Primary care flow sheet for hepatitis C virus

Tool for improved monitoring

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Abstract

Objective To develop an expert-guided, evidence-based, primary care flow sheet for the monitoring of patients living with chronic untreated hepatitis C virus (HCV).

Design Delphi consensus process.

Setting Ontario and British Columbia.

Participants Five hepatologists and 4 family physicians experienced in HCV care.

Main outcome measures There were 3 rounds of consultation and revision. In round 1, participants ranked (on an 11-point scale) the importance of 27 possible clinical elements that fell under the categories of background patient information, counseling topics, and biochemical parameters; indicated the ideal frequency of such interventions (in months); and suggested additional elements. Results were collated and elements that were ranked with an average score greater than 4.9 were included in further iterations. The second and third rounds involved the circulation of draft flow sheets, and participants were asked to flag erroneous or missing elements. All comments were integrated.

Results Group consensus was achieved following 3 iterations. The final flow sheet to improve monitoring of HCV in primary care includes 31 clinical elements that fall under the categories background patient information, key counseling topics, and biochemical parameters (and the intervals for such interventions).

Conclusion A diverse group of experienced clinicians came to a consensus regarding optimal primary care monitoring and counseling of the untreated HCV population. Future steps include refinement and pilot-testing of this flow sheet in order to optimize its usefulness within the family medicine setting.

EDITOR'S KEY POINTS

- Despite the availability of national hepatitis C virus (HCV) guidelines, there does not currently exist a widely used, nationally endorsed clinical flow sheet to aid in the care of patients living with chronic HCV. Flow sheets and checklists are a means of making guidelines more useful for family physicians. Considering the relative complexity of HCV care, a simple tool might be beneficial in the primary care process.

- This study provides a consensus-approved HCV care flow sheet containing suggested standards of care for patients living with chronic HCV and areas to record key elements of care. The section of the flow sheet that received the most feedback from participants was the biochemical test section. The area of greatest difficulty for participants was indicating the ideal interval periods for testing.

This article has been peer reviewed.
Can Fam Physician 2016;62:e384-92

Schéma thérapeutique en soins primaires pour le virus de l'hépatite C

Outil pour une meilleure surveillance

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Résumé

Objectif Élaborer un schéma thérapeutique à l'intention des soins primaires, sous la direction d'experts et fondé sur des données probantes, concernant la surveillance des patients vivant avec l'hépatite C chronique non traitée.

Conception Méthode consensuelle Delphi.

Contexte Ontario et Colombie-Britannique.

Participants Cinq hépatologues et 4 médecins de famille expérimentés dans les soins pour le virus de l'hépatite C (VHC).

Principaux paramètres à l'étude Il s'est déroulé 3 rondes de consultations et de révisions. Durant la première ronde, les participants ont classé par rang d'importance (sur une échelle de 11 points) 27 éléments cliniques possibles qui portaient sur les rubriques suivantes : renseignements sur les antécédents du patient, sujets de counseling et paramètres biochimiques. Ils indiquaient la fréquence idéale de ces interventions (en mois) et suggéraient des éléments additionnels. Les résultats ont été rassemblés et les éléments qui ont reçu une cote supérieure à 4,9 ont été inclus dans les itérations ultérieures. Les deuxième et troisième rondes comportaient la distribution de l'ébauche du schéma thérapeutique et les participants ont été appelés à signaler les éléments erronés ou omis. Tous les commentaires ont été incorporés.

Résultats Le groupe en est venu à un consensus après 3 itérations. Le schéma thérapeutique final pour améliorer la surveillance du VHC en soins primaires compte 31 éléments cliniques qui se classent sous les catégories des renseignements sur les antécédents du patient, des principaux sujets de counseling et des paramètres biochimiques (et les intervalles entre ces interventions).

Conclusion Un groupe diversifié de cliniciens expérimentés en est venu à un consensus concernant la surveillance et le counseling optimaux en soins primaires pour la population infectée au VHC non traitée. Les futures étapes incluent le peaufinage et la mise à l'essai de ce schéma dans le but d'optimiser son utilité dans le milieu de la médecine familiale.

POINTS DE REPÈRE DU RÉDACTEUR

- En dépit de l'accessibilité de lignes directrices nationales sur le virus de l'hépatite C (VHC), il n'existe actuellement pas de schéma thérapeutique largement utilisé et endossé nationalement pour aider dans les soins aux patients qui vivent avec une hépatite C chronique. Les schémas thérapeutiques et les listes de vérification sont des façons de rendre les lignes directrices plus utiles pour les médecins de famille. Étant donné la complexité relative des soins pour le VHC, un outil simple pourrait se révéler bénéfique dans le processus des soins primaires.

- Cette étude a pour résultat un schéma thérapeutique approuvé par consensus concernant les soins pour le VHC, qui comporte des normes de soins suggérées pour les patients qui vivent avec l'hépatite C chronique, de même que les éléments de soins importants à consigner. La section du schéma thérapeutique qui a reçu le plus de commentaires des participants portait sur les analyses biochimiques. Le sujet qui posait le plus de difficultés aux participants était la détermination des intervalles idéaux entre les analyses.

Cet article a fait l'objet d'une révision par des pairs.
Can Fam Physician 2016;62:e384-92

The Public Health Agency of Canada estimates that 242 521 people are infected with hepatitis C virus (HCV) in Canada. Based on a 2013 analysis, it is likely that most of these individuals are unaware of their infection.[1] The main risk factors for HCV infection are intravenous drug use, blood transfusion before 1992, and immigration from an endemic area.[2,3] The chronic and progressive nature of liver disease from HCV infection has a considerable effect on the health and economic well-being of the population. The Ontario Burden of Infectious Disease Study ranks HCV infection as the infectious disease with the greatest health burden (the number 1 infectious disease of 51 evaluated pathogens), as measured by health-adjusted life-years.[4]

In Canada, most people living with HCV infection are first diagnosed, and initially managed, by their family physicians. While many of these patients with HCV proceed to receive medications for treatment, a large proportion of patients never receive therapy for many reasons, including being ineligible, not having access, or choosing not to receive it.[5] Factors involved in the decision to treat include the following: expected adherence, drug and alcohol use, and consideration of other poorly controlled serious medical conditions.[6] Although there are no absolute contraindications to HCV treatment, for the aforementioned reasons, there exists a large group of untreated HCV patients who require long-term care and monitoring.

Monitoring of chronic HCV is often led by the family physician and focuses on assessing for and delaying the progression of cirrhosis while also assisting the patient in overcoming relative contraindications to treatment. To achieve this goal, family physicians are required to routinely evaluate biochemical parameters and provide counseling. Despite the breadth of biochemical tests available for hepatic monitoring, no single, minimally invasive, widely accessible test is yet available to accurately assess hepatic disease progression. Therefore, physicians are often required to use a combination of blood tests (liver enzymes, platelet count, etc) and imaging (eg, ultrasound) to determine the likelihood of cirrhosis and hepatocellular carcinoma. Unfortunately, determining which tests to order, how frequently to order them, and how best to interpret results is difficult and not clearly delineated in many existing North American HCV clinical care guidelines.[7-11] Although many studies and guidelines highlight the usefulness of monitoring liver enzymes, prothrombin time, platelet count, and ultrasound findings,[7] few provide evidence-based guidance regarding the ideal frequency of such testing.[12] For example, the 2002 National Institutes of Health consensus statement on HCV management[7] captures this sentiment, stating that it is difficult to develop care guidelines owing to the paucity of existing scientific data. This lack of clear guidance regarding chronic HCV care could result in a diversity of approaches—ranging from incomplete to overly aggressive care.

Routine counseling regarding chronic HCV infection can address a variety of topics, depending upon the individual patient's goals and the particular clinical context. Counseling patients with HCV often focuses upon addressing modifiable risk factors for disease progression (eg, HIV prevention, hepatitis B vaccination, alcohol use, central obesity) and barriers to treatment (eg, drug and alcohol use, chronic medical conditions).[6,8] Despite the importance of such counseling, there are few clinical tools available to provide guidance regarding effective counseling methods for chronic, untreated HCV (**Table 1**).[7-11] As a result, there appears to be variations in the HCV-related counseling provided by family physicians.

Given the lack of straightforward guidance for Canadian primary care clinicians providing chronic HCV care, it is no wonder that only 36% of family physicians indicate confidence in monitoring patients with HCV.[7,8,13] It is within this context of unclear HCV guidelines for chronic HCV care and a paucity of HCV primary care tools that this current study was developed. The aim of this study was to create a primary care–oriented HCV clinical flow sheet to aid family physicians in collecting baseline patient information, providing counseling, and monitoring biochemical markers of disease.

METHODS

In this study, the Delphi method was used as a means of bringing together and promoting dialogue among a group of HCV experts, with the ultimate goal of creating a practical care flow sheet. This method was chosen because it allowed for the assembly of a diverse group and provided rich qualitative data using a feasible approach.

The Delphi method is a survey technique aimed at gathering the ideas and opinions of a panel of individuals and, through an iterative and structured process of written responses, coming to a consensus as a group. In particular, it requires the distribution of a questionnaire (composed of open- or closed-ended questions) to a carefully selected panel of experts, and the completion of the questionnaire by each individual without discussion or interaction with other panel members. The results of initial questionnaires are collated by researchers and then redistributed to individual members, who then predict, comment, and respond to the new information via a questionnaire.[14] This process repeats until an essential consensus is reached among the experts.

The study authors (1 hepatologist [H.S.] and 2 family physicians [L.S.S., Z.v.A.]) identified and recruited Delphi panel members from the Canadian physician community based on their reputation for being experienced in the care of patients with HCV.

Table 1. Comparison of biochemical monitoring and counseling recommendations in several North American HCV guidelines

	RECOMMENDATIONS	
GUIDELINES	KEY PARAMETERS FOR BIOCHEMICAL MONITORING	KEY COUNSELING POINTS
National Institutes of Health,[7] 2002	• Laboratory tests or screening include the following: liver-associated chemistries, platelet count, and prothrombin time. If patient has cirrhosis, consider AFP testing and ultrasound every 6 mo	• Clean syringe provision • For IVDU, promote hand washing, no equipment sharing, and avoidance of contact with others' blood • If you have multiple partners or are in short-term relationships, use condoms • Avoid sharing household items • If you are a health care worker, use universal precautions • If pregnant, avoid fetal scalp monitoring and prolonged labour after rupture of membranes
Pinette et al,[8] 2009	• Laboratory tests or screening include the following: ALT, AST, total bilirubin, GGT, and albumin levels, INR, HCV viral load, and HCV genotype. If patient has cirrhosis, consider ultrasound every 6 mo	• Reduce liver damage: limit alcohol; maintain a healthy weight; stop smoking; receive hepatitis A and B vaccines • Reduce transmission: never donate blood, organs, semen, or tissue; never share drug-injection material; avoid higher-risk sexual behaviour; use condoms or dental dams for sex; breastfeed unless nipples are cracked or bleeding; never share sharp instruments or personal hygiene materials; consider health risks of tattooing and body piercing; and discuss your HCV status with drug-using partners • Consider medication use: avoid benzodiazepines, aminoglycosides, and narcotics including codeine; avoid use of ASA or NSAIDs if possible; use of acetaminophen, oral contraceptive pills, and statins is safe; and keep your health care provider informed about complementary therapies • Live well: adhere to follow-up care; be informed; be physically active; and reduce stress
Guidelines and Protocols Advisory Committee,[9] 2004	• If ALT levels are normal or less than 1.5 times the ULN, repeat the ALT test at 3, 6, and 12 mo • If ALT levels remain normal or less than 1.5 times the ULN after 1 y of monitoring, perform a follow-up qualitative HCV RNA test (eg, PCR) at 12 mo. If the HCV RNA test results are positive, repeat ALT measurement annually; if results are negative, repeat once at 24 mo. If results are negative 2 y in succession, no further testing is required unless the patient has been exposed to new risk factors • If ALT levels are more than 1.5 times the ULN on at least 2 of 3 measurements within 6 mo, specialist referral is recommended • If patient has cirrhosis or hepatitis B virus, perform AFP testing and ultrasound every 6 mo	• Do not share or reuse needles • Avoid alcohol • Eat a healthy diet • Receive hepatitis A and B vaccines • Do not let others contact your blood • Do not share spoons or straws for cocaine use • Do not share anything with blood on it • If you have multiple partners or are in short-term relationships or are menstruating, use condoms • Tell your health care providers that you are infected with HCV

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GUIDELINES	RECOMMENDATIONS	
	KEY PARAMETERS FOR BIOCHEMICAL MONITORING	KEY COUNSELING POINTS
Myers et al,[10] 2015*	• Signs and symptoms of advanced liver disease include the following: jaundice, ascites, encephalopathy, and portal hypertension–related hemorrhage • Characterization of chronic infection includes HCV RNA and HCV genotype • Assessment of liver disease includes the following: CBC; ALT, AST, GGT, alkaline phosphatase, bilirubin, albumin, and creatinine levels; INR; and abdominal ultrasound • Testing for viral co-infections include the following: anti-hepatitis A virus immunoglobulin G antibodies, HB_sAg, hepatitis B surface antibody, and anti-HIV • Assessment of liver disease severity can be completed with the following: biopsy, serum markers (eg, APRI score), FibroTest or FibroScan, other image-based tools	• Assess risk factors: IVDU, receipt of potentially contaminated blood products or tissues, and origin from a high-prevalence region • Assess cofactors that might accelerate disease progression: alcohol abuse, obesity, co-infections • Assess contraindications to interferon-based therapy
American Association for the Study of Liver Diseases,[11] 2016	• Assessment of liver disease severity includes the following: liver-directed physical examination, routine blood tests (ie, serum ALT, albumin, and bilirubin levels, INR, CBC), serum fibrosis marker panels, liver imaging (eg, ultrasound, CT scan), liver elastography. If patient has cirrhosis, consider ongoing imaging surveillance	• Abstain from alcohol • Reduce risk of HBV and HIV transmission; receive hepatitis B and A vaccines • Recommend lifestyle changes for patients with obesity and metabolic syndrome • If patient has cirrhosis, avoid ulcerogenic drugs • Avoid HCV transmission to others (do not share needles, etc)

AFP—α-fetoprotein, ALT—alanine aminotransferase, APRI—AST to platelet ratio index, ASA—acetylsalicylic acid, AST—aspartate aminotransferase, CBC—complete blood count, CT—computed tomography, GGT—γ-glutamyl transpeptidase, HB_sAg—hepatitis B surface antigen, HBV—hepatitis B virus, HCV—hepatitis C virus, INR—international normalized ratio, IVDU—intravenous drug use, NSAID—nonsteroidal anti-inflammatory drug, PCR—polymerase chain reaction, ULN—upper limit of normal.

*These biochemical monitoring and counseling points were presented as part of a pretreatment assessment. These guidelines also included tests to exclude other causes of liver disease and contraindications to treatment, which are not included in this table.

To inform the creation of the flow sheet we conducted a review of articles published from 1946 to present (using MeSH terms *hepatitis C; primary health care; family practice; physicians, family; general practice; general practitioners; medical records; disease management; documentation; guideline adherence*) and reviewed gray literature pertaining to flow sheets for HCV care. The results of this search were used to generate an extensive list of patient characteristics, counseling points, and biochemical markers a family physician might include in the routine care of patients with HCV.

Our Delphi method included 3 rounds of consultation and revision. In round 1 we presented panel members with a potential list of variables to include on the flow sheet. Participants were asked to rank the importance of each of the 27 variables using an 11-point scale (0 = unimportant, 10 = essential), indicate the ideal frequency of such interventions (in months), and provide further variables of interest.

Results of the initial questionnaire were collated and elements that were ranked with an average score greater than 4.9 were included in the second questionnaire. Responses to the questions regarding the optimal "interval of testing" were also collated and the mode value (most frequently occurring suggested interval) was identified. In addition, all new suggested elements (generated by participants) were included in the subsequent questionnaire. The integration of participant comments was completed by one of the family physician authors (Z.v.A.) and reviewed by the other 2 authors (L.S.S., H.S.) in an attempt to ensure unbiased interpretation of comments.

In round 2, a mock care flow sheet was presented based on the results of the first round. Panel members were asked to use the track changes tool in Microsoft Word to comment on items that were unclear or incorrect. All suggested changes were incorporated into the subsequent questionnaire (round 3). This integration of participant comments was also completed by 1 family physician author (Z.v.A.) and reviewed by the other 2 authors (L.S.S., H.S.).

In round 3, panel members were asked to approve the final version of the flow sheet and indicate if any

critical changes were required (a draft of the final care flow sheet was attached to the questionnaire). These final edits were included in the final flow sheet. Participants were also asked for a brief description of their practice type and location.

RESULTS

Study participants included 5 hepatologists and 4 family physicians. Eight of the 9 participants practised within the greater Toronto area in Ontario, while 1 participant practised in Vancouver, BC. Of the 9 participants, 7 were community-based physicians and 2 were academic-based physicians; 7 participants were men.

Results from round 1 are described in **Table 2**. The response rate for this round was 100%. Most of the 27 initial elements were deemed "important" by study participants (ie, average score of > 4.9), and therefore were included in the subsequent questionnaire. There were 6 items with an average score of 4.9 or less (marijuana avoidance [4.8], acetaminophen avoidance [4.2], weight loss [4.4], α-fetoprotein testing [2.1], and computed tomographic scan [1.5]), so those items were removed (**Table 2**).

Items that were suggested as additions to the original flow sheet by participants included the following: fibrosis stage, viral load, hepatitis A and B vaccines, financial security, drug insurance, influenza vaccine, pneumococcal vaccine, HIV status, and albumin, bilirubin, and creatinine levels. All of these suggestions were incorporated into the second questionnaire (round 2). Only 4 of the 9 physicians responded in a specific manner (versus a range) to all questions pertaining to "interval of testing." Responses included "once," "unknown," and various other month intervals (eg, every 3 months, every 6 months). Most of these respondents were hepatologists (3 out of 4 respondents). Unfortunately, none of the respondents provided additional comments to explain and justify his or her rationale for the suggested testing intervals.

Round 2 included 31 items, and 8 out of 9 respondents replied to the questionnaire. Emerging themes in this round included the following: adding greater detail regarding the patient's financial security, merging the "biopsy" and "fibrosis stage" elements (as well as the addition of the FibroTest or FibroScan nomenclature), adding details on how to calculate the aspartate aminotransferase to platelet ratio index (APRI) score, and including further refinement of the ideal intervals for testing.

Because 1 of the 9 participants in round 2 had been lost to follow-up, round 3 had a sample size of 8 participants. All 8 participants responded to the round 3 questionnaire. The flow sheet included 30 variables, and all participants approved of the flow sheet in its final form. Six of the 8 physicians suggested additional "nonessential" edits, which were incorporated into the final product. The final flow sheet includes 31 clinical elements: 16 pertain to patient background information, 5 to counseling, and 10 to biochemical monitoring (**Figure 1**). Ultimately, group consensus was achieved following 2 iterations of the questionnaire and, in total, 8 of the 9 physicians completed all 3 rounds (1 physician did not respond after the first round).

Of the 3 sections of the flow sheet (patient background information, counseling topics, and biochemical monitoring), the section that produced the most feedback from participants was the section on biochemical tests. Ultimately, invasive tests (eg, liver biopsy), controversial

Table 2. Participant responses to the round 1 questionnaire: *Responses are based on an 11-point scale (0 = unimportant and 10 = essential).*

ITEM	AVERAGE IMPORTANCE SCORE
Patient background information	
• Genotype	10.0
• Contraindication to treatment	9.1
• Specialist name	6.3
• Biopsy findings	7.7
• Ultrasound findings	7.1
Counseling	
• Alcohol avoidance	7.2
• Cigarette avoidance	5.6
• Marijuana avoidance	4.8
• Acetaminophen avoidance	4.2
• NSAID avoidance	6.7
• Weight loss	4.4
• Safe-sex practices	6.8
• Avoidance of needle sharing	8.7
• Hepatitis A vaccine	8.0
• Hepatitis B vaccine	8.7
Biochemical monitoring	
• AST	7.5
• ALT	7.5
• Platelet	7.7
• AFP	2.1
• HCV RNA	9.4
• MELD score	5.8
• Ultrasound	8.7
• CT scan	1.5
• Liver biopsy	5.3
• HIV	9.1

AFP—α-fetoprotein, ALT—alanine aminotransferase, AST—aspartate aminotransferase, CT—computed tomography, HCV—hepatitis C virus, MELD—model for end-stage liver disease, NSAID—nonsteroidal anti-inflammatory drug.

Figure 1. Flow sheet for monitoring HCV

PATIENT BACKGROUND INFORMATION	RESULTS AND DATE
• Relative contraindications to treatment	❑ Pregnancy ❑ History of anaphylaxis to treatment ❑ Hepatic decompensation ❑ Inability to adhere to contraceptives for 6 mo ❑ Coronary artery disease ❑ Solid organ transplant recipient (except liver) ❑ Current alcohol abuse
• Barriers to treatment	❑ Psychiatric illness ❑ Severe coexisting medical condition ❑ Poor compliance ❑ Unstable housing
• Treatment history (if applicable)	
• Specialist name	
• Genotype	
• Viral load (HCV RNA)	
• Biopsy or FibroTest or FibroScan findings	
• Ultrasound findings	
• HIV status	
• Received hepatitis A vaccine	
• Received hepatitis B vaccine -Value of hepatitis B surface antibody titre	
• Flu vaccine	
• Pneumococcal vaccine	
• Financial security	❑ Employed ❑ Disability ❑ Social assistance ❑ Old age security ❑ Supported by partner or family member ❑ Other
• Drug insurance	❑ Ontario Drug Benefit ❑ Trillium ❑ Private ❑ None ❑ Other
• Disease progression or other comments	

COUNSELING	FREQUENCY, MO	DATE OF MOST RECENT COUNSELING
• Alcohol reduction or avoidance	6-12	
• Cigarette avoidance	12	
• Avoidance of NSAIDs (instead consider < 3 g/d of acetaminophen [if patient has cirrhosis])	12	
• Safe-sex practices	12	
• Avoidance of sharing needles or other drug-injection paraphernalia	6-12	

BIOCHEMICAL MONITORING	FREQUENCY, MO	RESULTS AND DATE
• INR (If prolonged, consider referral)	12	
• PLT count (If PLT count <160 x 10^9/L, consider referral)	12	
• Albumin level (If albumin level is < 3.5 g/L, consider referral)	12	
• ALT (Expert opinion suggests that if ALT rises by > 20% on consecutive tests, consider referral)	12	
•AST (to calculate APRI score)	12	
• APRI score* (Calculate APRI score as follows: [AST level/AST ULN] x [100/PLT count]. If score is > 1.5, consider referral)	12	
• If patient has cirrhosis, ultrasound	6-12 (only if patient has cirrhosis)	
• HIV	Baseline and every 12 mo (if at risk)	
• Baseline HB_sAg	Once	
• Baseline TSH	Once	

ALT—alanine aminotransferase, APRI—AST to PLT ratio index, AST—aspartate aminotransferase, HB_sAg—hepatitis B surface antigen, HCV—hepatitis C virus, INR—international normalized ratio, NSAID—nonsteroidal anti-inflammatory drug, PLT—platelet, TSH—thyroid-stimulating hormone, ULN—upper limit of normal.

*For more information on calculating APRI score, visit Hepatitis C Online at **http://hepatitisc.uw.edu/go/evaluation-staging-monitoring/evaluation-staging/calculating-apri**.

tests (eg, α-fetoprotein level), and calculations that did not have a meaningful effect upon primary care decision making (eg, MELD [model for end-stage liver disease] score) were dismissed by study participants. Final recommendations for biochemical monitoring included the following: baseline hepatitis B surface antigen testing, baseline thyroid-stimulating hormone level, international normalized ratio, platelet count, albumin level, aspartate aminotransferase and alanine aminotransferase measurement, APRI score, and HIV testing every 12 months, as well as ultrasound every 6 to 12 months (**Figure 1**).

DISCUSSION

Using the Delphi method, this study successfully allowed for the sharing of knowledge among a diverse group of Canadian physicians, and hence the production of a consensus-approved HCV care flow sheet. Each round of the study captured the evolving priorities of the group and highlighted the diversity of perspectives among participants. Early in the study, there was emphasis on the importance of assessing genotypes, contraindications to treatment, avoidance of needle sharing, ultrasound assessments, and HIV testing. As the study progressed, greater attention was placed upon the inclusion of practical details within the chosen variables such as elucidating financial stability, defining methods of determining fibrosis, and clarifying methods of calculating the APRI score.

Few studies have addressed the ideal intervals for testing, and national guidelines often omit such detail. This was also the area of greatest difficulty for our participants. While consensus was ultimately achieved regarding the ideal intervals for testing and counseling, it should be recognized that these values are based on expert opinion and not on clinical data or a formal cost-benefit analysis. However, given the relatively slow, or else infrequent, progression of disease from chronic infection to cirrhosis (2% to 20% after 20 to 30 years of infection) to hepatocellular carcinoma (1% to 4% per year), intervals that are between 6 and 12 months seem reasonable.[15] Furthermore, most respondents who provided input regarding intervals for testing were hepatologists—a finding in keeping with the aforementioned low self-perceived confidence of family physicians in providing HCV monitoring.

Despite the availability of national HCV guidelines, there does not currently exist a widely used, nationally endorsed clinical flow sheet to aid in the care of patients living with chronic hepatitis C. Furthermore, current guidelines often lack practical details and are written in a manner that makes them relatively obtuse and inaccessible.[16] As a means of making guidelines more accessible to and useful for family physicians, various organizations have developed care flow sheets and checklists for other specific diseases. One popular example is the flow sheet that was developed by the Canadian Diabetes Association for patients with diabetes to aid in the tracking of key diabetes-related testing and counseling.[17] In practice, such physician prompts and checklists have resulted in improved preventive care outcomes.[18] Considering the relative complexity of HCV care, combined with the comorbid and psychosocial challenges faced by many people living with HCV, it is hoped that a simple care tool will add order and structure to the primary care process.

Comparison of the current study's care recommendations with those proposed by several HCV guidelines suggests a general congruence in included items, yet also great variability among existing guidelines and minimal detail regarding ideal testing intervals (**Table 1**).[7-11] It is therefore hoped that the proposed care flow sheet will serve as a unification of current recommendations and a practical means of guiding chronic HCV care within a family medicine setting.

Limitations

One of the main limitations of this study relates to study recruitment. Although there were benefits to individualized recruitment of physicians experienced in HCV care, this recruitment method inherently required that most participants had an affiliation with the investigators, therefore creating a clear selection bias.

Furthermore, this recruitment method also resulted in an unfortunate geographic homogeneity of the participants (ie, most clinicians were from the greater Toronto area). This urban bias was initially thought to be acceptable because previous studies have indicated that there is a greater prevalence of HCV in urban, versus rural, regions.[19] However, this urban bias might have resulted in the creation of a flow sheet that neither adequately addresses the needs of rural clinicians nor focuses on the tests available in resource-limited environments. It is important to include rural clinicians in HCV care provision, as recent studies indicate that clinicians providing HCV care were actually more likely to practise in rural, versus urban, settings—likely owing to the limited access to specialist care present in rural regions.[20]

It is hoped that subsequent study of the practical usefulness of this flow sheet will include rural and urban communities, resulting in modifications to the flow sheet that reflect the varied needs of these populations.

Conclusion

Despite the current paucity of data available to inform long-term HCV care decisions, a diverse group of experienced clinicians were able to come to a consensus, via the Delphi method, regarding optimal primary care counseling and monitoring of the untreated HCV population. The tangible result of this consensus was the

production of a care flow sheet containing suggested standards of care for patients living with chronic HCV and areas to record key elements of care. Future steps include refinement and pilot-testing this clinical tool in urban and rural environments so as to optimize its usefulness within the family medicine setting. Further study might also investigate the perceived barriers to HCV care provision for urban and rural clinicians.

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Contributors
All authors contributed to the concept and design of the study; data gathering, analysis, and interpretation; and preparing the manuscript for submission.

Competing interests
None declared

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