Perspectives from the field – diagnostic algorithms for scale-up of screening and assessment in MSF programmes

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International HIV/Viral Hepatitis Coinfection Satellite Meeting
Workshop – 19 July 2014

MSF has documented high rates of co-infection in our HIV cohorts

• 52.3% in North-East India
• 67.2% in IVD population in Iran
• 10.3% in Kibera, Nairobi, Kenya
• 15.7% in Mozambique
• 53.3% in Ukraine
• 31% in Kachin, Myanmar

MSF plans to have HIV/HCV treatment programs

Grant from UNITAID
"Ensuring access to the HCV treatment revolution for HCV/HIV"

• India – Manipur
  – At risk: IDU, "hidden" sex workers
  – Screening for co-infection began in 2010
  – In September 2013: co-infection prevalence of 40% in Churachandpur and Chandel, and 20% in Moreh
• India – Mumbia
  – At risk: IDU, MSM, sex workers/clients
  – Screening for co-infection began in 2012
  – 2 patients started HCV treatment with SoC in 2013
• Iran - Darvazeh-Geh, Teheran
  – At risk: IDU and their relatives, sex workers
  – State screening is not provided
Continued…

- **Kenya - Kibera, Nairobi**
  - At risk: IDU, blood/blood products during transfusion
  - State screening is not provided (no national guidelines)

- **Mozambique - Chamanculo, Maputo**
  - At risk: IDU, MSM, mobile populations (migrant workers & miners)
  - State screening is not provided (no national guidelines)

- **Myanmar – Kachin**
  - At risk: IDU, MSM, sex workers (especially in mining areas) and migrants (due to conflict and mining)
  - MSF currently screens all HIV patients who start ART for HCV
  - The MoH is currently preparing national guidelines

- **Ukraine**
  - At risk: IDU, MSM, PLWHA
  - Of those with HIV/TB co-infection, HCV seropositivity rate is 62% (no PCR confirmation performed as yet)
  - Guidelines are in place however there is a lack of access

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**Potential to simplify diagnostics with new DAAs**

**PRE-TREATMENT**

<table>
<thead>
<tr>
<th>Current PEG-based</th>
<th>Current all-oral SOF, RBV</th>
<th>Ideal all-oral, RBV-free, pan-genotypic</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV antibody</td>
<td></td>
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<tr>
<td>HCV viral load</td>
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<tr>
<td>HCV genotype</td>
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<tr>
<td>Fibrosis staging</td>
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</tbody>
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Data in the literature support the use of dried blood spots for viral load and genotyping (limit of detection can be as low as 250 IU/mL)

*NOT YET STD OF CARE*

Currently exists as an EIA but potential to adapt to a RDT lateral flow format (Daktari have a cartridge/device-based prototype)
Potential to simplify diagnostics with new DAAs

### ON TREATMENT

<table>
<thead>
<tr>
<th>Current PEG-based</th>
<th>Current all-oral SOF-RBV</th>
<th>Ideal all-oral RBV-free, pan-genotypic</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBC with differential: baseline, week 2, 4 and every 4 weeks thereafter</td>
<td>Haemoglobin: baseline, week 2, 4 and every 4 weeks</td>
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<tr>
<td>LFTs: baseline, week 4 and every 4-8 weeks</td>
<td>Creatinine: baseline, week 2, 4 and every 4 weeks</td>
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<tr>
<td>Electrolytes: baseline, week 4 and every 4-8 weeks</td>
<td>Pregnancy: baseline and every 4 weeks</td>
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<tr>
<td>TSH: baseline, week 4 and every 12 weeks</td>
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<tr>
<td>Glucose: baseline, week 4 and every 4-8 weeks</td>
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<tr>
<td>HCV VL: baseline, week 4, 12, 24 and/or end of treatment</td>
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<tr>
<td>Pregnancy: baseline and monthly for women of childbearing age</td>
<td>HB and Cr readily available in RLS due to HIV treatment programs</td>
<td></td>
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</table>

*Many of these tests not available in RLS*

### POST-TREATMENT

<table>
<thead>
<tr>
<th>Current PEG-based</th>
<th>Current all-oral SOF-RBV</th>
<th>Ideal all-oral RBV-free, pan-genotypic</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV VL: 24 weeks after treatment</td>
<td>HCV antigen: week 12</td>
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<tr>
<td>Pregnancy: Monthly for 6 months post-treatment</td>
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**NOT YET STD OF CARE**

Currently exists as an ELISA but potential to adapt to a RDT lateral flow format (Daktari have a cartridge/device-based prototype)

→ Need further data on viral load values if relapsing on DAA-based treatment to see whether limit of detection and sensitivity are sufficient (e.g. 2000 IU/mL)

### Need for a TPP

→ to describe the new generation of molecular/antigen platform required— for example

- **Need two target product profiles:**
  - centralised test
  - decentralised / point-of-care test
- **Assay characteristics** (sample type, collection method, volume, preparation; consumables needed; reagent characteristics (cold chain etc); price)
- **Instrument characteristics** (open/closed; qualitative / quantitative; power requirements; cost)
- **Performance** (intended use; protocol; type of end-user; hands-on time; time to result; accuracy and limit of detection; level of skill and training required)
- **Connectivity** (quality control; transcription; geopositioning)
- **Quality** (WHO PQ (or other IMDRF strict regulatory authority); internal quality controls; proficiency testing)
For more information on the current and future landscape of diagnostics

• WHO 2014 HCV Guidelines:

• MSF 2014 HCV Landscape:
  – http://msfaccess.org/content/diagnosis-and-treatment-hepatitis-c-technical-landscape

• UNITAID Diagnostics Technology Landscape:
  – Q4 2014