

MÉDECINS DU MONDE 世界医生组织 DOCTORS OF THE WORLD منظمة أطباء العالم LÄKARE I VÄRLDEN MEDICI DEL MONDO ΓΙΤΡΟΙ ΤΟΥ ΚΟΣΜΟΥ DOKTERS VAN DE WERELD MÉDICOS DO MUNDO MÉDICOS DEL MUNDO 世界の医療団 ÄRZTE DER WELT दुनिया के डॉक्टर MÉDECINS DU MONDE 世界医生组织 DOCTORS OF THE WORLD منظمة أطباء العالم LÄKARE I VÄRLDEN MEDICI DEL MONDO ΓΙΤΡΟΙ ΤΟΥ ΚΟΣΜΟΥ DOKTERS VAN DE WERELD MÉDICOS DO MUNDO MÉDICOS DEL MUNDO 世界の医療団 ÄRZTE DER WELT दुनिया के डॉक्टर MÉDECINS DU MONDE 世界医生组织 DOCTORS OF THE WORLD منظمة أطباء العالم LÄKARE I VÄRLDEN MEDICI DEL MONDO ΓΙΤΡΟΙ ΤΟΥ ΚΟΣΜΟΥ DOKTERS VAN DE WERELD MÉDICOS DO MUNDO MÉDICOS DEL MUNDO 世界の医療団 ÄRZTE DER



Section 3: Testing and Diagnosis of Hepatitis C

Dr. Jules Alla Kouadio (Médecins du Monde)
*Training “Hepatitis C and HR for PWUD”,
20th-24th Sept. 2016, Nairobi, Kenya*

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Learning objective of the session

introducing the participants to the main tests used to identify exposure to hepatitis C, whether a person is actively infected and to assess and monitor liver health

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Learning objectives:

1. Recognise the benefits of hepatitis C
2. Discuss antibody testing and RNA testing and explain results
3. Identify the tests used for understanding liver disease progression (biopsy/Fibroscan)

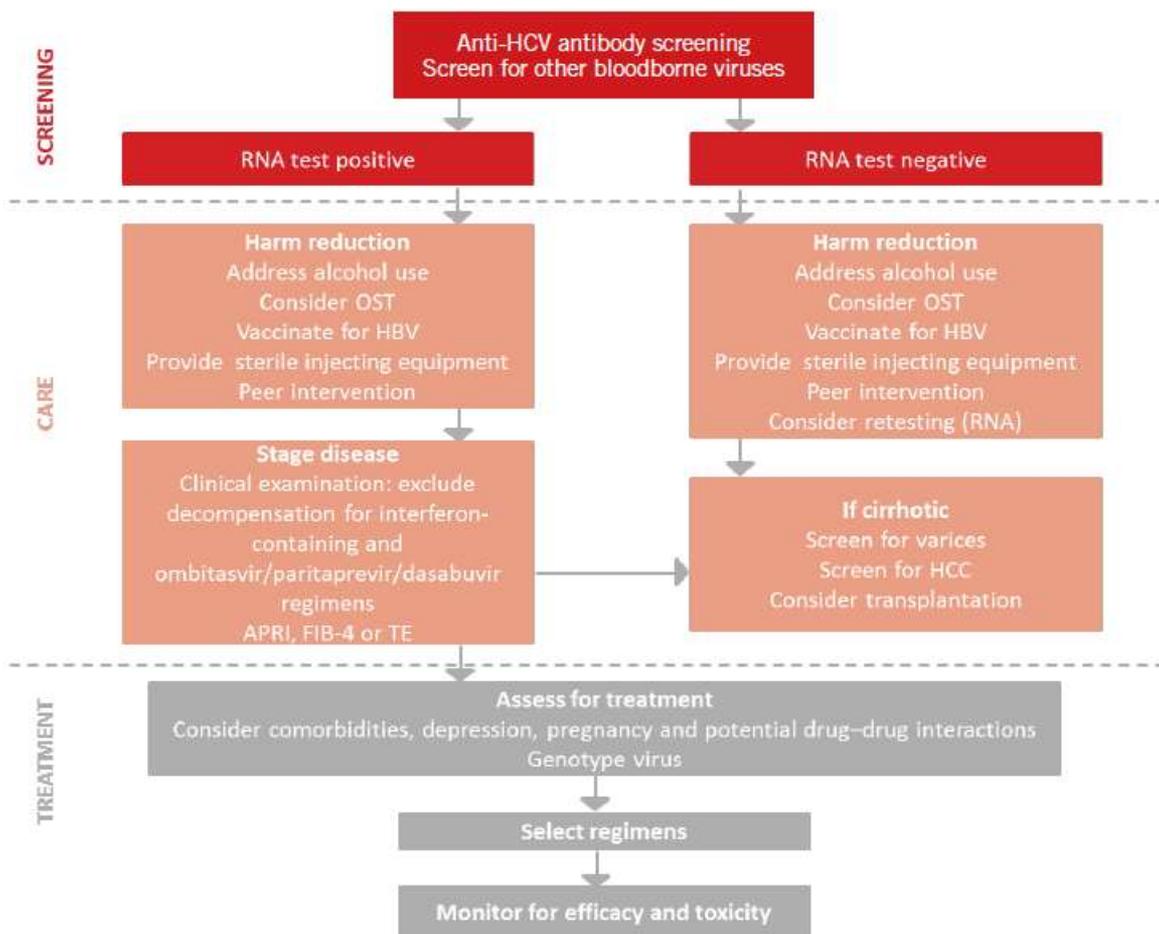
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Outline of the presentation

1. Screening of Hepatitis C
2. Confirmation of Hepatitis C
3. Assess the degree of liver fibrosis and cirrhosis
4. Prioritized for treatment



APRI: aminotransferase/platelet ratio index; HBV: hepatitis B virus; HCC: hepatocellular carcinoma; HCV: hepatitis C virus; OST: opioid substitution therapy; TE: transient elastography

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Plan

- 1. Screening of Hepatitis C**
2. Confirmation of Hepatitis C
3. Assess the degree of liver fibrosis and cirrhosis
4. Prioritized for treatment



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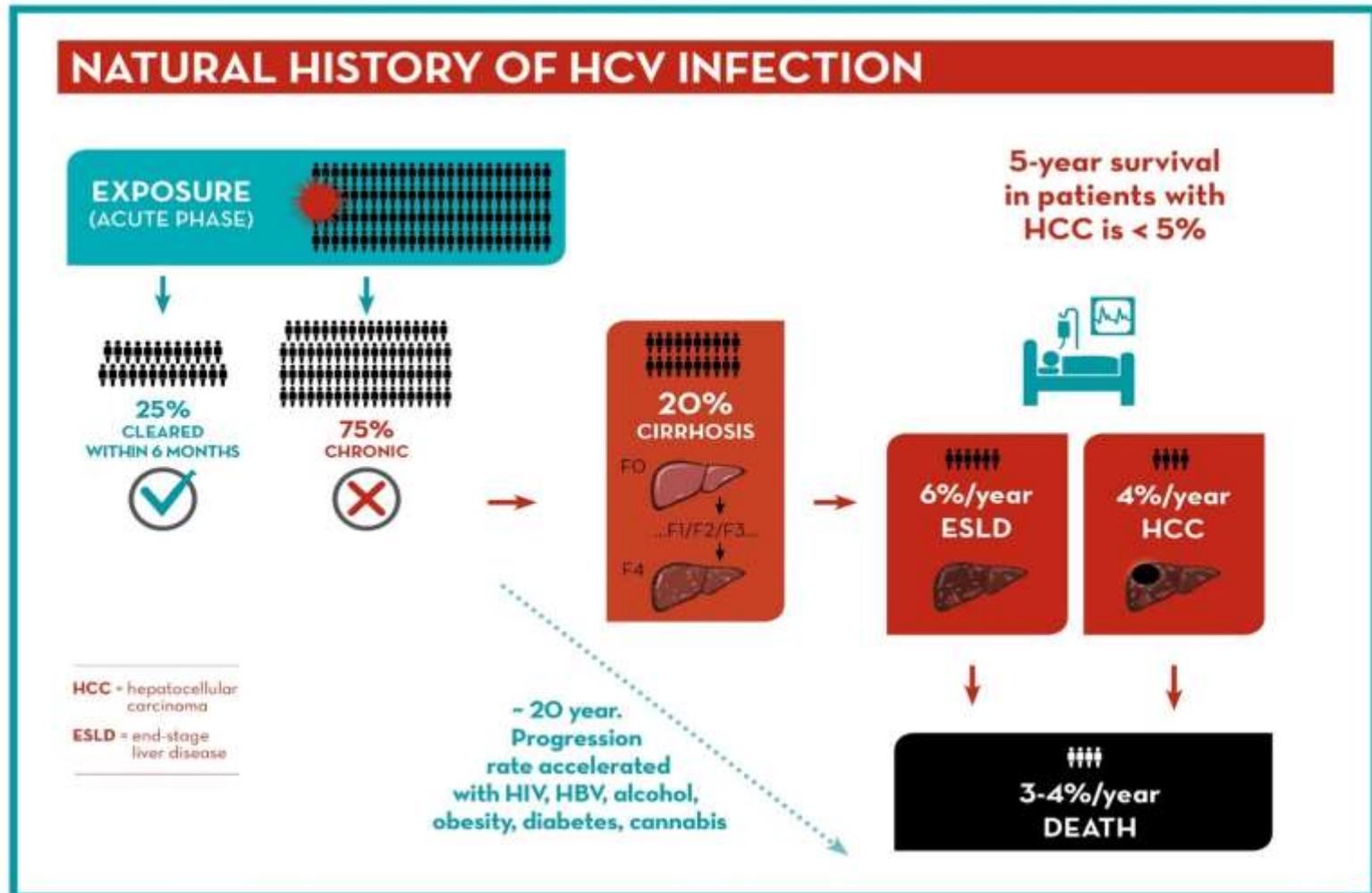
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1. What is an antibody?
2. What does it mean if someone has positive HCV antibody?



HCV natural history





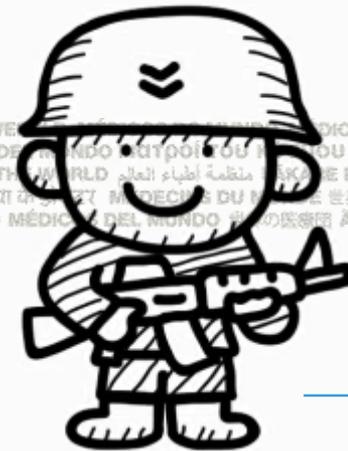
1. Screening of Hep C = antibodies

- » HCV antibody test (screening test)
- » Anti-HCV usually become detectable between **8 and 12 weeks after infection** and 90% of patients have HCV antibody after 12 weeks.
- » In Kenya, MdM used **SD Bioline** and is about to use OraQuick, both are lateral flow immunoassay.

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Interpretation of screening test results

- » The results are given as reactive and non-reactive.
- » Negative result indicates that the person is not infected with Hep C virus
- » But there is risk behaviors, need to confirm again after 12 weeks.
- » Positive result indicates that the patients **had infected with Hep C virus once in his lifetime**. It does not indicate that the patient have Chronic Hepatitis.
- » Patients who have viral clearance remain positive for HCV antibody.
- » It is important to tell the patient that HCV Ab test is a screening test and once it is positive, the patients needs to confirm with HCV RNA PCR test.



Interpretation of screening test results (1/3)

- » The results are given as reactive and non-reactive.
- » Negative result indicates that the person is not infected with Hep C virus.
- » But there is risk behaviors, need to confirm again after 12 weeks (**window period**)
- » There is a risk of false negative result for HIV+ people





Interpretation of screening test results (2/3)

- » Positive result indicates that the patients **had infected with Hep C virus once in his lifetime**. It does not indicate that the patient have Chronic Hepatitis.
- » Patients who have viral clearance remain positive for HCV antibody.
- » It is important to tell the patient that HCV Ab test is a screening test and once it is positive, the patients needs to confirm with HCV RNA PCR test.



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Interpretation of screening test results (3/3)

- » Invalid = you must do the test again.
- » If 2 rapid tests are invalid you need to perform a viral load test



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If someone is anti-HCV positive

- » What are you going to tell your patient?
- » Is he/she at risk of transmitting the virus?

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Plan

1. Screening of Hepatitis C
2. **Confirmation of Hepatitis C**
3. Assess the degree of liver fibrosis and cirrhosis
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Existing recommendation from 2014

It is suggested that nucleic acid testing for the detection of HCV RNA be performed directly following a positive HCV serological test to establish the diagnosis of chronic HCV infection, in addition to nucleic acid testing for HCV RNA as part of the assessment for starting treatment for HCV infection.

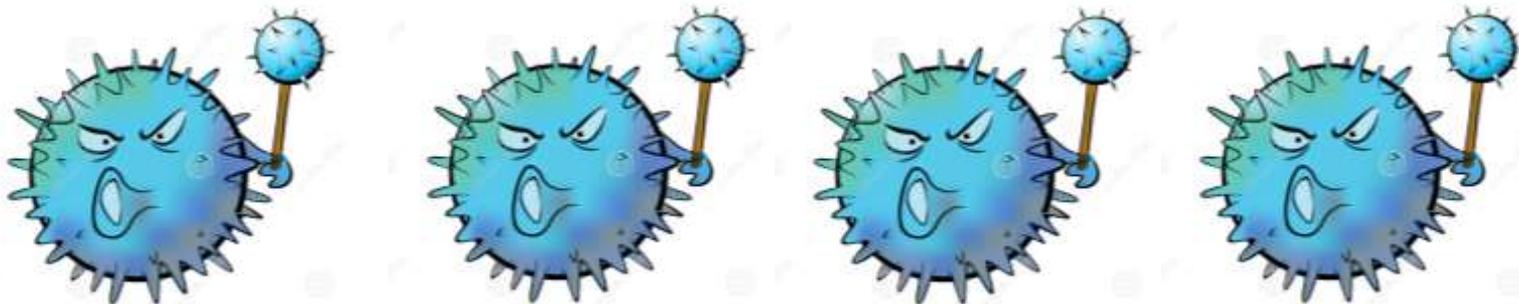
Conditional recommendation, very low quality of evidence



2. Confirmation of Hep C = viral load

» HCV RNA PCR (viral load testing)

- HCV RNA is detected within 1-2 week after initial infection.
- Confirmation test for active HCV infection. Also use for treatment monitoring.
- Qualitative testing: virus there, yes or no?
- Quantitative testing: how much virus is there?



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Serologic pattern of acute HCV infection with progression of chronic infection

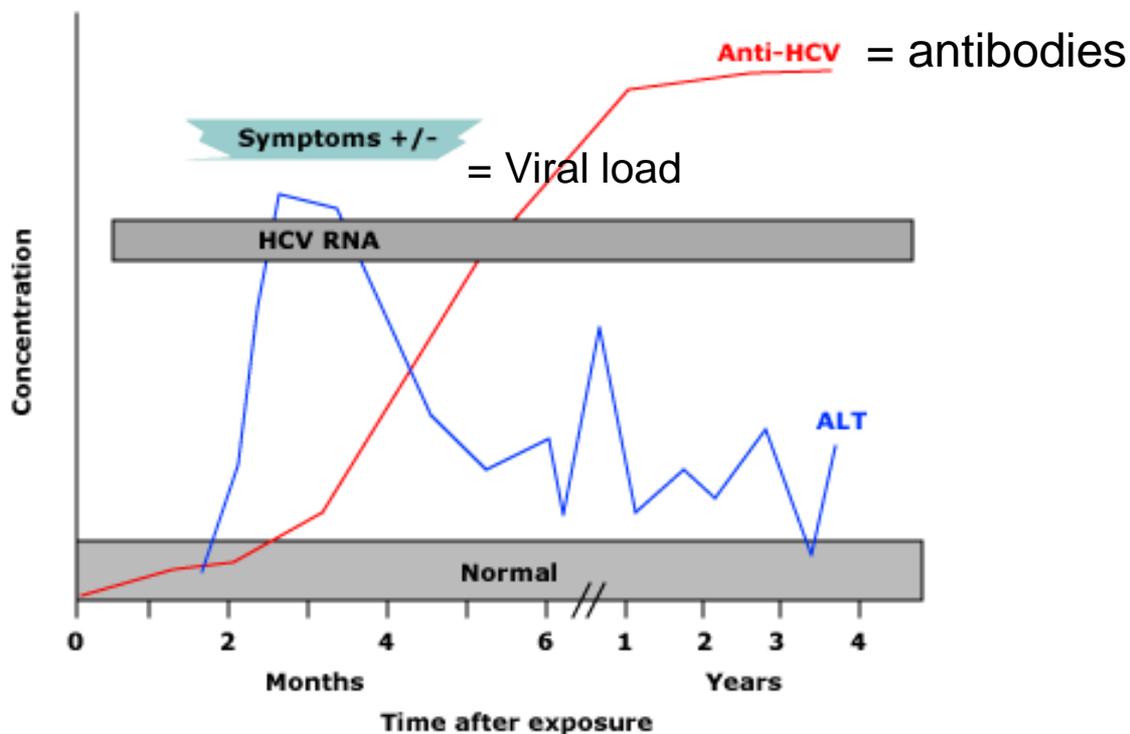


Figure provided by the Centers for Disease Control and Prevention.



LABORATORY REPORT

ROUTINE

Patient Info: SS / F
 Doctor Info: Dr. Aay Win
 Center Info: Sein Thitzar(Mythaymyer)
 Collected Date: 02-May-16
 Result Due Date: 05-May-16
 Lab Ref No.: CH1 - 2023

PROC	RESULT
HCV Viral Load	HCV RNA NOT DETECTED
HCV Real Time (PCR)	Below Detection Limit

This report is generated by Rotor-Gene Real-Time Analysis using artus® HCV RG RT-PCR Kit.

Analytical Sensitivity of artus® HCV RG RT-PCR Kit - 33.6 IU/ml
 Linear Dynamic Range of artus® HCV RG RT-PCR Kit - 65 IU/ml - 10⁶ IU/ml

* artus® HCV RG RT-PCR KIT reports the result only in IU/ml and it does not provide conversion from IU/ml to copies/ml. For estimation of viral concentration in copies/ml, the conversion of [1 IU/ml = 4 copies/ml] recommended by WHO paper titled "WHO Consultation on International Standards for In vitro Clinical Diagnostic Procedures on Nucleic Acid Amplification Techniques (NAT)" can be considered.

Run Date 4-May-2016

Prof. Ne Win
 M.B., B.S., M.Med.Sc (Pathology)
 PhD (Molecular Pathology)



Patient ID:
 Printed Date: 05 May, 2016



Result ID:



Order ID:



Created by:

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LABORATORY REPORT

Patient Name: _____ Collected on: 5-Mar-16
 Age/ Sex: 55/ Female Reported on: 8-Mar-16
 Requested By: Dr. U. Noy Win Lab Registration No: CMI-A28719VR
 Referred Center: Sein Thitsar (Myitthaigon)

PROCEDURE	RESULT
HCV Viral Load	HCV RNA DETECTED
HCV Real Time (PCR)	1.623 x 10 ⁵ IU/ml [More than 1.0 x 10 ⁴ IU/ml]

This report is generated by Abbott Zeev examine analysis using artus® HCV RG RT-PCR kit.

artus® HCV RG RT-PCR Kit - 35.6 IU / ml

Upper Dynamic Range of artus® HCV RG RT-PCR Kit - 65 IU / ml - 10⁷ IU / ml

* artus® HCV RG RT-PCR kit reports the result only in IU/ml and it does not provide conversion from IU/ml to copies/ml. For estimation of viral concentration in copies/ml, the conversion of (3 IU/ml = 4 copies/ml) recommended by WHO paper titled "WHO Consultation on International Standards for In vitro Clinical Diagnostic Procedures based on Nucleic Acid Amplification Techniques (NAT)" can be considered.

Prof. No Win

M.B., B.S., M.Med.Sc (Pathology)
PhD (Molecular Pathology)

Collect ID: _____ Result ID: _____ Green ID: _____ Created by: _____

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Plan

1. Screening of Hepatitis C
2. Confirmation of Hepatitis C
- 3. Assess the degree of liver fibrosis and cirrhosis**
4. Prioritized for treatment

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Existing recommendation from 2014

In resource-limited settings, it is suggested that aminotransferase/platelet ratio index (APRI) or FIB-4 be used for the assessment of hepatic fibrosis rather than other non-invasive tests that require more resources such as elastography or FibroTest.

Conditional recommendation, low quality of evidence

Note: This recommendation was formulated assuming that liver biopsy was not a feasible option. FibroScan®, which is more accurate than APRI and FIB-4, may be preferable in settings where the equipment is available and the cost of the test is not a barrier to testing.



3. Assessing level of fibrosis

» Blood biochemistry:

- Aminotransferase/platelets ratio index (APRI)
- FIB-4

» Imaging techniques:

- Fibroscan (Transient elastography)
- ultrasound

» Liver biopsy (previously gold standard for accessing fibrosis; but invasive and risk of complications like bleeding)

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Test	Components	Requirements	Cost
APRI	AST, platelets	Simple serum and haematology tests	+
FIB-4	Age, AST, ALT, platelets	Simple serum and haematology tests	+
FibroTest	gGT, haptoglobin, bilirubin, A1 apolipoprotein, α2-macroglobulin	Specialized tests. Testing at designated laboratories	++
FibroScan®	Transient elastography	Dedicated equipment	+++

ALT: alanine aminotransferase; APRI: aminotransferase/platelet ratio index; AST: aspartate aminotransferase; gGT: gamma glutamyl transpeptidase

Online score calculators are available:

- <http://gihep.com/calculators/hepatology/fibrosis-4-score/>
- <http://www.hepatitisc.uw.edu/page/clinical-calculators/apri>



Imaging Technique-Fibroscan

- » Fibroscan (transient elastography) is measuring mass liver tissue, 1cm in diameter and 5cm in length.
- » Vibration towards the liver tissue by ultrasound probe.
- » It follows by pulse echo, and velocities are measured.
- » Fibrosis is usually indicated with METAVIR Fibrosis score.

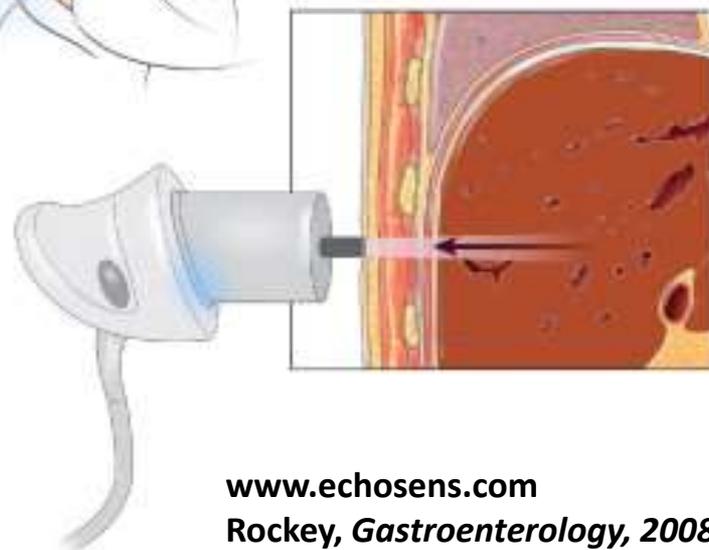


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Fibroscan (transient elastography)



www.echosens.com
Rockey, *Gastroenterology*, 2008

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Birth date :

Code :

Admitting

diagnosis :

Fibroscan exam

3/29/2016 5:29:08 AM

Exam type : Medium

Operator :

Referring

physician :

Median stiffness : 4.0 Kpa

IQR : 0.5 Kpa

IQR/med. : 13 %

Valid measures : 10

Success rate : 100 %

Legal notice

FibroScan® is a medical device designed for use as a diagnostic aid. Measurements should be performed by a certified operator. Results should be interpreted by a specialist in liver medicine according to the clinical context, taking into account the number of valid measurements, their dispersion (IQR) and the success rate.

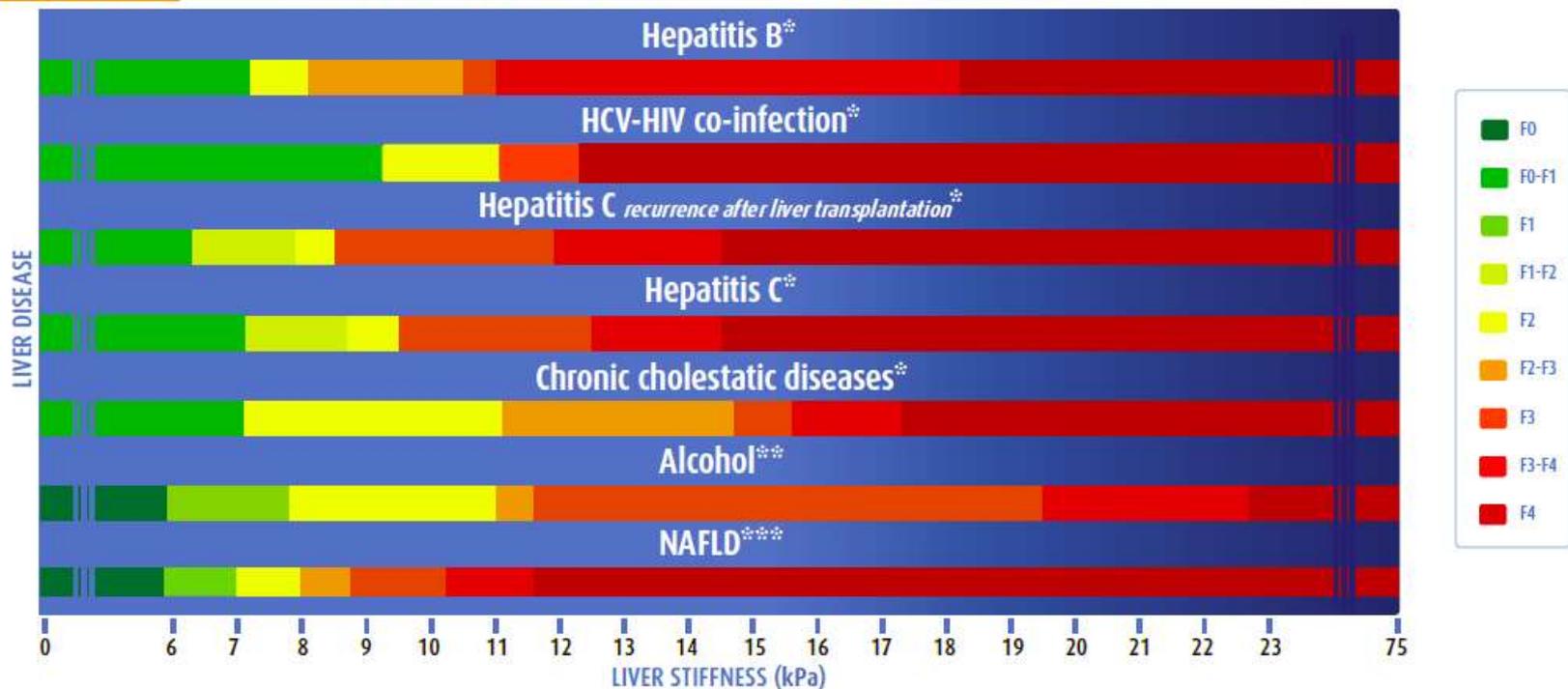
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SCORING CARD

CORRELATION BETWEEN LIVER STIFFNESS (kPa) & FIBROSIS STAGE



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What will it change in you counselling with the patient?

- » To know that the Fib-4, APRI of Fibroscan show an F3 stage?
- Or an F0-F1 stage?

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Plan

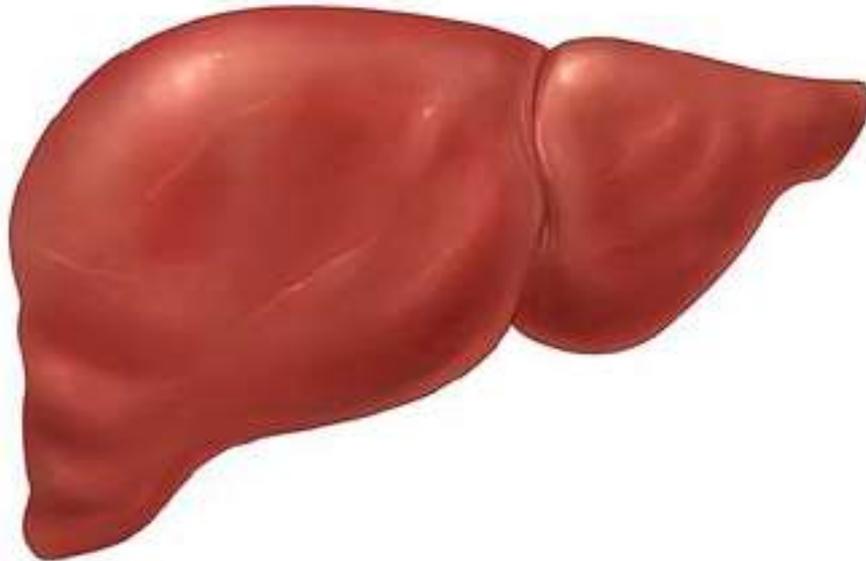
1. Screening of Hep C
2. Confirmation of Hep C
3. Assess the degree of liver fibrosis and cirrhosis
 - **Specific evaluation for cirrhosis**
4. Prioritized for treatment

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Normal Liver



Liver with Cirrhosis



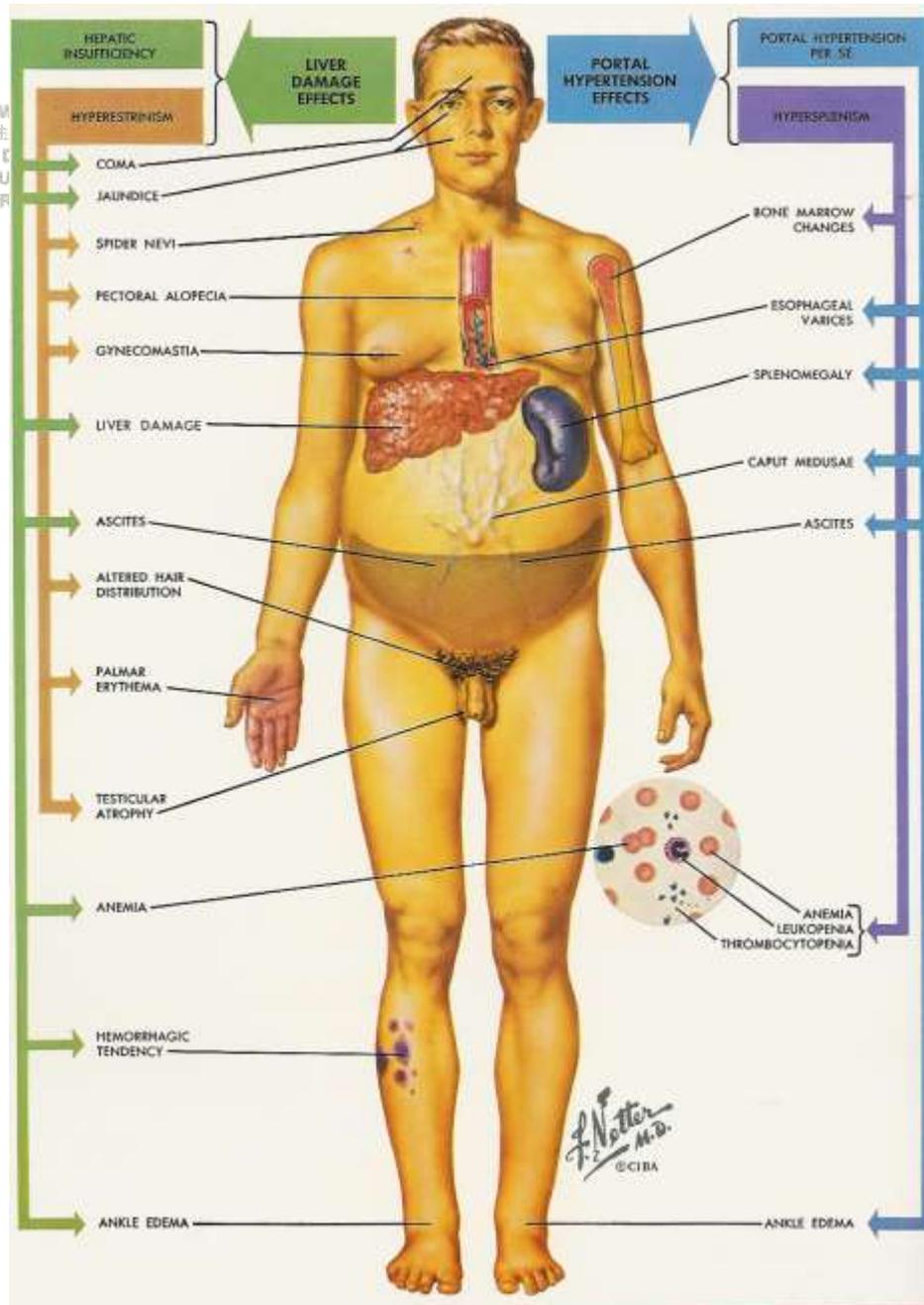
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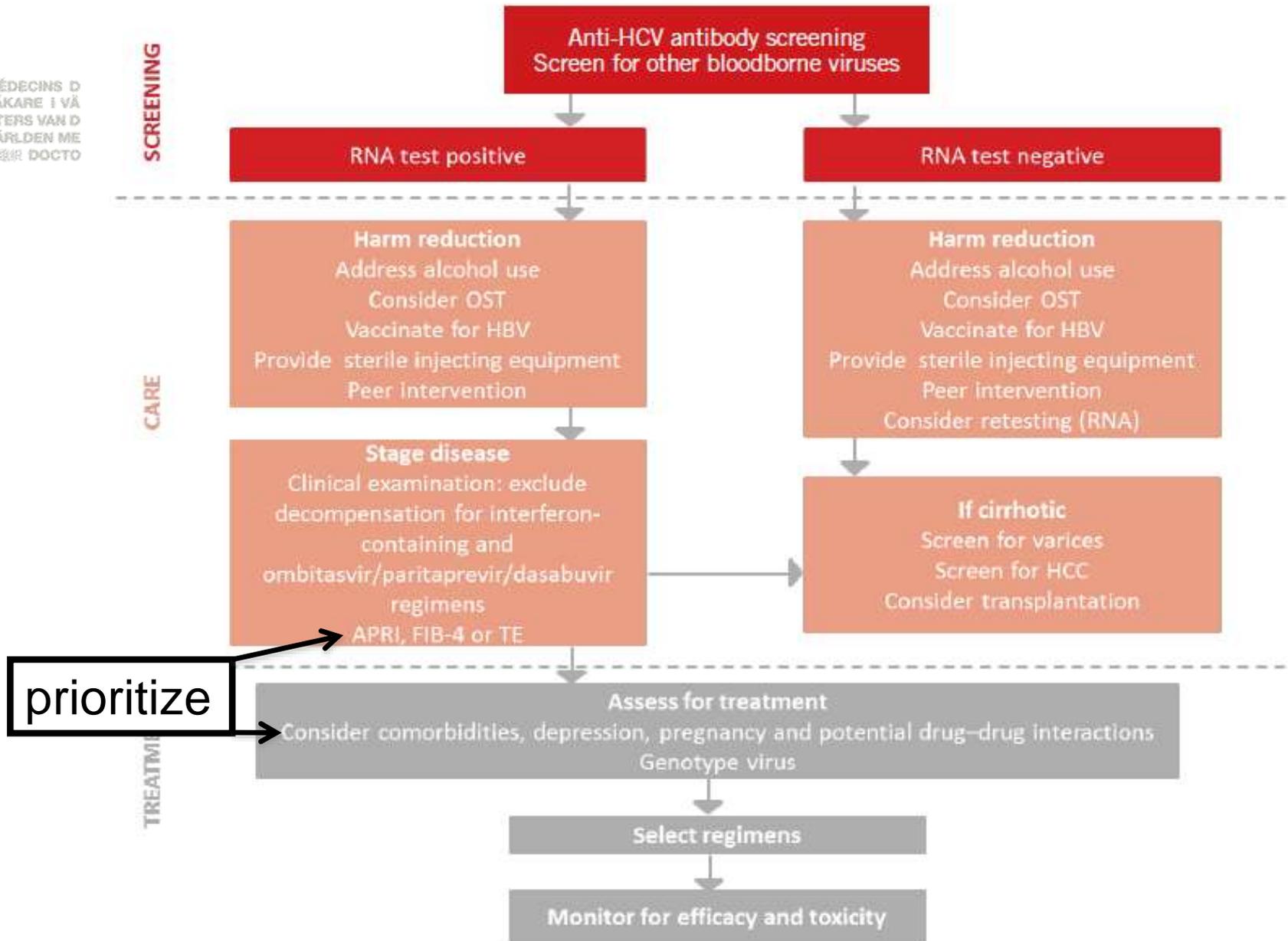
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Plan

1. Screening of Hep C
2. Confirmation of Hep C
3. Assess the degree of liver fibrosis and cirrhosis
 - Specific evaluation for cirrhosis
- 4. Prioritized for treatment**



APRI: aminotransferase/platelet ratio index; HBV: hepatitis B virus; HCC: hepatocellular carcinoma; HCV: hepatitis C virus; OST: opioid substitution therapy; TE: transient elastography

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GUIDELINES FOR THE SCREENING, CARE AND TREATMENT OF PERSONS WITH CHRONIC HEPATITIS C INFECTION

UPDATED VERSION
APRIL 2016
GUIDELINES

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Exercise 1 (30 mins)

Divide participants into groups of 3 to 5 and ask them to complete the table below (you can draw the table on flipcharts)

Test outcome	Interpretation	Further Action
HCV antibody -		
HCV antibody +		
HCV antibody +, HCV RNA +		
HCV antibody + , HCV RNA -		

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Solution for exercise 1

Test outcome	Interpretation	Further Action
HCV antibody -	No HCV antibody detected	If the person has no risk behavior, no further action required. If the person has risk behaviors, need to tested again after 12 weeks because of window period.
HCV antibody +	The person has been infected with HCV infection in his life time/ presumptive HCV infection	Need to test HCV RNA/viral load for the confirmation.
HCV antibody +, HCV RNA +	Current HCV infection	Need to do liver fibrosis assessment.
HCV antibody + , HCV RNA -	No current HCV infection: spontaneous cure of treatment successful	No further action required. This person is at risk of reinfection

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Exercise 2 (30 mins)

Divide participants into groups of 3 to 5 and ask them to complete the table below (you can draw the table on flipcharts)

Test outcome	Interpretation	Further Action
APRI score = <F2		
APRI score = F4		
Fibroscan = F0		
Fibroscan = F3		

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Solution for exercise 2

Test outcome	Interpretation	Further Action
APRI score = <F2	no significant fibrosis = Liver not too damaged	No urgent need of treatment Look for factor of progression Reassure the patient Follow up of fibrosis
APRI score = F4	cirrhosis = Liver damaged	Urgent need of treatment Look for factor of progression Refer to doctor for cirrhosis management
Fibroscan = F0	No fibrosis	No urgent need of treatment Look for factor of progression Reassure the patient Follow up of fibrosis
Fibroscan = F3	Significant fibrosis (close to cirrhosis)	Urgent need of treatment Look for factor of progression Follow up of fibrosis, Consider annual fibroscan

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