

The Hepatitis C Care Cascade: Increasing Comprehensive Screening and Diagnosis

2018 James A. Vohs Regional Quality Award

TOOLKIT

For questions or additional resources please contact:

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Executive Summary

Chronic hepatitis C is the most common US blood borne infectious disease, affecting the large Baby Boomer age population (born 1945-1965) and those at-risk due to blood exposure. Hepatitis C virus (HCV) kills more Americans than any other infectious disease. Significant gaps persist for screening, diagnosis, triage to care, and curative treatment.

The Kaiser Permanente Mid-Atlantic States (KPMAS) hepatitis C virus testing cascade of care (HCV Pathway) is a technology driven, care coordinator-supported process to screen at-risk patients for HCV chronic infection (initial testing with HCV Antibody, confirmed by HCV RNA), co-infection testing (hepatitis B virus, HIV, hepatitis A virus), liver assessment (including staging) and physician referral.³ The multistep pathway closes patient care gaps, improves quality, and eliminates unnecessary physician work. Ultimately, improvements in HCV screening and care can offset cirrhosis, liver failure, and liver transplant.

Learn more about why this project was initiated by watching our video: https://quality-patient-safety.kaiserpermanente.org/hepatitis-c-care-cascade/

Program Overview

The HCV Pathway is initiated by a unique KP HealthConnect order code which triggers HCV Antibody testing, and if positive, is followed by reflex test confirmation for HCV RNA, Hepatitis B Surface Antigen (HBsAg) and HIV Antibody (co-morbidities that will impact engagement in care). Patients with a HCV chronic infection (HCV Antibody+, HCV RNA+) receive additional HCV Assessment Labs (including liver function tests and hepatitis A screening), Fibroscan (a non-invasive test to determine liver damage) and a referral for ongoing care. Patients who are HCV+/HIV+ co-infected are referred to Infectious Disease for assessment and treatment for both infections. HCV+/HBV+ coinfected patients are referred to gastroenterology.

Results in Brief

- Since the HCV Pathway was implemented in Nov. 2014, total KP Mid-Atlantic States regional HCV Antibody testing has doubled.
- The percent of total KP Mid-Atlantic States Baby Boomers screened once for HCV Antibody (per USPSTF recommendations) has increased from 21% (Oct. 2014) to 60.7% (Dec. 2017). KPMAS performance outstrips the external benchmark for Baby Boomer screening of 13% (National Health Interview Surveys).⁴
- Physician time spent per HCV tested patient has decreased.

Results are in preparation for publication as of Dec 2018; for additional information on results, please contact the project team

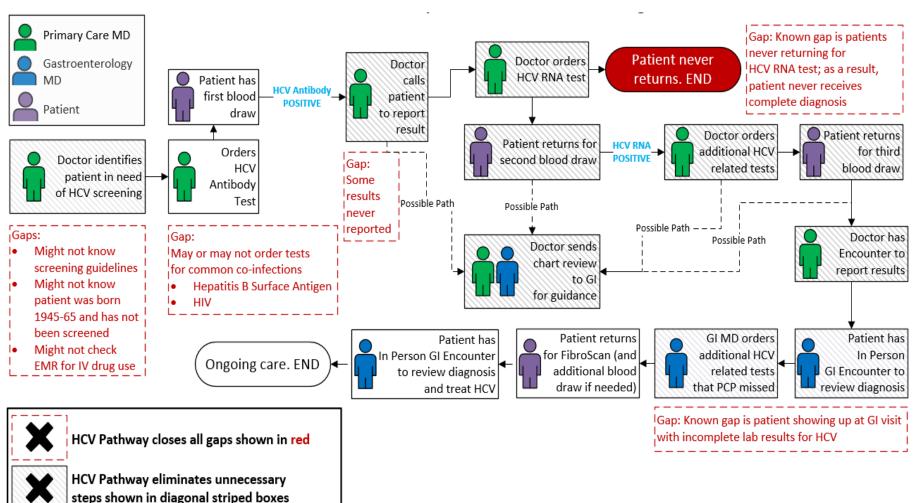
- Centers for Disease Control and Prevention. Hepatitis C Kills More Americans than Any Other Infectious Disease. 2016; https://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html.
 Accessed April 20, 2018.
- 2. U.S. Department of Health and Human Services. Action Plan for the Prevention, Care, & Treatment of Viral Hepatitis 2014-2016. https://www.hhs.gov/sites/default/files/viral-hepatitis-action-plan pdf
- Jones MC, Rodriguez CV, Redd J, Sloane DA, Winston BJ, Loftus BC. Streamlining Screening to Treatment: The Hepatitis C Cascade of Care at Kaiser Permanente Mid-Atlantic States. Clin Infect Dis.
- 2016;62(10):1290-1296

 Monica L Kasting ARG Richard R Reich Richard G Roetzheim David R Nelson Flizabeth Shenkman and Susan T Vadanaramnil Henatitis C Virus Screening Trends: Serial Cross-Sectional Analysis



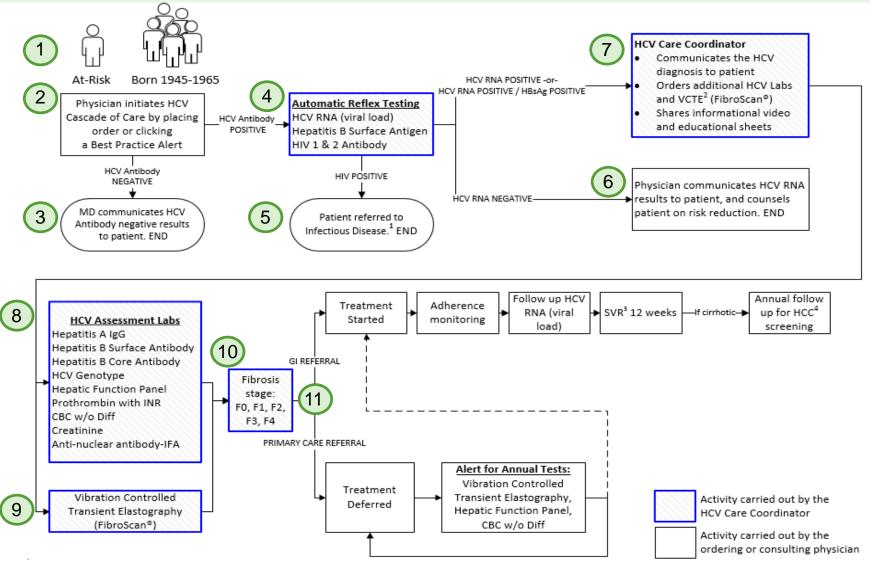
Usual Care Process for HCV Screening

- The process below highlights how usual care for hepatitis C virus screening looked prior to the implementation of the HCV Pathway
- Red boxes indicate known care gaps that were closed by the HCV Pathway; striped boxes indicate steps that were eliminated by the HCV Pathway





HCV Pathway Overview –Figure 1





^{*}Infectious Disease physician completes HCV workup concurrent with HIV treatment

Jonas MC, Rodriguez CV, Redd J, Sloane DA, Winston BJ, Loftus BC. Streamlining Screening to Treatment: The Hepatitis C Cascade of Care at Kaiser Permanente Mid-Atlantic States. Clin Infect Dis. 2016;62(10):1290-1296

² Vibration Controlled Transient Elastography

³Sustained Virologic Response

⁴Hepatocellular Carcinoma

HCV Pathway Detailed Description (1/2)

The numbered steps on this page match the prior page 6 "HCV Pathway Overview - Figure 1" numbered steps

- 1. We developed an algorithm to drive best practice alerts within the Kaiser Permanente electronic medical record (EPIC based KP HealthConnect). The best practice alerts identify patients born 1945-1965—the 'birth cohort'—who are eligible for HCV Ab screening and without documentation in the electronic medical record of prior HCV testing. Additional best practice alerts identify patients at-risk due to social history (sexual, IV drug use).
- 2. Physicians place one order (HCV Pathway 86803G) which grants authorization for the complete pathway, obviating the need for signing/co-signing of additional testing orders. The order includes a button to document verbal consent for HIV testing, to comply with local statutes (varies by state). When the HCV screening order is placed, an EMR "after visit summary" prints for the patient, outlining the screening steps, providing HCV information, introducing the Hepatitis C Care Coordinator, and providing contact information for questions.
- 3. If the patient is negative for HCV Antibody, the physician reports results using standardized text (.HCVneg) and the HCV Pathway ends.
- 4. The HCV Pathway order initiates a group of laboratory tests that automatically reflex—which means positive test results trigger additional downstream testing of multiple specimens collected at a single laboratory visit. The clinic based laboratory draws one EDTA (Ethylenediaminetetraacetic acid) and one SST (serum separator tube) tube from each patient. The EDTA specimen is immediately processed for HCV Ab testing. If positive or indeterminate, the sample is tested for hepatitis B surface antigen (HBsAg) and HIV 1 & 2 Ab. The SST specimen is used for quantitative HCV RNA testing. Patients testing positive for HCV Ab and HCV RNA return for a second blood collection. This specimen is used for the HCV Assessment Labs set (see pg. 6 for a complete list of laboratory tests).
- 5. If the patient is positive for HIV, the patient is referred to Infectious Disease for follow up and does not continue through the HCV Pathway.
- 6. If the patient has been exposed to HCV but has cleared the virus (HCV Ab positive, HCV RNA negative), the Coordinator sends a reminder note to the ordering provider to communicate these results. The physician reports results using different standardized text, which includes recommendations for healthy behaviors. These patients do not need to proceed further through the HCV Pathway.
- 7. The HCV Care Coordinator, a research nurse, closes gaps in the HCV screening pathway by tracking progress through each step (including outreach and reminders) and managing patient follow-up. The HCV Coordinator calls mono-infected HCV patients and co-infected (HCV and HBV) patients to report their results. Patients are offered informational sheets and a KPMAS produced HCV educational video. The Coordinator orders the HCV Assessment Labs and instructs the patient to return for a second blood draw. The Coordinator schedules the Fibroscan test and provides test preparation instructions.
- 8. The HCV Assessment labs include liver function tests and other relevant tests. The Coordinator tracks these results to ensure they are completed. These will be reviewed by the gastroenterologist, along with the Fibroscan results.



HCV Pathway Detailed Description (2/2)

The numbered steps on this page match the page 6 "HCV Pathway Overview - Figure 1" numbered steps

- 9. The Coordinator ensures the patient completes the Fibroscan test.
- 10. The gastroenterologist interprets the Fibroscan result and assigns a fibrosis score (F-score). The gastroenterologist reviews the HCV Assessment Lab results and leaves a result note commenting on relevant features of the lab tests or Fibroscan results. The HCV Care Coordinator receives the final interpreted results and notes from the gastroenterologist.
- 11. At the conclusion of the testing pathway (once the HCV Assessment Labs and Fibroscan results are completed), the Coordinator calls the patient to report the final F-score result, and explains next steps. The HCV Care Coordinator also adds HCV and associated diagnoses to the EMR Problem List.
 - The Coordinator refers all patients who would like to pursue HCV treatment to gastroenterology. Steps downstream of the gastroenterology visit referral (including assessment for treatment, treatment, etc.) are outside of the scope of the HCV Pathway and are managed by gastroenterology and clinical pharmacy.
 - The Coordinator refers patients not pursuing treatment at this time to primary care. Patients referred to primary care receive continued monitoring—including annual follow-up Fibroscan, alpha-fetoprotein, complete blood count and liver function tests. Steps downstream of the primary care referral (including annual screening) are managed by primary care physicians, with best practice alerts developed by the HCV Pathway team.

KPMAS Program Implementation

- Below shows the phasing of our HCV Pathway implementation
- Many program components can be implemented individually

2014:

- Nov. 2014: Pilot Started: deployed HCV Pathway and Fibroscan in one service area as pilot
 - Hired and trained HCV Care Coordinator (LPN)
 - Trained gastroenterology medical assistants on Fibroscan; educated physicians on Fibroscan interpretation
 - Launched Best Practice Alert (BPA) for Baby Boomer age patients
 - Launched patient education documents
- Dec. 2014: Launched three HCV patient educational videos online
 - Hep C: The Basics
 - Hep C: Managing Your Diagnosis
 - Hep C: Treatments

2015:

- Mar. 2015: Regional Expansion: expanded HCV Pathway and Fibroscan to all three service areas (entire region; 5 Fibroscan machines live)
- Mar. 2015: Implemented enhanced KP HealthConnect tool for Fibroscan interpretation support for gastroenterology physicians
- Sept. 2015: Presented HCV Pathway at KP HIV, AIDS and Hepatitis Conference
- Oct. 2015: Hired second HCV Care Coordinator (LPN)
- Oct. 2015: Revised 'After Your Diagnosis' patient educational sheet to be Baby Boomer specific
- Nov. 2015: Implemented improved HCV Care Coordinator Reporting Workbench Workflow Management Tool
- Dec. 2015: Expanded Baby Boomer age BPAs to include OB/GYN , added Tracking BPA for F0-1 patient annual follow up Fibroscan

2016:

- Jan. 2016: 1st CME about HCV Screening and Treatment
- Feb. 2016: Published in Clinical Infectious Diseases
- Mar. 2016: Purchased Fibroscan Pediatrics Probe, and modified eConsult questions to add cochlear implant exclusion
- Apr. 2016: Modified HCV Assessment labs to streamline orders
- Apr.2016: Presented HCV Pathway at EPIC Expert Group Meeting
- July 2016: Translated patient education documents into five languages
- Nov. 2016: Purchased 6th Fibroscan machine
- Dec. 2016: Added BPAs for at-risk patients (sexual history, IV drug use) and contraindications for annual Fibroscan

2017:

- Jan. 2017: 2nd CME about HBV and HCV Screening and Treatment
- July 2017: Added HCV Pathway to preference list for all departments
- Oct. 2017: BPAs fire in nearly all medical specialties
- Dec. 2017: Presented HCV Pathway at Regional Chiefs meeting in all 3 service areas

2018:

- Jan: Deployed Continued Attenuation Parameter (CAP) FibroScan feature for measuring steatosis/fatty liver
- Feb: Purchased 7th FibroScan machine
- Apr. 2018: Added HCV Pathway to HIV Pre-exposure prophylaxis order
- Apr., Aug. 2018 3rd and 4th CMEs about Hepatitis
- Nov: Replacing single HCV Ab order with HCV Pathway in all regional order sets, SmartSets and User Lists





KPMAS Program Team Description

Leadership Involvement:

- Bernadette Loftus, MD, Associate Executive Director Mid-Atlantic States, championed this HCV project, offered input on program design, removed barriers, and secured financial resources.
- Michael Horberg, MD was the Executive sponsor, providing design input, physician engagement, and subject matter expertise.
- The Gastroenterology Chiefs and our HCV Care Coordinators served as subject matter experts. For example, our GI Chiefs continue to refine our lab testing lists to ensure they are optimal.
- An Executive Consultant, Cabell Jonas, PhD, covered project and program management, HealthConnect and lab builds, Fibroscan
 deployment, HCV Care Coordinator training, program improvement and maintenance, and communications. Our team continues to refine
 and revise the pathway, including managing quality and performance improvement.

Team and Research Involvement:

- We collaborated with several technical teams to implement program components. Our HCV Care Coordinators provide ongoing suggestions for program improvement. For example, the Coordinators mentioned patients were having financial challenges, so we streamlined access to Medical Financial Assistance.
- Our laboratory leadership and laboratory teams created and launched the reflex testing process; Executive support ensured our project secured lab staff time.
- Our KP HealthConnect team innovated around automatic best practice alerts and the unique HCV pathway order. Because our work was on the MAPMG Operational Plan, we were prioritized for KP HealthConnect work. We continue to refine our KP HealthConnect processes, including adding/modifying best practice alerts, refining the order structure and replacing the single HCV Antibody order regionally.
- Our quality and analytics partners provided data on performance and outcomes.
- Our physician-in-chiefs, adult primary care chiefs (including module chiefs), infectious disease chiefs, and OBGYN chiefs communicated to frontline physicians. These physicians offer input on pathway revisions and updates- for example, suggesting we activate the Baby Boomer screening best practice alert in all departments.
- Our operational team collaborates with MAPMG research—the Mid-Atlantic Permanente Research Institute—in an ongoing manner around program implementation and evaluation.

Patient, Family, Member Involvement:

• KP members provide ongoing feedback about the program to our Coordinators and clinicians. For example, most of our Baby Boomer patients diagnosed with HCV do not know when or how they contracted the disease. The original "After Your Diagnosis" educational sheet, which focused on transmission primarily via IV drug use and unsafe sex, was alarming because they had never engaged in these behaviors. So, the project team created a Baby Boomer specific "After Your Diagnosis" sheet that broadens the discussion about disease transmission and states that most Boomers don't know how they contracted HCV.



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- HCV Pathway Overview
- KPMAS Program Journey
- Sustained Improvement Over Time Chart

Toolkit

- A. Toolkit Summary of Resources
- B. Guidance on Where to Start

A. Toolkit – Summary of Resources

HealthConnect / Technology Components

- 1. Best Practice Alerts to identify eligible Baby Boomer age patients
- 2. Best Practice Alerts to identify at-risk patients due to social history (sexual or drug use)
- 3. Order to initiate the HCV Pathway (86803G)
- 4. After Visit Summary text for the HCV Pathway order
- 5. Order set for the HCV Assessment Labs
- 6. Smartphrases for physician documentation

Laboratory Staff Education Resources

- 7. Clinic based lab workflow documents for reflex testing
- 8. Regional lab workflow documents for reflex testing

Patient Education Resources

- *Available in English, Spanish, Farsi, Urdu, Vietnamese
- 9. Hepatitis C Screening Test What You Should Know*
- 10. HCV Pathway Patient Information*
- 11. Hepatitis C: After Your Diagnosis (general)*
- 12. Hepatitis C: After Your Diagnosis (Baby Boomer age)
- 13. Patient educational videos (available upon request)
 - Hep C: The Basics
 - Hep C: Managing Your Diagnosis
 - Hep C: Treatment Options

HCV Care Coordinator Specific Components

- 14. Hepatitis C Care Coordinator Job description
- 15. Hepatitis C Care Coordinator Training manual (full document available upon request)
- 16. HealthConnect Reporting Workbench workflow management tool (tool demo available upon request)

Physician Education Resources

- 17. Physician education for Primary Care and Gastroenterology
- 18. Smartphrase to describe the HCV Pathway to Physicians
- 19. CME educational presentations for physicians (available upon request)

Fibroscan Specific Components

- 20. Fibroscan Pre-test Patient Instructions (adult)
- 21. HealthConnect result entry fields for Fibroscan
- 22. Example Fibroscan result printout
- 23. Fibroscan Operator SmartSet (for conducting visit)
- 24. Fibroscan Operator job aid for documenting Fibroscan results
- 25. Fibroscan interpretation tool for physicians (KP HealthConnect)
- 26. Best Practice Alerts for follow up Fibroscan for untreated patients

Data and Analytics

27. Sample report for Fibroscan data





B. Guidance on Where to Start

If your team is uncertain about whether to implement the complete HCV Pathway, or have limited resources at this time, below are high-value items that can be implemented rapidly with minimal or no resources

Implement Item #1: Best Practice Alerts to identify eligible Baby Boomer age patients

This Best Practice Alert alerts physicians if their patient is of Baby Boomer age and has never been tested with HCV Antibody. Activating this Best Practice alert relieves physicians from needing to individually identify HCV-screening eligible patients. This alert can be linked to your existing HCV Antibody test order.

Implement Item #5: Order set for the HCV Assessment Labs

This order set contains the laboratory workup for patients diagnosed with chronic HCV (HCV Ab+ HCV RNA+). This order set can be easily assembled from hepatitis and liver assessment orders already in HealthConnect.

Implement Item #13: Hepatitis C: After Your Diagnosis (Baby Boomer age) patient educational sheet for a new HCV diagnosis

In our experience, Baby Boomer age patients are particularly sensitive about the language used to explain their chronic HCV diagnosis. These patients may or may not have engaged in risky sexual practices or drug related behaviors. Many do not know how or when they contracted HCV—for many, the disease was acquired decades ago. Our team created an accurate but revised Baby-Boomer specific patient informational sheet that explains the HCV diagnosis.

Available on the clinical library: https://clm.kp.org/pkc/mas/cpg/cpg/PreventiveCare/KP-HepatitisC-BabyBoomers.pdf

Implement items #10 & #12: Begin using the translated patient educational sheets (Spanish, Farsi, Urdu, Vietnamese)

We obtained certified translated patient educational sheets for four languages. The following content was translated:

- Hepatitis C Screening Test What You Should Know This general educational sheet describes HCV screening (not HCV Pathway specific).

 Organizations should edit this document to include their correct phone contact information.
- Hepatitis C: After Your Diagnosis (general age) This general educational sheet offers information to those with a chronic HCV diagnosis. Organizations should edit this document to include their correct phone contact information.



1. Best Practice Alerts (BPA) to identify eligible Baby Boomer age patients

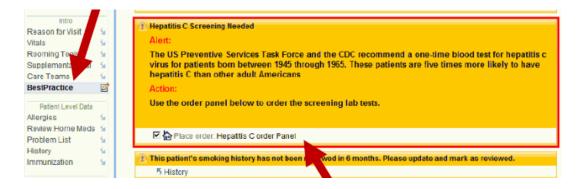
Purpose:

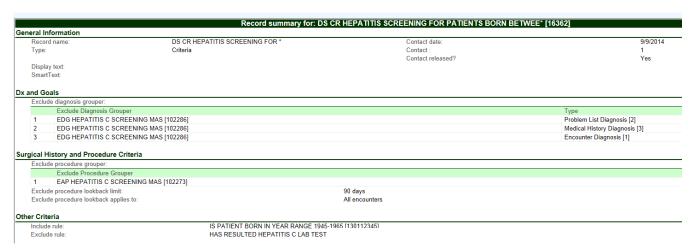
This Best Practice Alert alerts physicians if their patient is of Baby Boomer age and has never been tested with HCV Antibody. Activating this Best Practice alert relieves physicians from needing to individually identify HCV-screening eligible patients. This alert can be linked to your existing HCV Antibody test order.

Implementation team: EPIC / KP HealthConnect team

Baby Boomer Screening Best Practice Alert Build

- a. Include: Patient born in year range 1945-65
- b. Exclude:
 - Patients with Hepatitis C on Problem List or Medical History Diagnosis or Encounter Diagnosis.
 - Patients with resulted HCV Antibody test (from any source) – see KPMAS groupers below







2. Best Practice Alerts to identify at-risk patients due to social history

Purpose:

These Best Practice Alerts signal to physicians if their patient is at-risk for HCV

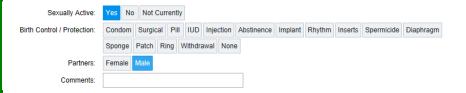
- Due to sexual practices (men who have sex with men)
 or
- Due to IV drug use

These alerts can be linked to your existing HCV Antibody test order.

Implementation team: EPIC / KP HealthConnect team

At-Risk Patient Screening Best Practice Alert Build (men who have sex with men)

- a. Include:
 - Male patient with Social History → Sexually Active YES → Partners: MALE
- b. Exclude: Patients with resulted HCV Antibody test (from any source)



At-Risk Patient Screening Best Practice Alert Build (IV drug use)

- a. Include:
 - i. Patient with Social History → Drug Use YES→
 Types: IV
- b. Exclude: Patients with resulted HCV Antibody test (from any source)



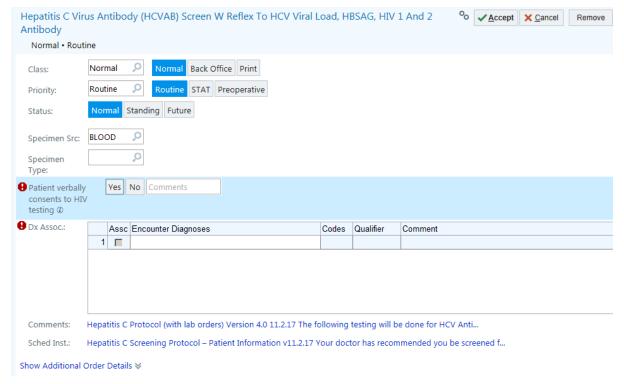
3. Order to initiate the HCV Pathway (86803G)

Purpose:

This new order was built to initiate the HCV Pathway. To implement, your lab team must be prepared to reflex HCV Antibody positive tests to HCV RNA, Hepatitis B Surface Antigen, and HIV 1&2. At minimum, the lab team should reflex HCV Antibody positive tests to HCV RNA. This order includes a button to capture patient verbal consent for HIV testing. The EAP for this order is available in HealthConnect. The Comments include a description of the HCV Pathway order and process, for physicians. The Scheduled Instructions include the After Visit Summary information for patients (shown on the following page).

Implementation team: EPIC / KP HealthConnect team, Laboratory team

86803G - HEPATITIS C VIRUS ANTIBODY (HCVAB) SCREEN W REFLEX TO HCV VIRAL LOAD, HBSAG, HIV 1 AND 2 ANTIBODY (KPMAS HCV Pathway order)





4. After Visit Summary text for the HCV Pathway (86803G) Order

Purpose:

This unformatted text can be inserted into the HealthConnect HCV Pathway order Scheduled Instructions section, to print in the After Visit Summary. Translations of this information are available in Spanish, Farsi, Urdu, and Vietnamese (see supplementary files). This information is also provided in a formatted, color print version, available on the Clinical Library here and in #11 of this toolkit https://clm.kp.org/pkc/mas/mem ed/healthed/Prevention and Self Care/HCV-Antibody-Protocol Patient-Information.pdf

Implementation team: EPIC / KP HealthConnect team

Hepatitis C Pathway - Patient Information

Your doctor has recommended you be screened for Hepatitis C. The test for Hepatitis C is a blood test. Please go to the lab to have blood drawn. Depending on your results, you may need more testing. You may test positive for the Hepatitis C antibody. If you do, more tests will be run on your blood sample. These include an HIV test. Please tell your doctor if you DO NOT WANT TO BE TESTED FOR HIV. If you test positive for the Hepatitis C antibody, you will have a follow-up test. Your follow-up test may show that you have Chronic Hepatitis C. If you do, your doctor may want you to return to the lab to have more blood tests. A Hepatitis C Coordinator will reach out to you to schedule these tests. Your doctor may want you to undergo a non-invasive test. The test is called Fibroscan® (hepatic transient elastography). A Hepatitis C Coordinator will reach out to you to schedule this test. You should fast (not eat or drink anything EXCEPT for water) for 3 hours before this test.

Your doctor will send your results through the patient portal at www.KP.org. If you are not registered with www.KP.org, your doctor will mail your results. If you need more tests, a specially trained Hepatitis C Coordinator will reach out to you to let you know. This nurse will also help you schedule your other tests. If you have any questions, the Hepatitis C Coordinator you speak with is happy to answer them.

Frequently Asked Questions:

How will I get results from these tests? You can receive your test results through your patient portal at www.KP.org. Your primary care physician, a nurse, or a Hepatitis C Coordinator may also call or mail to you the results.

Where can I learn more about Hepatitis C? Your doctor can give you more information about Hepatitis C. You can also find information online by searching "hepatitis C" at www.KP.org.

What are all of the tests that will be run? You will receive a test to see if you are positive or not for the Hepatitis C antibody. If you are positive, more tests will be run on your blood sample. These tests are a Hepatitis C test (to measure viral load), a Hepatitis B test, and a HIV test. Your follow-up test may show that you have Chronic Hepatitis C. If you do, your doctor may want you to return to the lab for more blood tests. These new blood tests will need a new blood sample. The tests include different hepatitis B tests, tests to check your liver function (hepatic function panel), and the type of hepatitis C (genotype) and tests to check your body chemistry (including prothrombin, complete blood count, and creatinine).

Your doctor may also want you to have a non-invasive test called Fibroscan® (hepatic transient elastography). This test checks the stiffness of your liver. You should fast (not eat or drink anything EXCEPT for water) for 3 hours before the Fibroscan test.

5. Order set for the HCV Assessment labs (O215991)

Purpose:

This order set contains the laboratory workup for patients diagnosed with chronic HCV (HCV Ab+ HCV RNA+). This order set can be easily assembled from hepatitis and liver assessment lab orders already in HealthConnect.

Implementation team: EPIC / KP HealthConnect team, with approval from Gastroenterology

HEPATITIS C ORDER GROUP POST-HCV RNA MAS 0215991 (KPMAS order panel for HCV Assessment Labs)

HEPATITIS A VIRUS IGG (HAV IGG) [86708B]
HEPATITIS B VIRUS SURFACE ANTIBODY (HBSAB) [86706B]
HEPATITIS B VIRUS CORE ANTIBODY (HBCAB), TOTAL [86704B]
HEPATITIS C VIRUS GENOTYPE [87902B]
HEPATIC FUNCTION PANEL (ALB, TBILI, DBILI, ALKP, TPROT, ALT, AST) [80076B]
PT AND INR [85610H]
CBC NO DIFFERENTIAL [85027A]
CREATININE, SERUM [82565C]
ANA, IFA [86038P]





6. Smartphrases for physician documentation

Purpose:

These smartphrases are provided for physicians to easily report HCV negative test results, or results for those who are HCV Ab + / HCV RNA – (exposed to HCV but cleared the virus).

Implementation team: EPIC / KP HealthConnect team

.HCVneg (for the physician to report the HCV Antibody negative result to the patient)

Your Hepatitis C antibody test is negative. This means you have never had Hepatitis C infection. To stay healthy, do not share needles or drugs and practice safer sex.

.HCVAbposVLneg (for the physician to report the HCV Antibody + HCV RNA – results to the patient)

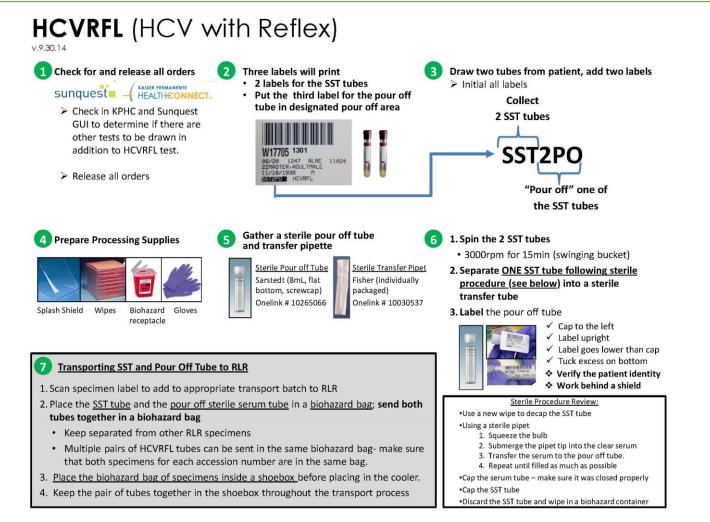
Your Hepatitis C antibody test was positive but your Hepatitis C viral load is negative. This means you may have been exposed to Hepatitis C in the past but are not chronically infected (you "cleared the virus"). There is always a chance of reinfection, so to stay healthy, do not share needles or drugs and practice safer sex.

7. Clinic based lab workflow documents for reflex testing

Purpose:

These educational documents were provided to the clinic-based lab staff to assist with collecting the right number of tubes, and shipping those tubes to the Regional lab for processing and testing.

Implementation team: Laboratory team (managers and clinic based teams)



8. Regional lab workflow documents for reflex testing (1/3)

<u>Purpose</u>: These educational documents were provided to the Regional lab staff to assist with handling, labeling, and processing the HCV Pathway specimen tubes. The KPMAS HCV Pathway involves storing one tube (the sterile serum pour off tube) in a Regional Lab freezer while the HCV Ab test is being run. If the HCV Ab test is negative, this additional sterile serum pour off tube is discarded. If the HCV Ab test is positive, the sterile serum pour of tube is used for HCV RNA testing.

Implementation team: Laboratory team (managers and Regional lab based teams)

HCVRFL (HCV with Reflex)- RLR Processing Workflow

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- Check the shoebox for bagged HCV specimens on top of sample racks
- 2. Remove specimens from bag
- 3. CONFIRM there is (1) SST tube and (1) pour off tube

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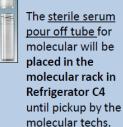
If any tubes are missing:

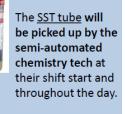
- >IMMEDIATELY notify the center lab
- ➤ Reprint the label
- Take the single tube to Molecular (if staffed) to be separated. On weekends, the processor will need to perform the sterile pour off.
 - a) pull a sterile aliquot for the HCV viral load testing
 - b) write the date and time of receipt/separation and the initials of the person aliquoting on the label
 - c) share the remainder with the HCV testing to meet the timeframe for serum separation
- 4. Place 2 tubes in the designated rack labeled HCVRFL
- 5. Specimen batch final tracked at RLR

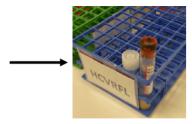
If samples are received late or on a weekend:

- SST and sterile serum pour off tubes can be stored in the molecular rack and Centaur rack in Refrigerator C4
- Semi-Auto Chem tech will pick up tubes the next day

2 Step 2: Separate the HCV Reflex Rack before distribution / pickup by the chemistry tech







8. Regional lab workflow documents for reflex testing (2/3)

Continued from prior page

HCVRFL (HCV with Reflex)- RLR Chemistry Workflow

v.10.6.14





The HCVRFL rack will be delivered to the Centaur workbench by processing personnel -and/or-

Semi-automated chemistry techs will pick up the rack from processing throughout the day and/or-

The Semi-automated chemistry tech will retrieve late arriving or weekend specimens in the morning from the designated rack in Refrigerator C4.



✓ HCVRFL specimens will be given priority testing status whenever possible.

√ HCV testing will be performed and resulted according to established laboratory procedures.

2 Step 2: Run HCVRFL Test

- 1. Positive or Indeterminate HCVRFL results:
 - Will trigger 2 labels to print on label printer RLRE by the corner of the Remstar in semi-automated chemistry area.
 - A faxmail will also be reflexed.



- The <u>HIV, HBSAG label</u> will be placed on the SST tube for retesting on the Centaur.
- The chemistry tech will place the tube in the appropriate rack for the next run of those tests on the Centaur.



- The <u>HCVVLP</u> label will be placed in the designated box by the RLRE printer.
- These labels will be delivered to Molecular throughout the day and/or picked up by Molecular staff throughout the day.

CENTAUR INSTRUMENT ISSUES

Chem tech will promptly notify molecular techs of any Centaur instrument issues or testing issues that may delay the availability of HCV results, so that the "hold" time of specimens in Molecular upright freezer will be extended before the transfer of those hold specimens to chest freezer.

FRIDAY HCV TESTING

Reflexed HCVVLP labels from Friday HCV testing will <u>need to be taken to the molecular as soon as possible to initiate testing on Friday if possible.</u>

Regional lab workflow documents for reflex testing (3/3) 8.

Continued from prior page

HCVRFL (HCV with Reflex)- RLR Molecular Workflow

v.10.6.14



Step 1: Locate and Store Samples



Chemistry tech puts the sterile serum pour off tube in the molecular rack in Refrigerator C4 (until pickup by the molecular techs)

Molecular techs will pick up **HCVRFL** pour off tubes from:

- Designated racks in Processing
- Refrigerator C4 throughout the day



When the pour off tubes are received in the molecular department:

Techs will file them in designated freezer racks according to the last digit of the accession number and place in -70C upright freezer

Molecular Tech: End-of-shift note on retrieving specimens:

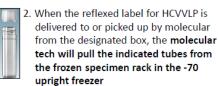
The second shift molecular tech will ensure that all specimens received by the end of the shift (especially on Friday nights) have been picked up from processing or from designated rack in refrigerator C4 and placed in the molecular -70 freezer before leaving for the night.

Step 2: Relabel Tube for HCVVLP Testing



1.The HCVVLP label* will be placed in the designated box by the RLRE printer by Chemistry staff

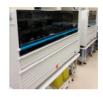
*These labels will be delivered to Molecular throughout the day and/or picked up by Molecular staff throughout the day.





Attach the label to the tube after pulling from the rack and ready for the next available **HCVVLP** test run.

Step 3: HCVVLP Testing



- **HCVVLP** testing will be run and results verified according to procedure.
- Based on test volumes, an additional HCVVLP test run may need to be initiated.

CENTAUR INSTRUMENT ISSUES

*Chem tech will promptly notify molecular techs of any Centaur instrument issues or testing issues that may delay the availability of HCV results, so that the "hold" time of specimens in Molecular upright freezer will be extended before the transfer of those hold specimens to chest freezer.

Step 4: HCVRFL Sample Storage, Discard

- 1. Molecular techs will pull the remaining frozen HCVRFL pour off tubes that were not needed for HCVVLP testing (after confirming no late testing of HCV testing* see note at left)
- 2. Package into plastic bags.
- 3. Label and transfer to the -70C chest freezer for additional storage.
- 4. The disposal of the bags of un-used hold specimens will be based on available storage space in the ultra low chest freezer.

Hepatitis C Screening Test – What You Should Know

Purpose:

This general educational sheet describes HCV screening (content is not HCV Pathway specific). Organizations should edit this document to include their correct phone contact information.

Implementation team: Physician, care team

HEPATITIS C VIRUS TEST: WHAT YOU SHOULD KNOW

Hepatitis C is an infection of the liver caused by a virus. This virus spreads when blood or body fluids from an infected person enter another person's body.

HEALTH NOTES

Hepatitis C virus tests are blood tests that check for substances in the blood that show whether you have hepatitis C now or had it in the past. The tests can also tell you what type of hepatitis C you have and how severe the disease is.

Why are these tests done?

You may need these tests if:

- You have symptoms of hepatitis.
- You may have been exposed to the virus. You are more likely to have been exposed to the virus if you inject drugs, have many sex partners, or are likely to be exposed to body fluids (such as if you are a health care worker).
- . You have had other tests that show you have liver
- You were born between 1945 and 1965; per a US Preventive Service Taskforce recommendation.

The tests also are done to help your doctor decide about your treatment and see how well it works.

How can you prepare for these tests?

You do not need to do anything before you have these tests.

What happens during these tests?

A health professional takes a sample of your blood.

What else should you know about these tests?

- . The tests can tell your doctor what type of hepatitis C you have and how severe it is. This can help your doctor determine treatment and see how effective it is.
- If you have the tests soon after you were infected with hepatitis C, they may show that you do not have the disease even when you have it. This is because the substances that show you have

hepatitis C can take weeks or months to develop, so they may not be in your blood yet. Your doctor may want you to be tested again.

- If the tests show you have long-term hepatitis C, you need to take steps to prevent spreading the
- . If tests show that you have the Hepatitis C antibody detected, your blood sample will be tested for Hepatitis B and HIV.

What happens after these tests?

- . You will probably be able to go home right away.
- . You can go back to your usual activities right away.

When should you call for help?

Watch closely for changes in your health, and be sure to contact your doctor if you have any

Follow-up care is a key part of your treatment and safety. Be sure to make and go to all appointments, and call your doctor if you are having problems. It's also a good idea to keep a list of the medicines you take. Ask your doctor when you can expect to have your test results.

For more information

Visit kp.org/health

· Learn about Hepatitis C in the Health Encyclopedia.

Call Kaiser Permanente Medical Advice

 Talk to your medical advice nurse 24 hours a day, seven days a week by calling (703) 359-7878 or 1-800-777-7904, If you are deaf or hard of hearing, call 711 or 1-800-201-7165. Ask the Relay Operator to dial 1-855-632-8278.

https://clm.kp.org/pkc/mas/mem_ed/healthed/Prev ention and Self Care/Hep-C-Virus-Test What-You-

Should-Know.pdf

Hepatitis C or here:

This information has been translated into Spanish, Farsi, Urdu, and Vietnamese.

Available on the clinical library by searching for

The information presented here is not intended to diagnose health problems or to take the place of professional medical care. If you have persistent medical problems, or if you have further questions, please consult your doctor or member of your health

REGIONAL HEALTH EDUCATION, HEALTH PROMOTION AND WOMEN'S HEALTH 0041-1040 Revised/reprinted 8/14 Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. 2101 East Jefferson Street, Rockville, MD 20852





10. HCV Pathway – Patient Information

Purpose:

This HCV Pathway specific educational sheet describes the HCV Pathway screening tests and introduces the role of the Coordinator and the Fibroscan test. Organizations should edit this document if their HCV Pathway tests differ from those in KPMAS. This information also prints in the patient After Visit Summary (see #4/page 17 of this toolkit) when the HCV Pathway is ordered.

Implementation team: Physician, care team



Hepatitis C Screening Protocol: What You Need to Know

Patient Information

Your doctor has recommended you be screened for Hepatitis C. The test for Hepatitis C is a blood test. Please go to the lab to have blood drawn.

Depending on your results, you may need more testing.

- You may test positive for the Hepatitis C antibody. If you do, more tests will be run on your blood sample.
 These include an HIV test. Please tell your doctor if you DO NOT want to be tested for HIV.
- If you test positive for the Hepatitis C antibody, you will have a follow-up test. Your follow-up test may show
 that you have Chronic Hepatitis C. If you do, your doctor may want you to return to the lab to have more
 blood tests. A Hepatitis C Coordinator will reach out to you to schedule these tests.
- If you test positive for the Hepatitis C antibody, you will have a follow-up test. Your follow-up test may show
 that you have Chronic Hepatitis C. If you do, your doctor may want you to undergo a non-invasive test. The
 test is called Fibroscan® (hepatic transient elastography). A Hepatitis C Coordinator will reach out to you to
 schedule this test

Your doctor will send your results through the patient portal at www.KP.org. If you are not registered with www.KP.org, your doctor will mail your results. If you need more tests, a specially trained Hepatitis C Coordinator will reach out to you to let you know. This nurse will also help you schedule your other tests. If you have any questions, the Hepatitis C Coordinator you speak with is happy to answer them.

FAQ:

How will I get results from these tests? You can receive your test results through your patient portal at www.KP.org. Your primary care physician, a nurse, or a Hepatitis C Coordinator may also call or mail to you the results.

Where can I learn more about Hepatitis C? Your doctor can give you more information about Hepatitis C. You can also find information online by searching "hepatitis C" at www.KP.org.

What are all of the tests that will be run? You will receive a test to see if you are positive or not for the Hepatitis C antibody. If you are positive, more tests will be run on your blood sample. These tests are a Hepatitis C test (to measure viral load), a Hepatitis B test, and a HIV test. Your follow-up test may show that you have Chronic Hepatitis C. If you do, your doctor may want you to return to the lab for more blood tests. These new blood tests will need a new blood sample. The tests include:

- · a different Hepatitis B test,
- . tests to check your liver function (hepatic function panel), and the type of hepatitis C (genotype) and
- · tests to check your body chemistry (including prothrombin, complete blood count, and creatinine).
- Your doctor may also want you to have a non-invasive test called Fibroscan® (hepatic transient elastography). This test checks the stiffness of your liver.

Available on the clinical library by searching for Hepatitis C or here:

https://clm.kp.org/pkc/mas/mem_ed/healthed/Prevention_and_Self_Care/HCV-Antibody-Protocol_Patient-Information.pdf

This information has been translated into Spanish, Farsi, Urdu, and Vietnamese.





11. Hepatitis C: After Your Diagnosis (general)

Purpose:

This general educational sheet offers information to those with a chronic HCV diagnosis. Organizations should edit this document to include their correct phone contact information.

Implementation team: Physician, care team

HEPATITIS C: AFTER YOUR DIAGNOSIS

Hepatitis C is an infection of the liver caused by a virus. This virus spreads when blood or body fluids from an infected person enter another person's body. This can occur when people share needles that have the virus on them. Less often, hepatitis C can spread through sex and sharing items such as razor blades or toothbrushes. Needles used for tattoos and body piercings can also spread the virus. In the past, people got the virus through blood transfusions and organ transplants. But since 1992, all donated blood and organs have been screened for hepatitis C. So getting the virus this way is now very rare.

HEALTH NOTES



For more information

Visit kp.org/health

 Learn about Hepatitis C in the Health Encyclopedia.

Call Kaiser Permanente Medical Advice

 Talk to your medical advice nurse 24 hours a day, seven days a week by calling (703) 359-7878 or 1-800-777-7904, If you are deaf or hard of hearing, call 711 or 1-800-201-7165. Ask the Relay Operator to dial 1-855-432-8278 The virus doesn't always cause symptoms. But you may feel tired. And you may have a headache, sore muscles, nausea, and pain in the upper right belly. Other symptoms include yellowish skin and dark urine. Home treatment can help ease symptoms. And your doctor may prescribe antiviral medicine.

Long-term infection can lead to severe liver damage. So make sure to go to your follow-up appointments.

Follow-up care is a key part of your treatment and safety. Be sure to make and go to all appointments, and call your doctor if you are having problems. It's also a good idea to know your test results and keep a list of the medicines you take.

How can you care for yourself at home?

- Do not drink alcohol. Alcohol can damage the liver. Tell your doctor if you need help to quit. Counseling, support groups, and sometimes medicines can help you stay sober.
- Do not take drugs or herbal medicines. They can make liver problems worse.
- Do not share needles or drug paraphernalia.
- Be safe with medicines. If your doctor prescribes antiviral medicine, take it exactly as prescribed. Call your doctor if you think you are having a problem with your medicine.
- Make sure your doctor knows all of the medicines you take. Some medicines, such as acetaminophen (Tylenol), can make liver problems worse. Do not take any new medicines unless your doctor tells you to. This includes over-the-counter medicines.
- Maintain a healthy lifestyle. Get plenty of exercise if you feel up to it.
 Eat a healthy diet.
- Drink plenty of fluids, enough so that your urine is light yellow or clear like water. If you have kidney, heart, or liver disease and have to limit fluids, talk with your doctor before you increase the amount of fluids you drink.

Available on the clinical library by searching for Hepatitis C or here:

https://clm.kp.org/pkc/mas/mem_ed/healthed/Prevention_and_Self_Care/Hep-C_After-Your-Diagnosis-MAS.pdf

This information has been translated into Spanish, Farsi, Urdu, and Vietnamese.

12. Hepatitis C: After Your Diagnosis (Baby Boomer age)

Purpose:

In our experience, Baby Boomer age patients (born 1945-1965) are particularly sensitive about the language used to explain their chronic HCV diagnosis. These patients may or may not have engaged in risky sexual practices or drug related behaviors. Many do not know how or when they contracted HCV—for many, the disease was acquired decades ago. Our team created an accurate but revised Baby-Boomer specific patient informational sheet that explains the HCV diagnosis.

Implementation team: Physician, care team



People born during 1945 through 1965 are 5 times more likely than other adults to be infected with hepatitis C. Many people with hepatitis C do not have symptoms and can live for decades without knowing they have the virus. Therefore, doctors screen this age group for hepatitis C using a blood test.

Hepatitis C is an infection of the liver caused by a virus. This virus spreads when blood or body fluids from an infected person enter another person's body. In many situations, people do not know how they got the virus, or when they were infected.

People can get the virus many different ways. Hepatitis C can be spread through sharing items that touch blood, such as razor blades, needles (for body piercing or tattoos), or toothbrushes. Health care workers may have come into contact with infected blood during their work. People traveling internationally may have contracted the virus if health care supplies were re-used. In the United States, before 1992, the virus could be passed through blood transfusions or organ transplants. Hepatitis C can also be spread through unprotected sex or by sharing drug paraphemalia (sharing needles or straws).

Once you have been diagnosed with hepatitis C, your doctor and health team will work with you to manage your illness.

- Be sure to go to all appointments. Follow up care is important.
- Your doctor may ask you to come in every year for lab tests and a test that measures liver stiffness (Fibroscan).

- Call your doctor if you are having problems or if new symptoms appear. The virus doesn't always cause symptoms. But you may feel tired. You may have a headache, sore muscles, nausea, and pain in the upper right belly. Other symptoms include vellowish skin and dark urine.
- It's also a good idea to know your test results and keep a list of the medicines you take.

How can you care for yourself at home?

· Maintaining your health

- » Maintain a healthy lifestyle. Get plenty of exercise if you feel up to it. Eat a healthy diet.
- Drink plenty of fluids, enough so that your urine is light yellow or clear like water. If you have kidney, heart, or liver disease and have to limit fluids, talk with your doctor before you increase the amount of fluids you drink.
- » If you feel depressed, talk to your doctor about treatment. Many people who have long-term illnesses get depressed. Keep in mind that antiviral medicine can make depression worse.

Available on the clinical library by searching for Hepatitis C or here:

https://clm.kp.org/pkc/mas/cpg/cpg/PreventiveCare/KP-HepatitisC-BabyBoomers.pdf

This information has been translated into Spanish, Farsi, Urdu, and Vietnamese.

. Be safe with medicines

- » Make sure your doctor knows all of the medicines you take. Some medicines, such as acetaminophen (Tylenol), can make liver problems worse. Do not take any new medicines unless your doctor tells you to. This includes over-the-counter medicines and herbal medicines.
- » If your doctor prescribes antiviral medicine, take it exactly as prescribed. Call your doctor if you think you are having a problem with your medicine.

Stop using alcohol and drugs (if you are using them)

- » Do not drink alcohol. Alcohol can damage the liver. Tell your doctor if you need help to quit.
- » Do not take drugs. They can make liver problems worse. Do not share needles or drug paraphernalia if you are using drugs. If you are using drugs, your doctor can help you quit.

Practice safe sex

» Reduce your number of sex partners if you have more than one. Unless you are in a long-term relationship in which neither partner has sex with anyone else, always use latex condoms when you have sex.

To avoid spreading hepatitis C to others:

- Wash your hands—and any object that has come in contact with your blood—thoroughly with water and soap.
- Tell your doctor, dentist, and anyone else who may come in contact with your blood about your illness.
- Prevent others from coming in contact with your blood and other body fluids. Keep any cuts, scrapes, or blisters covered.
- Do not share your personal items. These include razors, toothbrushes, towels, and nail files.
- Tell the people that you live with or have sex with about your illness as soon as you can. If you need help with these conversations, please let your doctor know. Your doctor is happy to help.
- Make sure that all equipment is sterilized if you have acupuncture, or if you get a tattoo/body piercing.
- If you are using drugs, don't share needles or other equipment (such as cotton, spoons, and water) with others. Find out if a needle exchange program is available in your area, and use it. Get into a drug treatment program.
- Don't donate blood or blood products, organs, semen, or eggs (ova).

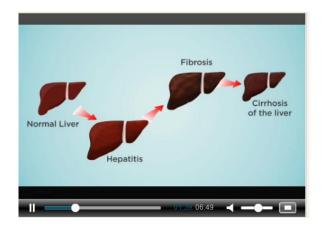


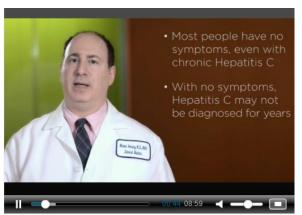
13. Patient educational videos (available upon request)

Purpose:

We created three patient educational videos about HCV. These provide an overview of the disease, managing a diagnosis, and treatment options. In KPMAS, these videos are posted on our gastroenterology physicians' My Doctor Online web pages.

Implementation team: Physician, My Doctor Online web team





Patient educational videos (available upon request)

- Hep C: The Basics (6:00 minutes)
- Hep C: Managing Your Diagnosis (9:00 minutes)
- Hep C: Treatment Options (6:00 minutes)

Please contact the project team for files of these videos

14. Hepatitis C Care Coordinator Job Description (1/3)

Purpose:

This job description is to recruit a Hepatitis C Care Coordinator for the program. The KPMAS team has two Coordinators, both LPN level.

Implementation team: Human Resources, project team

Position Summary:

As an advocate for the patient, Hepatitis C Care Coordination Research Nurse helps patients newly diagnosed with hepatitis C navigate the hepatitis C testing pathway. The nurse position is a key role in launching an improved hepatitis C testing pathway in the Mid-Atlantic region. Additionally, the nurse will help support the Clinical Trials Program as needed.

Certain job duties may be conducted remotely.

Specific responsibilities include:

<u>Patient communication:</u> The Hepatitis C Care Coordination Research Nurse will communicate results to hepatitis C positive patients. The Research Nurse will schedule additional laboratory and diagnostic testing using phone calls or patient secure messages (on KP HealthConnect).

<u>Patient information management (registry use and management)</u>: The Hepatitis C Care Coordination Research Nurse will manage a registry of hepatitis c positive patients. The Research Nurse will keep detailed records of patient results, progress through the testing pathway, communications, and patient and physician outreach. The Research Nurse will keep these records up-to-date at all times.

<u>Care Coordination</u>: The Hepatitis C Care Coordination Research Nurse will work closely to coordinate Care Coordination with physicians and other Care Coordination team members. This includes tracking patient progress by monitoring charts in KP HealthConnect, communicating with physicians about outstanding results, communicating with physicians about lab results or test results, and working with physicians to ensure steps are not duplicated or missed.

Quality improvement and outcome activities: The Hepatitis C Care Coordination Research Nurse will work with the physician sponsor and project manager to perform quality improvement activities on the hepatitis C Care Coordination testing pathway. This includes continually evaluating the pathway, offering suggestions for improvement, sharing information about pathway challenges, and providing ongoing feedback to project sponsor and project manager about possible areas of improvement.



14. Hepatitis C Care Coordinator Job Description (2/3)

Continued from prior page

Characteristic Duties and Responsibilities:

- Track patients through hepatitis C testing, including communicating results, scheduling appointments, and coordinating with physicians
- Manage a detailed registry for hepatitis C; maintain thorough and organized notes and registry using KP HealthConnect and Excel
- Understand and explain the multi-step hepatitis C testing Care Coordination pathway to patients, physicians and staff
- Explain the basics of hepatitis C and answer basic patient questions about the disease
- Provide education about hepatitis C by answering patient questions and sending educational material to the patient
- Complete all necessary clinical documentation in KP HealthConnect for activities (includes completing phone encounters, secure messages, staff messages etc.)
- Promptly alert physicians or Care Coordination team to missing results or other issues
- Monitor the hepatitis C testing pathway and offer feedback on any issues that could be improved
- Foster and maintain cooperative relationships with other departments, patients, medical staff, and sponsors
- Attend two-day training session about the hepatitis C testing pathway and role of the Hepatitis C Research Nurse
- Support clinical trials research nurse to execute clinical trials studies with recruitment, consenting, performing study visit per research protocol and completing case report forms, as needed.
- Attend research and clinical staff meetings, conferences, and in-service education of nursing and medical staff
- Foster and maintain cooperative relationships with other departments, patients, medical staff, and sponsors
- Responsible for knowing and following all Mid-Atlantic Permanente Medical Group, Kaiser Permanente, and Mid-Atlantic Permanente Research Institute policies and procedures



14. Hepatitis C Care Coordinator Job Description (3/3)

Continued from prior page

Education/License/Certification:

Licensed Nurse (LPN) preferred.

Qualifications:

- Preferred one year of experience in patient interactions or two years of clinical research Nurse experience
- Experience in hepatitis C or infectious disease patient Care Coordination strongly preferred
- Enthusiastic about performance improvement and quality improvement
- Proficient in EPIC or KP HealthConnect
- Comfortable managing and protecting sensitive patient health information
- Proficient with spreadsheet applications (Microsoft Excel)
- Proficient with word processing applications (Microsoft Word)
- Ability to maintain meticulous records
- Strong written and oral communication skills
- Strong project management and organizational skills
- Ability to work with minimal supervision and in self-directed manner
- Ability to interact on a scientific level with medical staff, physicians, and project team (project sponsor and project manager)

15. Hepatitis C Care Coordinator Training Manual

Purpose:

The Hepatitis C Care Coordinator was a new role for KPMAS, so the team developed a staff training manual. This 30-page manual covers all of the workflow steps for the Coordinator and includes resources such as job aids, scripts for patient conversations and outreach, letter templates etc.

Implementation team: Clinical lead, HCV Care Coordinators, HR or Program/Project manager (depending on resources)

HCV	HBsAg	HIV	Result	Coordinator Action					
HCV AB + / HCV RNA +	HBsAg -	HIV	Patient	Coordinator Action See section 1. A ii					
HCV AB + / HCV RNA +	HBSAg -	negative	only has	Tele Enc with patient to explain HCV diagnoses.					
		Hegative	HCV HCV	In Routing Comment note, add .HepCChronic, route to PCP and Ordering					
			ncv	Provider					
HCV AB + / HCV RNA -	LID-A-	HIV	Patient	CONTINUE HCV pathway See Section 2. A. i.					
Cleared the virus = no HCV	HBsAg -		has no						
infection		negative	infections.	 Enc: Clinical Documentation, add .ViralLoadNegativeAction, route to Pound and Ordering Provider 					
infection			infections.	and ordering revides					
HCV AB + / HCV RNA +	115.4	HIV	Patient is	END HCV PATHWAY					
, , , , , , , , , , , , , , , , , , ,	HBsAg +		co-	See. Section 1. A. iii					
Chronic HCV	Hepatitis B infection	negative	infected	Tele Enc with patient to explain HCV and HBV diagnoses.					
	Binfection		with HCV	In Routing Comment note, add .HepBCoInfectedGI, route to PCP and					
			and HBV	Ordering Provider					
			aliu nov.	Order extra HBV labs, ABD ULS, setup GI consult.					
				CONTINUE HCV pathway, refer to GI at end. See Section 2. A. iii.					
HCV AB + / HCV RNA -	HBsAg +	HIV	Patient						
Cleared the virus = no HCV	Hepatitis	negative	only has	Enc: Clinical Documentation					
infection	B infection		HBV.	In Routing Comment add .HepCNegHepBPosroute to PCP, Ordering					
				Provider and Hep B Coordinators (Venus – NOVA, Lauren – DCSM, BALT)					
,				END HCV PATHWAY					
HCV AB + / HCV RNA -	HBsAg -	HIV +	Patient	See Section 3. A. i.					
Cleared the virus = no HCV		HIV	only has	Enc: Clinical Documentation					
infection		infection	HIV.	In Routing Comment add .HIVPositiveAction, route to PCP, Ordering					
				Provider					
				END HCV PATHWAY					
HCV AB + / HCV RNA +	HBsAg -	HIV +	Patient is	See Section 3. A. i.					
Chronic HCV		HIV	CO-	Enc: Clinical Documentation					
		infection	infected	 In Routing Comment add .HIVPositiveAction, route to PCP, Ordering 					
			with HCV	Provider					
			and HIV.	END HCV PATHWAY					
HCV AB + / HCV RNA +	HBsAg +	HIV +	Patient is	See Section 3. A. i.					
Chronic HCV	Hepatitis	HIV	infected	Enc: Clinical Documentation					
	B infection	infection	with HCV,	 In Routing Note add .HIVPositiveAction, route to PCP, Ordering Provider 					
			HBV and	END HCV PATHWAY					
			HIV.						

Please contact the project team for the 30-page Hepatitis C Care Coordinator Training Manual (contact Cabell.Jonas@Kp.org)

Excerpts from the manual

Results Reporting Script 1: HCV Ab + Viral Load +:

First make sure you are speaking with the patient. If not (and you know the patient doesn't have a legal guardian), ask when OK to call back or give your call back number but do not state the nature of the call.

Hello, I'm [name] from Kaiser Permanente calling on behalf of your doctor- [Dr. X's] -office. Recently you had some tests done and we have your results back. Do you have a moment to review them?

No: "It's important that we review them because there are some things that you need to follow up on right away. When can I call you back?" -continue to process according to standard patient outreach attempts

Yes: Thank you. I wanted to let you know that your tests show that you have Hepatitis C viral infection. Is this a new diagnosis for you or something you were already aware of?

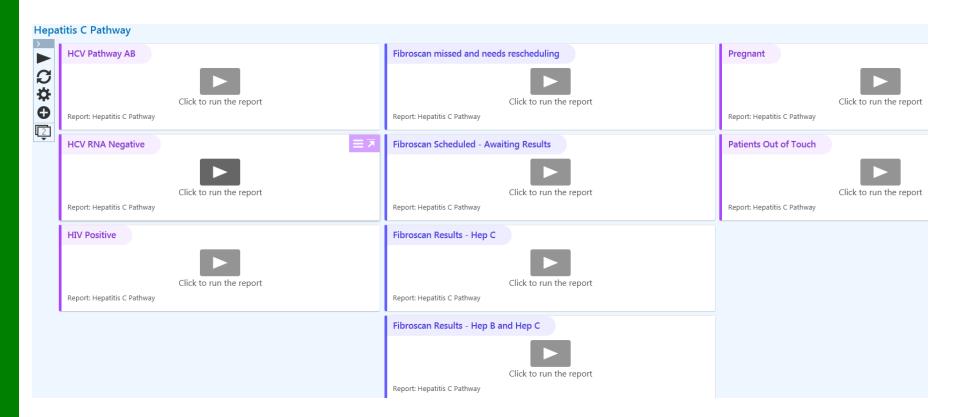


16. HealthConnect Reporting Workbench workflow management tool

Purpose:

This EPIC / KP HealthConnect based tool uses the Reporting Workbench module. This tool enables the Hepatitis C Care Coordinators to track patients through all steps of the HCV Pathway program. This tool is best demonstrated via a video demo – please reach out to our team if you are interested!

Implementation team: EPIC / KP HealthConnect team, Program/Project manager



Please contact the project team for a demo (contact Cabell.Jonas@Kp.org)



17. Physician education for Primary Care and Gastroenterology

Purpose:

Physician educational resources are available for primary care physicians (who most often order the HCV Pathway) and the Gastroenterology teams (physicians interpreting the Fibroscan). Files available upon request (contact Cabell.Jonas@kp.org)

Implementation team: Program/Project manager

Primary Care Physician Educational Resources

- 3 minute video overview of how to order the HCV Pathway
- 13 minute video describing the HCV Pathway
- 1 page overview of the HCV Pathway steps from the PCP perspective

Gastroenterology Physician Educational Resources

- 5 minute video overview of how to interpret the Fibroscan and document the results
- 1 page interpretation table for Fibroscan

Excerpts from the educational materials

HCV Pathway Summary for Ordering Provider

- PCP orders HCV Antibody Screen in response to the Best Practice Alert (also orderable by searching "O210117-HCV Antibody and Protocol Order Panel)
- If positive, patient's blood will automatically be reflex tested for HCV viral load, HBsAg, HIV 1 and 2 Ab**
- 3. Hepatitis C Coordinator tells patient they are Hepatitis C positive, orders two tests
 - Hepatitis C Order Group Post-HCV RNA Labs (13 labs) – patient returns for blood draw
 - **5. Fibroscan (econsult)** test takes place in the GI clinic
- Patients managed by PCP or GI based on severity of liver damage and disease
 - 6. F0-1: Managed by PCP
 - 7. F2-4: Managed by GI

.HCVPATHWAY describes these steps

HealthConnect Video:

https://myhelp.kp.org/files/58085

Keyword "Hepatitis C"

- If you see a **BPA**, click the link to order
- Do not place individual Hepatitis C test orders (HCV viral load etc.) these are now included in the order

Two Roles for the GI Physician in the New HCV Pathway

1 Interpreting Fibroscan Results

- This is the <u>primary role for GI</u> <u>physicians</u> in the Hepatitis C Screening Pathway
- All GI physicians in the service area chart review pool will be reviewing labs and interpreting Fibroscan results

2 Ordering the Hepatitis C Screen for Eligible Patients

- This is a <u>secondary role for GI</u>
 <u>physicians</u> because most BPAs
 /Hepatitis C Screening orders are
 taken care of in primary care
- Occasionally, GI physicians will see BPAs for patients eligible for Hepatitis C Screening and should click to order tests



18. Smartphrase to describe the HCV Pathway to Physicians

Purpose:

Smartphrase to describe the HCV Pathway for physicians – including the labs within the HCV Pathway steps and the role of the Coordinator.

Implementation team: EPIC / KP HealthConnect team

.HCVPATHWAY

The new HCV screening pathway - 86803G "HEPATITIS C VIRUS ANTIBODY (HCVAB) SCREEN W REFLEX TO HCV VIRAL LOAD, HBSAG, HIV 1 AND 2 ANTIBODY" should be placed for HCV screening, patients who are new to KP, or patients who have an incomplete Hepatitis C diagnosis (for example, missing Hepatitis C viral load tests).

Only this order triggers the support of the Hepatitis C Coordinator.

Do not place this order for patients with KNOWN Hepatitis C previously evaluated in KPMAS. For these patients, please send a chart review to GI or contact their prior GI specialist directly. Remember that all HIV/HCV co-infected patients will be followed by ID for their HCV also.

After you place the 86803G "HEPATITIS C VIRUS ANTIBODY (HCVAB) SCREEN W REFLEX TO HCV VIRAL LOAD, HBSAG, HIV 1 AND 2 ANTIBODY", a Hepatitis C Coordinator will reach out to your patients to communicate a diagnosis, schedule follow up lab tests, and schedule a Fibroscan test. If any action is needed by you, the Coordinator will reach out to you with instructions. Please 'Done' any labs that come into your Inbasket using .hepclabsabnormalcomment (for documentation)

Once the pathway is complete, the Hepatitis C Coordinator will call the patient with results and will enter a GI consult if the patient wants treatment. F0-1 patients who do not want treatment are managed by primary care – you will receive a Best Practice Alert when the patient is due for annual labs and repeat Fibroscan.

Please do not place additional lab orders. Please do not send GI consults through telemedicine, triage phone, or gut phone. Please direct medication/treatment questions to GI or the clinical pharmacist.

Questions?

Contact the Hep C Coordinators at 703-531-1661 (Halina Williams, LPN) or 703-674-7684 (Fariha Sarwar, LPN)



19. CME educational presentations for physicians (available upon request)

Purpose:

We have conducted several Continuing Medical Education (CME) presentations that provide a general overview of hepatitis as well as the specifics of the HCV Pathway. We are happy to share full slide presentations. Below is an overview of the topics covered.

Implementation team: Clinical lead

Topics covered in CMEs:

- Overview of hepatitis (all varieties; type of virus, prevention, transmission, disease presentation, testing, and progression, treatment options)
- Overview of hepatitis B (testing, clinical presentation, disease progression)
- Overview of hepatitis C (testing, clinical presentation, disease progression)
- Common co-infections
- Overview of liver fibrosis and cirrhosis
- Overview of hepatocellular carcinoma and surveillance
- At-risk patient groups (all varieties of hepatitis)
- Baby Boomer age patient risk for hepatitis C
- Overview of the HCV Pathway
 - Program description
 - Testing process
 - Fibroscan overview
 - Role of the Hepatitis C Coordinator
 - Communication to patient
 - Role of the ordering physician
 - Role of the gastroenterology physician





20. Fibroscan Pre-test Patient Instructions (adult)

Purpose:

These instructions are provided to adult patients pre-Fibroscan test through KP.org, mail or in the clinic.

Implementation team: Clinical lead



Your doctor wants you get a Fibroscan® – or transient elastography – test. This is a painless, non-invasive test. It measures your liver stiffness. This test may replace a liver biopsy in some patients.

There are a few things to know before getting your test:

- A nurse or the Hepatitis C Coordinator will schedule this test.
- · You go to the GI (gastroenterology) clinic for this test.
- Your doctor or a nurse may tell you to fast (not eat or drink) for three hours before your test. You
 can drink water.
- If you are pregnant, or if you have a pacemaker or defibrillator, talk to your doctor before getting this
 test.

A doctor, nurse, or Hepatitis C Coordinator may call you with results. If you have any questions, please call your doctor or the Hepatitis C Coordinator at (703) 531-1661 or (703) 922-1310.

Information about Fibroscan® (transient elastography):

What is Fibroscan? This is a painless, non-invasive test that measures the stiffness of your liver.

Why are you getting this test? Different conditions and diseases cause liver stiffness or damage. Doctors use Fibroscan® tests to understand how healthy your liver is. Your doctor may order a Fibroscan® to monitor:

- hemochromatosis
- · chronic viral hepatitis B and C
- · fatty liver disease
- · alcoholic liver disease
- · cirrhosis of the liver

Does Fibroscan® use radiation? No.

Does Fibroscan® hurt? No. A Fibroscan probe, which looks similar to an ultrasound probe - is placed on the outside of your skin, on your right side, by your rib cage. The probe will send out a light vibration on your skin.

How long will it take? The test typically takes between 15 to 30 minutes to complete.

Are there any risks? No. Fibroscan is a non-invasive and painless test.

Are there any alternatives to this test? One other option is a liver biopsy.

How will you get results from Fibroscan®? A doctor, nurse, or Hepatitis C Coordinator may call you with results.

Available on the clinical library by searching for Hepatitis C or here:

https://clm.kp.org/pkc/mas/cpg/cpg/Infectious%20D isease/Fibroscan Patient Instructions.pdf



21. HealthConnect result entry fields for Fibroscan

Purpose:

At this time (Nov 2018), Fibroscan/Echosens does <u>not</u> yet have a direct connection from the machine to feed data into EPIC / HealthConnect. Therefore, KPMAS created discrete HealthConnect results entry fields for Fibroscan data, enabling data reporting and research activities. In addition to entering Fibroscan results into the discrete data fields, clinical staff also upload the electronically scanned PDF report from the Fibroscan machine that shows the results values and the shear wave graphics. The EAP and LRRs for these results fields are available in HealthConnect.

Implementation team: EPIC / HealthConnect team, with approval from Gastroenterology

Using Fibroscan to measure fibrosis/liver stiffness

- 1. KPA is the result that Fibroscan produces when measuring liver stiffness
- 2. Gastroenterology physicians convert the KPA to a fibrosis (F-score) using an interpretation table
- 3. KPMAS also collects a FIB-4 score, which is not a value produced by the Fibroscan machine, but is used for comparison to the F-score produced through the KPA conversion.

For more information on Fibroscan interpretation, please contact our team (<u>Cabell.Jonas@KP.org</u>)

EAP 246154 - HEPATIC TRANSIENT ELASTOGRAPHY AKA Fibroscan (KPMAS results fields for Fibroscan results components)

LRR 26086 FIB-4 INDEX LRR 25896 F-SCORE, TRANSIENT ELASTOGRAPHY LRR 25895 KPA, TRANSIENT ELASTOGRAPHY

Component	Value	Flags	Low	High	Ref Range	Units	Comment
FIB-4 INDEX [26086]					1.100 1.500		19.4.
		1	_	_			
(PA, TRANSIENT ELASTOGRAPHY [25895]						kPa	

Using Fibroscan to measure fibrosis/liver stiffness and steatosis (fatty liver)

- 1. Fibroscan can also be used to measure steatosis/fatty liver in addition to fibrosis
- 2. dB/m CAP is the result that Fibroscan produces when measuring steatosis/fatty liver
- 3. Gastroenterology physicians convert the CAP to a steatosis (S-grade) using an interpretation table

EAP 251337 - HEPATIC TRANSIENT ELASTOGRAPHY W STEATOSIS AND CONTROLLED ATTENUATION PARAMETER AKA Fibroscan + CAP (KPMAS results fields for Fibroscan + CAP results components)

LRR 26086 FIB-4 INDEX

LRR 25896 F-SCORE, TRANSIENT ELASTOGRAPHY

LRR 25895 KPA, TRANSIENT ELASTOGRAPHY

LRR 27132 DB/M, CAP

LRR 27133 GRADE OF HEPATIC STEATOSIS, CAP

	Components	Sensitivities	Narrati <u>v</u> e	<u>I</u> mpression						
5	Component			Value	Flags	Low	High	Ref Range	Units	Comment
	FIB-4 INDEX [2	26086]								
	KPA, TRANSIE	ENT ELASTOGR	APHY [25895]						kPa	
	F-SCORE, TRA	ANSIENT ELAST	TOGRAPHY [2	5896]						
	DB/M, CAP [2]	7132]							dB/m	
	GRADE OF HE	EPATIC STEATO	SIS, CAP [27	133]						

22. Example Fibroscan result printout

Purpose:

In addition to manually entering Fibroscan results into the HealthConnect discrete data fields, clinical staff also upload the electronically scanned PDF report from the Fibroscan machine that shows the results values and the shear wave graphics.

Implementation team: EPIC / HealthConnect team, with approval from Gastroenterology

Below shows a sample scanned Fibroscan report including the results values (page left) and shear wave graphics (page right)



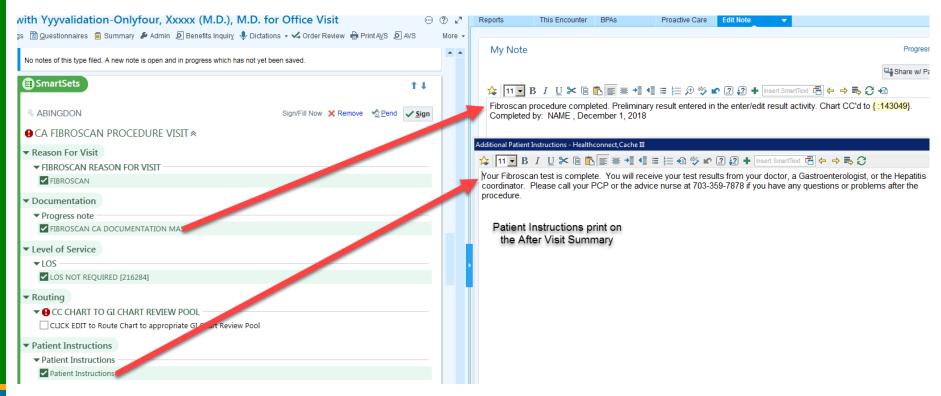
23. Fibroscan Operator SmartSet (for conducting visit)

Purpose:

This EPIC / HealthConnect based SmartSet guides Fibroscan operators (in KPMAS, these are medical assistants) through the steps of conducting the Fibroscan and entering in results data. At this time (Nov 2018), Fibroscan/Echosens does <u>not</u> yet have a direct connection from the machine to feed data into EPIC / HealthConnect.

Implementation team: EPIC / HealthConnect team

The Smartset below sets up the visit documentation for the Fibroscan operator (medical assistant). Once documentation is in place, the Fibroscan operator begins the Fibroscan.





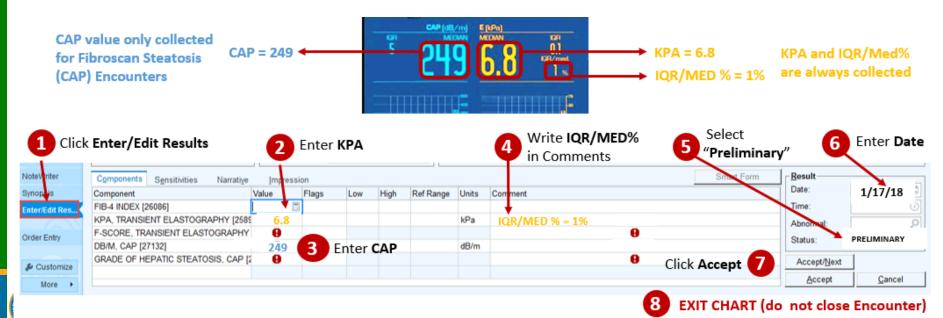
24. Fibroscan Operator job aid for documenting Fibroscan results

Purpose:

This job aid guides Fibroscan operators (in KPMAS, these are medical assistants) through the steps of entering Fibroscan results data into the discrete HealthConnect fields. At this time (Nov 2018), Fibroscan/Echosens does <u>not</u> yet have a direct connection from the machine to feed data into EPIC / HealthConnect.

Implementation team: EPIC / HealthConnect team, Fibroscan operators (medical assistants)

- Steps 1-9 guide the Fibroscan operator (medical assistants) through documenting the values from the machine screen (excerpt shown in blue) into the correct discrete HealthConnect results field
- In this example, the Fibroscan has been conducted for Fibrosis and Steatosis therefore results for KPA and dB/m CAP are both displayed.
- IQR/Med% must be <30% for the scan to be valid. Therefore this value is also documented in the Comments section.
- In the KPMAS workflow, the Fibroscan operator only enters the raw data (KPA, dB/M CAP) and exits the chart. The Gastroenterologist then enters the chart to interpret the data, entering in F-score and S-grade.
- KPMAS also collects a FIB-4 score, which is not a value produced by the Fibroscan machine, but is used for comparison to the F-score produced through the KPA conversion



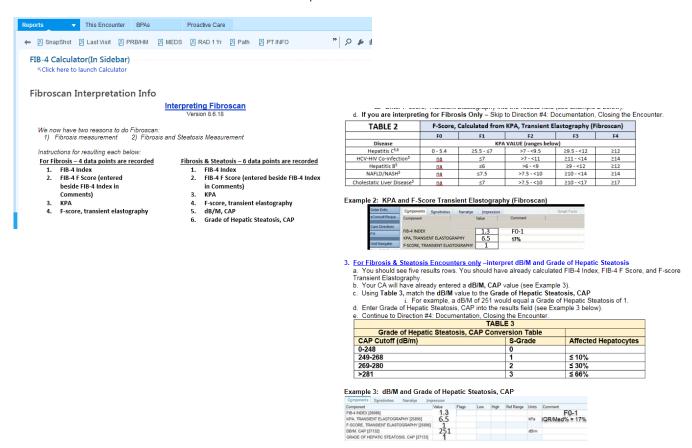
25. Fibroscan interpretation tool for physicians (KP HealthConnect)

Purpose:

In the KPMAS workflow, the Fibroscan operator enters the raw data (KPA, dB/M CAP) and exits the chart. The Gastroenterologist then enters the chart to interpret the data, entering in F-score and S-grade.

Implementation team: EPIC / HealthConnect team, Gastroenterology

Tables to interpret Fibroscan are available in HealthConnect for Gastroenterologists. Excerpts of this resource are below. Please reach out for additional information about Fibroscan interpretation



26. Best Practice Alerts for follow-up Fibroscan on untreated patients

Purpose:

Chronically infected HCV patients with an F score of 0-1 who are not being treated require an annual Fibroscan to assess liver health. These Best Practice Alerts fire on an annual basis. The Specialized Best Practice Alerts fire for patients with Fibroscan F0-1 score who are ineligible for the annual Fibroscan due to pregnancy or having an implantable electronic device (both contraindications for receiving Fibroscan test).

Implementation team: EPIC / KP HealthConnect team, with approval from Gastroenterology

General Best Practice Alert to Annually Monitor Untreated Patients using Fibroscan:

- i. Include:
 - i. Diagnosis of Hepatitis C
 - i. Fibroscan F-Score 0, 1
- ii. Exclude:
 - i. Qualifying HCV Medication

Specialized Best Practice Alert if Untreated Patient is Ineligible for Fibroscan:

FO-1 patients ineligible for follow up Fibroscan (due to pregnancy)

- a. Include:
 - i. Diagnosis of Hepatitis C
 - ii. Fibroscan F-Score 0, 1
 - iii. Problem List Pregnancy
- b. Exclude:
 - i. Qualifying HCV Medication

F0-1 patients ineligible for follow up Fibroscan (due to implantable electronic devices)

- a. Include:
 - i. Diagnosis of Hepatitis C
 - ii. Fibroscan F-Score 0, 1
 - iii. Problem List Implantable electronic device (from list)
- b. Exclude:
 - i. Qualifying HCV Medication





27. Sample report for Fibroscan data

Purpose:

We use monthly reports to ensure the Fibroscan resulting and interpretation is occurring in the correct manner. These reports are particularly useful during program launch or when bringing a new Fibroscan machine live.

<u>Implementation team:</u> Data analytics/reporting team, Gastroenterology team (operators, managers, physicians)

- In the example below, the KPA has been input correctly as "11" and the IQR/MED % is <30%, indicating a valid Fibroscan.
- The F-Score has been documented correctly as "3" by the interpreting Gastroenterologist
- The Lab_Status has changed from Preliminary to "Final" indicating the Gastroenterologist has completed interpretation and the result is finalized nd can be released to the patient.

	Α	В	С	D	Е	F	G	Н
1	FIBROSCAN RESULTS							
2								
3	MRN -	Pat Name	RESULT -	COMPONENT_NAME -	ORD -	COMPONENT_COMMEN -	LAB_STATUS -	LAB LOCATION -
4	222222	Test. Test Patient 1	01/01/2001	KPA, TRANSIENT ELASTOGRAPHY	11	IQR/Med% = 13%	Final result	FALLS CHURCH
5	222222	Test. Test Patient 1	01/01/2001	F-SCORE, TRANSIENT ELASTOGRAPHY	3		Final result	FALLS CHURCH

Program Contacts

Thank you for your interest in the KP Mid-Atlantic States Hepatitis C Care Cascade!

Please reach out to our project team for additional information about the program or the components shared here. We are happy to have a phone conversation or conduct a webinar with your team.

Program Leads

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