Improving patient access to hepatitis C antiviral medicines in Switzerland: understanding the financial risks for community pharmacies

Jérôme Berger[a,b], Aline Bourdin[a,b], Fatima Pires[a], Claudine Backes[a], Clémence Perraudin[a*], Olivier Bugnon[a,b*]

[*] co-senior authors

[a] Community Pharmacy Center, Department of Ambulatory Care & Community Medicine, University of Lausanne, Rue du Bugnon 44, CH-1011 Lausanne, Switzerland

[b] Community Pharmacy Practice Research, School of pharmaceutical sciences, University of Geneva, University of Lausanne, CMU 5-6, Rue Michel-Servet 1, CH-1211 Genève 4, Switzerland

Corresponding author:

Jérôme Berger
Community Pharmacy Center, Department of Ambulatory Care & Community Medicine, University of Lausanne, Rue du Bugnon 44, CH-1011 Lausanne, Switzerland
Phone: +41 21 314 78 55
Email: jerome.berger@hospvd.ch

E-mail addresses of authors:

AB: aline.bourdin@hospvd.ch
FP: fatima.pires@hospvd.ch
CB: claudine.backes@chuv.ch
CP: clemence.perraudin@hospvd.ch
OB: olivier.bugnon@hospvd.ch

Abstract

Rationale: As observed in other countries, some patients may experiment difficulties in obtaining their hepatitis C antiviral medicines (HCVm) in Swiss community pharmacies. There is a lack of data related to access to HCVm at the patient level, and notably related to the potential financial risks for the community pharmacies.

Aims : 1) To evaluate the potential financial risks for community pharmacist associated with the delivery of HCVm in the Swiss healthcare system; 2) to explore the attitudes and experiences of community pharmacists related to these risks and their consequences for the patients.

Method - A three-step approach was chosen as follows: 1) estimation of costs, incomes and gross financial results directly related to three-month treatment with Harvoni® based on the drug delivery process (data from 68 patients over two years); 2) sensitivity analyses; 3) exploration of local community pharmacists' attitudes and experiences related to the delivery of HCVm in the canton of Vaud (Western Switzerland).

Results - Two main risks were identified: 1) Incomes do not always cover costs; 2) Reimbursement issues could lead to an increase in the requirement for working capital. According to the survey, 23% (14/60) of pharmacies refused to deliver HCVm to at least one patient, and these patients had to find a solution mostly on their own.

Conclusions - The scenario analysis clarifies the causes of the possible refusal to deliver HCVm. With the growing number of high-priced medicines, the healthcare systems should have a clear strategy to encourage their delivery by community pharmacies by ensuring seamless and collaborative care for patients. The community pharmacists could be accountable to provide such services - if they get the education, training and remuneration.

Introduction

Hepatitis C is a worldwide major public health burden. Approximately 71 million people have chronic hepatitis C infection [1], including 40'000 in Switzerland (0.4% of the Swiss population) [2]. New hepatitis C antiviral medicines (HCVm) have markedly improved treatment efficacy and regimen tolerability. However, due to their high prices, many countries face challenges relating to patient access [3, 4].

In Switzerland, new HCVm (e.g. ledipasvir and sofosbuvir marketed under the tradename Harvoni®, or sofosbuvir marketed under the tradename Sovaldi®) have been approved since 2015 [5]. One package of ledipasvir and sofosbuvir (Harvoni®) costs CHF 14'631.30 (28 tablets) on the Swiss market [6], and two to three packages are needed for a full therapy cycle of eight to twelve weeks. These are reimbursed by basic compulsory health insurance according to certain conditions (Cf. online publication Box 1). As observed in other countries, some patients may experiment difficulties obtaining their treatment.

Community pharmacists' role has become more clinically and patient-oriented [7]. This is notably the case in the medication therapy management of HCV patients [8, 9]. Community pharmacists' should also facilitate the access to HCVm patients [4, 10]. Unlike other countries – e.g. in the United-States [4]- in Switzerland, HCVm delivery is not limited to hospital or specialty pharmacies. Any community pharmacy may provide such medicines. However, community pharmacies can face potential financial risks, as they must pay the wholesaler for the drug before receiving the corresponding reimbursement from the health insurance provider. Thus, the pharmacy may ultimately not be reimbursed for a medicine that has already been dispensed to the patient, e.g., in the absence of an agreement from the health insurer to guarantee the medicine's reimbursement and if the pharmacist does not check whether a prescription is inside the limited clinical conditions (Cf. online publication Box 1).

Access to HCVm has already been studied from a health systems perspective [3]. However, to our knowledge, there is a lack of data regarding the access to HCVm at the patient level, and notably related to the potential financial risks for the pharmacy that delivers the medicines.

The main objective of this study was to evaluate the potential financial risks for community pharmacies associated to the delivery of HCVm in the Swiss healthcare system. The second objective was to explore the attitudes and experiences of community pharmacists related to these risks and their consequences for the patients in the canton of Vaud (Western Switzerland).

Methods

A three-step study approach was chosen and consisted of the following: 1) estimation of costs, incomes and gross financial results directly related to the delivery of Harvoni® based on data from the Community Pharmacy Center (CPC) of the Department of Ambulatory Care & Community Medicine, University of Lausanne (Vaud, Switzerland); 2) sensitivity analyses to evaluate the impact of salary costs on the financial

results and extrapolation of these results to other community pharmacies; 3) exploration of local community pharmacists' attitudes and experiences around the delivery of HCVm.

First, all steps of the drug delivery process for a package of HCVm (including logistic services and cognitive pharmacist services) were described (Figure 1). Both time spent with the patient and on back-office work were taken into account. Three different scenarios ("usual", "simple" with all favourable parameters, and "complex" with all unfavourable parameters, according to clinical, therapeutic and organisational criteria; Cf. Table 1) were described and were based on the experience and time documented at the CPC for delivering HCVm to 68 patients (from June 2014 to June 2016). Cost estimates related to the delivery of a three-month treatment of Harvoni® (three packages) were compared for each scenario. Labour costs for technicians and pharmacists were estimated using the applicable Swiss salary scale in the canton of Vaud [11] (considering social security contributions, thus reflecting the full cost to the employer). The number of annual working hours corresponded to applicable normal working hours in Switzerland (42.50 h per week excluding holidays, absenteeism and down-time). Charges from banks (CHF 125.00), wholesalers (CHF 240.00) and billing service companies (CHF 18.00) were included *per se* in the analysis. General costs such as amortisation, rent or IT-related costs were not taken into account as these costs are difficult to estimate per prescription and can vary greatly between community pharmacies. Incomes including distribution margins (CHF 720.00) and FFS (CHF 22.65) are independent of cost and time spent and consequently were the same in all scenarios (Cf. online publication Box 1).

Second, a univariate sensitivity analysis was performed for each scenarios. This assessed the impact of the uncertainty generated by pharmacist and technician costs (±20%) as well as professional time spent (±20%), while leaving other parameters constant.

Third, the attitudes and experiences of community pharmacists in the canton of Vaud were evaluated using an online survey (Google Forms). Community pharmacies of the canton were invited to take part in the survey (n=249). Questions focused on the number of patients who had presented a prescription for HCVm in the last two years, the number of refused deliveries and the reason(s) for refusal, and patients' reorientation proposals to obtain the HCVm.

Results

The drug delivery process for a package of HCVm at the CPC, including the time according to the various scenarios, is described in Figure 1. The length of the whole process depended on the contract between each pharmacy and its billing office company (i.e. the shorter the reimbursement time, the higher the amount paid by the pharmacy to the billing office company). The whole process until the pharmacy received reimbursement took at least three months at the CPC. Sources of possible errors, omissions and repetitions

could increase the actual time required for each step (as illustrated in Figure 1 by the various times related to the three different scenarios).

Costs and incomes associated with the delivery of a three-month treatment of Harvoni® for the three scenarios are presented in Figure 2. In the “simple” and “usual” scenarios, the distribution margin and FFS covered the total cost of delivery: the delivery of the three-month treatment led to a gross benefit of CHF 456.00 in the “simple” scenario and CHF 399.00 in the “usual” scenario. In the “complex” scenario, delivery led to a direct gross loss of CHF 213.00. In the three scenarios, FFS did not cover the costs associated with cognitive pharmacist services.

Univariate sensitivity analyses demonstrated that the professional time spent showed more influence than labour cost on the financial results (Cf. Table 2). In each case, a gross benefit was obtained in the “simple” and “usual” scenarios, whereas a gross loss was always observed in the “complex” scenario.

Of the pharmacies invited to participate in the survey, 46% (114/249) responded. Approximately half of the respondents (53%, 60/114) had already encountered a patient with a HCVm prescription, and 23% (14/60) of these pharmacies had refused delivery to at least one patient. The main reasons cited for refusal were doubt regarding reimbursement (8/14), financial risk (6/14), and the commercial strategy of pharmacy chains (3/14). Patients were not always reoriented, and 71% (10/14) of the refusal cases had to find a solution on their own.

Discussion

The analysis of the time required to supply a patient with HCVm was based on the experiences at the CPC, but the results could be extrapolated to other pharmacies; the drug delivery process is the same in any community pharmacy, and labour costs and professional time had a minor impact on the financial results. However, with the CPC located in a university outpatient clinic as a community pharmacy, our experienced team was used to handling complex patients and HCVm, allowing for interprofessional interactions with in-house physicians. Consequently, the time estimates in this study are probably shorter than those that would be observed in most other community pharmacies. Therefore, the time estimates in our analyses (and consequently cost estimates) have to be considered as more favourable than in other pharmacies. All other things being equal, the financial results for other pharmacies would consequently be less positive than for our pharmacy.

The scenario analysis clarifies the causes of the possible refusal to deliver HCVm. The two main risks identified show that this attitude is understandable. Firstly, income does not always cover costs and the pharmacist has to ensure the financial sustainability of the pharmacy, as any manager of a private company.

The reimbursement value for pharmacists' services – set in Switzerland in 2001 – is probably no longer appropriate for the delivery of high-priced medicines, such as HCVm, since FFS never covers the cost of the basic cognitive pharmacist services. The healthcare systems should set up clear strategies to encourage the delivery of high-priced medicines, in favor of seamless and collaborative care of the patients. Secondly, doubts regarding reimbursement lead to increased requirements of working capital until the reimbursement is received or even to a direct loss in the case of non-reimbursement. The fact that patients were often not reoriented in cases of non-delivery was probably linked to the perception of these financial risks. Knowing that these risks were also evident to other colleagues, the community pharmacists probably did not have a clearly safe and local alternative to propose to the patient.

Depending on political decisions at health care system's and profession's levels, several alternatives are possible to allow patients to benefit from an individualised and seamless pharmaceutical care. The delivery of HCVm, and by extension of high-priced medicines, should be a clinical service proposed by each pharmacy willing to do so. In such case, the pharmacists' training should be included in the post-graduate curriculum, and the financial incentives should be appropriate. Such a specialty pharmacy service could also be limited to accredited pharmacies (e.g. as for immunization services in Switzerland). A network of specialty pharmacies that ensure the compounding of medicines for other pharmacies was created years ago in the canton of Vaud. Considering the growing number of patients under HCVm, the development of a similar model for HCVm could also be an alternative for pharmacists and patients. The systematic transfer of a copy of the agreement from the health insurer by the prescriber to the pharmacy (e.g., with the prescription) could also help community pharmacists mitigate potential financial risk. This would greatly facilitate HCVm, as well as high priced medicines, access for patients.

The main limitations of this study were linked to the fact that situations in "real life" are rarely as standardised as the scenarios that were analysed here (e.g., the clinical reality of a patient can be complex, but therapeutic and organisational aspects can be simple). However, our methodology allowed us to calculate a range of possible costs for each situation by determining extreme values. General costs were not taken into account since only direct costs linked to the delivery of HCVm were analysed. It is possible that in some situations, the gross financial result would not cover general costs. However, this study was not designed to answer these questions. Secondly, our case study, as well as opinion survey has been conducted in one Swiss canton. The reimbursement conditions being the same for all community pharmacies in the country, this model is generalizable at the national level. Moreover, the situation described for Harvoni® should be transposable to other HCVm (e.g. Sovaldi) as well as to other high-priced medicines introduced in different therapeutic areas (e.g., cancer, hepatitis, HIV).

Payment schemes and reimbursement systems vary greatly from country to country, which limits our ability to compare these results internationally. However, the worldwide trend towards an FFS system and the increased availability of expensive and complex drugs have created a shared challenge.

Conclusions

This study of patient access to high-priced HCVm in the Swiss canton of Vaud highlights the financial risks and the limitations of the Swiss reimbursement scheme for pharmacists' services. With the growing number of high-priced medicines, the healthcare systems should have a clear strategy to encourage their delivery by community pharmacies by ensuring seamless and collaborative care for patients. The community pharmacists could be accountable to provide such services - if they get the education, training and remuneration.

Funding

This research did not receive any specific grants from funding agencies in the public, commercial, or not-for-profit sectors.

Conflicts of interest

None to declare.

Acknowledgements

The authors thank the *Société Vaudoise de Pharmacie* for supporting the distribution of the questionnaire. We thank all respondents for their time and the collaboration to this research.

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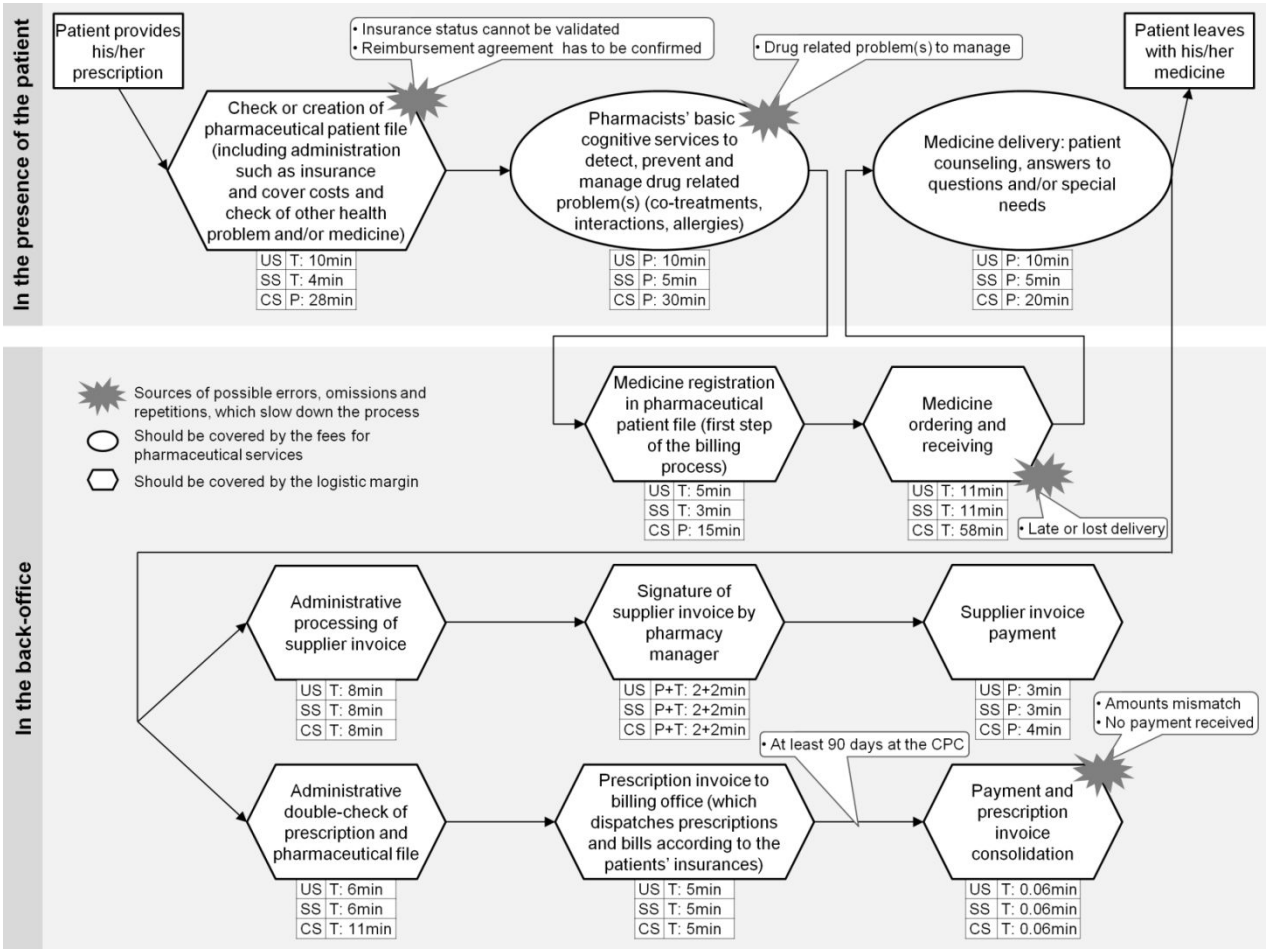
Figure 1: The drug delivery process (including time according to the various scenarios) for a package of hepatitis C antiviral medicines (logistic services and pharmacists' basic cognitive services) at the Community Pharmacy Center of the Department of Ambulatory Care & Community Medicine at the University of Lausanne (Vaud, Switzerland)



CPC: Community Pharmacy Center of the Department of Ambulatory Care & Community Medicine at the University of Lausanne (Vaud, Switzerland); CS: Complex Scenario; P: Pharmacist; SS: Simple Scenario; T: Technician; US: Usual Scenario

Figure 2: Gross financial results according to the three different scenarios (usual, simple and complex) of delivery of a 3-month treatment of Harvoni®

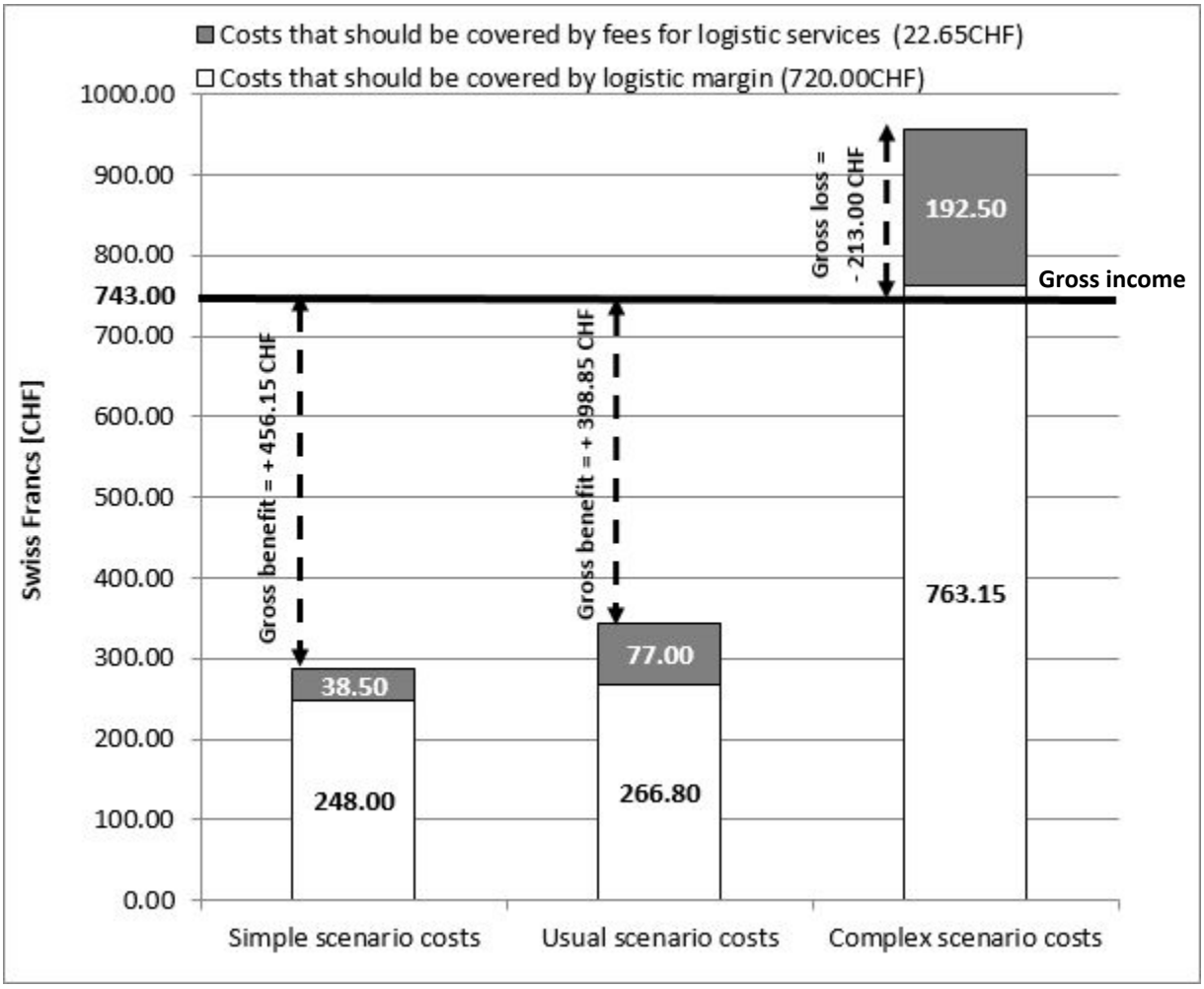


Table 1: Criteria used to compare three different scenarios of hepatitis C antiviral medicine delivery in a community pharmacy.

Criteria	Scenarios of hepatitis C antiviral medicine (HCVm) delivery		
	"simple"	"usual"	"complex"
Clinical	Patient without other health problem		Patient with other health problem(s)
	No other medicine is taken	Patient takes a maximum of 3 other medicines (mostly OTC and natural medicines)	Patient takes more than 3 medicines (mostly Rx)
	No drug-related problem[1]	Drug-related problem(s) managed by the pharmacist alone	Pharmacist must contact the physician to manage drug-related problem(s)
Therapeutic	HCVm prescribed in accordance with the approved indications and within the restricted medical indications	HCVm not prescribed in accordance with the approved indications or outside the restricted medical indications	
	Copy of the reimbursement agreement is transmitted to the pharmacy	Copy of the reimbursement agreement must be requested by the pharmacy	
	No further check of the reimbursement agreement is needed	Simple check of the reimbursement agreement is needed (e.g., confirm information by mail with the physician)	Thorough check of the reimbursement agreement is needed (e.g., contact health insurance to confirm it)
	Patient has usual questions (e.g., missed dose)	Patient has specific questions (e.g., travelling)	
	Patient has no special needs		Patient has special needs (e.g., adherence support)
Organisational	Pharmacist is only involved in basic cognitive services (e.g., checks for drug-related problem and patient advice). Technician executes the complete logistic workflow.		Pharmacist is also involved in the logistic workflow, with the help of a technician.
	HCVm in stock at the pharmacy	Simple order of HCVm is needed (e.g., standard mail order)	Special order of HCVm is needed (e.g., express mail order)
	No charge from the wholesaler		Special charge from the wholesaler

HCVm: hepatitis C antiviral medicines; OTC: over-the-counter medicine (that do not require a prescription from a physician); Rx: prescription medicine

[1] Definition according to http://www.pcne.org/working-groups/2/drug-related-problems

Table 2: Univariate sensitivity analysis assessing the impact of the uncertainty generated by pharmacist and technician costs as well as professional time spent linked to the delivery of Harvoni® other things being equal.

	"Standard scenario"	"Simple scenario"	"Complex scenario"
Base case	**+ 398.85**	**+ 456.15**	**- 213.00**
Pharmacist cost [Base case = 77.00 CHF/h]			
Low: 62 CHF/h	**+ 416.85** (+4.5%)	**+ 466.65** (+2.3%)	**- 139.50** (-34.5%)
High: 92 CHF/h	**+ 380.85** (-4.5%)	**+ 445.65** (-2.3%)	**- 286.50** (+34.5%)
Technician cost [Base case = 47.00 CHF/h]			
Low: 38 CHF/h	**+ 419.57** (+5.2%)	**+ 473.27** (+3.8%)	**- 175.63** (-17.5%)
High: 56 CHF/h	**+ 378.12** (-5.2%)	**+ 439.02** (-3.8%)	**- 250.38** (17.5%)
Professional time [Base case: see Figure 1]			
Low: -20%	**+ 437.73** (+9.7%)	**+ 483.57** (+6.0%)	**- 99.75** (-53.2%)
High: +20%	**+ 359.96** (-9.8%)	**+ 428.72** (-6.0%)	**- 326.26** (+53.2%)