

24 **ABSTRACT**

25 OBJECTIVES:

26 To empirically determine a categorization of people who inject drug (PWIDs) recently
27 infected with hepatitis C virus (HCV), in order to identify profiles most likely associated with
28 early HCV treatment uptake.

29 METHODS:

30 The study population was composed of HIV-negative PWIDs with a documented recent
31 HCV infection. Eligibility criteria included being 18 years old or over, and having injected drugs
32 in the previous 6 months preceding the estimated date of HCV exposure. Participant
33 classification was carried out using a TwoStep cluster analysis.

34 RESULTS:

35 From September 2007 to December 2011, 76 participants were included in the study. 60
36 participants were eligible for HCV treatment. Twenty-one participants initiated HCV treatment.
37 The cluster analysis yielded 4 classes: Class 1: *Lukewarm health seekers dismissing HCV*
38 *treatment offer*; Class 2: *Multi-substance users willing to shake off the hell*; Class 3: *PWIDs*
39 *unlinked to health service use*; Class 4: *Health seeker PWIDs willing to reverse the fate*.

40 CONCLUSION:

41 Profiles generated by our analysis suggest that prior health care utilization, a key element
42 for treatment uptake, differ between older and younger PWIDs. Such profiles could inform the
43 development of targeted strategies to improve health outcomes and reduce HCV infection among
44 PWIDs.

45

46 **Key words: Hepatitis C, intravenous drug abuse, treatment**

47 **INTRODUCTION**

48 The prevalence of HCV infection is estimated at 130-170 million people worldwide,
49 currently driven by the growing number of infections among people who inject drugs (PWID).[1]
50 Not treated, the majority (75-85%) evolve to chronic infection; and some (20%) develop
51 intractable and lethal diseases (cirrhosis, liver failure, hepatoma).[2]

52 Before the advent of well-tolerated, orally administered HCV treatment regimens,
53 traditional interferon-based antiviral treatment induced significant side effects that were deterring
54 some patients from completing the treatment course. For patients who achieved sustained viral
55 response equivalent to a cure, HCV treatment was shown to bring additional benefits, such as
56 reduction of risky drug-consumption behaviours,[3] and improvement of quality of life.[4] It is
57 likely that within the next three to five years, well-tolerated, orally administered Interferon-free
58 regimens will be available, thus improving the feasibility of treating difficult populations.[5] A
59 recent modeling study by Martin and colleagues suggested that significant decreases in HCV
60 prevalence can be accomplished by increasing simultaneously needle exchange program and
61 opiate substitution therapy coverage on the one hand, and HCV treatment coverage on the other
62 hand.[6] In large observational community-based drug users' cohorts, however, the HCV
63 treatment uptake was estimated at < 8%, or less than 1% annually.[7] Further, despite increasing
64 efforts to attract vulnerable population in treatment, the number of PWIDs treated annually still
65 stagnates.[8]

66 Barriers to HCV treatment were found to be multi-factorial and included factors impeding
67 optimal access at the level of the patient, system and practitioner.[7] Attempts to frame the
68 influence of multidimensional factors and conditions facilitating or impeding health care access
69 and outcomes can be guided by the Behavioral Model of Health Services Utilization, a

70 conceptual framework developed by Andersen and colleagues.[9] Reasons cited by PWIDs with
71 HCV for not seeking treatment include poor education about their condition and its treatment, an
72 absence of noticeable symptoms, fear of adverse effects of treatment, and other ongoing medical
73 comorbidities and social issues.[10] Beyond individual barriers, factors affecting treatment
74 uptake include financial coverage, housing stability and assessment by the physician of the risks
75 and benefits of immediate versus delayed treatment for HCV-chronically infected individuals.[7]
76 From a service development perspective, it is important to identify profiles of individuals
77 according to treatment uptake. Such profiles could help inform novel interventions to increase
78 treatment uptake in subgroups with specific characteristics. PWIDs recently infected by HCV
79 who are systematically offered treatment under universal financial coverage represent a unique
80 group to study in order to assess how individual profiles, as opposed to specific risk factors,
81 affect treatment uptake. Cluster analysis have been used in intervention research to unmask
82 unknown heterogeneity between concurrent groups by focusing more on inherent differences
83 between cases than on individual variables.[11]

84 The objective of this study was to empirically identify profiles associated with early HCV
85 treatment uptake among recently HCV infected PWIDs who were systematically offered HCV
86 treatment and were covered by universal health insurance.

87 **METHODS**

88 **A. STUDY POPULATION:**

89 The study population was composed of PWIDs recently infected with HCV, enrolled in
90 IMPACT, a study aimed at examining the effect of acute HCV infection and antiviral treatment
91 on the behaviors and quality of life of PWIDs who have access to specific targeted health
92 services. Eligibility criteria included being 18 years old or over, having injected drugs in the
93 previous 6 months or in the 3 month-period preceding the estimated date of HCV infection, and
94 living in the Greater Montreal area. Documented acute HCV infection was defined as either: 1) a
95 HCV antibody negative test, followed by either an HCV antibody or RNA positive test within 6
96 months of the HCV antibody negative test period; or 2) acute symptomatic infection with
97 evidence of hepatitis illness (i.e. jaundice or alanine aminotransferase (ALT) elevation over 400
98 U/L). Participants were recruited from two main sources: i) the St. Luc Cohort, a prospective
99 cohort study with semi-annual visits designed to examine individual and contextual factors
100 associated with HCV and HIV infections among current IDUs (i.e.: drug injection in the six
101 months prior to recruitment);[12]; ii) community and hospital-based collaborating clinics,
102 including the addiction medicine clinic at the Centre Hospitalier de l'Université de Montréal
103 (CHUM).

104 Eligible individuals were invited to participate in the study and were systematically
105 referred to the CHUM addiction medicine clinic for clinical assessment. PWIDs recently infected
106 with HCV, who did not resolve spontaneously after 20 weeks of estimated infection, were
107 offered HCV treatment regardless of their drug use or social conditions.

108 The research protocol has been approved by the Institutional Research Ethical Board of
109 the CHUM, and includes an authorization to access participants' clinical data, when available. A

110 \$30 stipend for travel costs was offered for each completed research visit.

111 **B. VARIABLES AND MEASUREMENT INSTRUMENTS:**

112 The variable of interest was “treatment initiation”, defined as receiving a first dose of
113 Pegylated interferon. Information was retrieved from the clinical chart, and validated with the
114 clinical nurse. Two measurement instruments were used to characterize participants. The SF-36
115 questionnaire was used to assess health related quality of life (QualityMetric Health Outcomes™
116 Scoring Software 4.0). This questionnaire has been extensively used and validated in various
117 patient settings as well as in the general population.[13] Using factor analysis, items of this
118 questionnaire are conceptually reduced to two main dimensions: physical and mental component
119 of quality of life, which were used for analysis in this study. A short interviewer-administered
120 questionnaire, derived from the St. Luc Cohort questionnaire,[14] was used to collect socio-
121 demographic characteristics, information on injection drug use practices, health related factors
122 and service utilization. Drug use consumption was documented for the prior 6 months.

123 Given the focus on healthcare utilization, the sample has been described according to the
124 Andersen model, with variables categorized as predisposing, enabling and need factors.[9]
125 Predisposing factors comprise individual variables associated with service utilization. Enabling
126 factors include contextual, systemic or structural variables associated with service utilization.
127 Need factors relate to diseases or risky behaviors that could impact on health and wellbeing.
128 Variables considered in our model were further chosen with respect to the current body of
129 knowledge on HCV treatment access for drug users.

130 **C. ANALYSES:**

131 Frequency distribution for categorical variables and mean values along with standard
132 deviations for continuous variables were used for descriptive analyses. Bivariate analyses using

133 Pearson Chi-square statistics for categorical variables and independent sample *t*-test for
134 continuous variables were conducted to compare PWID characteristics according to HCV
135 treatment initiation. Statistically significant differences were assessed at $P < 0.05$; *P*-values were
136 two-sided.

137 Participant profile was carried out by means of a TwoStep cluster analysis using SPSS
138 Statistics 20.0 package.[15, 16] Variables were introduced in the cluster analysis in an orderly
139 manner, categorical variables first, and then continuous variables. The first categorical variable
140 entered was “Having initiated HCV treatment”. Age categories and housing categories were
141 multi-categorical variables. The SF-36 physical and mental component scores were entered as
142 continuous scores in the model. The Log-likelihood method was used to determine inter-subject
143 distance. The first iteration yielded a two-class cluster model based on Schwarz Bayesian criteria
144 and Log-likelihood method, reflecting the overall contribution of participants to the inter-class
145 homogeneity. This cluster analysis was discarded because classes were not contrasted enough for
146 interpretation.[17] Finally the number of classes was set at 4 and produced an acceptable model.
147 The quality of the model was estimated as satisfactory by the class cohesion and separation test.

148 **RESULTS**

149 From September 2007 to December 2011, 76 participants infected with HCV within the
150 previous six months were recruited in Montreal, Canada. Sixteen (21%) cleared their infection
151 spontaneously and were not included in this investigation. Table 1 presents descriptive
152 characteristics of the 60 participants included in analyses, along with comparison analyses
153 between those who have initiated HCV treatment and those who have not. Overall, 21
154 participants (35%) had initiated HCV treatment.

155 The four-class cluster analysis is displayed on Table 2. Classes were labelled according to
156 the most prominent characteristics within classes. The four classes can be described as follow.

157 **Class 1:** *Lukewarm health seekers dismissing HCV treatment offer:* Younger participants (79%
158 under 30 y.o.), mostly females (86%), poorly educated (93% without a college degree), living
159 predominantly in stable housing (64%). Compared to other classes, they rank fourth as to cocaine
160 injection (64%), and second as to heroin injection. They have the lowest score on both physical
161 and mental components of Quality of life. They represent one of the two highest proportions of
162 participants followed-up by a family physician (35%), and the third lowest proportion of HCV
163 treatment uptake (14%).

164 **Class 2:** *Multi-substance users willing to shake off the hell:* mostly younger participants (87%
165 under 30 y.o), exclusively males, poorly educated, living mostly in stable housing. All members
166 (100%) of this class use IV cocaine and IV heroin. They rank first as regard alcohol
167 consumption, and have the highest proportion of methadone program involvement. 53% have
168 initiated a HCV treatment, ranking second of the 4 classes.

169 **Class 3:** *PWIDs unlinked to health service use:* Middle-age participants (64% between 30 and
170 40 y.o.), exclusively males, with the highest proportion of homelessness of all classes, injecting

171 mostly cocaine. They also report the lowest involvement in health service use. No one in that
172 class has initiated a HCV treatment.

173 **Class 4:** *Health seeker PWIDs willing to reverse the fate:* The oldest group (all over 30 y. o.),
174 mostly males, poorly educated, living predominantly (90%) in unstable housing conditions, and
175 using IV cocaine use. Participants in this class have the highest score on the physical component
176 of Quality of life, the highest proportion of health service use and the highest proportion of HCV
177 treatment initiation.

178 **DISCUSSION**

179 PWIDs face many challenges and experience competing needs when it comes to taking
180 care of their health. Overall, 35% of eligible PWIDs initiated treatment. The proportion of
181 participants treated in our study soon after diagnosis is greater than in most studies among HCV
182 infected active PWIDs.[18] This may indicate that delaying treatment, either for recently or
183 chronically infected individuals, might not be the best option to increase uptake. Findings from a
184 recent clinical trial conducted in Canada support this assumption: a higher overall sustained viral
185 response (65% vs. 39%) was found among PWIDs allocated to immediate versus delayed
186 treatment onset.[19]

187 This study was undertaken to draw profiles associated with HCV treatment uptake after
188 recent infection, in a setting where treatment was systematically offered under universal health
189 insurance coverage. Overall, results suggest that educated male and female PWIDs, and those
190 who had links with various health care services, as shown by prior hepatitis B vaccination,
191 Opiate Substitution Treatment (OST) participation and visit to a health care professional, were
192 more likely to initiate HCV treatment after recent infection, regardless of drug consumption. As
193 in McGowan study,[20] participants in class 2 and 4, who initiated treatment, were also
194 characterized by lower self-rated mental health quality of life. According to Anderson's model,
195 prior healthcare service utilization may enable further health service use.[9] Participants in class
196 2 and 4, which together comprise 90% of all participants treated, had higher proportions of
197 methadone program participation, hepatitis B vaccination and follow-up by family physician. In
198 a study conducted in Australia by Digiusto and colleagues,[21] participants who had consulted a
199 general practitioner for medication were more likely to have initiated HCV treatment.
200 Participation to a methadone maintenance treatment has been associated with a higher

201 willingness to be treated,[22] to increased treatment uptake [23] and to better outcomes.[24] In a
202 recent study among drug users followed in methadone and community clinics with enhanced
203 HCV treatment access, methadone was not associated with uptake.[25]

204 A salient characteristic of this cluster analysis was the identification of distinct profiles
205 according to treatment uptake, for which standard comparisons were not quite informative. For
206 instance, age was not statistically associated with treatment uptake in bivariate analysis.
207 However, the age distribution in clusters suggests that uptake profiles differ between older and
208 younger drug users. Class 1 and 2 comprised 24 of the 28 individuals under 30. In contrast,
209 class 3 and 4 included all but five individuals over 30.

210 Hence, when contrasting “younger” (class 1 and 2) and “older” (class 3 and 4) PWID
211 profiles, results from the cluster analysis suggest that the effect of health care utilization, an
212 important element for treatment uptake, differed between older and younger groups. Younger
213 individuals who initiated treatment reported being in methadone substitution treatment in higher
214 proportions. Vaccination and family physician attendance was reported by a substantial
215 proportion of older individuals initiating treatment, and by none of those who did not. In
216 addition, class profiles showed that housing status, namely living in a prison, a shelter or in a
217 therapy setting, was related to treatment uptake among older PWIDs, but not so among younger
218 drug users.

219 The seemingly positive impact of living in an institutional facility, either prison, therapy
220 or shelter, on treatment uptake among older participants in our study may indicate enhanced
221 linkages with healthcare services through service providers, relative to other individuals in this
222 cohort.[26] Conversely, class 3 profile includes a majority of homeless individuals, no one
223 having initiated HCV treatment. According to Andersen’s theory, when healthcare access is

224 determined by enabling factors, such as their housing situation among older participants,
225 systemic inequity is an issue.[9]

226 Active use of illicit drugs is a treatment barrier documented in many studies. Active illicit
227 drug use was associated with reluctance to initiate HCV treatment by the patient,[27] as well as
228 by the physician.[28] Alcohol abuse was also found associated with not initiating treatment.[29]
229 In our setting, however, the proportion of participants reporting drug and alcohol use was slightly
230 higher among initiates relative to participants who were not treated, consistent across all classes.
231 Active substance use was not a motive to deny treatment in this study. This finding suggests that
232 active drug use may not be an important factor in the decision to get treated in the absence of
233 systemic and practitioner-level barriers. It is also possible that ongoing drug use was linked to
234 more contact with health services, probably due to multiple health related consequences of drug
235 use overtime.

236 Results of this study are subject to numerous limitations. First, we acknowledge that our
237 sample may not be representative of drug users in other settings. If there has been some observed
238 shifts in its use, cocaine is still the most prevalent injection drug used in Eastern Canada.[30]
239 Moreover, cocaine use worldwide has remained stable, with indications of increases in Oceania,
240 Asia, Africa and some countries in South America.[31] Despite close clinical follow-up of
241 participants through laboratory analyses, our results could be biased by the self-reported
242 behavioral data related to alcohol and drug use. In general, self-reported data from PWIDs tend
243 to be accurate.[32] This study could also be subject to interviewer bias, which has been
244 mitigated, if not prevented, by regular retraining of interviewers to uphold the integrity of data
245 collection procedures and avoid imposition of systematic bias. A sample of 60 participants is
246 obviously low. Nonetheless, the quality of the model was estimated to be satisfactory.

247 **CONCLUSION**

248 This study underscores the importance of reaching beyond the individual-level factors in
249 characterizing vulnerable populations in relation to HCV treatment uptake. Looking at profiles
250 instead of individual variables can help tackle health related behaviors of PWIDs recently
251 infected with HCV. This natural experiment represents a novel approach to understanding how
252 specific patient characteristics can be used to develop targeted strategies to improve health
253 outcomes and reduce HCV infection. For example, systemic barriers should be recognized early
254 among those eligible for HCV treatment - such as difficulty to access decent accommodation or
255 job – and tackled strategically by linking patients with case manager and social worker services.

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257

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Table 1. Characteristics of participants and comparative analyses according to treatment initiation**(n=60)**

| | | Frequency distribution | | | | | | Comparison tests |
|---------------------|--|--------------------------|------|--|------|--|------|------------------|
| | | Total sample (N = 60) | | Treatment not initiated n = 39 (65%) | | Treatment initiated n = 21 (35%) | | P value* |
| | | n | % | n | % | n | % | |
| Age | <30 y.o. | 28 | 46,7 | 21 | 53,8 | 7 | 33,3 | |
| categories | 30-39 y.o. | 15 | 25,0 | 9 | 23,1 | 6 | 28,6 | 0.311 |
| | >40 y.o. | 17 | 28,3 | 9 | 23,1 | 8 | 38,1 | 0.133 |
| Gender | Female | 15 | 25,0 | 11 | 28,2 | 4 | 19,0 | 0.437 |
| | Male | 45 | 75,0 | 28 | 71,8 | 17 | 81,0 | |
| Education | Secondary or less | 44 | 73,3 | 30 | 76,9 | 14 | 66,7 | 0.397 |
| | College or above | 16 | 26,7 | 9 | 23,1 | 7 | 33,3 | |
| Housing | Stable housing (home, apartment, room) | 25 | 41,7 | 18 | 46,2 | 7 | 33,3 | |
| | Temporary housing (therapy, prison, shelter) | 22 | 36,7 | 12 | 30,8 | 10 | 47,6 | 0.217 |
| | Homeless | 13 | 21,7 | 9 | 23,1 | 4 | 19,0 | 0.858 |
| Alcohol consumption | | 36 | 60,0 | 23 | 59,0 | 13 | 61,9 | 0.825 |

| | | | | | | | | |
|---|---------------------|------|------|------|------|------|------|-------|
| IV drugs consumed | IV Heroine | 29 | 48,3 | 19 | 48,7 | 10 | 47,6 | 0.935 |
| | IV Cocaine | 53 | 88,3 | 34 | 87,2 | 19 | 90,5 | 0.705 |
| Vaccines received | Hepatitis B Vaccine | 17 | 28,3 | 7 | 17,9 | 10 | 47,6 | 0.015 |
| Quality of life scores | PCS Mean (SD) | 46,4 | 10,2 | 45,6 | 9,8 | 47,9 | 10,9 | 0.389 |
| | MCS Mean (SD) | 33,9 | 13,9 | 34,0 | 14,2 | 33,9 | 13,8 | 0.985 |
| Methadone | | 20 | 33,3 | 10 | 25,6 | 10 | 47,6 | 0.085 |
| Having been followed-up in the 6 prior months by a family physician | | 11 | 18,3 | 6 | 15,4 | 5 | 23,8 | 0.424 |

*Pearson Khi square.

Table 2. Participants typology (cluster analysis; N= 60)

| | | | Class 1 | Class 2 | Class 3 | Class 4 | Combined |
|-----------------------------|-------------------------|--|--------------------|--------------------|--------------------|--------------------|---------------------|
| | | | n = 14; (23.3%) | n = 15; (25.0%) | n = 11; (18.3%) | n = 20; (33.3%) | N = 60; (100.0%) |
| Predisposing factors | Age categories n (%) | <30 y.o. | 11 (78.6) | 13 (86.7) | 4 (36.4) | 0 (0.0) | 28 (46.7) |
| | | 30-39 y.o. | 3 (21.4) | 2 (13.3) | 7 (63.6) | 3 (15.0) | 15 (25.0) |
| | | 40 y.o. and over | 0 (0.0) | 0 (0.0) | 0 (0.0) | 17 (85.0) | 17 (28.3) |
| | Gender n (%) | Females | 12 (85.7) | 0 (0.0) | 0 (0.0) | 3 (15.0) | 15 (25.0) |
| | | Males | 2 (14.3) | 15 (100.0) | 11 (100.0) | 17 (85.0) | 45 (75.0) |
| | Education n (%) | Elementary/secondary | 13 (92.9) | 12 (80.0) | 6 (54.5) | 13 (65.0) | 44 (73.3) |
| College or over | | 1 (7.1) | 3 (20.0) | 5 (45.5) | 7 (35.0) | 16 (26.7) | |
| Enabling factor | Housing n (%) | Stable housing (home, apartment, room) | 9 (64.3) | 9 (60.0) | 5 (45.5) | 2 (10.0) | 25 (41.7) |
| | | Temporary housing (therapy, prison, shelter) | 4 (28.6) | 2 (13.3) | 0 (0.0) | 16 (80.0) | 22 (36.7) |

| | | | | | | | |
|-----------------------------------|---|---------------|-------------|------------|-------------|-------------|-------------|
| | | Homeless | 1 (7.1) | 4 (26.7) | 6 (54.5) | 2 (10.0) | 13 (21.7) |
| Need factors | IV Cocaine consumption n (%) | | 9 (64.3) | 15 (100.0) | 11 (100.0) | 18 (90.0) | 53 (88.3) |
| | IV heroine consumption n (%) | | 9 (64.3) | 15 (100.0) | 2 (18.2) | 3 (15.0) | 29 (48.3) |
| | Alcohol consumption n (%) | | 8 (57.1) | 13 (86.7) | 4 (36.4) | 11 (55.0) | 36 (60.0) |
| | Quality of Life (SF-36) (Mean (SD)) | PCS Mean (SD) | 45.7 (6.9) | 46.4 (9.4) | 46.7 (9.1) | 46.8 (13.4) | 46.4 (10.2) |
| MCS Mean (SD) | | 25.3 (12.1) | 37.0 (14.8) | 37.5 (8.1) | 35.7 (15.3) | 33.9 (13.9) | |
| Health service utilization | Methadone program n (%) | | 5 (35.7) | 8 (53.3) | 3 (27.3) | 4 (20.0) | 20 (33.3) |
| | Hepatitis B Vaccine n (%) | | 4 (28.6) | 3 (20.0) | 0 (0.0) | 10 (50.0) | 17 (28.3) |
| | Followed-up by a family physician n (%) | | 5 (35.7) | 1 (6.7) | 0 (0.0) | 5 (25.0) | 11 (18.3) |
| | Having initiated treatment n (%) | | 2 (14.3) | 8 (53.3) | 0 (0.0) | 11 (55.0) | 21 (35.0) |