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Evaluation of the care pathway in the context of the dispensing of emicizumab (Hemlibra) in community and hospital pharmacies in France: A patient satisfaction survey

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Trial registration:

<https://clinicaltrials.gov/ct2/show/NCT05449197>.

Abstract

Introduction: Since June 2021 in France, patients with haemophilia A with anti-factor VIII inhibitors and patients with severe haemophilia A without anti-factor VIII inhibitors, and treated with emicizumab (Hemlibra), have to choose the dispensing circuit community or hospital pharmacy.

Aim: To evaluate satisfaction of patients whether they choose dispensation from a community pharmacy or retained dispensation from the hospital pharmacy, to understand the main motivation for choosing the community or the hospital pharmacy.

Methods: All patients living in France, regardless of age, were eligible to participate. Between September 13, 2022, and January 9, 2023, 175 respondents answered the satisfaction survey, including 123 in community pharmacy and 52 in hospital pharmacy.

Results: Eighteen months after availability in community pharmacies, treatment accessibility is improved for the benefit of the patient. The door-to-door travel times are significantly reduced to the community pharmacy with an average gain of 16.5 min saved from the place of residence. Patients are mostly satisfied with the new dispensing circuit especially concerning the overall satisfaction ($p < .0001$), the travel time ($p < .0001$) and the strong relationship with the pharmacist ($p = .0022$) compared to hospital pharmacy.

Conclusion: Innovation in care pathways is showing its full potential in improving access to medication, made possible by the implementation of a rigorous organization accompanied by training to enable healthcare professionals involved in primary care to provide appropriate management.

KEYWORDS

community pharmacy services, emicizumab, health services accessibility, haemophilia A, patient satisfaction

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1 | INTRODUCTION

Treatment accessibility represents a problem for chronic rare diseases treated on a long-term due to exclusive accessibility in hospital pharmacy, with no possibility of home delivery in France, except for rare situations.¹ Significant changes in treatment accessibility are expected by patients community and carers² to reduce territorial constraints.^{3,4} As observed in a previous French study, both patients and hospital pharmacists pled for an evolution of the current dispensing circuit to improve access to treatment and reduce the burden of the disease, especially for active workers, parents and for patients living in rural areas.⁵

Emicizumab (Hemlibra) is the first prophylactic treatment that can be administered subcutaneously in haemophilia A with or without anti-factor VIII inhibitors.^{6,7} These new administration modalities are easier to implement than previous Factor VIII treatments, which required sometimes frequent intravenous injections.^{8,9}

In France, the cost of prophylaxis with emicizumab is fully covered by the national health insurance, subject to compliance with monthly dispensing requirements.^{10,11} In a move to improve accessibility to treatment, France and Australia have proposed a new dispensing circuit to offer patients with haemophilia A treated with emicizumab the option of accessing the product in a community pharmacy.^{12,13}

Since June 2021, the dispensing of emicizumab benefits of a dual dispensing circuit in France. Patients can choose the dispensing location; the community or the hospital pharmacy. This organizational advance constitutes a first experience of availability in community pharmacies of an antihemophilic treatment. This new dual dispensing circuit has been accompanied by a rigorous organization of care to meet several challenges.¹⁴ The main challenge is to enable efficient communication channels between stakeholders to guarantee continuity and safety of care for patients; the professionals of the regional centre for haemophilia and the community pharmacists. The French Reference Centre for Haemophilia organized a specific training program 'HEMOPHAR' to improve knowledge of the community pharmacists on haemophilia and its treatments, the organization of care and the practice in the community pharmacy.¹⁵

The national PASO DOBLE DEMI study aimed to evaluate this new organization of drug circuit and its impact on haemophilia care in France. The present study is the last step of the evaluation model which aimed to evaluate satisfaction of patients with haemophilia A with or without inhibitor whether they chose dispensation from a community pharmacy or retained dispensation from the hospital pharmacy, to measure the impact of changes on the travel time and to understand the main motivation for choosing the community or the hospital pharmacy.

2 | MATERIAL AND METHODS

2.1 | Study design

We designed a national cross-sectional survey to evaluate the satisfaction of patients treated with emicizumab whether they chose

community pharmacy or hospital pharmacy. This study is part of the fourth level of the Kirkpatrick evaluation model¹⁴ that we specifically designed to evaluate the overall impact of the new dual dispensing circuit including the impact on both community pharmacists (training and professional practices) and on patients or carers.

2.2 | Population and data collection

All patients with severe haemophilia A with or without inhibitor, regardless of age and treated with emicizumab, were eligible. For those younger than 18 years old, a legal representative filled out the questionnaire, and for those aged 18 years old or older who needed assistance in completing the questionnaire, this was completed with the help of carers or relatives.

Two specific e-questionnaires were developed with common and adapted questions depending on the two ways of dispensation ([Supplemental Appendix](#)). Respondents could complete the survey from any devices (smartphone, tablet or pc) by flashing the QR-code or using the short url address. Public communication was performed through social medias (Facebook, Instagram, Twitter, LinkedIn) with the support of the French Patients Representatives (Association Française des Hémophiles, AFH), the national rare bleeding disorders network MHEMO (*Filière des maladies hémorragiques constitutionnelles*) and with the participation of the hospital pharmacists from the regional Haemophilia Treatment centre.

2.3 | Statistical and geographical analysis

To guarantee the patients' anonymity, a specific module was implemented in the questionnaires; the ArcGIS Survey 123 (Version 3.17.54) from the Esri company. This module allows the calculation of the door-to-door travel times between the place of residence or the workplace, to the community or hospital pharmacy, without saving the exact postal address of the patients, nor the pharmacy's address. The only data saved in the database was the calculated door-to-door travel time in minutes, based on the average traffic.

Although we collected the number of patients per household, we did not calculate travel time per household since only five respondents belonged to the same household. It is therefore assumed that all respondents of this survey are statistically independent individuals.

The collected data included the preferred place from which to travel to the pharmacy; the place of residence, the workplace or other place. When respondents specified their preferred place, they also provided the estimated door-to-door travel time in minutes. In some cases, respondents also provided an estimation of the travel time from their non-preferred place. Duration difference was calculated when both estimations were completed; 57/123 in the group of patients dispensing in community pharmacy and 28/52 in hospital pharmacy.

Patient-reported dosing errors can provide an interesting perspective on health literacy and numeracy,¹⁶ as they can reveal gaps in understanding of drug dosage. From the declarative data regarding the injection rhythm and the dose of emicizumab provided by the

respondents, the posology was a priori calculated following the recommendations of the European Medicines Agency.¹⁷ We deduced the dose (mg/kg) according to the injection rhythm; 1.5 mg/kg for one injection weekly, 3 mg/kg for one injection fortnightly and 6 mg/kg for one injection monthly.

Baseline characteristics were described by counts and percentages for categorical variables, medians and interquartile range for continuous variables, mentioned in brackets in the following order in the results section; community and then hospital pharmacy. Bivariate analysis was assessed using the Pearson chi-square test for categorical variables and the nonparametric Wilcoxon rank test for continuous variables. When the numbers per group were less than five respondents, the *p*-value was not provided, indicated by an 'X' in tables. Statistical analysis was performed using the open-source R 4.1.1 software (<https://cran.r-project.org/>). The level of significance was set at a *p* value < .05.

2.4 | Ethical consideration

The study complies with the reference methodology for studies and evaluations in the health field; therefore, it did not require written consent to participate. The ethics committee of the Hospices Civils de Lyon approved the study (n°2022-06-01 obtained on June 14, 2022). The PASO DOBLE DEMI II study was registered in ClinicalTrials.gov (NCT05450640).

3 | RESULTS

3.1 | Baseline characteristics of the patients

Between September 13, 2022, and January 9, 2023, 175 respondents answered the satisfaction survey, including *n* = 123 in community pharmacy and *n* = 52 in hospital pharmacy, distributed over the French territory (Figure 1).

With approximately 450 active community pharmacies dispensing emicizumab in France during the data collection, and one patient by community pharmacy in general, the response rate is about 27.3% (*n* = 123/450).

All patients were male with a large majority of adults, dispensing in community pharmacy (65.0%, *n* = 80) and hospital pharmacy (71.2%, *n* = 37). The proportions of adults did not differ in these two groups (*p* = .5422), like for the legal representatives of paediatric patients (*p* = .3111). The patient groups were age-balanced with no statistical difference, by age in 10-year steps (Table 1). At the time of the study, 78.9% of patients were treated with emicizumab in community pharmacy for less than 1 year, whereas 82.7% of the patients in hospital pharmacy were treated for more than 1 year.

Slight differences were observed concerning the rhythm of injection with significantly more patients in the community pharmacy injecting the product every 2 weeks (67.5% vs. 50.0%, *p* = .0444).

3.2 | Use and posology of emicizumab declared by respondents

The majority of respondents declared that they never forget their dose (79.7% vs. 73.1%, *p* = .4474). The respondents who declared a tendency to forget their injection did so for less than a quarter (17.9% vs. 25.0%, *p* = .3852). As well, 88.6% of the respondents reported that they never forget to renew their prescription (91.1% vs. 86.5%, *p* = .0530). Both respondents in community and hospital pharmacy were aware of what to do if they missed a dose (86.2% vs. 90.4%, *p* = .6048).

Less than 10% of respondents experienced practical difficulties when administering emicizumab (10.6% vs. 7.7%), mainly due to transfer of the drug into the syringe (7/13 vs. 1/4) and during the administration of the product (6/13 vs. 3/4). Among all the respondents, less than 5% (*n* = 6) indicated that they did not know the injection dose of emicizumab; four patients in community pharmacy, one representative of child patient and one carer of adult patient. For respondents who felt they knew their dose, nearly 60% of the respondents expressed the dosage in mg (61.8% vs. 54.0%, *p* = .5574), 42.6% of representative of child patients (44.0% vs. 38.5%, *p* = .5036) and three carers (*n* = 1 vs. *n* = 2).

When comparing the use of emicizumab between respondent's profiles, patients collecting treatment in hospital pharmacy tend to forget more frequently their dose than patients in community pharmacy (*p* = .2835), but the trend is reversed among parents of child patients (*p* = .4172) (Figure 2). The same pattern was observed concerning the knowledge of the course of action in case of forget the dose (*p* = .9884 for patients and *p* = .2371 for legal representatives of child patients). Respondents in hospital pharmacy forgot dose more frequently to renew the prescription (*p* = .6440 for patients and *p* = 1 for legal representatives of child patients). All respondents in hospital pharmacy estimated that they knew the dosage of emicizumab, whereas 5.0% of adult patients and 2.4% of legal representatives of child patients estimated the opposite. We observed most frequently inconsistencies in the declared dosage among the respondents in community pharmacy compared to respondents in hospital pharmacy (*p* = 1 for patients and *p* = .2250 for legal representatives of child patients).

3.3 | Travel times

Access to the community pharmacy is mainly by car (66.7% vs. 88.5%, *p* = .0053) or by foot (26.8% vs. 1.9%) while the preferred means of transportation to the hospital pharmacy is by car or public transport (1.6% vs. 5.8%). The majority of respondents come from their place of residence (91.1% vs. 86.5%, *p* = .5307). We observed that 8.1% of the respondents make the travel from their workplace to the community pharmacy compared to 13.5% to the hospital pharmacy (*p* = .4185). The respondents in the pharmacy estimated that they spent less than 10 min inside the community pharmacy, which is significantly lower than inside the hospital pharmacy (81.3% vs. 40.4%, *p* < .0001).

TABLE 1 Baseline characteristics of the patients.

	Dispensing in community pharmacy n = 123	Dispensing in hospital pharmacy n = 52	p-value
Age of the patients			
0–10 year old	21 (17.1%)	8 (15.4%)	.9584
11–17 year old	23 (18.7%)	5 (9.6%)	.2032
18–30 year old	16 (13.0%)	8 (15.4%)	.8593
31–40 year old	19 (15.4%)	6 (11.5%)	.6607
41–50 year old	15 (12.2%)	11 (21.1%)	.1970
51–60 year old	12 (9.7%)	6 (11.5%)	.9343
61–70 year old	14 (11.4%)	5 (9.6%)	.9382
+71 year old	3 (2.4%)	3 (5.8%)	X
Presence of inhibitor			
With inhibitor	20 (16.3%)	13 (25.0%)	.2546
Without inhibitor	95 (77.2%)	32 (61.5%)	.0521
Treated with emicizumab			
Since less than 1 year	97 (78.9%)	9 (17.3%)	<.0001
Since 1 year or more	26 (21.1%)	43 (82.7%)	<.0001
Injection rhythm			
Weekly	38 (31.0%)	24 (46.2%)	.0791
Fortnightly	83 (67.5%)	26 (50.0%)	.0444
Monthly	2 (1.6%)	2 (3.8%)	X

TABLE 2 Comparison of the estimated travel times of patients travelling to the pharmacy either from the place of residence, or from the workplace.

	Travel time in minutes ^a	The respondent estimated that the travel time from the place of residence compared to the workplace was:			Estimated mean time saving, in minutes	
		Inferior	Equal	Superior		
Community pharmacy (n = 57)						
–Preferred choice: place of residence	n = 47	5 [5;7]	34 (72.3%)	10 (21.3%)	3 (6.4%)	16.5
–Preferred choice: workplace	n = 10	6.5 [5;13.75]	2 (20.0%)	0	8 (80.0%)	7.0
Hospital pharmacy (n = 28)						
–Preferred choice: place of residence	n = 21	15 [10;25]	10 (48.0%)	7 (33.3%)	4 (19.0%)	8.7
–Preferred choice: workplace	n = 7	5 [5;10]	0	1 (14.3%)	6 (86.0%)	14.7

^aMedian [quartile 1 ; quartile 3] in minutes.

The text messages were revealed by patients as a communication mode with their community pharmacist (13.8% vs. 1.9%).

3.5 | Satisfaction regarding pharmacy of dispensation

In community pharmacy, patients were mainly completely satisfied (87.0%) and somewhat satisfied (10.6%) regarding the information

provided by the reference centre for haemophilia to integrate this new dispensing circuit. The satisfaction regarding the new dispensing circuit in community pharmacy was also very satisfying for patients (completely satisfied 86.2%, somewhat satisfied 12.2%).

Satisfaction levels were comparable to the prescription renewal process ($p = .5660$) and to the treatment advice ($p = .7596$), but differed significantly concerning the overall satisfaction ($p < .0001$), the travel time ($p < .0001$) and the relationship with the pharmacist ($p = .0022$) ($n = 172$ respondents represented in Figure 4). If

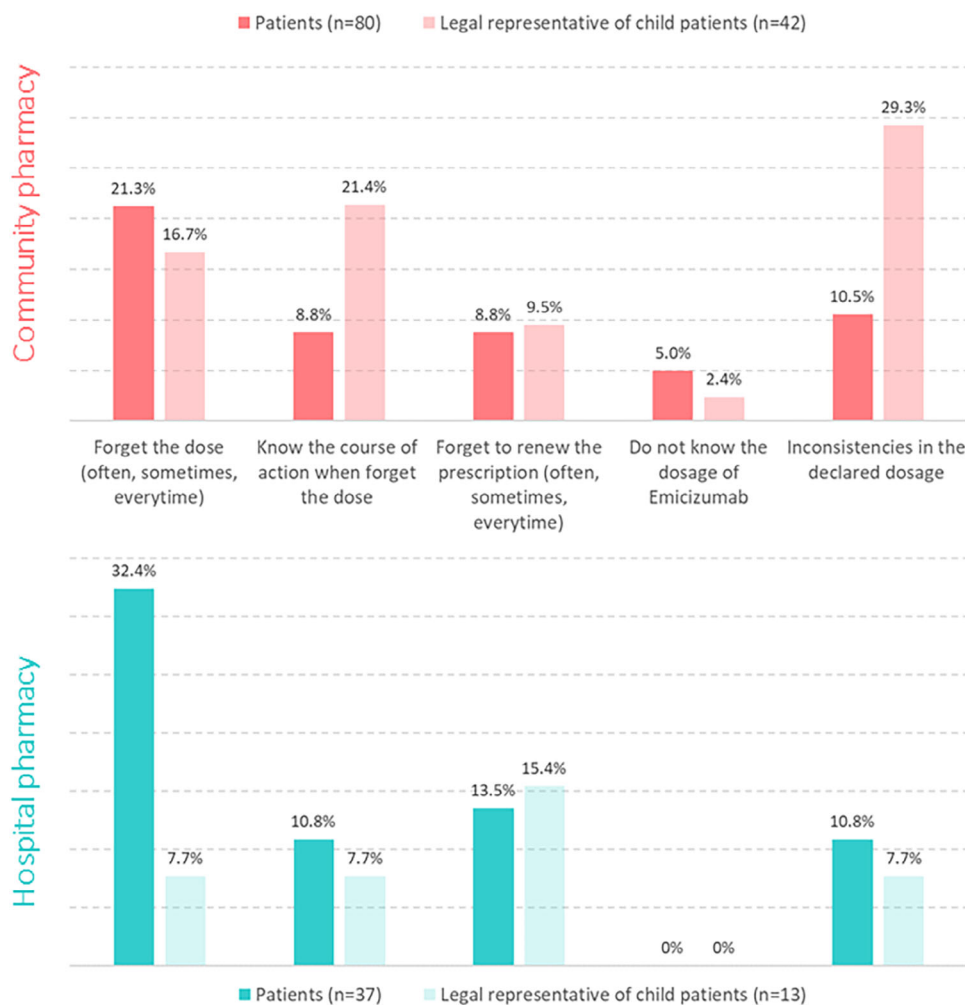


FIGURE 2 Use and posology of emicizumab depending on respondent's profiles (patients or legal representatives of child patients).

the patients themselves were equally satisfied with the pharmacy (51.9% vs. 55.3% of respondents completely satisfied, $p = .8088$), the representatives of child patients are significantly more satisfied from the dispensation in community pharmacy compared to hospital pharmacy (31.7 vs. 7.7%, $p = .0014$).

Among the carers who responded to the survey, one in community pharmacy was somewhat satisfied and two carers in hospital pharmacy were completely satisfied with the overall circuit for dispensation.

4 | DISCUSSION

Literature agrees that the patient preference takes a central place in the therapeutic decisions, especially for chronic diseases, engaging patients and carers in the long term adherence to medication strategy. While some algorithms proposed to define a patient-oriented process to determine the best treatment options or enable the best clinical outcomes,^{18,19} the PASO DOBLE DEMI study represents the first initiative in the literature to evaluate the evolution of the circuit of dispensing antihemophilic prophylactic treatment in hospital and community pharmacy.

Eighteen months after availability in French community pharmacies, treatment accessibility was significantly improved for the benefit of the patient; the door-to-door travel times were reduced to the community pharmacy, patients were mostly satisfied with the new dispensing circuit as shown in another study,²⁰ and safety and quality of the treatment administration were preserved. Also, the new scheme of care organization has made a place for the community pharmacists, with effective communication channels between healthcare professionals. Although we hypothesized a high level of literacy among patients and carers, a few inconsistencies in the declared posology were observed taking into account patients weights and injection rhythm. Further specific investigations must be performed to confirm the need for additional therapeutic education support and decision making to patients and caregivers.^{16,21}

The main limitation consisted in assessing the representativeness of the sample of respondents due to the constant evolution of patients having recourse to community or hospital pharmacy. Also, the information to participate relied on information for the general public on social networks and healthcare professionals in reference centre for haemophilia. The current representativeness of the collected sample is difficult to assess but the sample size of this national survey

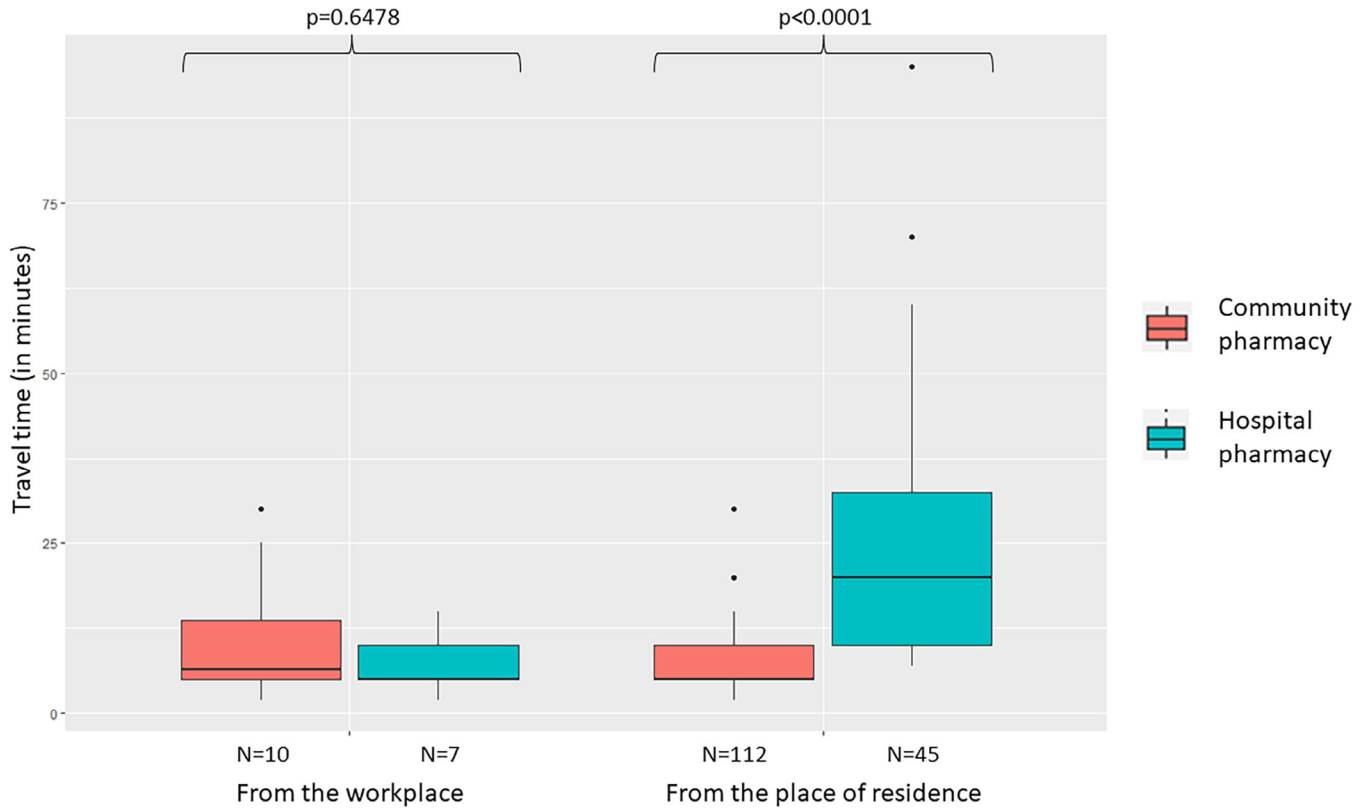


FIGURE 3 Comparison of the door-to-door travel times from the preferred place of the patient (residence or workplace) to the pharmacy for dispensing emicizumab (community or hospital pharmacy).

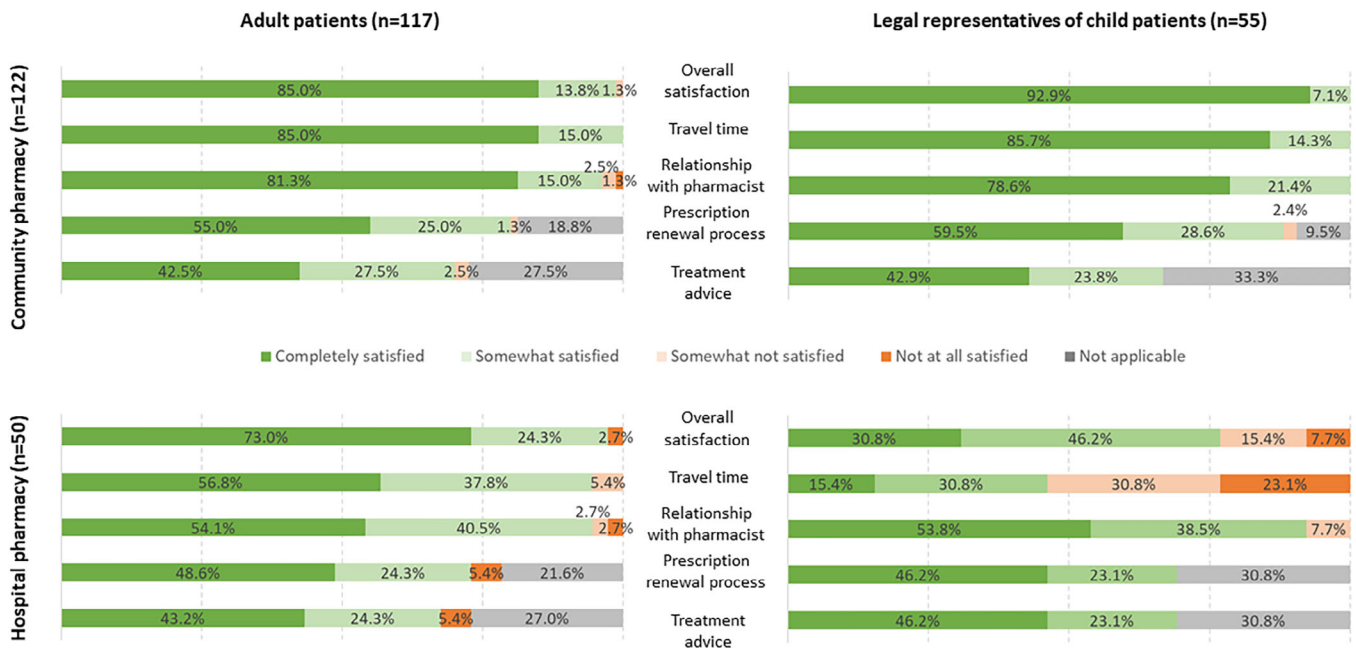


FIGURE 4 Satisfaction depending on the profiles of respondents (adult patients or legal representatives of child patients) whether choosing dispensation of emicizumab in community or hospital pharmacy (N = 172).

is consistent with other European studies,^{20,22,23} covering all ages of patients with no significant differences between community and hospital pharmacy, and all the French regions.

As another major limitation, the satisfaction levels were not assessed before the implementation of the dual dispensing circuit, so this study does not provide the evolution of the patient's satisfaction but rather the observation of the satisfaction after the introduction of the dual circuit. A recent regional observational study reported that the main determinants of dissatisfaction were parental burden (OR 2.5 [1.3; 4.8], $p = .008$) and waiting time at the hospital pharmacy (OR 1.5 [1.1; 2.0], $p = .016$, per 10 min increase).⁵

With 77.2% of patients without inhibitor in community pharmacy compared to 61.5% in hospital pharmacy, the comparison is borderline significant ($p = .0521$).²⁴ This difference is probably due to the fact that patients without inhibitor are less severe, and consequently more incentive and confident to choose the community pharmacy and away from the hospital professionals. We also observed that patients injecting every 2 weeks were more frequent in community pharmacy ($p = .0444$) which may reveal a strong self-engagement in improving quality of life and the personal habits for care.

Motivation for switching from the hospital to the community pharmacy rely partly on the pre-established relationship between the patient and the pharmacist.^{25,26} In addition, community pharmacists were more inclined to use innovative tools to maintain contact with patient or carers such as the mobile text messages.²⁷ Patients and carers were equally satisfied with the community pharmacist as with the hospital pharmacist.²⁰ Another initiative has been developed to improve the challenging treatment of haemophilia, particularly for patients who have limited access to haemophilia treatment centre or who have disabilities. This initiative involves the implementation of a mobile haemophilia outpatient care program.²⁸

One of the key findings of this study is that the dual circuit of dispensing is secure and in line with patient expectations. Consideration is being given to making other treatments available in community pharmacies, although this is more complex due to the need for emergency stocks in hospitals. Discussions are underway with the French authorities for health and patients association.

5 | CONCLUSION

Therapeutic innovation is widely documented in the scientific medical literature, but innovation in care pathways is now showing its full potential, and improving access to medication is one of them. The PASO DOBLE DEMI study showed that the dispensing in community pharmacies of a drug used in haemophilia treatment is possible and safe for patients. This dual circuit was made possible by the implementation of a rigorous organization and training program offered by the French Reference Centre for Haemophilia to enable healthcare professionals involved in primary care to provide appropriate management for patients with haemophilia.

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CONFLICTS IN INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ETHICS STATEMENT

The study complies with the reference methodology for studies and evaluations in the health field; therefore, it did not require written consent to participate. The ethics committee of the Hospices Civils de Lyon approved the study (n°2022-06-01 obtained on June 14, 2022). The PASO DOBLE DEMI II study was registered in ClinicalTrials.gov (NCT05450640).

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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