

Identifying the optimal care model for HCV care in Cambodia, and overcoming barriers to decentralization and scale-up: Médecins Sans Frontières' (MSF) pilot program



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DESCRIPTION

- Our Program:** MSF launched a pilot HCV program in Phnom Penh in Sept 2016, aimed at identifying a simplified, feasible care model that could be replicated and scaled-up across health facilities in Cambodia
- Current status:** MSF has since screened over 8,700 patients referred from hepatologists and 3,460 HIV patients, which include at-risk populations for HCV (injection drug users, transgender, etc). Among roughly 5,500 patients diagnosed, over 2,700 patients have been placed on HCV treatment using Ledipasvir/sofosbuvir and Daclatasvir/Sofosbuvir as of Oct 2017
- The Three Care Models:**

Full Model

During the first 6 months of the program, a full care package (**Full Care Model**) was implemented to patients with more comprehensive testing, consultations, and counselling sessions based on European guidelines

Simplified Model

Through careful monitoring of program performance, we gradually simplified the diagnostic pathways, decreased the number and types of tests, counselling, and consultation sessions that were identified as less clinically meaningful/ of lesser impact in order to identify a simpler model of care for HCV into the **Current Simplified Model**.

Rural Model

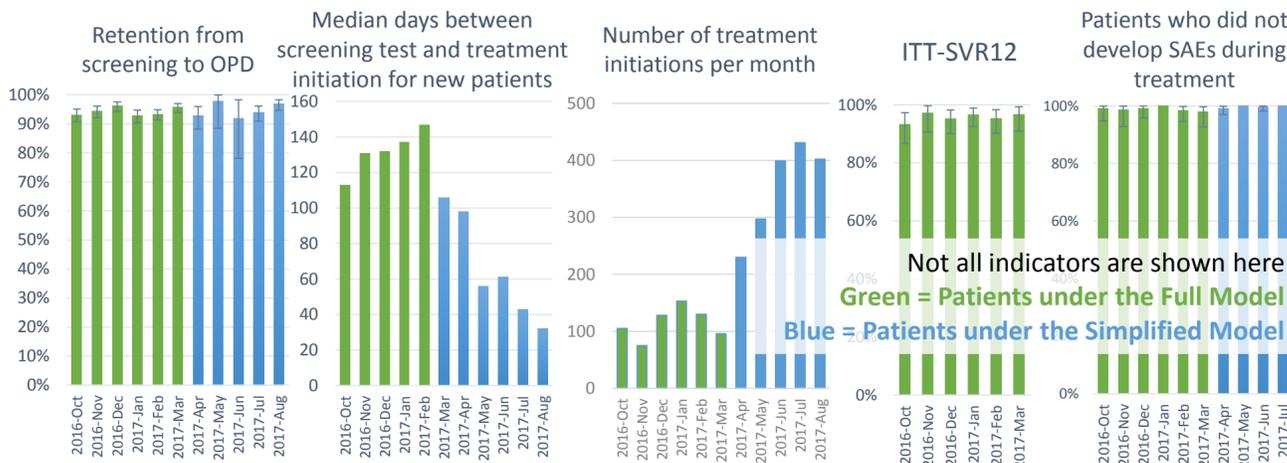
In the following months ahead, MSF will further analyze, interpret, and discuss existing clinical data with medical specialists, program collaborators (e.g. MOH, WHO), and researchers to pilot the optimal care model that is feasible and simple for scale-up and implementation in rural setting, that does not jeopardize the care quality and patient safety (**Rural Model**).

- Objectives:**
 - 1) Outline the three models of care (**Objective 1**)
 - 2) Demonstrate the impact of simplification on care quality and operational indicators (**Objective 2**)
 - 3) Describe the trade-offs of simplification and the major clinical question for the Rural Model (**Objective 3**)

Objective 1. Outline of action steps for patients in the three Models of Care

Full Model	Simplified	Rural
Visit 1 HCV Pre-test counselling ELISA test	Visit 1 POC Serology&PCR Fibroscan	Visit 1 POC Serology&PCR HIV & VL test
Visit 2 ELISA disclosure and counselling HCV PCR VL test	Visit 2 RDT disclosure and counselling PCR disclosure and counselling	Visit 2 Disclosure & assessment Counselling
Visit 3 PCR disclosure and counselling	Visit 3 Pre-treatment assessment Baseline blood test	Visit 3 Tests if needed D1 drug dispensing
Visit 4 Genotype test	Visit 4 Family planning HIV test	Visit 4 M1 drug dispensing
Visit 5 Fibroscan	Visit 5 Endoscopy (if >20kPa&PLT<75) Ultrasound (>45kPa only)	Visit 5 M2 drug dispensing
Visit 6 Fibroscan disclosure	Visit 6 Treatment initiation consultation Initiation counselling	Visit 6 End of treatment counselling
Visit 7 Pre-treatment assessment Pre-treatment counselling Baseline blood test Pregnancy test	Visit 7 D1 drug dispensing	Visit 7 SVR12 HCV VL test
Visit 8 Family planning HIV test	Visit 8 M1 drug dispensing	Visit 8 SVR12 disclosure
Visit 9 Endoscopy (>20kPa, PLT<150) Ultrasound (>14kPa)	Visit 9 M2 drug dispensing	Visit 9 Patient visit to health facility Counselling activity Pharmacy activity Labs and exams Doctor consultation
Visit 10 Treatment initiation consultation Initiation counselling D1 drug dispensing	Visit 10 End of treatment counselling Transaminase test End of treatment pill count	
Visit 11 D7 consultation Adherence/lifestyle counselling D7 drug dispensing	Visit 11 SVR12 HCV VL test	
Visit 12 D14 consultation Adherence/lifestyle counselling D14 drug dispensing	Visit 12 SVR12 disclosure	
Visit 13 M1 consultation Adherence/lifestyle counselling M1 drug dispensing Transaminase test	Visit 13 SVR12 HCV VL test	
Visit 14 M2 consultation Adherence/lifestyle counselling M2 drug dispensing	Visit 14 SVR12 disclosure	
Visit 15 End of treatment counselling End of treatment PCR VL test End of treatment pill count	Visit 15 SVR12 HCV VL test	
Visit 16 SVR12 test prescription Transaminase test SVR12 HCV VL test	Visit 16 SVR12 disclosure	
Visit 17 SVR12 disclosure Counselling on avoiding reinfection		

Objective 2. Impact of simplification on care quality, patient outcomes, and operational indicators



- ❖ Quality of care and patient outcomes remained high even after laboratory tests, consultations, and counselling sessions were reduced, demonstrating that **care quality was not jeopardized through the simplification** process
- ❖ **ITT SVR12** has consistently been over **95%** (N=779) in a cohort where **84% have advanced fibrosis (F3-F4)**

- Simplification was done through the monitoring of performance indicators and application of medical evidence obtained from various operational research studies that were conducted
- As of October 2017, roughly 900 patients were treated for HCV in the **Full Care Model** and 1800 patients have initiated HCV treatment in the **Simplified Care Model** at a National Hospital in Phnom Penh (capital)

Objective 3. Trade-offs of further simplification and major clinical questions for the Rural Model

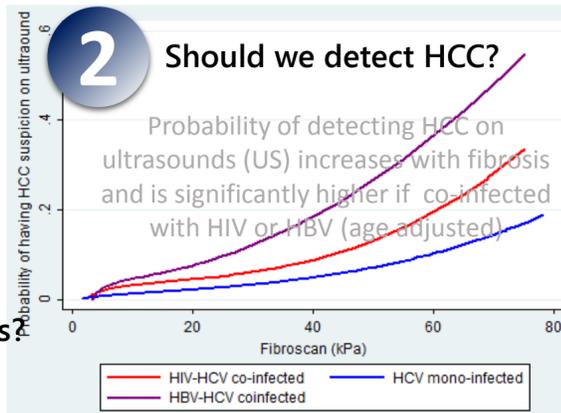
PUBLIC HEALTH IMPACT

We demonstrate that it is feasible for HCV programs to provide HCV care to a large volume of patients without sacrificing quality of care or patient outcomes by simplifying the diagnosis and treatment cascade and care continuum

1 Is assessing fibrosis necessary?

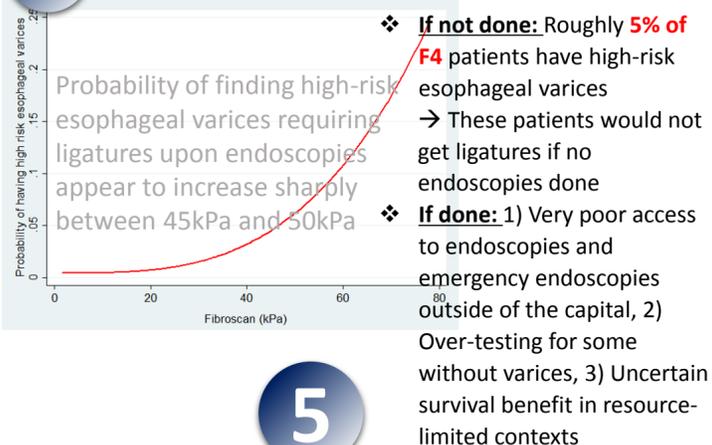
- ❖ **If not done:** 1) No fibrosis staging implies there is adequate quantity of drugs to treat all stages, 2) Cannot use it as criteria for further patient management such as using it as a criteria for lab test to diagnose decompensation
- ❖ **If done:** Fibrosis staging by fibroscan, APRI, FIB4 measurements are still very difficult to implement in resource-limited rural settings

2 Should we detect HCC?



- ❖ **If not done:** 5% of F4 patients have HCC suspicion upon US → These patients will not be detected if US are not provided
- ❖ **If done:** 1) Poor access to testing; 2) Wide variability in the quality of testing; and 3) Treatment of HCC not available for many

3 Should we identify and treat high risk varices?



- ❖ **If not done:** Roughly **5% of F4** patients have high-risk esophageal varices → These patients would not get ligatures if no endoscopies done
- ❖ **If done:** 1) Very poor access to endoscopies and emergency endoscopies outside of the capital, 2) Over-testing for some without varices, 3) Uncertain survival benefit in resource-limited contexts

4 What is the minimum lab set?

- ❖ Cold-chain for blood samples is resource intensive, and not sustainable in rural health centers
- ❖ Testing should be done only if it impacts clinical decision-making. The key challenge is how to stratify patients who need the lab tests at a health center level

5 How should we task-shift?

Reserving MDs to manage more complex cases such as decompensated patients or patients with comorbidities while task-shifting simpler cases to non-MDs is one way to task-shift. **10% of F4** patients are decompensated, **15%** are diabetic.

- ❖ **If not done:** Not possible to treat large volumes of patients.
- ❖ **If done:** Require easy-to-follow flow chart for separating the “complex” from “simpler” cases without relying on lab tests to do so. Sensitivity of identifying “complex” cases requiring referrals may be jeopardized by task shifting

WHY IS IT INNOVATIVE?

The care model we developed for Cambodia is innovative in a way that we prospective collected clinical data aimed at assessing and identifying a minimal screening and care package, effective in resource-limited settings without jeopardizing patient outcomes

CONCLUSIONS

Future programs aiming to extend HCV care to rural areas and scale-up should first determine if the priority of the HCV program is to manage cirrhosis (clinical approach) or to target HCV infection (public health approach), and evaluate the trade-offs and clinical value of each lab or exam in resource-limited contexts, if these tests are directed at cirrhosis management rather than expediting HCV treatment

CONFLICTS OF INTEREST

Authors have no potential conflicts of interest to declare

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