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What's Important to the Patient?: Informational Needs of Patients Making Decisions about Hepatitis C Treatment

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Abstract

Background & Objectives—Multiple treatment options with direct-acting antivirals (DAAs) are now available for hepatitis C virus (HCV). Study aims were to understand (1) The informational topics patients want to have to make informed treatment decisions; (2) The importance patients place on each topic; and (3) The topics patients prioritize as most important.

Methods—Mixed methods study utilizing two samples recruited from an academic liver center. Participants were not currently on treatment. Sample I (n=45) free-listed all informational topics deemed important to decision-making. Raw responses were coded into several broad and subcategories. Sample II (n=38) rated the importance of the subcategories from Sample I and ranked their highest priorities on two surveys, one containing topics for which sufficient research existed to inform patients (“static”), and the other containing topics that would require additional research.

Results—The topics listed by Sample I fell into 6 broad categories with 17 total subcategories. The most oft-cited informational topics were harms of treatment (100%), treatment benefits (62%)

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Compliance with Ethical Standards

All procedures performed in this study involving human participants were in accordance with ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable standards. Informed consent was obtained from all individual participants included in the study.

Donna Evon, Carol Golin, and Michael Fried developed the study concept and design. Teodora Stoica, Rachel Jones and Sarah Willis were involved in data collection and entry. Donna Evon, Carol Golin, Joseph Galanko, Rachel Jones, and Teodora Stoica were involved in the data analysis. Joseph Galanko conducted statistical analyses. All of the authors were involved with drafting or revising the manuscript for important intellectual content. All authors have given approval of the final manuscript. Dr. Evon is the guarantor of this work.

Disclosures of potential conflict of interest

Carol Golin, Teodora Stoica, Rachel Jones, Sarah Willis, and Joseph Galanko declare that they have no conflict of interests to disclose. Donna Evon has served as an *ad hoc* consultant and received a honorarium from Gilead. Michael Fried has received research funding from and served as a consultant for AbbVie, BMS, Gilead, Merck.

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and treatment regimen details (84%). Sample II rated 16 of 17 subcategories as “pretty important” or “extremely important.” Sample II prioritized (1) viral cure, (2) long-term survival, and (3) side effects on the survey of topics requiring additional research, and (1) liver disease, (2) lifestyle changes, and (3) medication details on the second survey of the most important static topics patients needed.

Conclusions—Patients weighed several informational topics to make an informed decision about HCV treatment. These findings lay the groundwork for future patient-centered outcomes research in HCV and patient-provider communication to enhance patients’ informed decision-making regarding DAA treatment options.

Keywords

Patient-centered; knowledge; decision-making; antiviral therapy

1 Background

Major advances in the development of drugs to treat people with chronic hepatitis C virus (HCV) have occurred in the last three years with the advent of direct acting antiviral (DAA) agents[1]. Several new all-oral interferon-free regimens are available and more are in development. Phase III drug trials of DAA regimens report cure rates consistently over 90% and significantly fewer adverse events compared to previous regimens[1].

With several highly efficacious regimens now available, providers and patients have several treatment options from which to choose. Studies across many medical conditions demonstrate that patients faced with treatment options are more likely to make better decisions when they feel fully informed about their options[2]. Consistent with a growing movement in medical decision-making, many HCV patients may want to be informed consumers of their healthcare options and actively participate in the decision-making process[3]. This process will now be two-pronged (1) Does the patient wish to start now or defer treatment given his/her individual characteristics? and (2) If immediate treatment is desirable, which treatment option is best for the individual given his/her characteristics? During interferon-based treatment, no treatment options existed, and many patients and providers deferred treatment due to low cure rates and frequent adverse events[4, 5]. Now that more treatment options are available, patients may be more interested in shared decision-making with their providers.

It is increasingly recognized that patients need adequate information and support to make preference-sensitive healthcare decisions with their providers[6]. Patients with HCV will likely want to understand the trade-offs (i.e., pros, cons) between their treatment options to compare cure rates, treatment durations, pill burden, side effects, and other benefits and harms that they personally find meaningful[7, 8]. To help educate and prepare patients to make choices consistent with their preferences, it is imperative to understand what types of information matter most. In other words, what types of information do patients think they need to make informed, value-concordant decisions regarding HCV treatment?[9] This information will serve two purposes, one involving clinical practice, the other involving future research. First, the data may help clinicians address patients’ informational needs and

communicate more effectively about treatment options to ensure that specific topics are thoroughly covered[10]. Patients who engage in decision-making are more informed, have greater decisional certainty, greater knowledge of risks, take a more active role in their healthcare, may adhere better to treatment, and may have better communication with providers[2]. Second, understanding patients' informational needs can directly guide future patient-centered outcomes research (PCOR) by ensuring that information that matters most to patients is being obtained and disseminated[11].

To date, few studies have elucidated the informational topics that patients perceive to be important to decision-making regarding HCV treatment. This gap in the literature hinders patient-centered research and effective patient-provider communication to support shared decision-making. The aims of the current study were to thoroughly evaluate: (1) the informational categories (topics) patients felt they needed to make an informed decision about HCV treatment; (2) the importance placed on each topic; and (3) which topics ranked as the highest priorities needed to make treatment decisions.

2 Methods

2.1 Participants and Setting

Participants were recruited from a large academic liver center. Eligible patients were HCV RNA positive, at least 18 years old, English-speaking, and currently *not* on HCV therapy. Patients who were treatment naïve or treatment experienced were eligible. Patients who were unable to provide informed consent, medically or psychiatrically unstable, co-infected with HIV or hepatitis B, or being evaluated or wait-listed for liver transplantation, were excluded.

Two groups of patients participated in the current study. Participants comprising Sample I were enrolled from November 2013 – January 2014, coinciding with the approval of two new DAA regimens: simeprevir/sofosbuvir and sofosbuvir/ribavirin. Provider and patient decisions at this point were to (a) initiate treatment with one of these two regimens or (b) wait for newer DAAs medications. Initiating IFN-based treatment was rarely being recommended. Participants comprising Sample II were enrolled from February – March 2015, shortly after sofosbuvir/ledipasvir was approved by the Food and Drug Administration (FDA), therefore the treatment options patients and clinicians faced were to (a) initiate treatment with currently-approved DAAs or (b) wait for others to be approved. With Sample I, the aim was to obtain a comprehensive list of all potential informational categories (topics) participants felt they needed to make an informed decision about HCV treatment. With Sample II, the first aim was to confirm the informational categories derived from Sample I, and the second aim was to understand the relative importance of each topic and how participants prioritized these topics regarding the most critical information needed.

2.2 Study Procedures

Study methods were approved by the UNC IRB and all participants gave written, informed consent before participation. Participants engaged in a 15-minute, individual interview with research staff using an interview guide. After completing the interview, participants

completed self-administered surveys. Liver-related variables were extracted from medical records.

2.3 Sample I Data Collection and Analysis

2.3.1 Free-Listing Technique—During the interview, participants were asked in an open-ended fashion to “free-list” all the different types of information he/she needed to make an informed decision about either doing treatment or selecting between potential treatment option, for example “between Treatment A and Treatment B”[12, 13]. The question posed was completely hypothetical (e.g., What information do you feel you would need to make an informed decision about doing HCV treatment or making a choice between “Treatment A and Treatment B”); No specific treatment regimens were described. With the free-list method, participants are continuously prompted to list additional information until they have exhausted all ideas and no new topics are forthcoming. Each informational topic provided by the participant was recorded in a database. Recruitment for Sample I ended when thematic saturation of new information had been achieved (i.e., no new topics were listed after five consecutive participants). After all free-listed items were entered into the database, two separate raters (D.M.E., C.E.G.) organized the raw responses into broad categories and subcategories. Where there were discrepancies regarding best fit of responses into the categories, the raters discussed and came to consensus on goodness-of-fit for each response in each category. The proportion of participants who endorsed each subcategory was calculated. Endorsement of each subcategory was counted only once per subject. The proportion of participants who endorsed any subcategory were counted only once under that broad category.

The investigators noted a distinction between several of the categories and subcategories, such that some informational categories desired by patients were judged by the investigators to already exist in the literature or public domain. We herein refer to these categories as “*static informational topics*”, which included questions about the number of pills in an existing treatment regimen or how HCV is transmitted. This information is static and already available on the internet or imparted by a clinician and does not require additional scientific investigation. In contrast, other informational categories needed by patients were judged by the investigators to require additional scientific investigation to obtain the specific information that participants sought. We herein refer to these categories as “*informational topics for future research*”, which included topics such as various harms of DAA therapies on the liver and effects on other pre-existing conditions. Two parallel surveys for administration during the same study visit were developed to use with Sample II to obtain priority rankings: (a) one survey represented the eight “*static informational topics*” and (b) the other survey represented the nine “*informational topics for future research*”.

2.4 Sample II Data Collection and Analysis

A second, independent sample was recruited to first confirm the informational categories derived from the Sample I data, and then to understand the importance and prioritization of each topic in terms of information patients needed.

2.4.1 Free-Listing Technique—The same free-listing method used with Sample I was used with Sample II. Free-listed responses that were judged to fit poorly into a pre-existing category derived from Sample I were noted as exceptions and two raters came to consensus on whether these fit into a pre-existing category or required the creation of a new category. Recruitment for Sample II ended when thematic saturation of new categories had been achieved (i.e., no new categories needed to be created after five consecutive participants). The proportion of participants who uttered responses that fell under each subcategory and broad category was calculated.

2.4.2 Importance Ratings—Sample II participants were then given a list of pre-existing subcategories derived from the Sample I analysis, and asked to rate how important each type of information was to their decision-making. Importance ratings were based on a 5-point Likert scale: “Extremely important=5”; “Pretty important=4”; “Somewhat important=3”; “Not that important=2”; and “Not important at all=1.” Two split-half versions of the form were used to control for order effects. The mean importance score, averaged across participants, was calculated for each subcategory.

2.4.3 Topic Priority Selection and Ranking—During this last exercise, Sample II participants were asked to identify the subcategories they felt were most important regarding information they needed to make a treatment decision. First, participants were presented with the first survey which reflected the eight *static informational topics*, and asked to select and rank their priorities on this survey. Then, they were presented the second survey which included the nine *informational topics for future research*, and asked to select and rank their priorities on this form. On each of the surveys, participants first highlighted the 5 most important types of information needed to make a decision. Of those 5 highlighted subcategories, participants then assigned a priority ranking to their top three: 1=highest priority or most important piece of information; 2=second priority; and 3=third priority or third most important. This funneling approach was utilized because the literature suggests that respondent burden can become high when the number of items to rank is greater than 5 and results in ambiguity in ranking assignments[14]. Participants’ responses on the two separate surveys were computed as follows: Subcategories not highlighted =‘0’; subcategories highlighted but not prioritized = ‘1’; the subcategory ranked as 3rd priority =‘2’; the subcategory ranked as 2nd priority = ‘3’; the subcategory ranked as 1st priority = “4”. The mean score for each subcategory from all participants was calculated and could range from 0–4, with higher scores indicating a higher priority for that informational topic.

2.5 Exploratory Analyses

We speculated that certain patient characteristics may be associated with specific subcategories. Bivariate analyses were conducted between 5 patient characteristics (i.e., age, race, education level, cirrhosis status, and treatment experience) and each of the 17 subcategories in the combined sample.

3 Results

3.1 Sample I

Thematic saturation of free-listed informational topics was achieved with 45 study participants in Sample I. Characteristics of participants comprising Sample I are listed in Table 1.

3.1.2 Free-Listed Informational Needs—A total of 98 separate free-listed raw responses were obtained from Sample I, and were organized into 6 broad informational categories (excluding Access to Treatment), and 15 subcategories created under several of the broad categories (Table 2).

All 45 (100%) participants free-listed at least one informational need that fell into the broad category labeled “Harms of Treatment.” Five subcategories of Harms of Treatment were identified that captured all of the participants’ responses. Almost every participant (96%) indicated that information related to treatment side effects (a subcategory) would be important to making an informed decision. Free-listed patient responses included “What are the side effects of treatment?” and “Does the treatment medication affect concentration or mood?” Also, falling under Harms of Treatment, over half of participants (60%) required information about how treatment would negatively impact their quality of life or functioning (e.g., “Will treatment affect my ability to work?”, “Will treatment affect my family or social life?”). Almost half (40%) were also concerned with Out of Pocket Costs of Treatment (e.g., “How much will treatment cost me personally?”). Over 25% were also concerned about treatment worsening their liver, other medical conditions, organs, or symptoms and indicated that this information could impact decision-making (e.g., “Does the treatment affect my other conditions?”, “Will it damage my liver more?”).

The majority of participants (84%) free-listed at least one informational need that fell into the broad category “Details of the Treatment Regimens.” Three subcategories were identified that captured these responses. Many participants (64%) indicated that details about the treatment protocol were important (e.g., “How long does treatment last?”, “How many doctor visits do I attend?”). Details about the actual HCV medicines (44%) were also important (e.g., “How is treatment administered?”, “Do the medicines interact with other meds I am taking?”). Lifestyle changes needed during treatment were listed by 18% (e.g., “Will there be a change in my diet?”, “Can I drink alcohol while on treatment?”). These logistical issues were deemed important to informed decision-making.

Information about various “Benefits of Treatment” was important to 62% of participants and comprised another broad category with three subcategories. Half of participants indicated that information about Viral Cure was important to decision-making (“What is the cure rate?”, “What are my chances of getting rid of Hep C?”, “Can the virus come back?”). Other benefits of treatment that mattered to participants included impact on long-term survival (20%) (e.g., “Will I live longer if I undergo treatment?”) and potential improvements to other medical conditions, HCV symptoms, and functioning (16%) (e.g., “What are the long-term benefits of getting rid of Hep C?”, “Will I feel better after treatment?”)

Close to half of participants indicated they needed basic information about the hepatitis C virus and liver disease in order to make informed decisions. These topics comprised the final two broad categories. Participants (64%) said they required general information about their liver disease (“What is the stage of my liver disease?”, “Do I have cirrhosis?”). Forty-two percent of participants wanted general information about HCV which fell into four subcategories: Symptoms of HCV (16%), details about the virus (11%), how is HCV transmitted (10%) and availability of social support for patients or families (6%).

Finally, we noted two distinctions with regard to these 6 broad categories and the subcategories and organized them into (a) *static informational topics* and (b) *informational topics for future research*. Making these two distinctions led to developing two separate surveys to be used with Sample II participants.

3.2 Sample II

Sample II consisted of 38 study participants with HCV, the majority of whom were male (66%), Caucasian (63%), and on average, 57 years old. Over 1/3 had cirrhosis (Table 1).

3.2.1 Free-Listed Informational Needs—Thematic saturation was reached with 38 participants when no new raw responses required the creation of a new category not already derived from the Sample I analysis. The majority of Sample II’s responses were confirmed to fit very well under the 6 broad and multiple subcategories derived from Sample I. However some responses were judged to fit poorly under the pre-existing categories. These new informational topics related to access to treatment and health insurance coverage and were judged to fit better under a newly created broad category, labeled “Access to Treatment.” Under this broad category, two new subcategories emerged. With the creation of a final 7th category, the Sample I responses were re-analyzed. The final 7 broad and 17 subcategories are listed in Table 2.

3.2.2 Importance Ratings—As shown in Figure 1, the 38 participants rated all of the informational subcategories, on average, as either “Extremely Important” or “Pretty Important.” On average, participants rated of highest importance, the information about “Viral cure” ($\bar{x}=4.95$), while the lowest rated item on importance ($\bar{x}=3.42$) was for “Availability of HCV support groups.”

3.2.3 Priority Rankings—As shown in Figure 2, on the survey consisting of 9 *informational topics for future research*, Sample II ranked, on average: “Viral cure” as their highest priority ($\bar{x}=2.32$), followed by “Long-term survival” ($\bar{x}=1.92$), and “Side effects of treatment” ($\bar{x}=1.53$). These patient priorities inform areas for further investigation. The For the 8 *static informational topics*, Sample II ranked: “Liver disease” as the highest priority ($\bar{x}=2.45$), followed by “Lifestyle changes needed during treatment” ($\bar{x}=1.97$), “Details about the Hep C medicines” ($\bar{x}=1.95$), and “Details of the treatment protocol” ($\bar{x}=1.47$). These patient priorities have relevancy for clinicians.

3.3 Exploratory Analyses

Bivariate analyses between the five patient characteristics and each of the 17 subcategories revealed only a few associations significant at $p < .05$. All results were nonsignificant once Bonferroni correction was applied for multiple comparisons.

4 Discussion

The findings from this study demonstrate that patients with HCV wish to consider a plethora of information to assist them with making informed decisions about their HCV treatment options. Patients' informational needs fell into seven broad themes, including harms and benefits of treatment, details about the treatment regimen, access to treatment, risk of not doing treatment, and basic educational needs about HCV and liver disease. Furthermore, patients rated almost all informational topics as "very important" or "extremely important" to their decision-making. The data derived from this study provide an in-depth understanding of the most important informational needs of patients contemplating HCV treatment, are consistent with previous studies [15, 16], and have direct implications for both patient education and PCOR initiatives in HCV research.

With regard to informational topics important to patient decision-making, it was interesting that many patients, over half of whom were previously treated or had cirrhosis, felt they needed very rudimentary information about the virus and their liver disease to make a decision. Previous studies have shown that patients with HCV have low funds of knowledge about the virus and its treatment, which is consistent with findings from the current study [17–19].

Patients also believed information on the specific details of the HCV medications and treatment protocol was important (e.g., how are medications administered, do they interact with other medications or comorbidities, treatment duration, number of pills, visits, labs, and procedures). These informational needs will likely remain important to patients as new DAA regimens become available and cure rates may be equitable, but other treatment details may vary. Patients were also interested in information about lifestyle changes needed during treatment. Some patients also wanted to consider the risk of not doing treatment at all. Access to treatment, insurance coverage, and out of pocket costs were important factors that patients wanted to consider to inform their decisions and are anticipated to be topics that will remain salient in the future. Preliminary findings from these exploratory analyses suggest that all patients desired these informational topics, regardless of age, race, education, cirrhosis status or prior experience with HCV treatment.

These findings have implications for clinical practice, including patient-provider communication and patient education. Clinicians may use the informational categories elucidated in this study as a guide to educating their patients to promote informed decision-making [8, 20]. For instance, information is readily available about basic information on HCV, liver disease, and details about the treatment regimens that can address several of the static informational topics patients requested. Patient-friendly fact sheets, such as those on www.HCVadvocate.org, thoroughly address many informational needs and can be provided to patients to reinforce information presented during the clinical encounter. Thoughtful

patient-provider communication reinforced by educational materials may improve patient knowledge and retention, shared decision-making, patient satisfaction, motivation, personal responsibility, which may lead to improving medication adherence when they ultimately initiate therapy[2, 9].

Several treatment harms and treatment benefits matter greatly to patients, many of which will require additional research to satisfactorily answer patients' questions about the new treatments. In particular, patients highly prioritized information about viral cure, chances of long-term survival if cured, and side effects of treatment as requisite information needed to support informed decision-making. Currently the only data available on the short-term harms or benefits of DAA treatment are derived from pharmaceutical-sponsored trials and there are insufficiencies in these data[1].

In these registration trials, adverse events are captured by the clinician, not the patient. However, most side effects, such as headaches and nausea, are inherently subjective. Who is best to judge subjective experiences—the patient or the physician? Research with other medical populations demonstrates that clinician-reported adverse events woefully underrepresent the frequency and severity of these events compared to patient-reported experiences[21]. Patient-reported outcome (PRO) measures may provide more reliable and valid measurement of patients' subjective experiences. Secondly, industry-sponsored trials typically report results only up to 12-weeks post treatment, however, patients are interested in longer-term effects of treatment. Therefore, future studies should extend follow-up a few years past the end of treatment to capture harms that linger or develop, or other subjective benefits of cure. Patients were also concerned about quality of life impairment. A few PRO studies derived from industry-sponsored trials of sofosbuvir demonstrate a return to baseline scores at 12-weeks post-treatment[22]. However, more research is needed on the other DAA regimens and in a broader spectrum of patients treated in clinical practice[23]. Patients also inquired about potential harms of the medications on their liver, other organs, or pre-existing conditions, consistent with previous work[15]. Clearly, more post-marketing studies of the new DAAs prescribed in real world practice are needed[23] especially in light of recent FDA warnings for the use of some DAAs with particular patients[1]. In conclusion, several potential harms and benefits of DAA treatment have not been well-studied, and thus may serve as prime patient-centered outcomes that can be evaluated in future PCOR studies (e.g., PROP UP ([Clinical trial.gov](https://clinicaltrials.gov/ct2/show/study/NCT02601820): NCT02601820); PRIORITIZE ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02786537): NCT02786537)).

With regard to treatment benefits, viral cure was of utmost priority to patient decision-making and is consistent with a few other studies, including a recent qualitative study based in the VA system and a conjoint analysis conducted during interferon-based triple therapy in which patients were willing to incur more harms if it gave them a greater chance of cure[15, 24]. More real-world data on cure rates outside of drug registration trials are required to capture outcomes in a more diverse range of patients[23]. Information regarding other long-term patient-reported benefits such as increased survival if cured and improvements in extrahepatic symptoms and pre-existing conditions are needed, as these benefits were also prioritized as important to patients contemplating treatment. At this point in time, providers can share what knowledge we do have with patients; however it is worth mentioning to

patients that there are still limitations in our current understanding about many short-term and long-term harms and benefits, especially about very specific issues, and more science is needed before we can definitively answer some patients' concerns.

Though not the intent of this study, we observed some differences in the proportion of free-listed responses provided by Sample I and Sample II. For instance, Sample I seemed more concerned with Treatment Harms compared to Sample II, while a larger proportion of Sample II were concerned with Treatment Benefits and Access to Treatment. Whereas Sample I reported needing general information about HCV and liver disease to facilitate decision-making, the proportion of patients in Sample II free-listing these topics was lower. While the reasons for these differences are not clear, we speculate that they may reflect a historical trend. Sample I was interviewed November 2013 to January 2014 which coincided with the approval of the first two new DAAs, so consumer knowledge was relatively low regarding the new DAAs. Sample II was interviewed a year later (February–March 2015) shortly after sofosbuvir/ledipasvir was approved, covered in the media, and heavily marketed. It is possible that time and exposure to post-marketing advertising could have had an impact on consumer familiarity with the new DAAs and the particular types of information patients felt were important to decision making at that time.

We also noted that different study methods (e.g., free-list, ratings of importance, rankings of top three priorities) used to solicit informational needs from participants led to slightly different sets of responses. The free-list technique where participants simply report all types of information seemed to lead more patients to focus on harms and risks of treatment. In contrast, when presented with an *a priori* list of informational topics, participants prioritized chance of cure as a top priority. Thus various study methods solicited slightly different response sets, suggesting that it may be beneficial to take a multi-method approach to soliciting patient information.

This study has a few limitations. The data were collected from patients who were referred to a large academic hepatology center for treatment. As such, the informational topics derived from these samples may be different from the informational needs of the larger community of people living with HCV who are not engaged in specialty care or those receiving HCV care through the VA system. People who inject drugs may have more questions about re-infection or likelihood of HCV coming back after being cured, than patients treated in a tertiary care liver center. The sample sizes were relatively small, but consistent with qualitative research methods where sample size is often not established *a priori* but rather based on thematic saturation[25] which was achieved with both of these samples.

5. Conclusion

Several DAA treatments for HCV are now recommended and patients, providers, and other stakeholders will have multiple options to choose from[1]. Knowing what treatment issues matter most to patients, is important for both patient education as well as designing patient-centered studies[11]. Patient-provider communication should focus on what is currently well-known in the literature and help to distill the pros and cons of each treatment option relative to what is most important to the individual patient[9]. The findings from this study

also provide the foundation on which to develop future PCOR studies to evaluate treatment issues that have not been well-studied but are salient to patients contemplating their treatment options.

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References

1. AASLD-IDSA. [Accessed May 9, 2016] HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. <http://www.hcvguidelines.org>
2. Stacey D, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev.* 2014; 1:Cd001431.
3. Kittner JM, et al. Defer or treat? Reasons for treatment decisions in patients with chronic hepatitis C genotype 1 in the early era of directly acting antiviral agents. *Dig Liver Dis.* 2014; 46(1):67–71. [PubMed: 24125691]
4. Volk ML. Antiviral therapy for hepatitis C: why are so few patients being treated? *J. Antimicrob. Chemother.* 2010; 65(7):1327–1329. [PubMed: 20460398]
5. Fried MW, et al. Peginterferon alfa-2a plus ribavirin for chronic hepatitis C virus infection. *N. Engl. J. Med.* 2002; 347(13):975–982. [PubMed: 12324553]
6. Elwyn G, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ.* 2006; 333(7565):417. [PubMed: 16908462]
7. O'Connor AM, et al. Toward the 'tipping point': decision aids and informed patient choice. *Health Aff (Millwood).* 2007; 26(3):716–25. [PubMed: 17485749]
8. Fraenkel L, et al. Variation in Treatment Priorities for Chronic Hepatitis C: A Latent Class Analysis. *Patient.* 2016; 9(3):241–9. [PubMed: 26518200]
9. Barry MJ, Edgman-Levitan S. Shared decision making--pinnacle of patient-centered care. *N Engl J Med.* 2012; 366(9):780–1. [PubMed: 22375967]
10. Legare F, Witteman HO. Shared decision making: examining key elements and barriers to adoption into routine clinical practice. *Health Aff (Millwood).* 2013; 32(2):276–84. [PubMed: 23381520]
11. Frank L, Basch E, Shelby JV. The PCORI perspective on patient-centered outcomes research. *JAMA.* 2014; 312(15):1513–1514. [PubMed: 25167382]
12. Borgatti, S. *The Ethnographic Toolkit.* Newbury Park, CA: Sage Publications; 1999. Cultural consensus theory.
13. Weller, SC., Romney, AK., editors. *Systematic Data Collection.* Sage Publications; Newbury Park, CA: 1988.
14. <https://www.surveygizmo.com/survey-blog/alternative-ranking-questions/>. May 13, 2016].
15. Zuchowski JL, et al. Qualitative analysis of patient-centered decision attributes associated with initiating hepatitis C treatment. *BMC Gastroenterol.* 2015; 15:124. [PubMed: 26429337]
16. Fraenkel L, et al. What do patients consider when making decisions about treatment for hepatitis C? *Am J Med.* 2005; 118(12):1387–91. [PubMed: 16378783]
17. Rashrash ME, et al. An evaluation of hepatitis C knowledge and correlations with health belief model constructs among African American "baby boomers". *J Infect Public Health.* 2016; 9(4): 436–42. [PubMed: 26706773]
18. Allison WE, et al. Knowledge about Hepatitis C Virus Infection and Acceptability of Testing in the 1945–1965 Birth Cohort (Baby Boomers) Presenting to a Large Urban Emergency Department: A Pilot Study. *J Emerg Med.* 2016; 50(6):825–831.e2. [PubMed: 26954104]
19. Denniston MM, et al. Awareness of infection, knowledge of hepatitis C, and medical follow-up among individuals testing positive for hepatitis C: National Health and Nutrition Examination Survey 2001–2008. *Hepatology.* 2012; 55(6):1652–61. [PubMed: 22213025]

20. Surjadi M, et al. Formal patient education improves patient knowledge of hepatitis C in vulnerable populations. *Dig Dis Sci*. 2011; 56(1):213–9. [PubMed: 20972850]
21. Basch E. The missing voice of patients in drug-safety reporting. *N Engl J Med*. 2010; 362(10): 865–9. [PubMed: 20220181]
22. Younossi Z, Henry L. Systematic review: patient-reported outcomes in chronic hepatitis C - the impact of liver disease and new treatment regimens. *Aliment Pharmacol Ther*. 2015; 41(6):497–520. [PubMed: 25616122]
23. Sulkowski MS, et al. Effectiveness of Simeprevir Plus Sofosbuvir, With or Without Ribavirin, in Real-World Patients With HCV Genotype 1 Infection. *Gastroenterology*. 2016; 150(2):419–29. [PubMed: 26497081]
24. Kauf TL, et al. Patients' willingness to accept the risks and benefits of new treatments for chronic hepatitis C virus infection. *Patient*. 2012; 5(4):265–278. [PubMed: 22775534]
25. Guest G, Bunce A, Johnson L. How Many Interviews Are Enough?: An Experiment with Data Saturation and Variability. *Field Methods*. 2006; 18:59–82.

Key points for Decision Makers

- Patients contemplating HCV treatment want a great deal of information to make informed treatment decisions.
- The most commonly cited informational topics included treatment harms such as side effects, treatment benefits such as viral cure, details of the treatment regimen, details about the virus, liver disease, and risks of not doing treatment.
- The most important topics that require additional investigation were information about viral cure, long-term survival, and treatment side effects. The most important topics for which we have sufficient information that can be shared with patients include liver disease, lifestyle changes needed for treatment, and details about the medications and treatment protocol.

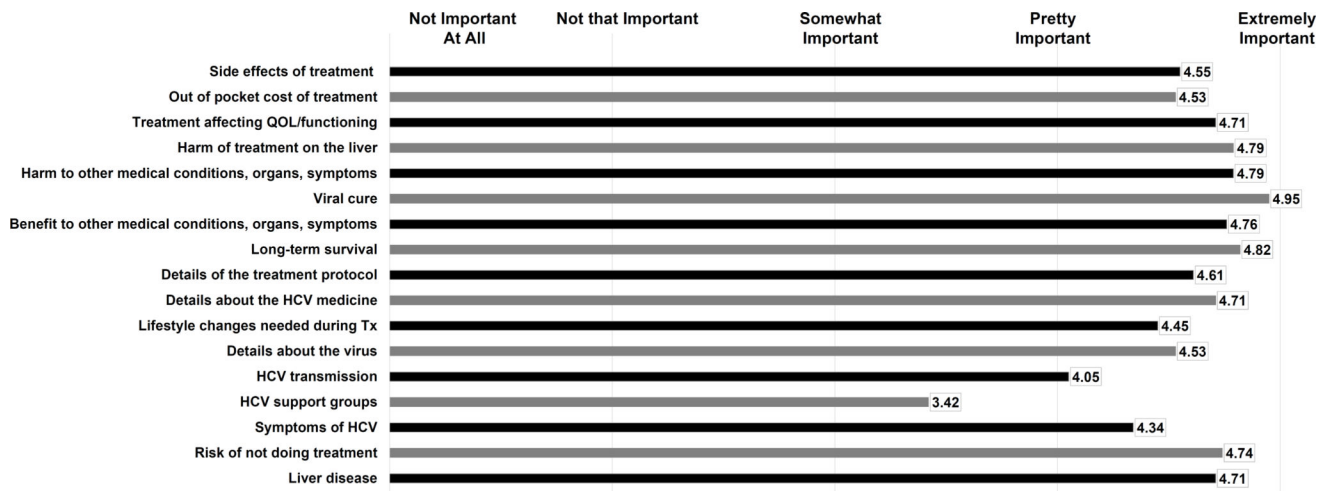


Fig 1. How Important is Information to Patient Decision-Making (Sample II; n=38). Based on sample mean from 5-point Likert scale ranging from 1=Not Important at all to 5=Extremely Important

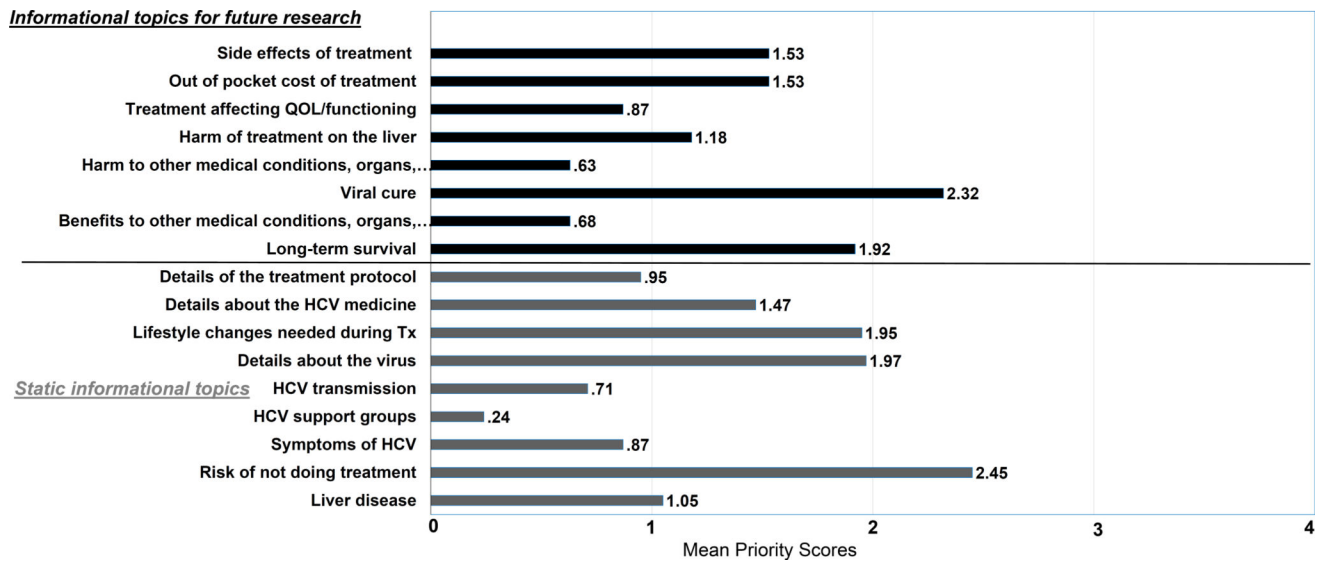


Fig 2. Mean priority scores for informational topics that require future research and static informational topics (Sample II; n=38) Based on range of 0–4, with higher mean score indicating higher patient priority.

Table 1

Summary of patient characteristics

Patient Characteristics	Sample 1 n=45 Mean or %	Sample 2 n=38 Mean or %
Age (mean, range)	55 (35–72)	57 (31–75)
Sex		
Male	58%	66%
Female	42%	34%
Race		
Caucasian	80%	63%
African-American	20%	32%
Other	0%	3%
Marital Status		
Married	36%	39%
Single	42%	34%
Separated/Divorced/Widowed	22%	26%
Educational Status		
High school equivalent or less	31%	45%
Greater than high school	69%	55%
Annual Income		
\$40,000 or less	63%	72%
\$41,000 or greater	38%	28%
Employment Status		
Full time or part-time employed	38%	39%
Unemployed	16%	21%
Disabled, Retired, Other	47%	39%
Insurance Status		
Private	49%	38%
Medicaid or Medicare	31%	35%
Uninsured/self-pay	20%	27%
Genotype		
Genotype 1	72%	89%
Genotype 2–6	28%	11%
Evidence of Cirrhosis		
Yes	36%	34%
No	64%	66%
Treatment Experience		

Patient Characteristics	Sample 1 n=45 Mean or %	Sample 2 n=38 Mean or %
Naïve to HCV treatment	40%	21%
Previously treated	60%	79%

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Table 2

Broad Categories and Subcategories Free-Listed by Participants

Broad Categories and Subcategories Free-Listed by Participants	S/R*	Sample 1 N=45 % (n)	Sample 2 N=38 % (n)
Harms of Treatment	R	100% (45)	92% (35)
Side effects of treatment		96% (43)	84% (32)
Out of pocket cost of treatment		40% (18)	29% (11)
Treatment affecting quality of life/functioning		60% (27)	11% (4)
Harm of treatment on the liver		7% (3)	3% (1)
Harm to other medical conditions, organs, symptoms		24% (11)	3% (1)
Benefits of Treatment	R	62% (28)	76% (29)
Viral cure		49% (22)	76% (29)
Benefit to other medical conditions, organs, symptoms		16% (7)	13% (5)
Long-term survival		20% (9)	3% (1)
Access to Treatment	S	20% (9)	26% (10)
Treatment accessibility and other means of access		2% (1)	18% (7)
Health insurance coverage		18% (8)	11% (4)
Treatment Regimens	S	84% (38)	82% (31)
Details of the treatment protocol		64% (29)	61% (23)
Details about the HCV medicine		44% (20)	37% (14)
Lifestyle changes needed during treatment		18% (8)	8% (3)
Hep C Virus	S	42% (19)	11% (4)
Details about the virus		24% (11)	0% (0)
HCV transmission		22% (10)	8% (3)
HCV support groups		13% (6)	3% (1)
Symptoms of HCV		16% (7)	0% (0)
Risk of Not Doing Treatment	S	24% (11)	3% (1)
Liver Disease	S	64% (29)	3% (1)

Note:* S=Static Informational Topic. R=Informational Topics for Future Research