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

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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

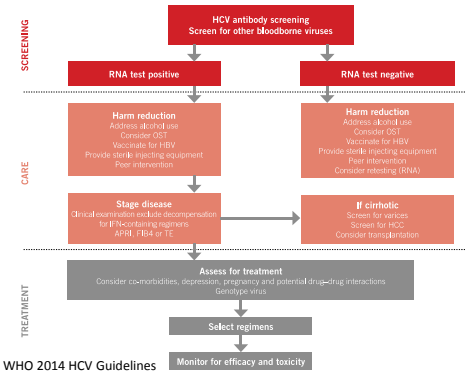
"Ensuring access to the HCV treatment revolution for HCV/HIV"

- **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

FIGURE 8.1 Patient treatment pathway



Source: WHO 2014 HCV Guidelines

Potential to simplify diagnostics with new DAAs PRE-TREATMENT

Need further options for serological RDTs suitable to RLS:
Accurate (incl HIV co-infection), simple to perform, WHO PQed, affordable (<$2)

Current PEG-based	Current all-oral SOF-RBV	Ideal all-oral, RBV-free, pan-genotypic
HCV antibody		HCV antigen ?
HCV viral load (6-7 [WHO])	HCV viral load (4 [EASL] / 2)	
HCV genotype		
Fibrosis staging (APRI / FIB-4)	Fibrosis staging Only for financial rationing	

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

Current PEG-based	Current all-oral SOF-RBV	Ideal all-oral, RBV-free, pan-genotypic
CBC with differential: baseline, week 2, 4 and every 4 weeks thereafter	Haemoglobin: baseline, week 2, 4 and every 4 weeks	
LFTs: baseline, week 4 and every 4-8 weeks	Creatinine: baseline, week 2, 4 and every 4 weeks	
Electrolytes: baseline, week 4 and every 4-8 weeks	Pregnancy: baseline and every 4 weeks	
TSH: baseline, week 4 and every 12 weeks		
Glucose: baseline, week 4 and every 4-8 weeks		
HCV VL: baseline, week 4, 12, 24 and/or end of treatment		
Pregnancy: baseline and monthly for women of childbearing age		

Hb and Cr readily available in RLS due to HIV treatment programs

Many of these tests not available in RLS

Potential to simplify diagnostics with new DAAs POST-TREATMENT

Current PEG-based	Current all-oral SOF-RBV	Ideal all-oral, RBV-free, pan-genotypic
HCV VL: 24 weeks after treatment	HCV antigen: week 12 ?	
Pregnancy: Monthly for 6 months post-treatment		

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:
  - http://www.who.int/hiv/pub/hepatitis/hepatitis-c-guidelines/en/
- MSF 2014 HCV Landscape:
  - http://msfaccess.org/content/diagnosis-and-treatment-hepatitis-c-technical-landscape
- UNITAID Diagnostics Technology Landscape:
  - Q4 2014