Global Hepatitis Framework

Axis 1: Partnerships, resource mobilization and communication

Axis 2: Data for policy and action

Axis 3: Prevention of virus transmission

Axis 4: Screening, care and treatment
Context for the guidelines

- Focus on low- and middle-income countries
- Huge geographical difference in standards of care
- Rapidly changing therapeutic environment
- Lack of existing WHO hepatitis C guidelines
- WHO guidelines have a political dimension
- Strict evidence-based process for WHO guidelines
Guideline development at WHO

1. Scoping the document
2. Setting up Guideline Development Group and External Review Group
3. Disclosure and management of secondary interests
4. Formulation of the questions (PICO) and choice of the relevant outcomes
5. Evidence retrieval, assessment and synthesis (systematic review(s))
6. Formulation of the recommendations (GRADE)
   - Including explicit consideration of:
     - Benefits and harms
     - Values and preferences
     - Resource use
7. Dissemination, implementation (adaptation)
8. Evaluation of impact
9. Plan for updating
Elements of WHO recommendations

• Strength of evidence:
  – High quality: further research is very unlikely to change the confidence in the estimate of effect
  – Moderate quality: further research is likely to have an important impact on the confidence in the estimate of effect and may change the estimate
  – Low quality: further research is very likely to have an important impact on the confidence in the estimate of effect and is likely to change the estimate
  – Very low quality: uncertainty about the estimate.

• Strength of recommendation:
  – Strong – confidence that the benefits of the intervention outweighed the risks.
  – Conditional - benefits of the intervention probably outweighed the risks
## Considerations for strength of recommendation

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problem</td>
<td>Is the problem a priority?</td>
</tr>
<tr>
<td></td>
<td>Are a large number of people affected?</td>
</tr>
<tr>
<td>Benefits and Harms</td>
<td>Are the desirable anticipated effects large?</td>
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<tr>
<td></td>
<td>Are the undesirable anticipated effects small?</td>
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<td>What is the overall certainty of this evidence?</td>
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<tr>
<td>Values</td>
<td>How certain is the relative importance of the desirable and undesirable outcomes?</td>
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<tr>
<td></td>
<td>Are the desirable effects large relative to the undesirable effects?</td>
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<tr>
<td>Resource Use</td>
<td>Are the resources required small?</td>
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<td>Is the incremental cost small relative to the net benefits?</td>
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<tr>
<td>Equity</td>
<td>What would be the impact on health inequities?</td>
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<tr>
<td>Acceptability</td>
<td>Is the option acceptable to key stakeholders?</td>
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<tr>
<td>Feasibility</td>
<td>Is the option feasible to implement?</td>
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</tbody>
</table>
Topics for WHO hepatitis C screening, care and treatment guidelines

- Awareness
  - Who should be tested for hepatitis C (antibodies)
  - When to confirm HCV infection (PCR)

- Testing

- Referral
  - Care: what interventions to slow progression of liver disease
  - How to assess stage of liver fibrosis

- Disease-stage assessment
  - When to start treatment
  - What medicines to treat with

- Treatment

- Monitoring
  - How to monitor for response to treatment and drug adverse reactions
Recommendations

• Screening of at-risk groups
• Confirmation of chronic infection
• Alcohol-reduction intervention
• Non-invasive fibrosis assessment
• Assess all persons with chronic HCV for treatment
• Peg-IF and ribavirin
• DAAs
Other considerations

• Genotyping

• When to start

• Placing these recommendations in the context of known prevention interventions

• Special populations
  – Children
  – Persons who inject drugs
  – HIV co-infection

• Implementation and operational considerations
Next steps

- Peer review
- Technical editing
- Modification to include recommendation on new DAAs
- Approval by Guidelines Review Committee
- Pre-production
- Translation
- Launch at EASL 2014
- Adapt and update
Axis 4: WHO’s role in improving access to hepatitis therapy

Awareness
- World Hepatitis Day observance
- Improved prevalence estimates
- Prequalification of diagnostics
  - Screening/testing guidelines

Testing

Referral

Disease-stage assessment
- Treatment guidelines
- Laboratory standards
- Prequalification of molecular diagnostics
- Health-care worker training
- Prequalification of generic medicines
- Multi-stakeholder engagement

Treatment

Monitoring
### Status of WHO hepatitis-related guidelines development

<table>
<thead>
<tr>
<th>Guidelines</th>
<th>Status</th>
<th>Publication date</th>
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<tbody>
<tr>
<td>Hepatitis C treatment</td>
<td>Draft document</td>
<td>April 2014</td>
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<tr>
<td>Hepatitis B treatment</td>
<td>Guidelines Development Group formulating questions</td>
<td>December 2014</td>
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<tr>
<td>Hepatitis surveillance</td>
<td>Draft document in review</td>
<td>Mid 2014</td>
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<td>Hepatitis screening and testing</td>
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WHO-GHP approach to strengthening national hepatitis control plans

Advocacy

Country burden of disease estimates
Country planning tools
WHO guidelines
Technical assistance

National hepatitis control plans
Thank you