Hepatitis C Disease Burden and Strategies to Minimize its Consequences in the Future

Assumptions and Outputs for Romania

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The big burning picture of HCV disease:
- prevalence, incidence, demographics

Disease control strategies in order to minimize the future HCV disease burden
- increasing the pool of diagnosed people
- increasing access to therapy
- increasing the level of therapy/treatment efficacy
THE MAGNITUDE OF HCV INFECTION worldwide

- A global public health issue - significant morbidity and mortality
- Up to 180 million individuals chronically infected worldwide (2.5-3% of the world’s population) (WHO 2015)
- 350,000-500,000 people die annually of HCV-related causes

- 15 - 17 million persons (2% of adults) HCV infection in the Europe region (WHO 2015)
- Long-term HCV infection translates in a heavy burden of liver-related morbidity and mortality
- Hepatitis C the leading cause of liver cirrhosis, cancer, transplantation
But it’s not all about prevalence!

• **Silent epidemic**

• 75% of infected people are *not aware* of their HCV-positive status and remain *undiagnosed*

• Diagnosed as *advanced HCV-associated liver disease* - cirrhosis, liver cancer

• Only 3-5% of infected individuals receive treatment annually worldwide

• Causing a large economic impact - costs for patient and society

• **Costs increase with disease progression**
### HCV historical epidemiology in Romania: Prevalence & demographics at a glance

<table>
<thead>
<tr>
<th>Country Population</th>
<th>19.6 million</th>
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| HCV Infection Prevalence | 3.23% seroprevalence in adult general population in Romania | A nationwide cross-sectional survey in general adult population conducted between 2006-2008 through a multistage random cluster sampling method |
|--------------------------|----------------------------------------------------------|
| Genotype distribution    | Genotype 1 is almost exclusively 1a 1b 99.1% |
| Genotype route of transmission | Nosocomial Sexual & perinatal – few cases |
| IVDU – increasing in younger subjects | Major risk factor: unsafe blood supply & unsafe medical procedures in the past |
| HCV gender distribution  | Female 3.94% Male 2.95% |
| Age groups               | 19-29: 1.61% 30-39: 1.04% 40-49: 3.85% 50-59: 4.35% 60-69: 5.39% |
| Regional/by counties     | 4.25% Moldavia 3.35% Walachia 2.63% Transylvania |
|                         | Significant regional differences |
## Historical epidemiology in Romania: Current HCV burden

<table>
<thead>
<tr>
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<th>N or/and %</th>
<th>Comments</th>
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<tbody>
<tr>
<td><strong>HCV Disease Burden</strong></td>
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<td>Leading cause of</td>
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<tr>
<td>• chronic hepatitis</td>
<td>64%</td>
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<td>• liver cirrhosis</td>
<td>59%</td>
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<tr>
<td><strong>HCC</strong></td>
<td>49.5%</td>
<td>out of HCC cases diagnosed in tertiary centers</td>
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<td><strong>Special populations</strong></td>
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<td>Chronic Kidney Disease</td>
<td>&gt;11—→20%</td>
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<td>HIV/HCV co-infection</td>
<td>~40-50% out of HIV+ population</td>
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<td><strong>HCV diagnosis rate</strong></td>
<td>16%</td>
<td><strong>Low</strong></td>
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<tr>
<td><strong>Treated</strong></td>
<td>60,000</td>
<td>&gt;56,500 treated between 2002-20015 w/ Peg/RBV (~50% SVR in real life)</td>
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<td>2002-2015</td>
<td>A very fey in clinical trials and EAP</td>
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<tr>
<td></td>
<td>Peg/RBV</td>
<td>99% SVR</td>
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<td>5850</td>
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<td>2016</td>
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<td><strong>DAAs</strong></td>
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Trends in epidemiology of HCV-related diseases in Romania

The next 15 years

Total Infected Cases (Viremic) - Romania

- Baseline: 100,000
- 2025: 50,000
- Decline by 20%

Liver related Deaths - Romania

- Baseline: 3,400
- 2025: 2,700
- Increase by 30%

HCC - Romania

- Baseline: 1,900
- 2025: 2,400
- Increase by 25%

Decompensated Cirrhosis - Romania

- Baseline: 65,000
- 2025: 66,700
- Increase by 30%

**OUTLINE**

- The big burning picture of HCV disease:
  - prevalence, incidence, demographics

- Disease control strategies in order to minimize the future HCV disease burden
  - increasing the pool of diagnosed people
  - increasing access to therapy
  - increasing the level of therapy/treatment efficacy
Increasing diagnosis/screening
WHO SHOULD BE SCREENED FOR HCV INFECTION: Birth cohort screening

- An aggressive screening programme
- The birth cohort screening
A NATIONAL SCREENING PROGRAMME
HCV

2017
European Structural Founds
Operational Programme
Human Resources Development
Increasing access

“… costs of the new antiviral agents DAAs are as breathtaking as their effectiveness”

(Jay H. Hoofnagle & Averell H. Sherker; NEJM 2014; 370: 1552-1553)
## PARADIGM OF THERAPY in Romania

### 2015-2016

- **Restricted access:**
  - 5800 p reimbursed therapy
  - F4 and a part of F3
  - Inadequate options for sp populations: **NO**
    - decompensated cirrhosis
    - transplant recipients

- **Treatment option**
  - Only 1 option:
    - Viekirax/Exviera

### 2017-2018

- **Restricted access:**
  - 10,000 p reimbursed therapy
  - F4, F3 and a part of F2
  - Adequate options for sp populations: **YES**
    - decompensated cirrhosis
    - transplant recipients
    - dialysis
    - medical personnel

- **Treatment option**
  - 3 options:
    - Viekirax/Exviera or Zepatier
    - or Harvoni

- **Limited prescription/settings:**
  Academic Centers of Gastroenterology/Hepatology and Infectious Diseases
TREATING 5000-10,000 HCV/year
Predictable Outcomes

Liver-related Deaths

HCC
- Base
- 2000 treated/year, ≥F3
- 5000 treated/year, ≥F3
- 2000 treated/year, ≥F4
- 5000 treated/year, ≥F4

Cirrhosis
- Base
- 2000 treated/year, ≥F3
- 5000 treated/year, ≥F3
- 2000 treated/year, ≥F4
- 5000 treated/year, ≥F4

Decompensated Cirrhosis
- Base
- 2000 treated/year, ≥F3
- 5000 treated/year, ≥F3
- 2000 treated/year, ≥F4
- 5000 treated/year, ≥F4
HOW TO IMPROVE THE THERAPY UPTAKE?

- Active screening programme
- National HCV Registry
- Elimination of restricted access
- Diagnosed = treated patient (waiting list?)
CONCLUSIONS

- Increasing diagnosis
- Access to therapy
- High treatment efficacy
- Education in order to prevent (re)infection

- Increase capacity of screening- *birth cohort screening*
- Increase capacity of treating more patients
- *Treatment providers/setting/resources*
- Adoption of new, more efficacious therapies for hepatitis C