Hepatitis C in Romania
Stopping a Silent Killer – Cure and Control for Hep C Epidemic
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Stopping a Silent Killer - Cure and Control for Hep C Epidemic

A reference paper guide for sustainable and resilient public policy in the field of Hepatitis C

HCV infection is a global public health concern

- HCV infection is a major public health concern worldwide, including Romania.
- There are almost 664,000 infected persons (3.3% prevalence), 75% of which are unaware of the disease.
- Untreated HCV infection may lead to severe chronic hepatic disease with worse outcome evolution to cirrhosis and hepatocellular carcinoma.
- There are high risk groups that represent a reservoir for spreading the disease – iv drug users, sex workers, homeless persons, persons wearing tattoos / piercing, etc.
- There might be > 550,000 people (up to 80% from the former infected persons) in different stages of fibrosis and chronic liver disease, people that once identified should be treated immediately (OPEN ACCESS treatment protocol: first diagnosed, first treated).
- Without a sustained testing campaign, approximately 2,500 patients are nevertheless identified annually with hepatitis C virus replicative infection. Out of these patients, only a small part have access to existing interferon-free therapeutic schemes, in the context of not very advanced chronic hepatopathy, with existing protocols allowing inclusion on therapy of advanced liver disease patients.
- Presently, based on therapeutic experience in the past two years, we can affirm that acute and chronic infection with hepatitis C virus is curable and by far cost-efficient, in the context of using the new therapies in the so called interferon-free schemes.

HCV infection acute / chronic is treatable and curable!
**Priority Number 1**

*Test more, treat more!*

*Early detection of HCV infection is improving the odds of a successful and budget effective treatment*

The application of this recommendation requires taking into consideration which populations meet these criteria. In some countries with a high seroprevalence of HCV or low level of infection control, HCV testing might be recommended for the general population. Clearly, this would have significant resource implications.

➢ **Forum Guidance: Access cases and manage it through a consistent and sustained elimination program**

- Plan of action: It’s imperative to achieve the elimination of HCV virus infection. Early Detection in direct connection with elimination of HCV virus represents the foundation for a medically successful treatment and a cost-consciousness approach

  - Short term objectives: due to disease specificity of the infection and its insidious nature, getting the right cases requires more than awareness, a structured approach towards cure and control will allow the breaking of epidemiological cycle; identification of a solution allowing that any positive diagnosed patient is mandatory reported in a national operational registry with the aim of rapidly establishing viremic status and securing access to curative therapy as soon as possible but not less than 3 months; currently existing Hepatitis C management infrastructure needs further addressing to adequately cope with the level of need;

  - Long term objective: a set of institutional partnerships is required across ministries to effectively address the spreading of the disease, for achievement of European target of eliminating the disease by 2030, identification and appropriation of adequate
resources allowing GPs and local HC providers to effectively participate in a national HCV elimination program

✓ **Forum Recommendations:**

Develop and implement a General National Testing Program whilst reinforcing the need of reporting in a National Operational Registry from all healthcare stakeholders operating HCV testing

**Plan of action – draft**

Objective: Identification of people infected with HCV

Period: January – December 2018

*Who should be tested upfront?* – Define population to be tested – focus on high risk groups

- People born before 1990
- Persons wearing tattoos/piercings
- Professional truck-drivers
- Sexual workers
- IV drug users
- Healthcare professionals at risk – surgeons, nurses
- Patients with tuberculosis
- Patients with STD
- People in correctional facilities
- People addressing transfusion centers for the purpose of blood donation
- Employees undergoing their mandatory yearly medical assessments (Labour Medicine assessments)
Who should perform the testing? – Define categories of healthcare professionals delegated and empowered to perform testing and check the currently existing limitations and restrictions to the current practice norms (e.g. General Practitioners are currently prohibited from sampling blood in their medical offices) to ensure a flawless, uninterrupted process

- General Practitioner Offices (Individual Medical Offices – CMIs)
- Hospitals
- Local Public Health Authorithies (DSP)

Where the tests should be performed? – Define sites and process (medical templates for registration and follow up)

What type of tests and where are technically processed to read results?

- the proposed solution is prioritarily Elisa testing kit for Hep B, Hep C and HIV
- to be performed in hospital laboratories,
- secondary, non-invasive tests can be used where suitable and affordable for usage – e.g. in private clinics performing labor medicine assessments, at GPs’ offices

A successful General National Testing Campaign will require both a institutional drive and highly specific information and communication tools. Trust in the medical profession is essential and public figures can serve as image vectors.
The process flow recommended for the implementation of the National Testing Program is briefly presented in the Table below:

<table>
<thead>
<tr>
<th>Concerned Stakeholders</th>
<th>Processes</th>
<th>Regulatory Endorsement, Communication, Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ministry of Health</td>
<td>Decide and enforce the testing of defined population categories, performed by GPs, read by hospital laboratories and reported by the referring GPs in the National Registry</td>
<td>Legislation Implementation norms</td>
</tr>
<tr>
<td>Ministry of Internal Affairs</td>
<td>Ministry of Justice&lt;br&gt;Ministry of National Defense&lt;br&gt;Ministry of Labor</td>
<td>Funding for Program</td>
</tr>
<tr>
<td>NGOs</td>
<td>Ministry of Health to call for tender acquisition procedure for test kits</td>
<td>Endorsement from</td>
</tr>
<tr>
<td>Prefectures</td>
<td>Acknowledge and endorse the decision of the Ministries in relation to their corresponding mayors</td>
<td></td>
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</tbody>
</table>
| Mayors’ National Association  
National Association of the Chairman of the County Councils | Implement the decision via funding for the program and ensuring the clearance of the regulatory frame | Decision communicated to subordinated medical practices  
Financial compensation /EMC points for GPs and other participating healthcare professionals activities, funding for hospitals laboratories |
|---|---|---|
| General Practitioners  
Other HCPs  
(Labor medicine, Prisons Medical Personnel, National Defense Medical Personnel, other medical institutions dealing with high risk population defined in the National Program) | Identify the targeted population and call for testing at the earliest available opportunity  
Test kits to be distributed by MoH through DSPs (Directii de Sanatate Publica) to GPs and Other HCPs delegated to test the high risk population included in the National Program for Testing | Management of the testing program : identify population, plan testing, schedule, test, conduct the follow–up, report and refer |
<p>| Hospital laboratories | Receive the blood samples for test, perform the test, read the test and communicate back to the GPs and Other Personnel delegated the results | Perform, read, report results to GPs and Others in timely manner |</p>
<table>
<thead>
<tr>
<th>National Registry</th>
<th>Receives all testing results input from GPs and Other HCPs immediately after testing (online) Evaluate and report results quarterly</th>
<th>Monitor implementation through monthly reported testing numbers versus planned testing numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seronegative subjects</td>
<td>Receive educational material regarding primary prevention and how to deal with HCV seropositive people in the community</td>
<td>Educational materials to be provided to GPs and others HCPs for distribution</td>
</tr>
</tbody>
</table>
| Seropositive subjects | Are called back to the GPs and Others to:  
- be informed about the result  
- be registered in the National Registry, each registered subject will receive an unique registration code for proper identification within the Registry  
- be referred to Infectionists or Gastroenterologists belonging | To be given clear instructions regarding steps to take – where, when, to whom – patient obligations and rights |
<table>
<thead>
<tr>
<th>to HepC accredited Treatment Centers</th>
<th>Determine viral load for all referred seropositive subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Centers</td>
<td>- if « no viral load » – the case is closed in the National Registry</td>
</tr>
<tr>
<td></td>
<td>- if « viral load detected », the subject is included in the protocol for diagnosis and treatment of the chronic liver diseases, monitored in National Registry</td>
</tr>
<tr>
<td></td>
<td>« No viral load » result needs to be communicated to GPs – for closing down the patient file in the National Registry</td>
</tr>
<tr>
<td></td>
<td>« Viral Load Detected » – prescription management and monitoring to be considered based on inclusion criteria (F0, F1, F2, F3, F4)</td>
</tr>
</tbody>
</table>
Priority Number 2

HCV infection is 100% preventable

While the HCV virus is 10 times more infectious than HIV, it is also up to 100% preventable. Transmission ways have been identified and thoroughly documented, therefore prevention measures should be easily to identify and then implemented.

Regardless, immediate preventive actions should be undertaken at hospital level, combined with a growing education of the general public, in line with the right to prevention stipulated in the European Chart of Patient’s Rights.

Rationale: High rates of anti-HCV seropositivity has been found for frequent hospitalization (7.1%), haemodialysed patients (11.1%), transfusion of blood products (9.5%), serious traffic, work or domestic accidents that needed hospitalization or medical care (6.4%), surgical interventions (4.3%) and for emergency surgical interventions (4.7%), and for transplanted patients (3.8%), even for invasive dental procedures (3.4%).

Medical staff interacting with infected patients, particularly with patients who are unaware that they carry HCV, are a particularly important risk group. The most important process of infection for this category is daily exposure to nosocomial infections. According to the National Institute for Statistics, there are about 56,000 doctors and 133,000 nurses and auxiliary medical personnel. Most of these individuals live and work daily under risk of nosocomial infections, including infections with HCV.

✓ Forum Guidance: Know the way, show the way, go the way

✓ Plan of action: Establish and implement National Prevention Standards by 2020
Forum Recommendations:

1. Define, enforce and monitor National Prevention Standards
   a. enforce and monitor the general Safety precautions in all medical facilities,
   c. prevention of transmission within and from IDU,
   d. prevention of sexual transmission, especially men-to-men,
   e. prevention in transmission by risky practices (tattooing, piercing),
   f. prevention of transmission within and from inmates,
   g. prevention in vertical transmission (mother-to-child).

Plan of action – draft

Objective: Define, enforce and monitor National Prevention Standards

Period: January – December 2018

Evaluation and reporting: yearly
<table>
<thead>
<tr>
<th>National Prevention Standards</th>
<th>Actions</th>
<th>Stakeholders</th>
</tr>
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<tbody>
<tr>
<td>Primary prevention Kindergarten</td>
<td>National Program for Immunization Prevention curriculum with basic hygiene rules (e.g. notions related to using water, soap, toilets, how to « eat a snack », manicure, pedicure, regular check-up for identification of asymptomatic carriers of communicable diseases</td>
<td>MoH for content Ministry of Education for implementation Ministry of Labor and Social Protection Local Authorities Community leaders NGOs</td>
</tr>
<tr>
<td>Primary school Gymnasium</td>
<td>Prevention curriculum should include also notions related to:  - personal intimate hygiene</td>
<td></td>
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<tr>
<td>High school</td>
<td>Prevention curriculum should include also notions related to:  - sexual education  - family planning  - STDs  - Tatoo/piercing  - Iv drug</td>
<td></td>
</tr>
</tbody>
</table>
| Secondary prevention | Identification of asymptomatic carriers of communicable diseases | MoH  
Ministry of Justice  
Ministry of National Defense |
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</thead>
<tbody>
<tr>
<td></td>
<td>Diagnosis</td>
<td>Therapy</td>
</tr>
</tbody>
</table>
| Tertiary prevention   | Prevention against the occurrence of complications of chronic disease | Infections Disease Specialists  
Gastroenterologists  
Internal Medicine Specialists  
GPs |
HCV infection is up to 100% curable

Innovative treatment of HCV infection with DAA is cost-effective

➢ Forum Guidance: Ensure a Policy of Open-Access, Best-in-Class Treatment, Universality and Equity and treat 99% of the HCV infected population by 2030

❖ Plan of action: Ensure Open-Access, Best-in-Class Treatment, Universality and Equity and treat 99% of the HCV infected population by 2030

- Short term objective: identification of a solution allowing multi-annual budgeting together with open access healthcare solution for chronic Hepatitis C based on competition of multiple solution providers together with “no fibrosis” criterion;

- Long term objective: seamless regulatory and legal framework supported by appropriate public healthcare funding and responsible corporate engagement from the providers of curative solutions that will allow disease elimination;

- No specific selection criteria to allow infected population access to treatment; relevant regulatory and legal framework to be adapted so to allow the functioning of the principle “first come – first treat” (curative solutions available to patients with F0, F1, F2, F3, F4) as the only viable solution for the envisaged objective: treatment of 99% of the HCV infected population by 2030.

A national policy is a commitment to a goal and a guide with actions to be implemented. It is a framework for the coordinated measures to be undertaken by the actors in the field. (Ref 1 WHO)

✓ Forum Recommendations:

1. Adhere to the 4 principles of Healthcare in European Union as well as to the Objectives related to Hepatitis C in EU and WHO.
2. Adapt the resources (infrastructure, financial and human resources) with the scientific guidelines from EASL and WHO recommendations.

3. Ensure the human and financial resources to facilitate OPEN-ACCESS to innovative treatment (DAAs) of all patients.

4. Identify a solution allowing multi-annual budgeting together with open access healthcare solution for chronic Hepatitis C based on competition of multiple solution providers together with “no fibrosis” criterion.

5. Improve access to treatment for people living below the poverty line, currently having limited exposure to healthcare physicians and hospitals (especially in the rural areas), where their disease could be traced in a timely manner and targeted for treatment.

6. Increase evidence based treatment uptake to enable resources optimization on long term.

7. Adapt to the evolutive nature of the epidemic and specifically the shift in HCV genotype by giving treating doctors multiple tools to address the various susceptibility types.

8. Effective implementation of Single Registry (through unification of registries currently kept by various authorities).


10. Ensure an effective follow up and policy correction mechanism to achieve 2030 elimination target and budgetary efficiency.