

A Nurse Model of All Inclusive Care in The Era of Direct Acting Antiviral Therapy for Hepatitis C Virus Infection: One Year First French Experience

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ABSTRACT

Introduction: Mobile hepatitis team (MHT) was created in 2013 and cured almost 1000 HCV patients in 10 years in an outreach and test to cure approach. MHT used HCV POCT, HCV real time viral load by GENEXPERT system, liver fibrosis measure by FIBROSCAN and nurse DAA prescription. The missing link from a “all in one” nurse care was DAA prescription which requires a doctor. Methodology: using a health local protocol, our trained nurses could prescribe DAA to no cirrhotic HCV patients and follow up until sustained virological response.

Results: As of December 31th, 2023, 39 out of 89 HCV patients in the Viral Hepatitis Expert Service benefited from this protocol, or 44%. Detailed results were detailed on Table 2. Twelve patients were in a situation of recontamination by drug use (31%), 75% in the same living area. Treatment compliance was 95% for the group of patients treated with IDE versus 90% for patients treated by the hepatologist. The main differences between the two groups were less men, younger age, reinfection status, more patients starting treatment at day of DAA prescription and no death in nurse prescription group.

Conclusion: Our results support the hypothesis that an all care nurse model of care is equivalent to hepatologist management of HCV infection. It is a simple and effective tool that frees up physician time, enhances nursing work. There are no disadvantages highlighted after one year of operation. After validation by the national high authority of health, this protocol can be applied to other teams in France.

Keywords: Direct acting antiviral agents; HCV; Nurse

INTRODUCTION

In 2016, the World Health Organization (WHO) set an ambitious goal to eliminate hepatitis C as a major public health threat by 2030 [1]. Specific targets include increasing sterile needles/syringes distributed from 20 to 200 per person per year for PWID, reducing new hepatitis C infections by 80% and hepatitis C-related deaths by 65%, increasing hepatitis C diagnoses from <20% to 90% and the number of people receiving hepatitis C treatment from less 10% to 80%. Drug injection was main contamination route of hepatitis C virus (HCV) in France and western Europe since 1990 [2]. Although highest European HCV screening rate in France, 33% of patients didn't take care of hepatitis C because there were no diagnosed [3]. On 2018, the International Network of Hepatitis in

Substance Users (INHSU) published recommendations for good practices about HCV pathway on drug users [4], Emphasizing the treatment of all drug users to minimize contamination and re-infection.

From 2016 French Health Ministry guidelines and French hepatology association recommendations (5-6) were to treat all inmates and drug users, even fibrosis level with direct antiviral agents (DAA). Also, HCV treatment for all was effective in France since 2017. Success rate of DAA, one or two pills per day for 8 or 12 weeks' therapy, was 95 to 97%. Before that, access of HCV screening, care and treatment in drugs users, prisoners and homeless was low in France. They were considered as difficult to treat populations. All these patients need support especially psycho-educative interventions. Perpignan (in south of France) is very low-income area of 600 000 people. There were many active drugs users. Main characteristics associated local insecurity therefore low-price cocaine, national attractiveness for consumers and traffickers, overconsumption with these lower price, local manufacture of cannabis and road transport effects redistribution of drugs purchased in Spain. This was the only place in France where coke rail was sold between 2 to 5 dollars, 50% lower than the price in the rest of France. There was also high number of homeless including women and children and community migrants. The Mobile Hepatitis Team (MHT) was set up in 2013, following the publication of an scientific report on reducing risks of infection amongst drugs users in 2011 [2], which recommends screening all drug users for HCV and establishing multidisciplinary clinics with 'all-in-one' screening to treatment and providing medical and social care. MHT main objective 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. MHT was composed of 1 hepatologist, 3 nurses, 1 secretary, 1 social worker, one health care worker, for a cross-disciplinary approach. Resources include two specific cars, on van, serology point-of-care testing (POCT), and two mobile FIBROSCAN®. Forty-two different medical and social units were partners: low and high threshold drug units, retention and detention center medical units, outside psychiatric units, emergency and homeless food/hosting units. We proposed part or all of our services to our medical and social partners. There were 15 services for half million people area in south of France. All services were free for patients and for partners. Services were organized in 4 successive steps:

For early detection and primary prevention

1. On-sites screening by serology Point of Care Testing PDBS (dried blood test) for HIV HBV HCV.
2. Green thread: outside dried blood test (DBS) and FIBROSCAN® in specific converted truck in outdoor sites.
3. BOUSSOLE, an outreach open center 5 days a week for reception, orientation information and support of vulnerable people.
4. Prevention information sessions toward drug users in day-care or housing structures.
5. Free blood tests in primary care for patients without social insurance.
6. Training of socio-medical institutions staff with trimestral days of exchange or on-demand and on-premises.

For linkage to care and fibrosis assessment:

7. Social screening and diagnosis (by using EPICES, specific social score).
8. On-premises mobile FIBROSCAN® for indirect measurement of liver fibrosis in site.
9. Advanced on-site liver specialist consultations.

For access to treatment:

10. Easy and rapid access to pre-treatment commission with hepatologists, nurses, pharmacist, social worker, GP, psychiatric and/or addictologist.
11. Low cost mobile phones lending to patients to keep in touch with MHT.

For follow up during and after treatment

12. Individual sessions of therapeutic education inside an ARS (Regional Health Agency) authorized program.
13. Collective educative workshops (nurse, psychologist, sophrologist, nutritionist, pharmacist).
14. Expert patient support with Peer to peer educational program.
15. Dedicated cirrhotic patients one day hospitalizations.

FIBROSCAN was a technic using liver stiffness for measurement of hepatic elasticity to detect liver fibrosis and liver cirrhosis. It was uninvaseive testing with rapid results, combined with DBS/POCT. It was performed by a nurse trained in the framework of a Memorandum of Cooperation (HSPT-Law Article 51). DBS HCV / HIV / HBV were an alternative to serology blood test, but in case of positive test, blood test confirmation was necessary. Nurse could do it in 20 minutes on digital puncture for immediate results and could repeat to know HCV status as soon as necessary. We also used a telephone interpreting service to enable treatment of people who do not speak French. Every social or medical MHT partner could choose and access to part or all our services. They choose only services what they need. Our services did not replace existing services but only completed them. We had also specific services: PSY-C F for psychiatric patents, DEPIST C PHARMA for pharmacists, HOPITAL ZERO HEPATITIS for hospitalized patients, PRISON ZERO HEPATITIS for inmates, immersion sessions for other hepatitis teams and community, regional and European actions. We cured almost 1000 HCV patients on 10 years [7-13]. MHT linkage to care was reported on Figure 1.

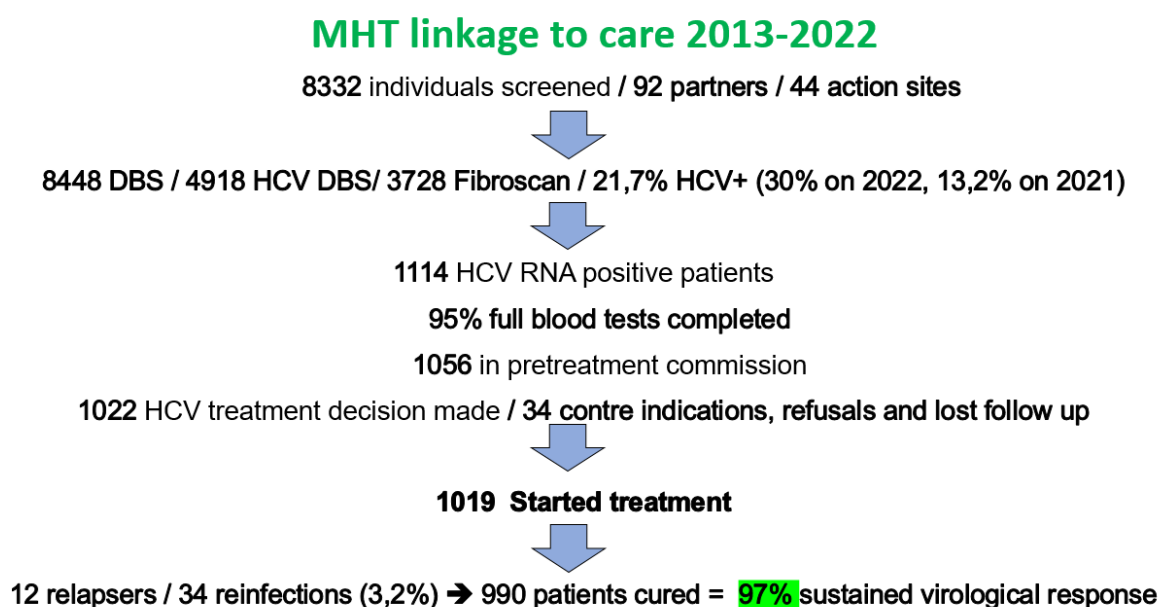


Figure 1: MHT linkage to care 2013-2022.

State of the literature

Medline research on 2024 1st February found only 2 references to key words HCV nurse treatment. The first study was published on 2019 from an Australian team [14]. Their initial hypothesis was that however, not enough

healthcare providers are available to deliver treatment to the population living with chronic HCV. To demonstrate that a nurse practitioner (NP) model of care is non-inferior to specialist gastroenterologist (SG) management of HCV infection, as measured by sustained viral response at 12 weeks (SVR12) after initiation of DAA therapy. It was a retrospective cohort database study in a single-center outpatient study. All patients with chronic HCV treated in the period 3rd March 2016 to 31st May 2019 were retrospectively analyzed. In this time period, a total of 1638 patients with chronic HCV had completed treatment. Nine hundred and four patients were eligible for the study, of which 541 were managed by an SG, and 363 managed by an NP. Of the 904 patients treated with DAA, 764 (84.5%) achieved SVR12. There was no statistical difference ($P > 0.05$) in achieving SVR12 between patients treated by an SP ($n = 481$, 88.9%) and those treated by an NP ($n = 281$, 77.4%). Their conclusions were that an NP model of care is non-inferior to SG management of HCV infection, as evidenced by equivocal success in achieving SVR12 between the two treatment groups. Therefore, an NP model of care is a viable option in the era of DAA therapy for HCV infection. Ongoing investment into the delivery of NP care could increase treatment uptake of HCV, with the aim of decreasing overall burden of disease.

The second study came from Canadian team [15]. Their initial hypothesis was that Increasing direct-acting antiviral (DAA) treatment uptake is key to eliminating HCV infection as a public health threat in Canada. People living with human immunodeficiency virus (HIV) and hepatitis C (HCV) co-infection face barriers to HCV treatment initiation. They wanted to identify interventions that could support HCV treatment initiation based on patient and HCV care provider perspectives. Eleven people living with HIV with a history of HCV infection and 12 HCV care providers were recruited for this qualitative descriptive study. Participants created ranked-ordered lists of potential interventions during nominal groups ($n = 4$) and individual interviews ($n = 6$). Following the nominal group technique, transcripts and intervention lists underwent thematic analysis and ranking scores were merged to create consolidated and prioritized lists from patient and provider perspectives. Patient participants identified a total of eight interventions. The highest-ranked interventions were multidisciplinary clinics, HCV awareness campaigns and patient education, nurse- or pharmacist-led care, peer involvement, and more and better-prepared health professionals. Provider participants identified 11 interventions. The highest-ranked were mobile outreach, DAA initiation at pharmacies, a simplified process of DAA prescription, integration of primary and specialist care, and patient-centred approaches. Participants proposed alternatives to hospital-based specialist HCV care, which require increasing capacity for nurses, pharmacists, primary care providers, and peers to have more direct roles in HCV treatment provision. They also identified the need for structural changes and educational initiatives.

Our team also met in 2022 with a nurse from a university hospital in Dublin, Ireland who was regularly prescribing hepatitis C treatments (data not published). So we had the project to complete the simplified journey of patients with hepatitis C by the missing link of prescribing DAAs by nurses to lead to management of hepatitis C treatment only nurse.

Objectify

Delegate to an IDE trained throughout the patient journey (simplified according to AFEF/HAS criteria) from diagnosis to cure of chronic viral hepatitis C, including the prescription of DAAs. In the same TEST TO TREAT session, the delegated IDE performs patient information and admission in the protocol, FIBROSCAN, C viral load in real time, educational assessment, elimination of contraindications indications, treatment and

implementation of clinical and biological follow-up. The inclusion criteria are those of the simplified course, major non-cirrhotic patient and without co-morbidities, informed and having given consent. Three exemptions are included in the protocol: IDE prescription of direct hepatitis C antivirals according to CPR and simplified HAS pathway, clinical nursing follow-up of DAAs and prescription of biological follow-up of direct hepatitis C antiviral treatments.

Methodology

Inclusion criteria and non-inclusion criteria were detailed in [Table 1](#). Nurse training detailed program was reported on [Table 2](#). It was not phase IV study and we don't need any IRB or specific authorization. The study protocol was approved by the nursing commission and the hospital medical commission. All patients received an information leaflet and gave their consent to participate in the study. The analysis of differences between patients included in the protocol and those treated out of protocol by the hepatologist was done with the statistical test of Chi2.

Table 1: Inclusion and non-inclusion criterias.

Inclusion criterias

1. Patient with proven viral hepatitis C, viral load C is positive (blotter, blood test, Genexpert® delocalized medical biology) less than 6 months old OR.
2. Patient with proven viral hepatitis C, viral load C is positive (blotter, blood test, Genexpert® delocalized medical biology) older than 6 months.
3. Patient with a positive hepatitis C serology (POCT or blood tests) proven.
4. Patient who has been informed and given consent.
5. compliance with all eligibility criteria.
6. Patient with no non-inclusion criteria.

Non-inclusion criterias

1. Pregnant woman or without effective contraception.
2. HBV and/or HIV co-infection.
3. Severe renal failure.
4. Poorly controlled comorbidities (alcohol, diabetes, obesity).
5. Severe liver disease F3F4 (Fibrotest 0.58 or Fibrometer 0.786 or Fibroscan > 10 KPA).
6. None responder or relapser from previous direct antiviral treatment.

Table 2: Nurse detailed training program.

A: Theoretical training

The theoretical and practical training is carried out by a hepatologist doctor, specialist in viral hepatitis, assisted by internal and external health professionals at the Centre Hospitalier de Perpignan Number of hours: 35

- Presentation of training: objectives, procedure, evaluation
- Pre-test 20 questions
- Hepatitis C natural history and epidemiology
- Screening and diagnosis

- Cirrhosis and its complications
- Primary liver cancer
- Treatment of acute and chronic hepatitis C

Historical

- Indications and contraindications
- Adverse effects: nature, frequency and management
- Non-drug treatments
- Practical arrangements
- Simplified and complex route
- Clinical and biological monitoring
- Other viral hepatitis
- Other causes of acute and chronic liver disease
- Differential diagnosis
- HCV contamination and health representations
- Gender specificities of viral hepatitis and liver diseases
- Social protection system in France
- Social cover for foreigners within and outside the Community
- Social monitoring of chronic diseases
- Post-test 20 questions

B: Practical training Number by mentoring

1. attend 30 consultations in pairs with the doctor on the maintenance, prescription, interpretation and delivery of results on different types of situation: prescription of biological screening and follow-up tests, interpretation and delivery of results, direct antiviral prescribing, biological monitoring and adverse reaction management.
2. AND perform 30 visits under the supervision of the delegating physician.

Table 3: Detailed results.

Treated patients follow up	Nurse follow up	Hepatologist follow up	Difference
number of patients	39	50	na
Aude area	9	8	ns
Pyrénées-Orientales area	30	42	na
women	13	14	ns
men	26	36	p < 0,01
mean age	44	49	p < 0,01
previous HCV treatment	13	12	ns
none responder	0	1	ns
relapser	1	4	p < 0,01
re-infection	12	7	p < 0,01
FIBROSCAN value			
mean value	5.6	17.8	p < 0,01
F0-F1-F2	39	24	p < 0,01
F3-F4	0	26	p < 0,01
treatment started	38	50	na
time between treatment decision and beginning (days)	7.5	7.4	ns
patients started treatment first day	11	3	p < 0,01

patients started treatment the following day	6	7	ns
follow-up at 2023/12/31			
sustained virological response	13	16	ns
discontinuation of treatment	2	0	ns
not started treatment	1	0	ns
ongoing treatment	7	9	na
ongoing virological response	15	20	na
follow-up change	1	1	ns
lost of follow up	1	1	ns
death	0	3 (2 liver cancer and 1 cardiac etiology)	p < 0,01

RESULTS

After agreement of the hospital authorities and declaration to the Regional Health agency and nurses training, the local cooperation protocol was established on 23 January 2023 and 3 IDE acceded to it under the coordination of a hepatologist. As of December 31th, 2023, 39 out of 89 HCV patients in the Viral Hepatitis Expert Service benefited from this protocol, or 44%. Detailed results were detailed on [Table 2](#). Twelve patients were in a situation of recontamination by drug use (31%), 75% in the same living area. Treatment compliance was 95% for the group of patients treated with IDE versus 90% for patients treated by the hepatologist. The main differences between the two groups were less men, younger age, reinfection status, more patients starting treatment at day of DAA prescription and no death in nurse prescription group. The typical patient of nurse group was a man, 42 years, drug user and homeless.

DISCUSSION

Our results support the hypothesis that an all care nurse model of care is equivalent to hepatologist management of HCV infection, as evidenced by equivocal success in achieving SVR12 between the two treatment groups. Therefore, task-shifting DAA-based HCV therapy to an all care nurse model of care is a viable and effective option to increase access to HCV treatment and assist the healthcare system currently strained by a paucity of hepatologiste and general practionners. benefits are that the local protocol is a simple tool to put in place, applicable immediately with a posteriori control of the regional health agency. It is a simple and effective tool that frees up physician time, enhances nursing work. There are no disadvantages highlighted after one year of operation. The strengths of this study are that the data were comprehensive and there was a large cohort of patients engaged in the service. Our results are equivalent to other foreign models used to treat similar populations [\[16,17\]](#). After validation by the national high authority of health, this protocol can be applied to other teams in France.

PERSPECTIVES

After 12 months of implementation, the protocol is a success that allowed the rapid implementation of DAA treatments especially for patients recontaminated by HCV and thus be able to hope to cut the chain of transmission in active drug users. It is a culmination of the simplified AFEF/HAS path that allows to reduce the time of support all in one type TEST TO CURE approach. A new local nurse protocol is planned on 2024 for the follow-up and treatment of chronic HBV patients.

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