National Hepatitis plan

Dr JP Mulkay
Clinic of Hepatology
Department of Hepato-Gastro-entrology
National hepatitis Plan

• Hepatitis B: plan non-existent.
  • People’s migration from endemic countries.
  • Reimbursement of treatment not adapted to the reality.
    • Cirrhotic patient with normal transaminases.
    • Prevention of Perinatal HBV Transmission (High viral load).
    • HBV reactivation on chemotherapy and immunosuppressive therapy

• Hepatitis C: plan available.

• Hepatitis Delta: plan non-existent
  • People’s migration from east European countries.
  • Treatment not reimbursed.
• In June 2012, an inter-ministerial conference decided to adopt a plan of action against Hepatitis C.
• Published and brought out by the minister of Health on 8 August 2014.
• Developed through collaboration between government, hepatologists, HIV specialists, patients groups, Harm reduction groups, professional groups of gastro-enterologists.
• Goals of the plan:
  • Reduce transmission.
  • Increase the number of HCV+ patients aware of their diagnosis.
  • Enhance patients’ care pathway and quality of live.
Hepatitis C plan Belgium 2014-2019

6 strategic axis

1. Prevention
2. Testing
3. Linkage to care and Health care pathway
4. Hep A and Hep B vaccination
5. Scientific Research.
6. Epidemiologic follow-up.
HCV plan (12/05/2014): 22 actions

• **Prevention**
  • 1. Inform and sensibilize
  • 2. Enforce the capacities of psychological/medical/social actors
  • 3. Develop prevention

• **Screening**
  • 4. Develop a national HCV screening strategy
  • 5. A HCV blood test in the hospital
  • 6. Better inform GP’s
  • 7. Inform the population on risks and screening
  • 8. Retest after cure with PCR in certain risk groups
  • 9. Organise a follow up plan for detected cases

• **Healthcare pathway: linkage to care and treatment**
  • 10. Develop a HCV expertise network
  • 11. Reimbursement should not be dependent on a biopsy.

• **Healthcare pathway: linkage to care and treatment**
  • 12. Minimalize the administrative burden for treatments.
  • 13. Take into account the children.
  • 14. Evaluation of fibrosis regarding international guidelines
  • 15. Develop a national point for information
  • 16. Enforce the capacities of psychological/medical/social actors
  • 17. Drugs delivery by hospital pharmacies
  • 18. Speed up access to new HCV medication
  • 19. More rationale on PCR testing

• **Vaccination**
  • 20. Vaccination HAV en HBV

• **Clinical Research**
  • 21. Support further research in HCV

• **Epidemiologic follow-up**
  • 22. Database with HCV pos patients
Prevention

1. Inform and raise awareness on prevention.
2. Enforce the capacities of psychological, medical and social actors.
3. Develop prevention.
Prevention

- Lack of good prevalence data by groups.
- Lack of government support to develop awareness campaigns.
- HCV not regarded as a priority for education programs for physicians.
- Awareness levels of general population, high prevalence groups and GP’s are not measured.
- Low GP’s awareness about current treatment effectiveness.

☑ Strong harm-reduction programs.
Prevention
Screening

4. Develop a national HCV screening strategy.
5. Offer a HCV blood test in the hospital (free and anonymous).
   • Helpcenter Antwerpen, Elisa Bruxelles, CHU de Liège.
7. Inform the population on risks and screening.
8. Retest after cure with PCR in certain risk groups.
9. Organize a follow up plan for detected cases.
Screening
Linkage to care and Health care pathway

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Linkage to care and Health care pathway

10. Develop a HCV expertise network.

- HCV Working group meetings to plan the future of HepC care between nov/14 and April/15.

The Disease Burden of Hepatitis C in Belgium: An update of a realistic disease control strategy

P. Stürkel¹, D. Vandijck², W. Laleman³, P. Van Damme⁴, C. Moreno⁵, S. Blach⁶, H. Razavi⁷, H. Van Vlierberghe⁸

(¹) Cliniques Universitaires Saint-Luc, Université Catholique de Louvain (UCL), Brussels, Belgium; (²) Ghent University, Ghent, Belgium; (³) Hasselt University, Dept. of Health Economics & Patient Safety, Diegem, Belgium; (⁴) University Hospitals Louvain, KU Leuven, Leuven, Belgium; (⁵) Université d’Antwerpen, Antwerp, Belgium; (⁶) Erasme University Hospital, Université Libre de Bruxelles, Brussels, Belgium; (⁷) Center for Disease Analysis (CDA), Louisville, Colorado, USA; (⁸) Ghent University Hospital, Ghent, Belgium.

Mitigating the burden of hepatitis C virus among people who inject drugs in Belgium

Catharina Mathier¹, Stefan Bourgeois², Sarah Blach³, Christian Briko³, Jean-Pierre Molkay⁴, Homie Razavi⁵, Geert Robays⁶

(¹) Department of Public Health and Primary Care, University Hospitals Leuven, KU Leuven, Leuven, Belgium; (²) ZNA Campus Sint-Luc, Antwerp, Belgium; (³) Center for Disease Analysis, Louisville, CO, USA; (⁴) Department of Gastroenterology and Digestive Oncology, CHU Charleroi, Liege, Belgium; (⁵) Department of Gastroenterology and Hepatology, University Hospitals Leuven, KU Leuven, Leuven, Belgium; (⁶) Department of Hepatology, CHU Saint-Pierre, Brussels, Belgium; (⁷) Center for Disease Analysis, ZNA Campus Sint-Luc, Antwerp, Belgium; (⁸) Université catholique de Louvain (UCL), Brussels, Belgium; (⁹) Université d’Antwerpen, Antwerp, Belgium; (¹⁰) Ghent University Hospital, Ghent, Belgium; (¹¹) Ghent University, Ghent, Belgium; (¹²) Hasselt University, Dept. of Health Economics & Patient Safety, Diegem, Belgium; (¹³) ULB Hôpital Erasme, Université Libre de Bruxelles, Brussels, Belgium.
Linkage to care and Health care pathway

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19. More rationale on PCR testing.
Linkage to care and Health care pathway

10. Develop a HCV expertise network
11. Reimbursement should not be dependent on a biopsy.
   • Either a liver biopsy, or
   • Either one elastography test (Fibroscan, Shear wave elastography or ARFI).
     + one biological fibrosis score (Fibrotest, FIB-4, APRI).
   • Maximum age of elastography and lab values: 1 year.
   • Results to be kept in file of patient.
Linkage to care and Health care pathway

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18. Speed up access to new HCV medication
19. More rationale on PCR testing (labeled centers).
Linkage to care and Health care pathway
20. Vaccination HAV and HBV.

- Implemented and recommended > 20 years.
- Specific populations.
  - Infants and children.
  - Hemophiliacs.
  - Hemodialysis patients.
  - Candidates for organ transplants.
  - Family members
  - Unvaccinated teenagers.
  - Mentally handicapped.
- Health workers.
- PWID ??
Vaccination
Clinical research

21. Support further research in HCV
Clinical research
Epidemiological follow-up

22. Database with HCV positive patients.
Epidemiological follow-up
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Hepatitis C plan: 2017

6/22 27%
ROAD TO ELIMINATION: BARRIERS AND BEST PRACTICES IN HEPATITIS C MANAGEMENT
Overview of the status of HCV care in Europe and Australia
<table>
<thead>
<tr>
<th>Country</th>
<th>Strategic plan in place</th>
<th>Year of the latest plan</th>
<th>Plan status</th>
<th>Objectives of the plan</th>
<th>Plan monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Yes</td>
<td>2014</td>
<td>-</td>
<td>Targets not updated in latest recommendations</td>
<td>Governance body to monitor plan implementation (Yes)</td>
</tr>
<tr>
<td>Belgium</td>
<td>Yes</td>
<td>2014</td>
<td>-</td>
<td>-</td>
<td>Monitoring of impact of each initiative (Yes)</td>
</tr>
<tr>
<td>Denmark</td>
<td>No</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>France</td>
<td>Yes</td>
<td>-</td>
<td>2016 + Updated recommend. in 2018</td>
<td>Targets not updated in latest recommendations</td>
<td>-</td>
</tr>
<tr>
<td>Germany</td>
<td>Yes</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Italy</td>
<td>Yes</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Portugal</td>
<td>X</td>
<td>-</td>
<td>In progress</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Spain</td>
<td>X</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Switzerland</td>
<td>X</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>England</td>
<td>X</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Scotland</td>
<td>X</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

1. Strategic plan refers to government supported strategies to tackle HCV
<table>
<thead>
<tr>
<th>Awareness and prevention</th>
<th>Testing and diagnosis</th>
<th>Linkage to care, access to qualified health services</th>
<th>Access to medication</th>
<th>Monitoring and evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Network-based approach&quot; to increase awareness and reach out through educating and training peers of those at risk</td>
<td>Screening and diagnosis prioritized within high prevalence groups</td>
<td>HCV treatment delivered in addiction clinics</td>
<td>Although not broad access, DAA coverage for some key risk groups patients regardless of their level of fibrosis</td>
<td>Mandatory reporting of all HCV diagnosed patients</td>
</tr>
<tr>
<td>Awareness campaigns targeting common settings of high prevalence groups (e.g. included within harm reduction programs)</td>
<td>Testing sites extended to multiple settings, focused on those used by high prevalence groups</td>
<td>HCV treatment delivered within prison facilities</td>
<td>No drug or alcohol consumption restrictions to access treatment</td>
<td>HCV registry tracking all patients to monitor progress</td>
</tr>
<tr>
<td>Strong government support of campaigns targeting high prevalence groups’ awareness</td>
<td>Free and anonymous testing offered to all patients</td>
<td>Well developed and integrated programs for PWID and PLHIV, integrating HCV testing and support in clinics</td>
<td>DAA coverage for all patients regardless of their level of fibrosis</td>
<td>Database with all diagnosed patients</td>
</tr>
<tr>
<td>Strong third-sector support of campaigns targeting high prevalence groups’ awareness</td>
<td>Initiatives to increase health care professionals’ knowledge of HCV and identification of risk factors</td>
<td>Good referral system in place within National Healthcare Service</td>
<td>Full treatment coverage by national health care system, with no co-payment requirements</td>
<td>Registry with all patients eligible for DAA treatment</td>
</tr>
<tr>
<td>HCV training provided to support professionals in contact with HCV patients</td>
<td>Well developed screening programs for key high prevalence groups - e.g. PWID and ex-PWID</td>
<td>Direct access to specialists</td>
<td>Risk-sharing (e.g. funding caps) and price-volume agreements lead to significant discounts in treatment costs</td>
<td>Treatment effectiveness measured from outcomes in the registry</td>
</tr>
<tr>
<td>Promotion of campaigns with prevention as a priority message</td>
<td>Well developed screening programs for key high prevalence groups - e.g. Routine screening of all prisoners, and PLHIV</td>
<td>Wide range of doctors able to prescribe treatment, including PCPs</td>
<td>Availability and management of funding for DAAs at national level</td>
<td></td>
</tr>
<tr>
<td>Strong harm reduction programs</td>
<td>Programs to reduce dropout in testing process (e.g. unique sample screening methods of blood samples)</td>
<td>PCPs able to provide treatment in their office if approved by specialist</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Belgian health care system

• In Belgium, responsibilities for health policy are shared between the federal level and the federated entities (regions and communities).
• The federal level is responsible
  • for the regulation and financing of compulsory health insurance;
  • the determination of accreditation criteria (that is, minimum standards for the running of hospital services);
  • the financing of hospital budgets and heavy medical equipment (e.g. CT and MRI scanners);
  • legislation covering different professional qualifications;
  • the registration of pharmaceuticals and their price control.
• The level of federated entities (regions and communities) governments are responsible
  • for health promotion and prevention;
  • maternity and child health services;
  • different aspects of elderly care, home care,
  • Coordination and collaboration in primary health care and palliative care;
  • the implementation of accreditation standards and the determination of additional accreditation criteria
  • the financing of hospital investment.
Conclusions

• National plan is a good project.
• It is essential for actions
  • To be well-defined
  • To include clear accountabilities, timelines, budgets, and key performance indicators.
• Wake-up authorities particularly federated entities.

Treatment without prevention and screening
It makes no sense !!!
Cirrhosis

<table>
<thead>
<tr>
<th>Compensated</th>
<th>Treat regardless of ALT, especially if HBV DNA &gt;2000 UI/ml.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decompensated</td>
<td>Treat regardless of ALT and HBV DNA.</td>
</tr>
</tbody>
</table>
EASL 2017 Clinical Practice Guidelines on the management of hepatitis B virus infection

European Association for the Study of the Liver

- All candidates for chemotherapy and immunosuppressive therapy should be tested for HBV markers prior to immunosuppression (Evidence level I, grade of recommendation 1).

- All HBsAg-positive patients should receive ETV or TDF or TAF as treatment or prophylaxis (Evidence level II-2, grade of recommendation 1).

- HBsAg-negative, anti-HBc positive subjects should receive anti-HBV prophylaxis if they are at high risk of HBV reactivation (Evidence level II-2, grade of recommendation 1).
## EASL, AASLD and APASL Guidelines

<table>
<thead>
<tr>
<th>Guidelines</th>
<th>HBeAg Positive</th>
<th>HBeAg Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HBV DNA, IU/mL</td>
<td>ALT</td>
</tr>
<tr>
<td>AASLD 2016</td>
<td>&gt; 20,000</td>
<td>≥ 2 x ULN</td>
</tr>
<tr>
<td>APASL 2016</td>
<td>&gt; 20,000</td>
<td>&gt; 2 x ULN</td>
</tr>
<tr>
<td>EASL 2017</td>
<td>&gt; 2000</td>
<td>&gt; ULN*</td>
</tr>
<tr>
<td></td>
<td>&gt; 20,000</td>
<td>≥ 2 x ULN</td>
</tr>
</tbody>
</table>

*N/A, not applicable.*

*In patients with HBV DNA > 2000 IU/mL, treatment indicated if ALT > ULN and/or at least moderate fibrosis.*