospitals and, consequently, promote the protection of risk groups by avoiding nonessential travel. In this context, a nationwide collaborative program,

known as "Operação Luz Verde" (OLV) (hereinafter referred to as OLV Initiative), was launched ensuring the access to these medicines through CP, as a free service that enabled the continuity of care and freedom of choice. This initiative was supported by the "Pharmacist Support Line" (LAF), a service coordinated by the Portuguese Royal Pharmaceutical Society that secured the exchange of information among stakeholders.[12] Starting from March 23, 2020, cross-country CP guaranteed the access in proximity to HOM.

This study aimed to measure the value generated by the intervention of CP in the dispensing of HOM within OLV Initiative.

Methods

Study Design

The OLV Initiative study (OLV study) was a national single-arm, before-and-after cohort study of patients and/or caregivers who had access to HOM through CP, engaged in the OLV Initiative.

Data Sources, Population, Time Period, and Variables

Three data sources were used for study purposes: pharmacy dispensing software Sifarma®, telephone questionnaires, and LAF database.

From the pool of patients of the LAF database, a simple random sampling technique was used to select OLV participating subjects (individuals who had at least 1 dispensed HOM recorded in the CP's dispensing software Sifarma on April 24, 2020). From May 15, 2020 to July 7, 2020, subjects were contacted by telephone, by the research team, for eligibility assessment and invited to participate in the study. Subjects had to be aged ≥ 18 years and understand and speak Portuguese. After giving verbal informed consent, participants—patients or caregivers—were interviewed for baseline data collection using a structured questionnaire regarding sociodemographic data (patient date of birth, employment status of the individual who gets the medicines at HP and/or CP), previous experience with the HP and the current experience with CP (satisfaction with business hours, waiting time, privacy during dispense, pharmacist' availability, global experience with the service), waiting and travel time, means of transportation (car, subway, train, bus, taxi, walk) and related costs (€), working absenteeism defined as working-day time lost (none, half-day, one day), hospital-pharmacy frequency visits (once a month, 2/2 months, 3/3 months, 6/6 months, other), health-related quality of life (HRQOL), and adherence to therapy.

A second telephone interview was performed 3 months after the index date (baseline questionnaire date) for follow-up data collection, namely HRQOL, adherence, and preferences regarding the setting to access the specialty medicines in the future. The last visit of the last patient occurred on October 10, 2020. In cases where the questionnaires were answered by the caregiver, the HRQOL and adherence measurements were not applied. The remaining variables were collected only for participants who reported being themselves to get the medicines at HP and/or with the transferring, at CP. Additionally, the CP dispensing software was used to assess the patients' sex and dispensed therapeutic indication of HOM.

The study received ethics clearance by the Ethics Committee of the Institute for Bioethics of the Portuguese Catholic University of Porto, ethics screening report number 03.2020. All principles of ethical research were followed according to the Helsinki Declaration. An oral informed consent was obtained from all participants. No incentives were provided for participation in the study.

Outcome Measures

Participants' satisfaction with CP and HP was measured using a 5-item Likert scale, and preference regarding the place of dispensing by a dichotomous closed-ended question.

Adherence was measured using the self-reported 7-item Measure Treatment Adherence (MTA) tool validated for the Portuguese Population.[13] The MTA is a psychometric tool derived from the Morisky et al[14] questionnaire and evaluates the individuals' behavior in relation to the daily use of medication.

HRQOL was assessed using the EQ-5D 3-level (EQ-5D-3L) generic instrument. The EQ-5D-3L covers 5 dimensions of health (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) each with 3 levels of functioning (1 = no problems, 2 = some problems, and 3 = severe problems).[15,16]

The economic impact per patient/visit and patient/year was estimated, through working absenteeism (days) and transportation costs (costs of mean of transportation and travel time) data.

Sample Size

To assure a maximum absolute error in the global estimates of 4% with a 95% confidence level, a sample of 600 subjects were estimated to be sufficient. The sample was randomly selected out of the total 9782 subjects registered in the OLV Initiative with at least one dispensed medication, at the beginning of the study.

Statistical Analysis

Descriptive statistics were estimated for the whole data set. Categorical variables were summarized by absolute and relative frequencies, including counts of missing observations. Continuous variables were summarized by the number of nonmissing values, using measures of central tendency and dispersion (mean and SD).

HRQOL and adherence were assessed using the EQ-5D-3L[16] and MTA[13] indexes, respectively, at baseline and 3-month follow-up. For participants that completed follow-up, mean change index score (endpoint-baseline) were also computed and compared using the Wilcoxon signed rank test with continuity correction, after rejection of normality assumption. Mean differences between the satisfaction and characterization of journey to CP and HP were also tested, using the appropriate test (paired Student's t test or Wilcoxon signed rank test, if the normality assumption was rejected). Working absenteeism per visit (CP and HP) was calculated considering the national average salary for men and women.[17] Transportation costs were estimated considering the mean of transportation and official tariffs. For subjects who refer to use their car, toll road charges were not considered. Average costs and savings per patient per year, arising from absenteeism and traveling changes, were calculated for both settings (CP and HP), multiplying the costs per visit per setting, by the average number of the participants' HP reported visits per year. Additionally, an extrapolation of total costs was conducted for the total number of patients who had received at least one HOM in CP by the end of the study period (n = 15 441).

All statistical tests consider a 5% significance level. Sampling was conducted in SAS software (SAS Institute, Cary, North Carolina). Data analysis was performed using MS Office, SAS, and R software (https://www.r-project.org/).

Results

Participants' Flow and Characteristics

A total of 659 subjects (patients/caregivers) were contacted by the research team. Of those, 38 did not meet the inclusion and exclusion criteria and 18 declined to participate, resulting in 603 participants enrolled. Compared with the participants, refusals had similar sex (P = .3283) and therapeutical indication distributions (P = .6438). Most participants (84.6%) were the patients themselves, that is, the users of the HOM. Over the study period, 28 participants were lost to follow-up. Participants' flow is depicted in Figure 1.

The mean patients' age was 55 years (SD = 16) and 50.6% were male. Overall, more than half of the individuals who got the medication were employed (50.4%), and the most prevalent therapeutic included HIV (25.2%) and oncology (20.6%). In most cases, the respondents (either the patients or caregivers) were the ones who travel to obtain the medicines. The baseline characteristics of participants are summarized in Table 1.

HRQOL and Adherence

The HRQOL and adherence scores are summarized in Table 2. Overall, most patients were adherent to HOM therapeutics. The transferring of the local of dispense from HP to CP not only maintained the high level of adherence to therapy but also significantly increased the mean score ($P < .0001$). Regarding HRQOL, there were no statistically significant changes ($P > .5757$) in the mean EQ-5D-3L score between baseline (0.7 ± 0.3) and 3-month follow-up (0.8 ± 0.3).

Participants' Satisfaction and Preferences

An improvement of satisfaction levels at CP was observed compared with HP. This increase was statistically significant in all the evaluated domains—pharmacist's availability, business hours, waiting time, privacy during dispense, and global experience. Additionally, 91% of participants reported to prefer to continue to have access to their medication at CP in a postpandemic scenario.

The satisfaction domain with lower scores in both settings was the privacy conditions. Results of satisfaction per setting and domain are depicted in Figure 2.

Figure 1. Participants' flow.

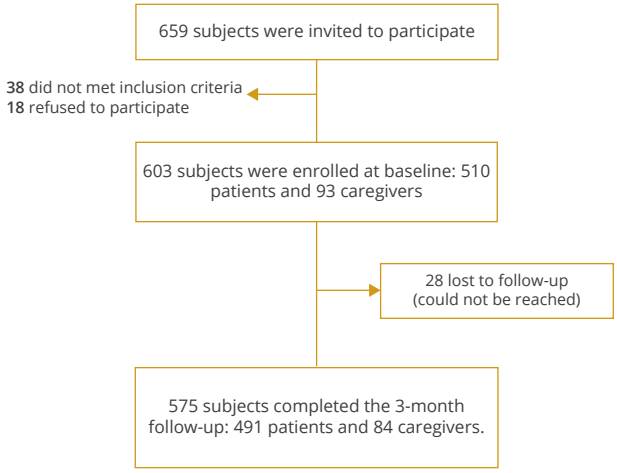


Table 1. Baseline sociodemographic and clinical characteristics.

Variables	Total (N = 603)
Age, years, mean (SD) (NR = 0)	55 (16)
Sex (male), n (%) (NR = 2)	305 (50.6)
Employment status, n (%) (NR = 4)	
Employed	302 (50.4)
Pensioner	220 (36.7)
Unemployed	46 (7.7)
Student	8 (1.3)
Other	23 (3.8)
More prevalent therapeutical indications,* n (%)	
HIV	152 (25.2)
Oncology	124 (20.6)
Transplant	67 (11.1)
Transplant/Crohn disease/colitis	59 (9.8)
Multiple sclerosis	46 (7.6)
Rheumatoid arthritis/psoriasis/ psoriatic arthritis	22 (3.6)
Participants, n (%) (NR = 0)	
Patient	510 (84.6)
Getting the medicine in person at HP	450 (88.2)
Getting the medicine in person at CP	373 (73.1)
Caregiver	93 (15.4)
Getting the medicine in person at HP	69 (74.2)
Getting the medicine in person at CP	72 (77.4)

CP indicates community pharmacy; HIV; human immunodeficiency virus; HP, hospital pharmacy; NR, nonrespondent.
*Accordingly, to the summary of product characteristics.

Characterization of a Journey to the CP and HP

In this study, a journey to the pharmacy (community or hospital) refers to the act of leaving home, arriving to the pharmacy, and returning home, which can take more than one travel mode. Additionally, the waiting time to be attended in the pharmacy was also considered. The mean number of travel modes was 1.0 ± 0.1 and 1.2 ± 0.4 for CP and HP, respectively, with a significant mean difference of 0.2 ± 0.4 modes. The main travel mode for HP was the subjects' car (62.8%), whereas walking (55.3%) was the most referred for CP. The mean journey time to HP and CP was 138.9 ± 117.2 and 23.9 ± 18.3 minutes, respectively, with a significant time gain of 114.5 ± 120.6 minutes per visit to CP. The average estimated saving per transferred visit to CP was €35.8 ± 52.4. A total of 27.6% of employed participants reported missing work at least half-day to get the medicines at the HP compared with 0.4% at the CP. Overall results are summarized in Table 3.

Annual savings estimated from the reported reduction in travel expenses (€226.8) and absenteeism (€64.8) account for a total of €262.1 per patient. Considering the 15 441 patients who received, at least once, their HOM in CP by the end of this study through this initiative, savings rose to approximately €4 million.

Discussion

During the first wave of the COVID-19 outbreak in Portugal, OLV Initiative was launched as a public health measure to promote access and continuation of care to patients receiving HOM.[11,12] Health professionals and stakeholders, with the institutional support of professional organizations and patient associations, joined efforts to guarantee access to outpatient specialty medicines to patients in a nationwide initiative. This study investigated the impact of transferring the dispensing of several HOM to CP.

Table 2. Patients mean scores for EQ-5D-3L index and MTA.

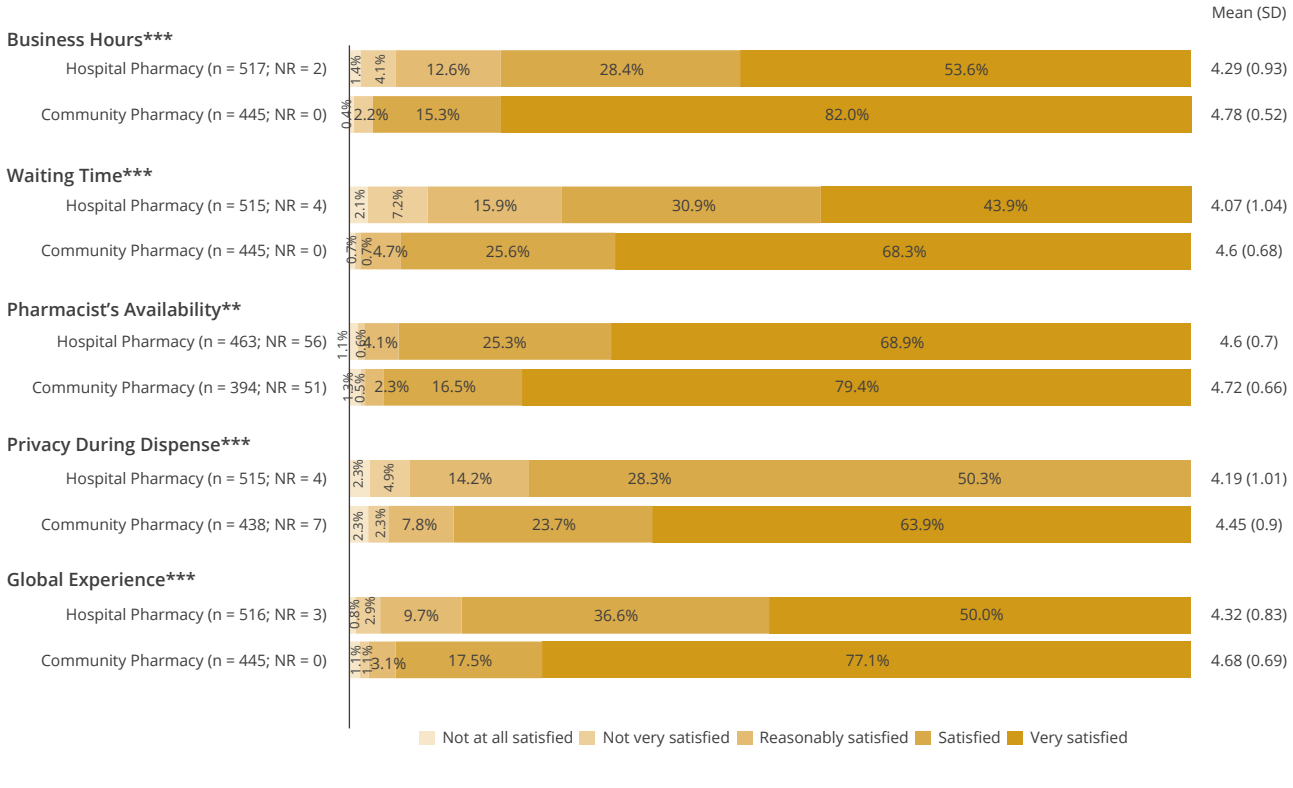
Variables	Baseline n = 504 (NR = 6)	3 months n = 486 (NR = 5)	*P* value*
EQ-5D index score, mean (SD)	0.7 (0.3)	0.8 (0.3)	.5757
MTA score			
Mean (SD)	5.8 (0.2)	5.9 (0.2)	< .0001
Score ≥ 5, n (%)	500 (99.2)	486 (100.0)	

EQ-5D-3L indicates EQ-5D 3-Level; MTA, 7-item Measure Treatment Adherence; NR, nonrespondent.
*Wilcoxon signed rank test.

The results suggest that switching the dispense of these medicines, from HP to CP, may have a significant and positive impact on patients and caregivers' satisfaction, savings, and adherence to therapy, with no known risks for patients nor negative impact on their quality of life. Community pharmacists worked collaboratively with the patients' hospital healthcare team—pharmacists and prescribers—creating a supporting network to patients, which guaranteed a timely, safe, and quality access to HOM.

The larger business hours, reduced waiting time, and proximity of CP seems to be very convenient and probably contribute to significantly higher satisfaction with CP than HP. It is worth emphasizing that high levels of satisfaction with the CP have been consistently reported nationally and internationally.[18-20] Moreover, higher convenience of CP location is reflected in the travel mode preferred by respondents, with the majority reporting going on foot to CP versus by car to HP. Given that geographical accessibility is a key dimension of access to medicines,[21] the proximity of CP to subjects also seems to contribute to reduce absenteeism and traveling time, resulting in savings to patients and caregivers. Similar findings were found in a pilot study[22] previously conducted in Portugal and framed by the National Strategy for Medicines 2016 to 2020 that foresaw the valuation of CP as healthcare providers, including the possibility of HOM dispensing at that setting.[23] The pilot was conducted in 2016/2017 and included people living with HIV under antiretroviral therapy, from one hospital in the country's capital—Lisbon.[22] Results showed a significant improvement of patients' satisfaction in all domains assessed and also a reduction in traveling time (34 ± 29 minutes) and waiting time (17 ± 29 minutes) for CP compared with HP.[22] Higher gains on travel times were found in this national study (101.1 ± 112.3 minutes), to the extent that hospitals outside large municipalities serve a population more dispersed and thus further away from hospital centers.[24]

Figure 2. Participants' satisfaction with the assessed dimensions of the community and hospital pharmacies.



NR indicates nonrespondent.

Table 3. Journey, absenteeism, and estimated costs per patient.

Variables	HP	CP	Mean difference	*P* value*
Travel modes (number)				
Mean (SD)	1.2 (0.4)	1.0 (0.1)	0.2 (0.4)	< .0001
Car	326 (62.8%)	195 (43.8%)	—	—
Public transportation	168 (32.4%)	8 (1.8%)	—	—
Walking	51 (9.8%)	246 (55.3%)	—	—
Taxi	24 (4.6%)	3 (4.6%)	—	—
Travel time (min)				
Mean (SD)	116.8 (109.5)	14.7 (13.0)	101.1 (112.3)	< .0001
Waiting time (min)				
Mean (SD)	22.0 (27.4)	9.0 (10.7)	13.2 (29.5)	< .0001
Journey time (min)				
Mean (SD)	138.9 (117.2)	23.9 (8.3)	114.5 (120.6)	< .0001
Work absenteeism n (%)				
None/less half-day	181 (72.4%)	235 (99.6%)		< .0001
Half-day	36 (14.4%)	1 (0.4%)		
One day	33 (13.2%)	0 (0.0%)		
n	250 (NR = 4)	236 (NR = 0)		
Frequency visits/year				
Mean (SD)	8 (3.5)	—		
Estimated costs/visit (€)				
Travel, mean (SD)	33.1 (47.8)	1.3 (3.1)	31.0 (47.2)	< .0001
Absenteeism,† mean (SD)	9.4 (16.6)	0.1 (1.6)	9.0 (16.3)	< .0001
Total, mean (SD)	37.7 (52.8)	1.4 (3.3)	35.8 (52.4)	< .0001
Estimated costs/year/patient‡ (€)				
Travel, mean (SD)	246.3 (415.0)	8.7 (17.1)	226.8 (405.1)	< .0001
Absenteeism,† mean (SD)	68.0 (132.2)	0.6 (9.7)	64.8 (130.9)	< .0001
Total, mean (SD)	278.5 (460.6)	9.1 (18.3)	262.1 (452.1)	< .0001

CP indicates community pharmacy; HP, hospital pharmacy.
*Paired Student's *t* test or Wilcoxon signed rank test, as appropriate.
†Estimated costs of absenteeism were only calculated to employed subjects.
‡For CP setting, it was assumed that the frequency visits per year was the same as for HP.

The satisfaction dimension assessed with lower value for both settings in the OLV study was the "privacy during dispense." Privacy constraints are widely recognized and frequently reported as a barrier, especially for people living with stigmatizing conditions as those taking some HOM.[18,25-27] This fact underlies the importance of the results presented in this study, showing a statistically significant improvement in the privacy domain. Nationwide, large efforts have been made by Portuguese pharmacies, who have invested in creating private counseling areas as their scope have been shifting to service provision.[28,29] This may explain the fact that > 86% of participants were satisfied or very satisfied with the privacy dimension.

To the best of our knowledge, at least 3 other European countries allowed, under emergency measures, the CP to expand their roles and dispense high-cost medicines that were previously only accessible in the hospital setting.[30] Indeed, the regular dispensing of specialty medicines that do not require in-hospital administration for treatment, as the case of some therapeutics for hepatitis C, HIV, multiple sclerosis, psoriatic arthritis, and others, is already provided by both the CP and HP in most jurisdictions.[31] Some examples are Australia with medicines for HIV and viral hepatitis,[32,33] Canada[34] with oral anticancer drugs, Belgium with immunosuppressants,[35,36] and France and Germany with antiretroviral therapy,[37,38] with CP being reimbursed for the service.

Consistent with previous international evidence,[37] when Portuguese participants were asked about the preferred setting to continue to refill their HOM, a very high proportion reported preference to continue to have access to their medication at CP, close to their home or place of work. The results highlight the importance of giving citizens freedom of choice, but also the relevant public health role performed by the network of CP in interprofessional collaboration, contributing to the system's efficiency.

Regarding HRQOL, no significant impact was observed with the transfer of HOM to CP, with patients maintaining their overall status at 3-month follow-up. Additionally, a significant, but possibly not clinically relevant, increase of adherence to HOM at CP was found, with patients presenting high levels of adherence at baseline. These findings suggest that the access to medicines and clinical stability of all patients were maintained given that adherence is crucial for the success of the therapy.[39,40] In line with these results, a recently published systematic review demonstrated the positive influence of medicines' dispensing by CP on health outcomes, quality of life, and satisfaction of patients.[41]

Overall results highlight the feasibility of enlarging the role of CP, making HOM available with improved convenience, and guaranteeing the continuing of care. The provision of this service by CP can also reduce some existent inequalities, given that patients from the inland (the most disadvantaged areas of the country) are those who had to travel greater distances to obtain their medicines.[24] Moreover, the transferring can be an important strategy to reduce the existent workload on hospital-pharmacy services.[42] Recent studies have demonstrated the new societal

demands, suggesting that a fully integrated, intersectoral, and interprofessional collaboration is required, to build upon the lessons and experiences of this COVID-19 global crisis.[43–45]

Strengths and Limitations

The main strength of this study is the use of real-world data of a nationwide representative sample of people using outpatient HOM and had the dispense transferred to CP, allowing a real picture of the impact of this transfer. Moreover, this study presented a high retention rate and included participants on different therapeutic classes of medicines, capturing a global picture and not only the view of a specific group.

This study also has some limitations. First, the study design was a before-and-after with no control group, thus being subject to bias, such as recall bias concerning the experience in the HP setting. To minimize this bias, the experience regarding HP setting (satisfaction and journey) was asked at baseline (before), reducing the time span between the last visit to the HP and the data collection point. Second, a social desirability bias could have occurred because participants were asked about subjective satisfaction measures. Third, variation in the interviewers may have contributed to intrainterview variability and influence participants' response, although this possibility was reduced by training the telephone interviewers. Fourth, considering the main data collection tool, questionnaires bias could also have occurred. Nonetheless, only validated tools and questions already piloted and used in previous similar studies were included in the telephone questionnaire.

Finally, this was a short-period study, which is insufficient to estimate long-term effects of the transferring. Therefore, it would be desirable to be able to continue with similar national initiatives or have access to big data from different data sources, to assess the long-term impacts of the initiative.

As future research, we aim to access the value of transferring the dispensing of HOM to the CP from the National Health Service perspective, to estimate a value to reward their contribution for the delivery of this service and encourage policy makers to reimburse it.

Conclusions

The study findings suggest that changing the dispense setting of outpatient specialty medicines from HP to CP will have a positive impact on people's HRQOL, adherence to therapy, satisfaction, access times, and savings, representing a crucial public health measure, although some major challenges need to be overcome, namely a sustainable regulatory and remuneration framework to leverage this service in the CP.

Article and Author Information

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