PAHO’s Comprehensive support to address hepatitis

- National Action planning
- Disease burden & investment case
- Access to medicines, & diagnostics
- EMTCT+
- Advocacy & Community participation
- Integrated, centralized data systems

Mobilizing action towards elimination
Hepatitis treatment – status in 2018

Nick Walsh
Regional Advisor Viral Hepatitis
Pan American Health Organization
Hepatitis treatment is liver cancer (HCC) prevention
Ideal scenario

- Curative treatment
- Highly effective vaccine
Ideal scenario

Curative treatment + Highly effective vaccine

Both cheap and safe
Hepatitis C

cDAAs cure > 95%

No vaccine
Hepatitis C

cDAAs cure > 95%

IPC +
Safe infections +
Blood screening +
safe sex +
harm reduction

Varies in expense and safety
HEPATITIS C TREATMENT
STATUS OF HEPATITIS C

Incidence:
1.75 million new infections / year
(Unsafe health care and injection drug use)

Prevalence:
71 million infected, all regions
HEPATITIS DEATHS, BY VIRUS AND REGION, 2015

96% hepatitis deaths from HBV and HCV (cirrhosis and hepatocellular carcinoma)

HEPATITIS DEATHS, BY VIRUS AND REGION, 2015

Number of deaths, 2015

<table>
<thead>
<tr>
<th>Region</th>
<th>HBV</th>
<th>HCV</th>
<th>HEV</th>
<th>HAV</th>
</tr>
</thead>
<tbody>
<tr>
<td>American</td>
<td>50,000</td>
<td>12,000</td>
<td>1,000</td>
<td>1,000</td>
</tr>
<tr>
<td>Eastern Mediterranean</td>
<td>50,000</td>
<td>12,000</td>
<td>1,000</td>
<td>1,000</td>
</tr>
<tr>
<td>European</td>
<td>50,000</td>
<td>12,000</td>
<td>1,000</td>
<td>1,000</td>
</tr>
<tr>
<td>African</td>
<td>50,000</td>
<td>12,000</td>
<td>1,000</td>
<td>1,000</td>
</tr>
<tr>
<td>South East Asia</td>
<td>50,000</td>
<td>12,000</td>
<td>1,000</td>
<td>1,000</td>
</tr>
<tr>
<td>Western Pacific</td>
<td>50,000</td>
<td>12,000</td>
<td>1,000</td>
<td>1,000</td>
</tr>
</tbody>
</table>
HEPATITIS DEATHS, BY VIRUS AND REGION, 2015

96% hepatitis deaths from HBV and HCV (cirrhosis and hepatocellular carcinoma)
# RISK OF CIRRHOSIS AT 20 YEARS FOLLOWING INITIAL INFECTION

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Cumulated incidence of cirrhosis</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cross sectional / retrospective</td>
<td>18%</td>
<td>15%-21%</td>
</tr>
<tr>
<td>Retrospective prospective studies</td>
<td>7%</td>
<td>4%-14%</td>
</tr>
<tr>
<td>Studies in non clinical setting</td>
<td>18%</td>
<td>16%-21%</td>
</tr>
<tr>
<td>All studies</td>
<td>16%</td>
<td>14%-19%</td>
</tr>
</tbody>
</table>

BEYOND SVR: IMPACT OF TREATMENT ON HEALTH OUTCOME

<table>
<thead>
<tr>
<th></th>
<th>HCV treatment OR</th>
<th>SVR OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatocellular carcinoma</td>
<td>0.392</td>
<td>0.203</td>
</tr>
<tr>
<td>Liver related mortality</td>
<td>0.363</td>
<td>0.126</td>
</tr>
<tr>
<td>All cause mortality</td>
<td>0.38</td>
<td>0.255</td>
</tr>
</tbody>
</table>

- No presentation stratified by initial fibrosis
- Patients with long term follow up tend to be patients with fibrosis treated with interferon rather than patients without fibrosis treated with direct acting anti-virals


*WHO HCV treatment guidelines 2018 systematic review working group*
## 2016 HCV guidelines remained complicated

### Persons without cirrhosis

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Daclatasvir/sofosbuvir</th>
<th>Ledipasvir/sofosbuvir</th>
<th>Sofosbuvir/ribavirin</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12 weeks</td>
<td>12 weeks&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>12 weeks</td>
<td></td>
<td>12 weeks</td>
</tr>
<tr>
<td>3</td>
<td>12 weeks</td>
<td>24 weeks</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>12 weeks</td>
<td></td>
<td>12 weeks</td>
</tr>
<tr>
<td>5</td>
<td>12 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>12 weeks</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Persons with cirrhosis

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Daclatasvir/sofosbuvir</th>
<th>Daclatasvir/sofosbuvir/ribavirin</th>
<th>Ledipasvir/sofosbuvir</th>
<th>Ledipasvir/sofosbuvir/ribavirin</th>
<th>Sofosbuvir/ribavirin</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>24 weeks</td>
<td>12 weeks</td>
<td>24 weeks</td>
<td>12 weeks&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>16 weeks</td>
</tr>
<tr>
<td>3</td>
<td>24 weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>24 weeks</td>
<td>12 weeks</td>
<td>24 weeks</td>
<td>12 weeks&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12 weeks&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12 weeks&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
Treat all people with HCV infection

• WHO recommends offering treatment to all individuals diagnosed with HCV infection who are 12 years of age or older, irrespective of disease stage. (Strong recommendation, moderate quality of evidence)

• WHO recommends to use pan-genotypic DAA regimens for the treatment of persons with chronic HCV infection aged 18 years and above (conditional recommendation, moderate quality of evidence).
# HCV treatment duration & availability

<table>
<thead>
<tr>
<th></th>
<th>Duration of treatment</th>
<th>Availability of product</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non cirrhotics (F0 – 3)</strong></td>
<td>12w</td>
<td>yes</td>
</tr>
<tr>
<td><strong>Cirrhotic (F4)</strong></td>
<td>12w</td>
<td>yes</td>
</tr>
<tr>
<td><strong>Originator</strong></td>
<td></td>
<td>'Access’ yes</td>
</tr>
<tr>
<td><strong>Generic</strong></td>
<td></td>
<td>no</td>
</tr>
<tr>
<td><strong>Sofosbuvir/Velpatasvir</strong></td>
<td>12w</td>
<td>yes</td>
</tr>
<tr>
<td><strong>Sofosbuvir/Daclatasvir</strong></td>
<td>12w</td>
<td>yes</td>
</tr>
<tr>
<td><strong>Glecaprevir/Pibrentasvir</strong></td>
<td>8w</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>12w</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>
Simplified testing and management algorithms

**Five key steps**

1. **Single quality assured RDT**
2. **Prompt or reflex HCV RNA or core Ag**
3. **Assess and triage:** Stage liver disease using NITs (APRI, FIB4, TE)
4. **Treat All with Pan-genotypic regimens**
5. **One-step monitoring:** One test of cure SVR12
ISSUES RELEVANT TO ‘TREAT ALL’: SYSTEMATIC REVIEWS

• No randomized control trials
• Risk of cirrhosis following initial infection
• Impact of treatment for patients with early fibrosis
• Safety of treatment
• Extra-hepatic manifestations
  • Prevalence
  • Effectiveness of treatment
• Public health impact of treatment as prevention
• Cost effectiveness
8 point approach to service delivery for treat all with pangenotypic regimens

1. Comprehensive **national planning for the elimination** of hepatitis C infection.
2. **Simple and standardized algorithms** across the continuum of care.
3. Strategies to **strengthen linkage** from testing to care, treatment and prevention
4. **Integration** of hepatitis testing, care and treatment with other services
5. **Decentralized services**, including task-sharing
6. **Community engagement** and peer support to address stigma and discrimination
7. **Efficient procurement and supply management** of medicines and diagnostics
8. **Data systems to monitor** the quality of individual care and the cascade of care
Specific public health approaches in 5 population groups

• These population groups experience **high incidence or prevalence, stigma, discrimination, criminalization or special vulnerability.**
  – Persons who inject drugs
  – Persons in prisons or other closed settings
  – Men who have sex with men
  – Sex workers
  – Indigenous populations
HEPATITIS B TREATMENT
Ideal scenario

- Curative treatment
- Highly effective vaccine
Hepatitis B

Effective, non-curative treatment + Vaccine - cheap, safe & effective

Treatment is relatively inexpensive, but lifelong
WHO Hepatitis B treatment guidelines 2015

- Key recommendations and rationale
  - Use of NITs for **staging** of liver disease
- **Who to treat?**
- **What treatment** to use? (First and Second-Line)
- How to **Monitor**? (ART, toxicity, HCC)
- **When to stop?**
- Prevention
- Implementation considerations
Prioritizing treatment for those that need it most

- Mortality in chronic viral hepatitis is from cirrhosis and liver cancer
- STAGING disease prioritizes patients with advanced liver disease or treatment, given limited resources.
### REVEAL-HBV cohort: Incidence of hepatocellular carcinoma

<table>
<thead>
<tr>
<th>Participant characteristic</th>
<th>Incidence rate (x_{100,000} Person-Years)</th>
<th>Adjusted RR (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>178</td>
<td>Ref</td>
</tr>
<tr>
<td>Male</td>
<td>530</td>
<td>3.0 (2.0 – 4.5)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-39</td>
<td>111</td>
<td>Ref</td>
</tr>
<tr>
<td>40-49</td>
<td>399</td>
<td>3.6 (2.0 – 6.4)</td>
</tr>
<tr>
<td>50-59</td>
<td>566</td>
<td>5.1 (2.0 – 8.9)</td>
</tr>
<tr>
<td>&gt;60</td>
<td>901</td>
<td>8.3 (4.6 – 15.0)</td>
</tr>
<tr>
<td><strong>Baseline HBV DNA (copies/ml)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;300</td>
<td>108</td>
<td>Ref</td>
</tr>
<tr>
<td>300 – 9999</td>
<td>111</td>
<td>NS</td>
</tr>
<tr>
<td>10000 – 99999</td>
<td>297</td>
<td>2.7 (1.3 – 5.6)</td>
</tr>
<tr>
<td>100000 – 999999</td>
<td>962</td>
<td>8.9 (4.6 – 17.5)</td>
</tr>
<tr>
<td>&gt;1 million</td>
<td>1152</td>
<td>10.7 (5.7 – 20.1)</td>
</tr>
<tr>
<td><strong>Baseline ALT (U/l)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;45</td>
<td>337</td>
<td>Ref</td>
</tr>
<tr>
<td>&gt;45</td>
<td>1342</td>
<td>4.1 (2.8 – 6.0)</td>
</tr>
<tr>
<td><strong>HBeAg serostatus</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBeAg -</td>
<td>264</td>
<td>Ref</td>
</tr>
<tr>
<td>HBeAg +</td>
<td>1130</td>
<td>4.3 (3.2 – 5.9)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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<th>Incidence rate ((x_{100,000} \text{-Person-Years}))</th>
<th>Adjusted RR (95%CI)</th>
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</tr>
<tr>
<td>&gt;45</td>
<td>1342</td>
<td>4.1 (2.8 – 6.0)</td>
</tr>
</tbody>
</table>
Progression of liver disease

<table>
<thead>
<tr>
<th>METAVIR stage</th>
<th>F0</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>F4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td>No fibrosis</td>
<td>Portal fibrosis without septa</td>
<td>Portal fibrosis with septa</td>
<td>Numerous septa without cirrhosis</td>
<td>Cirrhosis</td>
</tr>
<tr>
<td>HEALTHY LIVER</td>
<td><img src="image1" alt="Healthy Liver Image" /></td>
<td><img src="image2" alt="Fibrotic Liver Image" /></td>
<td><img src="image3" alt="Cirrhotic Liver Image" /></td>
<td><img src="image4" alt="Liver Cancer Image" /></td>
<td><img src="image4" alt="Liver Cancer Image" /></td>
</tr>
<tr>
<td>FIBROTIC LIVER</td>
<td><img src="image1" alt="Healthy Liver Image" /></td>
<td><img src="image2" alt="Fibrotic Liver Image" /></td>
<td><img src="image3" alt="Cirrhotic Liver Image" /></td>
<td><img src="image4" alt="Liver Cancer Image" /></td>
<td><img src="image4" alt="Liver Cancer Image" /></td>
</tr>
<tr>
<td>CIRRHOTIC LIVER</td>
<td><img src="image1" alt="Healthy Liver Image" /></td>
<td><img src="image2" alt="Fibrotic Liver Image" /></td>
<td><img src="image3" alt="Cirrhotic Liver Image" /></td>
<td><img src="image4" alt="Liver Cancer Image" /></td>
<td><img src="image4" alt="Liver Cancer Image" /></td>
</tr>
<tr>
<td>LIVER CANCER</td>
<td><img src="image1" alt="Healthy Liver Image" /></td>
<td><img src="image2" alt="Fibrotic Liver Image" /></td>
<td><img src="image3" alt="Cirrhotic Liver Image" /></td>
<td><img src="image4" alt="Liver Cancer Image" /></td>
<td><img src="image4" alt="Liver Cancer Image" /></td>
</tr>
</tbody>
</table>
Non-invasive tests (NITs) to assess for cirrhosis

- Important for decisions on prioritising who needs treatment
- Liver biopsy considered impracticable in low income settings

<table>
<thead>
<tr>
<th>NIT</th>
<th>Required Measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>APRI</td>
<td>AST, platelets</td>
</tr>
<tr>
<td>FIB-4</td>
<td>Age, AST, ALT, platelets</td>
</tr>
<tr>
<td>FibroTest</td>
<td>5 serum markers</td>
</tr>
<tr>
<td>FibroScan</td>
<td>Transient elastography</td>
</tr>
</tbody>
</table>

**RECOMMENDATION**

- **APRI** is the preferred NIT to assess for presence of cirrhosis (APRI score >2 in adults) in resource-limited settings.
- Transient elastography or FibroTest may preferred NIT in settings where they are available and cost is not a major constraint.

**STRENGTH**  **EVIDENCE QUALITY**

- Conditional  Low
HBV antiviral treatment

- In adults and those > 12 years, nucleos(t)ide analogues (NAs) which have a high barrier to drug resistance (tenofovir or entecavir) are recommended. (*Strong recommendation, moderate quality of evidence*)
  - NAs with a low barrier to resistance (lamivudine, adefovir or telbivudine) can lead to drug resistance and are not recommended. (*Strong recommendation, moderate quality of evidence*)
  - Persons with confirmed or suspected antiviral resistance, a switch to tenofovir is recommended. (*Strong recommendation, low quality of evidence*)
Hepatitis B treatment decision tree

Population

HBsAg

CIRRHOSIS AGE

ALT

HBV DNA

Cirrhotic patients or APRI >2

Persistently elevated

>20,000

Treatment recommended

2,000-20,000

Treatment deferred

<2,000

Treatment deferred

Non cirrhotic patients aged >30

Fluctuating

Persistent elevated

0-2,000

Treatment deferred

Normal

Non cirrhotic patients <30

Treatment deferred

HBsAg+

Treatment deferred

HBsAg-
Conclusion

- Hepatitis treatment is cancer prevention
- The burden of hepatitis in the Caribbean for HBV > HCV
- Treatment is not possible without diagnosis
- Prices are continuing to reduce
- PAHO stands ready to support action to increase the availability of diagnosis and treatment in the Caribbean
QUESTIONS, COMMENTS
PAHO’s Comprehensive support to address hepatitis

Disease burden & investment case

National Action Planning

Access to medicines, & diagnostics

Mobilizing action towards elimination

Advocacy & Community participation

Integrated, centralized data systems
The utility of the investment case for hepatitis

Nick Walsh
Regional Advisor Viral Hepatitis
Pan American Health Organization
The challenge facing hepatitis

• Funders increasingly prioritizing to cope with fewer resources and more goals.

• Hepatitis programmes need to know:
  – Domestic resource mobilization?
  – External donor funding?
  – Innovative financing mechanisms?
Integration = sustainability

• The core of sustainable financing is a programme optimized in cost and impact.

• Benefit from lessons learned with HIV/AIDS and avoid:
  – off-budget, parallel systems, or
  – separate delivery and financing arrangements.

• It is necessary to understand the key aspects of services (who benefits, how organized) and design finance accordingly.
Possible responses?

• **Disease-specific approaches:**
  – earmarked taxes (like in tobacco control)?
  – dedicated funding sources (like GFATM)?

• But, let’s **consider the lessons** of these experiences:
  – **sustainability** is not just about **revenue**,
  – **purchasing, pooling** and **delivery** must be efficient too.
The UHC lens: our only alternative

The unit of analysis is the health system:
• Develop the financing strategy at the sectoral level, not for “hepatitis” only.
• Formulate goals at population level, not just for hepatitis programme beneficiaries.

• On health financing: can priority interventions be integrated into benefit packages and purchasing arrangements?
  – Can hepatitis be the disease that solves a health system problem?
• Beyond health financing: will not strong, unified support systems also serve priority interventions?
  – Think IT, procurement...
The investment case

• The investment case is a strategic decision making tools to inform the most effective and cost-efficient policy suite to address hepatitis...i.e.:

What is the public health and economic impact of population level interventions to address hepatitis in a country
Process of disease burden and economic analysis

Disease burden estimates

- Disease progression model, transmission models for HBV/HCV (either or both)
- Prevalence estimates over time (to 2030)
- Liver related disease (LRD) outcomes over time - cirrhosis, HCC and deaths

Intervention scenarios:

- Comparing public health impacts* of different population level treatment strategies
  - Baseline (no interventions)
  - Status quo (no further intervention)
  - Reduce mortality objective
  - Elimination objective

Cost Estimation

- Direct costs (all healthcare costs such as diagnosis, staging, and hospitalisation associated with management of infection and sequelae)
- Indirect costs (lost productivity and life expectancy), measured in DALY/VSLY
- Cost of antiviral therapies (current practice vs. new DAAs/recommended therapies)
CEA
- current practice vs standardized care and treatment package
- old (if applicable) vs new antivirals
- price points for cost saving for new medicines

Budget Impact
- Direct and antiviral costs over time

Financing Strategies
- Who will pay? Payment scenarios involving stakeholders:
  - Govt vs health insurance vs individual
  - Combination scenarios
  - Co-payment estimations (only where applicable)

Cost Sensitivity
- Sensitivity analysis to identify uncertainties in cost inputs
Our investment case work so far

- Brazil (HBV, HCV)
- Colombia (HCV)
- Chile, Argentina (HCV) ongoing
- No countries of the Caribbean or Central America
- Not all countries need an investment case, especially where burden is very low
HEPATITIS C
Incidence (back calculated from prevalence)

\[ \text{Prevalence}_{\text{Year } x} = \sum_{t=1950}^{x} (\text{Incidence}_t - \text{Mortality}_t - \text{Cured}_t) \]

In 2016, an estimated 3200 new infections occurred.

Key determinant: when national blood donor screening commenced.
Impact of different strategies on prevalence, HCV related liver disease and deaths

Total Infected Cases (Viremic) — Colombia

Decompensated Cirrhosis — Colombia

HCC — Colombia

Liver Related Deaths — Colombia

- 2016 Base
- Treat 5,000 in 2025
- Treat 10,000 in 2025
- WHO Targets
The upfront investment can be decreased by lower diagnosis and treatment prices as shown in the elimination scenario.
Elimination is the most cost-effective scenario.
HEPATITIS B
Increasing birth dose (BD) vaccination to 90% and 3 dose (3D) vaccination to 95% starting in 2017 will reduce incidence

- Based on the current perinatal prophylaxes coverage of 54% birth dose and 79% coverage of three doses it is estimated that the HBsAg+ prevalence among 5-year olds will reach 1.0% in 2036
- By increasing birth dose coverage to 90% and three dose coverage to 95% in 2017, the target of 1.0% is estimated to be reached in 2032

Increased vaccination will also reduce incidence among infants. Between 2017-2033, 100,000 new infections will be averted.
Most acute infections occur among adults but perinatal transmission remains a main risk factor for chronic infections.

Among non-infants, most new infections are occurring after birth (0-4) and among those aged 20-34.
The cost of catch up vaccination will depend on the age group selected.

The pediatric population have a much higher rate of progression to chronic HBV. There are 11.4 million susceptible to infection (1-17 years old), but vaccination of this population will require testing for core antigen first.
HBsAg+ Prevalence by Age

Effect of HBV BD on the birth cohort

Attrition – the impact of HBV disease
Healthcare costs will increase as more patients are diagnosed & require follow up. Drug pricing has a large impact on total spending.
Conclusions

- The investment case for hepatitis is a valuable strategic planning tool that carries weight in policy decision making.
- Ideally, it is carried out in conjunction with:
  - National Action Plan development
  - Increased access to diagnostics & medicines
  - Normative guidance development
QUESTIONS, COMMENTS