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DEPIST'C PHARMA : An innovative outreach HCV screening project in pharmacy for general population

REMY Andre-Jean[1], ALBERT Olivier[2], PUGET Eric[3], FONTAINE Sebastien[1], H BOUCHIRA Hakim, HERVET Jeremy[1], ROY Berengere[1], HAPPIETTE Arnaud[1]

[1]Mobile Hepatitis Team, Perpignan Hospital, France
[2]Pharmacy du Port, Port La Nouvelle, France
[3]harmacy Poirotte, Perpignan, France

ABSTRACT

Background and Aims: Hepatitis C testing is still insufficient in France. Beyond defined groups with risk behaviors, hepatitis C testing should now be directed at the general population. The French pharmacies territorial coverage is excellent, and pharmacists are increasingly involved in public health actions (therapeutic education, vaccination against the flu). French Public Health Act on Innovation thank to the "Article 51" allow enables health care teams to propose experiments aimed at improving the diagnostic and/or therapeutic management of a disease. This funding methods and organization is unprecedented. Our aim was to screen for hepatitis C in pharmacies with POCT performed by pharmacists. **Methodology**: Pharmacist recruitment was done on a voluntary basis from different pharmacies on a population pool of 600,000 inhabitants. Pharmacists received training and education appropriate to the POC testing. At request of the health authorities, screening was only proposed for patients with one or more risk factors (national health agency list). There were planned 10 tests per week per pharmacy over 12 months for a total of 5,000 tests. Expected prevalence was 10%. Patients with positive POCT were tested for HCV viral load real-time and for liver fibrosis assessment by FIBROSCAN. They could be treated with HCV antiviral direct agents. **Results**: 37 pharmacists representing 32 pharmacies were trained to POCT use and announcement of results during 4 half days session. 9 pharmacies were located in agglomeration, including 5 in working-class areas, 7 in rural area, 7 in seaside area and 2 in middle mountain

***Correspondence to Author:**
REMY Andre-Jean
Mobile Hepatitis Team, Perpignan Hospital,20 Languedoc avenue, 66046 Perpignan, France

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area. After 18 months of experimentation, 29 pharmacies have completed at least one POCT. We observed a decrease in the number of tests performed during the flu vaccination campaign and COVID pandemia and successive lockdowns; 547 tests were performed including 9 positives or a serological prevalence of 1.6%.; 7 patients had a negative viral load with 1 or 2 risk factors and a Fibroscan mean value at 4,5 KPa [fibrosis stage F1]; 2 patients had positive HCV viral load [prevalence 0.36%] and 3 to 9 HCV risk factors, mean Fibroscan value at 8.6 KPa [fibrosis stage F2]. They all were effectively treated and cured by direct antiviral agents. **Conclusion**: We have demonstrated the feasibility of hepatitis C screening by POCT performed by pharmacists regardless of geographic location. Prevalence was similar as general population. Targeting screening by risk factors does not identify all patients. Pharmacists represent very interesting local healthcare professional who could invest in COVID19 screening by POCT.

Keywords: hepatitis C, screening, pharmacists, POCT

Introduction

The objective of this project is to carry out the detection of hepatitis C in city pharmacies, actors of local care, effectively linking the territory and allowing to address the general population. The project consists of providing recruited and trained pharmacies with rapid diagnostic referral tests [POCT] for HCV for individuals with one or more risk factors for hepatitis C, identified from a questionnaire, and thus be able to reach a population ignorant that it is carrier. The ambition is to include 10 pharmacies in the territory of experimentation [GHT Aude Pyrénées], with a screening to the tune of 10 tests per week per pharmacy over 12 months of study, that is the realization of 5000 tests. The expected prevalence is 10%, corresponding to 500 positive tests for HCV in pharmacies. The positive viral load expected of these patients is 60%, which should result in the initiation of antiviral treatment for 300 new patients at the end of the project. Project strategy is outlined below. The diagram shows the breakdown of the project's strategic objectives [which correspond to the expected impacts] into more specific objectives [which correspond to the expected results] and then into operational objectives. KIDEPIST study conducted between September 2017 and September 2018 showed value of including the general population in hepatitis C screening and not just "at-risk group" populations. In this study, 170 patients were included in Perpignan, of varied origin and not only from a population at risk of drug users, inmates or migrants [1].

Hepatitis Mobile Team [HMT] was created in July 2013 to increase screening care and treatment of hepatitis B and C patients [2-7]. HMT was composed of one hepatologist, three nurses, one secretary, one social worker, one health care worker, for a cross-disciplinary approach. Our goal was to increase outreach screening care treatment access and cure of our target population. Target population was drugs users, prisoners, homeless, precarious people, migrants and psychiatric patients. We proposed part or all of our services to our medical and social partners. There were 15 services for 92 medical and social units in 600 000 people area. There were 4 steps: for early detection and primary prevention 1. screening by Point of Care Testing PDBS [dried blood test] for HIV HBV HCV 2. Green thread: outside POCT/DBS and FIBROSCAN** in specific converted van. 3. Outreach open center 4. Drug users information and prevention 5. Free blood tests in primary care for patients without social insurance 6. Staff training. For linkage to care and fibrosis

assessment: 7. Social screening and diagnosis [EPICES score] 8. Mobile liver stiffness Fibroscan* [indirect measurement of liver fibrosis] in site 9. Advanced on-site specialist consultation. For access to treatment: 10. Easy access to pre-treatment commission with hepatologists, nurses, pharmacist, social worker, GP, psychiatric and/or addictologist. 11. Low cost mobile phones for patients. For follow up during and after treatment 12. Individual psycho-educative intervention sessions 13. Collective educative workshops 14. Peer to peer educational program 15. Specific one day hospitalizations. All services were free for patients and for our 92 partners in 44 different . from 2013 July to 2022 December, we did 8848 DBS for 8332 people [4918 HCV DBS] and 3728 FIBROSCAN*. HCV new positive rate was 21.7%. Our HCV active file was 114 patients included these 21.3% new patients screened by DBS; 98% realized HCV genotype, HCV viral load and FIBROSCAN. DAA treatment was proposed to 96%; 95% started treatment, 2% were lost follow up and 3% refused treatment. After treatment, there was 12 relapse and 34 reinfections by drug injection [3.2%]. Our cured rate was 97%. Sociological evaluation of our program showed that 4 program qualities for patients were free access, closeness [outside hospital], speed [of the results] and availability [of nurse and social workers].

Day 1:

- Practical assessment and needs of pharmacists
- HCV Knowledge Update
- Place of local screening in prevention, risk reduction and access to care

Day 2

- Legal and ethical framework for the use of POCT
- Hygiene rules
- Rights and duties of the responder and the person screened
- POCT operation and use
- Hands-on learning of POCT use
- Hands-on handling exercises

Day 3

- Pre-Test and Post-Test Interviews: counselling, posture, interview content, communication of results, positive and negative, orientation
- Practice between all participants
- Patient linkage to care

Figure 1 : pharmacist training program

- Transfusion history prior to 1990
- Major surgery before 1990
- Whether or not single injection drug use
- Even single nasal use of drugs
- Handmade tattoos
- History of incarceration
- Maternal-Fetal Transmission from a woman positive for HCV
- Medical or odontological care under unsanitary conditions
- In HCV endemic country

Figure 2 : HCV risk factors

Step 1: Questionnaire to assess risk factors

- Pharmacists or pharmacy preparers propose a questionnaire to detect risk factors for patients in the pharmacy who have one or more "visible" risk factors ("indirect" targeting) or
- The customer, through the communication posters and flyers deployed in the pharmacy, expresses the request to be tested. The pharmacist offers the questionnaire with the risk factors to identify them and judge the relevance of conducting a POCT

Step 2: Collecting Consent

- If individuals have one or more risk factors, pharmacists collect their consent to participate in the experimental device DEPIST'C. A consent collection regarding the collection, storage, sharing and use of data is required. In order to obtain informed consent, pharmacies must post posters explaining the diagnostic process and orally explain the principle of the project.
- In case of non-consent, the person's journey stops. The pharmacist then gives him an information flyer.

Step 3: Perform HCV POCT screening

- If the person's consent is obtained, the pharmacist performs a screening via a HCV POCT previously provided by the THS.

Step 4: Orientation to appropriate medical management.

- If the screening is negative, the pharmacist explains the results, the patient's file is completed in the dedicated database and archived.
- If tested positive:

- Pharmacist informs DHS for appointment booking with patient.

The EMH support includes the following steps:

- Conducting a blood test with real-time C viral load measurement (and, if necessary, additional POCT HIV and/or HBV tests)

- An evaluation of the degree of liver fibrosis by Fibroscan

- At the same time as positive screening, the patient's doctor is informed by sending a standard report by fax or e-mail. This letter informs that the patient has "hepatitis C cured with no indication of treatment", or "hepatitis C cured with no indication of treatment with significant fibrosis to be explored" or "hepatitis C with indication of treatment".

This device allows to ensure a longer-term support adapted to the results. This can be done in a hospital setting or as part of a "Test to Treat" session as carried out by the MHT in its T3T (mobile screening structure) experiment project.

The patient may also choose to be followed by another hepatogastroenterologist than the MHT.

Figure 3 : HCV pathway

Preliminary implementation of the system

The project leaders were able to carry out first experiments of the device in 6 pharmacies in their region in May 2018. To do this, pharmacists were trained on hepatitis C [general knowledge of the disease]. Subsequently, the POCT could be carried out in the dispensary by nurses of the Mobile Hepatitis Team. These results of this preliminary device have been very positive, especially in terms of the membership of the staff of the pharmacy, pharmacists and preparers. This led the porters to consider the implementation of POCT directly by pharmacists. The project takes place in the Pyrénées-Orientales and Aude area. Geographical perimeter was chosen because of the high prevalence of hepatitis C in the region compared to the national average. Project

sponsors belong to the Hepatitis Mobile Team. This multidisciplinary team consists of a hepatologist, nurses, a secretary, a social worker and a social-health mediator. It provides free services for people with hepatitis C or for medical-social structures such as training and biological assessment. To be able to participate in the project, the participating pharamcies had to have a room adapted to confidentiality and a DASRI circuit [waste of infectious risk care activities] compliant. Before the testing was carried out, pharmacies signed an agreement with Perpignan hospital, under the aegis of pharmacist professional union. Pharmacies were then to undergo training, the provisional programme of which was provided by project promoters [figure 1]. If individuals have one or more risk factors, pharmacists collect their consent to participate in study. Patients must be over the age of 18. The recognized risk factors for hepatitis C are known [figure 2]. A collection of consent regarding the collection, storage, sharing and use of data is required. If user's consent is obtained, the pharmacist performs a screening via a HCV POCT. In order to obtain informed consent, pharmacies and surrounding medical offices must post posters explaining the diagnostic process and pharmacists must verbally explain the principle of the project. If the screening is positive, the patient is directed to management with the Hepatitis Mobile Team either on the premises of the pharmacy [in the format of a «Test to Treat» session] or on the premises of the medical team at Perpignan hospital. Before leaving participating clinic, patients who have received a positive or negative test, and the officinal teams, complete a satisfaction questionnaire to evaluate the device, especially on the theme of service to users. Management by the Mobile Hepatitis Team is in the same format as a "Test to treat" session and includes the following steps: real-time C viral load blood work-up [and if necessary additional POCT HIV and/or HBV tests]and an evaluation of liver fibrosis by Fibroscan ®. At the same time as a positive test, the patient's doctor is informed by sending a standard report by telephone or e-mail. This letter informs if the patient has "Hepatitis C cured with no indication of treatment", or "Hepatitis C cured with no indication of treatment with significant fibrosis to be explored" or "Hepatitis C with indication of treatment". For the volunteer pharmacies participating in the project, pharmacists are paid 14 euros per positive test and 4 euros per negative test; this is a graduation of the remuneration in the fixed part of the pharmacist. A communication to the general public and health professionals about the project was made in the form of press releases. A press conference to launch the device took place on 24 September 2019. The voluntary pharmacies ensured a communication of the project Depist'C via flyers and posters distributed by the promoters of the project. A day of training was dedicated to the preparation of pharmacies. Satisfaction questionnaires were distributed at the end of each day. Knowledge of hepatitis C [12-question evaluation] was evaluated with pharmacists; over 70% of correct answers were obtained.

In order to be able to participate in the project, the pharmacies must have a confidentiality room and a waste circuit of infectious risk care activities compliant. In advance of testing, pharmacies sign an agreement with the Centre Hospitalier de Perpignan, under the aegis of the regional union pharmacists professional union of pharmacists. The pharmacies were then to undergo training, the provisional programme of which was provided by the project promoters.

Each pharmacy committed to:

- Initial and then further training at 6 months of project launch

- Propose a POCT in the presence of one or more risk factors

- Perform 5-10 tests per week for one year

- Participate in a year of experimentation as soon as the agreement is signed

Pharmacists were paid differently depending on whether the HCV POCT was positive or negative. Their remuneration, set out in the

experimental specifications, is €14 in the case of a positive test against €4 in the case of a negative test. In the case of a positive POCT in pharmacies, a package of 181€ is then invoiced by the MHT to the Health Insurance to cover the costs related to the realization by the MHT of a Fibroscan, a measure of viral load and a specialized consultation with a doctor in order to implement an appropriate therapeutic strategy.. HCV pathway proposed in the experiment was detailed in figure 3.

The DEPIST C PHARMA project was selected under the national scheme Article 51. As such, the project is experimental and funded for a period of 18 months, initially extended to 27 months. This evaluation should make it possible to assess the operationality of the scheme, its effectiveness and efficiency and the reproducibility of the project in other territories.

The data collection phase of the intermediate and final evaluation combines a set of complementary tools adapted to each stakeholder profile and the nature of the information sought. The following table summarises the collection method envisaged by actor profile, with the indicative number of targets for each of the phases: Mobilization of the project monitoring data collected by the MHT and possible reprocessing of this data in order to make them usable for their analysis [project delivery data, results of screening and satisfaction questionnaires distributed to patients and evaluation questionnaires distributed to training participants] The main challenge concerning the mobilizable nature of the data consists in the reprocessing of the data collected by the MHT as part of the project monitoring in order to feed the selected indicators. The project consists in making available to recruited and trained pharmacies, POCT for HCV to individuals with one or more risk factors for hepatitis C, identified from a questionnaire, in order to reach an ignorant population that it is a carrier. The DEPIST C Pharma project is innovative in that it responds to the institutional desire to strengthen hepatitis C prevention through innovative actions «to go towards» target audiences, provides a specific mobile structure for coordinating drug testing in pharmacies [and management in the event of positive testing], involves new actors in drug testing: pharmacists, with a specific training specially created, offers a population screening targeted by pharmacists on the basis of a questionnaire of risk factors, ensures a management «everything in hand» rapid, from pharmacy screening to medical management and then MHT treatment proposal, implements innovative “out-of-walls” viral load screening and measurement tools and develops an unprecedented coordination between pharmacies on the one hand and a hospital team on the other. The experiment was planned to last 18 months from the date of inclusion of the first patient.

Results

The experiment began on 30 September 2019 with the inclusion of the first patient. an end was expected in March 2021. However, the Order of February 19, 2021 amended the Order of June 26, 2019 and extended the experiment to 27 months instead of 18 months, an end to December 31, 2021.Two additional days of training on the use and interpretation of HCV POCT were completed on November 22 and 29, 2019, resulting in the training of 16 additional pharmacists. A meeting between participating pharmacists was scheduled for January 28, 2020.

The geographical scope of the project is the GHT Aude-Pyrénées, which is home to the CH de Perpignan and covers a population of 600,000 inhabitants in the Pyrénées-Orientales department and the Narbonne health region. The geographical scope was chosen because of the high precariousness of the region with important indicators of precariousness, «indirect» risk factors for hepatitis C. Indeed these area group together 13.7% unemployed [3rd department of Metropolitan France], 10.7% of beneficiaries of the supplementary CMU [compared with 6.8% on a national average],

105 social income beneficiaries per 1000 inhabitants [the 1st department]. The Narbonese territory wass in these same characteristics.

Not all study objectives were achieved :

1/effective implementation with nclusion of 10 pharmacies : exceeded target , 23 pharmacies recruited

2/ place of realization: Aude Pyrénées Territorial coverage of 23 pharmacies well overlapping the territory of the GHT with distribution rural and city territory

3/ 18 months of experimentation : time lag with COVID crisis and extension to 27 months

4/ overall goal of5,000 tests : only 547 HCV POCT or 10% of target achieved

5/ screening of 10 tests per week per pharmacy : target not met with on average, the number of POCT tests performed is 23 per pharmacy over 27 months or less than one per pharmacy per week [0.88 tests/pharmacy/month 0.22 tests/pharmacy/week]

6/ anticipating prevalence in screening was 10%, corresponding to 500 positive tests for HCV in pharmacies : 9 patients with a positive POCT out of 547 or 1.6% positivity

7/ anticipation of viral positivity 60% : 2 in 9 people with a positive viral load or a viral positivity of 22%

8/ anticipation of antiviral treatment: was 300 new patients [6%] : only 2 people with a positive viral load were put on treatment [finalized] or 0.4% of the population tested

Discussion

The pharmacist, a front-line health actor

Pharmacies cover the entire territory and pharmacists are trusted health professionals for the French, [97% of French people trust their pharmacist according to an April 2020 FIFG survey] 1. Every day, 4.5 million people visit a pharmacy. Pharmacists have also become local public health actors through vaccinations [seasonal flu, COVID] and POCT [angina, COVID]. The DEPIST C PHARMA experiment aims to put pharmacies on the front line to help eradicate HCV by proposing the realization of POCT hepatitis C for people in the general population, clients of pharmacies, who present risk factors, as defined by HAS3.

Pharmacist participation greater than expected

The wearer [MHT] managed to mobilize 23 pharmacies [against 10 provided for in the specifications], allowing to have a well distributed territorial network within study area. Both rural and urban areas were covered, allowing for a heterogeneity of experimental situations and potential patients. The THS was able to recruit and train pharmacists within the time constraints. The training was appreciated and allowed pharmacists to update their knowledge on hepatitis C. The MHT was able to set up conditions for piloting and implementing the device allowing its operation and deployment in voluntary pharmacies recruited. The participating dispensing chemists had the necessary equipment. The experiment, which was planned to last 18 months from September 2019, has been extended, in view of the health crisis mobilizing pharmacists, to end in December 2021, a total duration of 27 months.

The objectives of the experiment are not achieved. The specifications provided for 10 POCT per week and per pharmacy for 50 weeks or 5,000 people screened of which 500 were expected POCT positive and ultimately 300 patients put on treatment. The mobilization of the 23 participating pharmacies for 27 months made it possible to carry out only 547 screenings, 9 of which were positive and only 2 patients with an active viral load were finally able to be put on treatment. The number of people screened is almost 10 times less than what was expected in the specifications, the positivity rate observed at the POCT is 1.6% against 10% initially expected and the active viral load and then the start of treatment corresponds to 0,4% of the population tested against 6% expected. No pharmacy has met the volume targets set out in the specifications and the observed prevalence is much lower than expected. Mobilizing

pharmacists [influenza vaccine campaigns and then Covid] to carry out POCT, as well as the issue of targeting/pre-selection were difficult in light of the rather broad risk factors5 and may explain the poor results, despite “remobilization” actions by the MHT. The pharmacists interviewed confirmed their interest in this experiment, but they also pointed out that the risk factor questionnaire, composed of 19 questions, is too dense and thus discourages the public from completing it. The risk analysis of those screened indicates that nearly one in three people who performed a POCT had a piercing [including earrings] or tattoo.

These characteristics, sometimes more visible than other risk factors, are easier to spot by the pharmacist but are very widespread in the general population. Thus the pharmacy screening proved to be akin to screening in the general population, as the positive figures confirm Over 27 months of experimentation, 9 patients were tested positive [8 invoiced] including 2 under treatment, Main objective of the project to contribute to the eradication of Hepatitis C.

Occitania is one of the four regions most affected by HCV in France, along with Ile-de-France, PACA and Guyana. If the health context [vaccination, Covid screening, etc.] has significantly reduced the availability of pharmacists for screening, It should be noted that many public health actions entrusted to pharmacists over the period will be sustainable and must be taken into account in their workload.

Pharmacists have also faced challenges in identifying and addressing potential patients, with risk factors being broad and questionnaires difficult to address. Results indicate that the strategy tested here is more similar to a general population screening not recommended by national health agency [8].

Conclusion

HCV elimination goal was 2030 for WHO [9-10] and 2025 for France [11-13]. POCT/DBD were useful tools for HCV screening [14]. We have demonstrated the feasibility of hepatitis C screening by POCT performed by pharmacists regardless of geographic location. Prevalence was similar as general population. Targeting screening by risk factors does not identify all patients. Pharmacists represent very interesting local healthcare professional who could invest in COVID19 screening by POCT and public health actions like vaccinations and colorectal cancer screening. Another experimentation of hepatitis screening could be done like in Spain [15].

Abbreviations:

DAA direct antiviral agents

DBS dried blod test

HCV hepatitis C virus

MHT Mobile Hepatitis Team

POCT point of care testing

T3T test to treat sessions

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