Treatment and Access to Drugs

Presenter:
Co-leads: Peter Beyer & Philippa Easterbrook
WHO Regional Advisor for South East Asia (SEARO): Razia Narayan Pendse
Session Objectives

By the end of this session, the participants: will be able to:

1. Formulate an approach to planning for hepatitis treatment and access based on the national planning tool
2. Identify common challenges for access to affordable care and treatment and identify possible solutions
3. Be familiar with approaches to treatment access adopted in different countries
Manual for Development and Assessment of national viral hepatitis plans

- Sections 5.2.3 Testing and 5.2.4 on Clinical Care and Treatment (pages 24 to 26)
- Example of a national plan structure (pages 30 to 32)
- Annex 5: Checklist for initiating or scaling up hepatitis treatment services
Checklist for initiating or scaling up hepatitis treatment services

<table>
<thead>
<tr>
<th>Communication, leadership and advocacy</th>
<th>Check if present</th>
<th>Comments</th>
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<tbody>
<tr>
<td>1. There is a person responsible for developing or updating national guidelines or protocols for patient management and monitoring.</td>
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<td>2. There is a person responsible for developing training materials for healthcare workers.</td>
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<td>3. There is a plan to communicate the service scale-up recommendations to: a. health-care facilities, including public, not-for-profit and private institutions, b. health-care workers, c. other relevant stakeholders, such as people with chronic hepatitis.</td>
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<td>4. There is a person responsible for advocacy with stakeholders, such as political leaders, health personnel and the mass media.</td>
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<th>Shifting and human resources</th>
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<td>5. The number of additional health-care workers needed to implement the scaling up of services is calculated.</td>
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<td>6. It is identified which cadre of health-care workers (physicians, health officers, nurses, midwives, community health workers, laboratory assistants, etc.) are needed.</td>
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<td>7. How these cadres of health-care workers can be recruited is identified.</td>
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<td>8. Task-shifting is being considered as a strategy to optimize available human resources for health and expanding service delivery.</td>
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<td>9. Training needs for various cadres of health-care providers are assessed.</td>
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<td>10. Capacity-building plans are in place, including how training will be delivered and paid for.</td>
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<th>Drugs and supplies</th>
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<td>11. Systems are in place for forecasting treatment needs.</td>
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<td>12. Systems are in place for procuring recommended drugs and other commodities at the best possible prices.</td>
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<td>13. The patient situation within the country is identified for globally available treatment options.</td>
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<tr>
<th>Drugs and supplies (continued)</th>
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<td>14. There is a transition plan to phase out suboptimal medicines.</td>
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<td>15. Supply management systems are strengthened to manage the increased demand for diagnostics and medicines.</td>
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<td>16. A regulatory process is in place to approve and register medicines and diagnostics in a timely manner.</td>
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<td>17. Laboratory quality control and external quality assurance systems are in place and fully functional.</td>
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<td>18. National laws allow for the purchase and importation of all necessary commodities.</td>
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<th>System organization</th>
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<td>19. Linkages and referral systems between testing and treatment services are adequate.</td>
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<td>20. Services are integrated and/or decentralized to support the implementation of recommendations for scaling up.</td>
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<td>21. Treatment access plans are developed in consultation with managers of other relevant programmes (e.g. HIV, TB, maternal and child health, harm reduction).</td>
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<td>22. Strategies at the policy and service delivery levels are in place to address possible disparities in access to care and treatment.</td>
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<td>23. Interventions are in place to promote and reinforce adherence to treatment and retention in care.</td>
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WHO NORMATIVE GUIDANCE considerations:

- **HCV (2014)**
- **HBV (2015)**
- **WHO Hepatitis Testing Guidelines (2016)**

- Who to screen? Populations and setting
- How to screen? Diagnostics for hepatitis
  - Implementation of testing recommendations
- Linkage to prevention & treatment
DIAGNOSTIC considerations:
Potential for Simplified Diagnostic Pathway

Adapted from UNITAID Hepatitis C Medicines and Diagnostics in the Context of HIV/HCV Co-Infection. 2013
EIA: enzyme immunoassay; NAT: nucleic acid test; RDT: rapid diagnostic test
Drug access and pricing: considerations

What is the appropriate treatment?
Is it available and affordable?
If not, why?
What are the options to achieve affordability?
Treatment and Access to Drugs

WHO South East Asia Regional Perspective

Presenter:
Razia Pendse
Regional Advisor – HIV/AIDS, STI and Hepatitis
WHO Regional Office for South East Asia
Regional Context

- Insufficient data
- 100 million people estimated to be living with chronic hepatitis B and 30 million people living with chronic hepatitis C
- 1.4 million estimated new cases and 300,000 deaths due to Hepatitis B and around half a million cases and 160,000 deaths due to hepatitis C each year
- Four countries in the region (DPR Korea, Indonesia, Myanmar and Thailand) have estimated 8% or more of the population with chronic hepatitis B virus infection; in Timor Leste it is estimated to be 6-7%
- India has nearly 40 million people with chronic hepatitis B infection and up to 12 million people chronically infected with hepatitis C
- 65% of people living with chronic hepatitis B and 75% of those with chronic hepatitis C are unaware of their status
National Response

• National Strategy for Hepatitis prevention, control and treatment available and updated in Indonesia; recently developed in Timor-Leste; being developed in Myanmar; initial process begun in the Maldives; technical advisory group on Hepatitis in India, agreement with multiple pharma companies for generic DAAs use in country and export to 91 developing countries

• Peg IFN and Ribavirin provided through the UHC scheme in Thailand, discussions on DAAs ongoing; few states in India providing DAAs for Hep C through state health programme but limited; price negotiations on DAAs ongoing in INO. Tenofovir available in all countries for HIV as first line but not for Hep B due to funding issues and/or national strategy
Opportunities and Challenges

• Increased interest in Hepatitis within national health programmes
• Awareness and interest on introduction/expansion of birth dose of HEP B
• Civil society advocacy
• Lack of national strategies and plans and dedicated department within MOH for HEP in many countries
• Not enough advocacy and commitment at higher levels
• Earmarked funding for HEP very limited
Role of WHO

- Strengthening surveillance for Hepatitis to get better data
- Advocacy and technical assistance to countries in the region on introduction/expansion of birth dose of Hepatitis B
- Support countries in price negotiation for affordable access to medicines for treatment of Hepatitis
- Support development/review and update of national strategies and guidelines on prevention, control and management of Hepatitis
Experience from WHO-CDC evaluation of Egypt treatment scale-up programme

- 130,000 on DAAs since September 2014
- Expansion from 26 to 36 treatment clinics
- High levels of commitment:
  - National Committee, Site clinical staff
  - Clinics open until 6pm, three shifts, 6 days a week
- Achieved lowest negotiated drug costs worldwide.
- National database with comprehensive dataset from largest patient population worldwide
Key messages from programme evaluation

1. Key performance indicators (KPIs) along cascade of hepatitis care at national and site level for monthly analysis and report:
2. Optimise data linkages to assess national impact of treatment programme (temporal trends in deaths, liver related deaths, liver cancers, liver related hospitalisations, new HCV infections)
3. Prioritisation on improving follow up rates and SVR visit.
4. Establish Programme Quality Assessment (regular site visits to provide onsite training; onsite reviews of patient pathway, adherence to protocol, with KPIs and other site indicators (wait times, patient satisfaction)
5. Prioritisation in treatment for those in greatest need
6. Ensuring equity in treatment access by geographic region and region
7. Strategic approach - adoption of 1-2 preferred drug combos for inclusion in national programme according to price (cost per cure), duration, FDCs, side effects, drug interactions
8. Approval of generics: Optimise regulatory requirements for generic approval
TOOLKIT
A Public Health Strategy for Tackling HCV

Global Hepatitis Summit 2015
Glasgow
Tracy Swan
Hepatitis C DAAs

Oral, direct-acting antivirals (DAAs) radically simplify HCV diagnostics, monitoring and treatment

- Cure rates >95% in many clinical trials
- Safe; tolerable: <3% dropped out of clinical trials due to side effects
- Because DAAs are so safe and effective, monitoring requirements are minimized – increases feasibility in RLS

Afdhal et al; NEJM 2014; Bansai et al; World J Hepatol 2015; Feld et al; NEJM 2014; Sulkowski et al; NEJM 2014
DIAGNOSE: HCV core antigen testing

ASSESS: Routine tests (general health, liver disease staging)

MONITOR: Routine tests
HCV core antigen test, 12 or 24 weeks post-treatment
TPP: First-Line IFN-Free Regimen

- **STRATEGIC:** Preserves options for second line
- **POTENT:** High genetic barrier, forgiving
- **UNIVERSAL:** Pan-genotypic; can be used in all populations, including HIV/HCV and with hormonal contraceptives, OST and other commonly used medicines
- **SIMPLE:** Minimal assessment/monitoring required; QD and preferably FDC; fixed duration; no food requirement, temperature stable, 2-year shelf life
- **SAFE, TOLERABLE and EFFECTIVE:** Cirrhosis trumps; cure rate of >80%

**Affordable**
Current Costs of Sofosbuvir, per Person (12 weeks)

- $84,000
- $56,000
- $53,000
- $27,000
- $7,000
- $900
- $750
- $344

Slide courtesy of Dr. Andrew Hill
HCV Package*: Diagnostics, Monitoring, Treatment

* Does not include prevention

van de Ven et al; Hepatology 2015
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* Does not include prevention
Access to HCV treatment: barriers and strategies

Céline Grillon – Médecins du Monde
World Hepatitis Summit
Glasgow Sept. 2-4 2015
Registration status worldwide of Sovaldi® and Daklinza®

- **Countries where Daklinza® is registered**
- **Countries where Sovaldi® is registered**
- **Countries where Daklinza® & Sovaldi® are registered**
- **High income countries**
New DAAs are not yet registered in most LMICs

- Support registration process – transparent procedure, authorize local trials when needed
- Consider fast track registration
- Pharma companies must fill registration dossiers
Prices

Patents allow pharmaceutical companies to keep prices artificially high
Countries included in Gilead voluntary licence
Low and middle income countries (LMICs) with more than 500,000 HCV cases

High income countries
Countries included in Gilead voluntary licence
Low and middle income countries (LMICs) with more than 500,000 HCV cases

(map by MdM 2015)
Prices

Patents allow pharmaceutical companies to keep prices artificially high

- Transparency on DAAs patent landscape
- Challenge patent legality – strict examination – patent opposition
- Patent barriers can be overcome through the use of Compulsory licenses
Quality

Currently no generic DAA prequalified

- Strengthen drug control authorities
- Support and rely on WHO PQ
Seek support

» contact@hepCoalition.org
» WHO Essential medicine department