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Re-imagining viral hepatitis care: keeping it simple

Juan Turnes (Spain)
Ivan Gardini (Italy)
Disclosures

Juan Turnes
• Speaker/consultant for AbbVie, Gilead Sciences and Merck Sharp & Dohme
• Research support grants from Gilead Sciences

Ivan Gardini
• EpaC Onlus has received grants from Gilead Sciences, AbbVie, AlfaSigma, Intercept and Merck Sharp & Dohme
RE-IMAGINING VIRAL HEPATITIS CARE:
KEEPING IT SIMPLE

Juan Turnes
Gastroenterology and Hepatology Department
Complejo Hospitalario Universitario de Pontevedra
COVID-19 has had an impact on all aspects of healthcare, but we need to keep focused on viral hepatitis elimination.

- Modelling study to analyse the impact of COVID-19 on hepatitis elimination efforts

**Global impact of a 1-year delay in HCV programming (relative to the status quo with no delay)**

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<tbody>
<tr>
<td>-906,000</td>
<td>-746,000</td>
<td>121,000</td>
<td>72,200</td>
<td>44,800</td>
<td>623,000</td>
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HCC: hepatocellular carcinoma
Galicia’s FOCUS programme: HCV and HIV population screening

Patient attending primary care facilities and physician determines need for blood draw

EHR determines eligibility based on age and prior testing

Ineligible

Eligible

EHR adds BBV tests to lab request

Physician or nurse informs the patient

Patient accepts

Opt out

Sample is sent to the lab

The linkage to care navigator is notified of the results

The first medical visit with a specialist is booked

Linkage to care navigator confirms patient attended the first visit

Patient linked to care

Patient not linked to care

Up to two times

Turnes J, unpublished data

FOCUS programme is supported by Gilead Sciences.
BBV: blood-borne virus; EHR: electronic health record
This requires a simple and efficient approach to patient management.

- How to access care
- Who to treat
- When to treat
- How to treat
- How to monitor

Complexity in the patient pathway will slow things down and lead to patient disengagement.

Turnes J, personal perspective
During the pandemic we implemented measures to simplify the patient pathway

**How to access care**
- EMR tools, combined with telehealth

**Who to treat**
- Advanced liver disease
- Vulnerable populations
- HBV patients initiating immunosuppressants
- FIB-4 and other serological non-invasive fibrosis scores

**When to treat**
- Patient risk assessed, otherwise treatment delayed

**How to treat**
- Pangenotypic treatment regimens
- Decentralised care
- New system to deliver hospital medications at home

**How to monitor**
- All scheduled follow-up visits switched to telephone calls

**Increased coordination with primary care and other specialties**

Turnes J, personal perspective
During the pandemic we implemented measures to simplify the patient pathway

But we need to keep evolving the pathway

Increased coordination with primary care and other specialties

fibrosis scores

Turnes J, personal perspective

EMR: electronic medical record
The impact of time to treatment on linkage to care

- Analysis of HCV testing and linkage to treatment among patients attending health services in Victoria, Australia after the introduction of DAAs

**Relatively low level of treatment uptake within 3 months of positive RNA test**

<table>
<thead>
<tr>
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<th>2016</th>
<th>2017</th>
<th>2018</th>
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<tr>
<td>RNA testing within 3 months of Ab+ (%)</td>
<td>73</td>
<td>81</td>
<td>84</td>
</tr>
<tr>
<td>DAAs within 3 months of RNA+ test (%)</td>
<td>22</td>
<td>35</td>
<td>41</td>
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DAA: direct-acting antiviral
Minimising time to treatment

Successful same-day test-and-treat model in France

Test → 5 hours → Treat

- (Adult with social insurance, HCV antibody, people with unknown viral load and previously treated patients with unchecked viral load after treatment)
- FibroScan®, HCV viral load, social interview, shared educational evaluation and harm reduction

Other strategies to minimise time to treatment include:

- Rapid point-of-care testing
- Reflex testing

References:
1. Remy AJ, et al. EASL 2019; Poster #FRI-250;
3. Casas M, et al. AASLD 2018; Poster #1568
Guidelines and non-invasive methods to assess liver disease

- WHO recommends the use of non-invasive serological tests (such as APRI) for the assessment of liver disease status prior to the treatment\(^1\)

The Spanish guidelines state that pre-treatment assessments may include the assessment of liver fibrosis by non-invasive methods (November 2019)\(^2\)

The French guidelines state that FibroScan® or serological tests can be used to assess liver disease severity (March 2018)\(^3\)

The EASL guidelines indicate the need to assess fibrosis/cirrhosis status before starting treatment, which can be performed using a simple non-invasive marker, such as FIB-4 or APRI (August 2018)\(^4\)

The Australian guidelines recommend a pre-treatment evaluation of liver fibrosis stage/cirrhosis with a non-invasive test in all individuals with chronic HCV infection (June 2020)\(^5\)


APRI: aspartate aminotransferase to platelet ratio index
Simplifying HCV clinical decision making: considerations with pangenotypic treatments in a new context

- **Telemedicine**
- **Decentralisation of services**

**PRE-TREATMENT**
- Minimised baseline testing

**ON-TREATMENT**
- Simple to explain and prescribe treatment regimen with minimal on-treatment monitoring

**POST-TREATMENT**
- Consistent efficacy rates across patients

Turnes J, personal perspective
Simplifying HCV clinical decision making: considerations with pangenotypic treatments in a new context

Telemedicine

Decentralisation of services

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POST-TREATMENT
Consistent efficacy rates across patients

Look out for our article on removing complexity from HCV guidelines (soon to be published in APT)*

What defines ‘simple’ in viral hepatitis management?

- A regular provider in the community
- Shortened time to treatment
- Serological NITs to evaluate liver disease
- Pangenotypic regimen of choice
- A stratified approach to assess EOT vs SVR12

Turnes J, personal perspective

NIT: non-invasive test
Simplifying viral hepatitis care

Ivan Gardini

President of EpaC Onlus, Italy
In Italy, the simplification of therapeutic pathways has been a subject of discussion even before the pandemic. A key driver of simplification is the lack of FibroScans (not all hospitals have a FibroScan machine available) which has slowed the start of treatment for many individuals, particularly in “special populations”

On the other hand, some specialists have already successfully adopted simplification of check-ups/control examinations during therapy (which has not affected SVR rates)

We believe that EASL can be a starting point for redefining flexible and simplified therapeutic paths, adaptable to the pandemic

The only concern of our organisation is ‘over-simplification’, which could lead to a decrease in the benefits for patients, and in some cases could be detrimental. An example of potential over-simplification, from a follow-up perspective, is in patients with intermediate stages of advanced fibrosis. If a FibroScan isn’t used in these patients, doctors and patients could underestimate the follow-up pathways which in turn could impact the risk of developing hepatocellular carcinoma

Gardini I, personal perspective