# Outcome of HCV treatment by direct acting antiretroviral (DAAs) among HCV/HIV co-infections in Vietnam

**3rd Asia Pacific AIDS & Co-infection Conference 2018**
**PA-4: Co-infections and complications**

**Thu Nguyen – Clinton Health Access Initiative Vietnam**

# Presentation contents

- Overview of viral hepatitis C in Vietnam, background and objectives
- Study design and methods
- Preliminary results
- Study conclusions and limitations

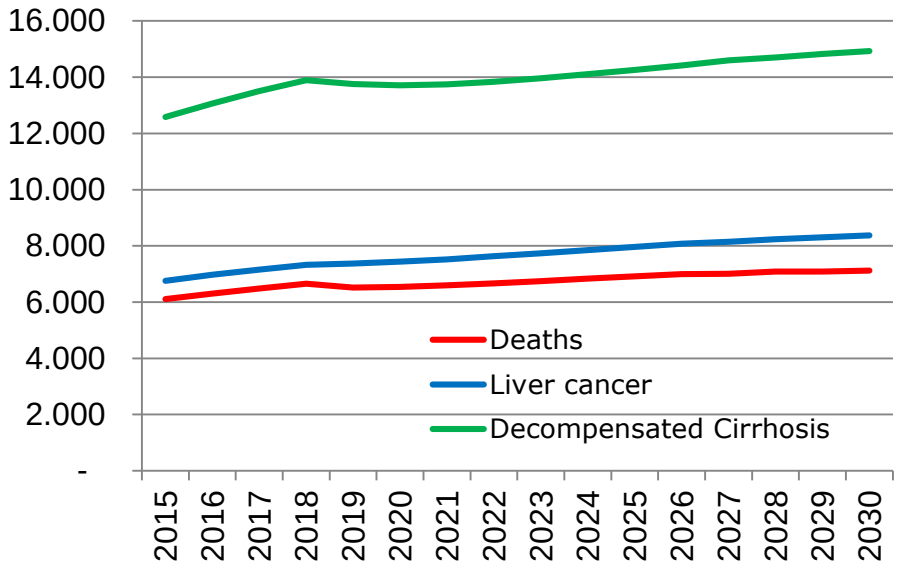
# Vietnam bears high burden of viral hepatitis

**Estimated number of infection, liver cancer and deaths due to viral hepatitis B and C (2017)**

| | Hepatitis B | Hepatitis C |
|---|---|---|
| Total # with chronic infection | 7,820,267 | 991,153 |
| Decompensated cirrhosis | 51,689 | 13,633 |
| Liver cancer | 14,087 | 5,992 |
| Death | 32,110 | 6,459 |

Diseases burden estimation by GDPM/MOH, US/CDC and WHO

**Projected number of liver cancer and deaths due to viral hepatitis C (2015 – 2030)**

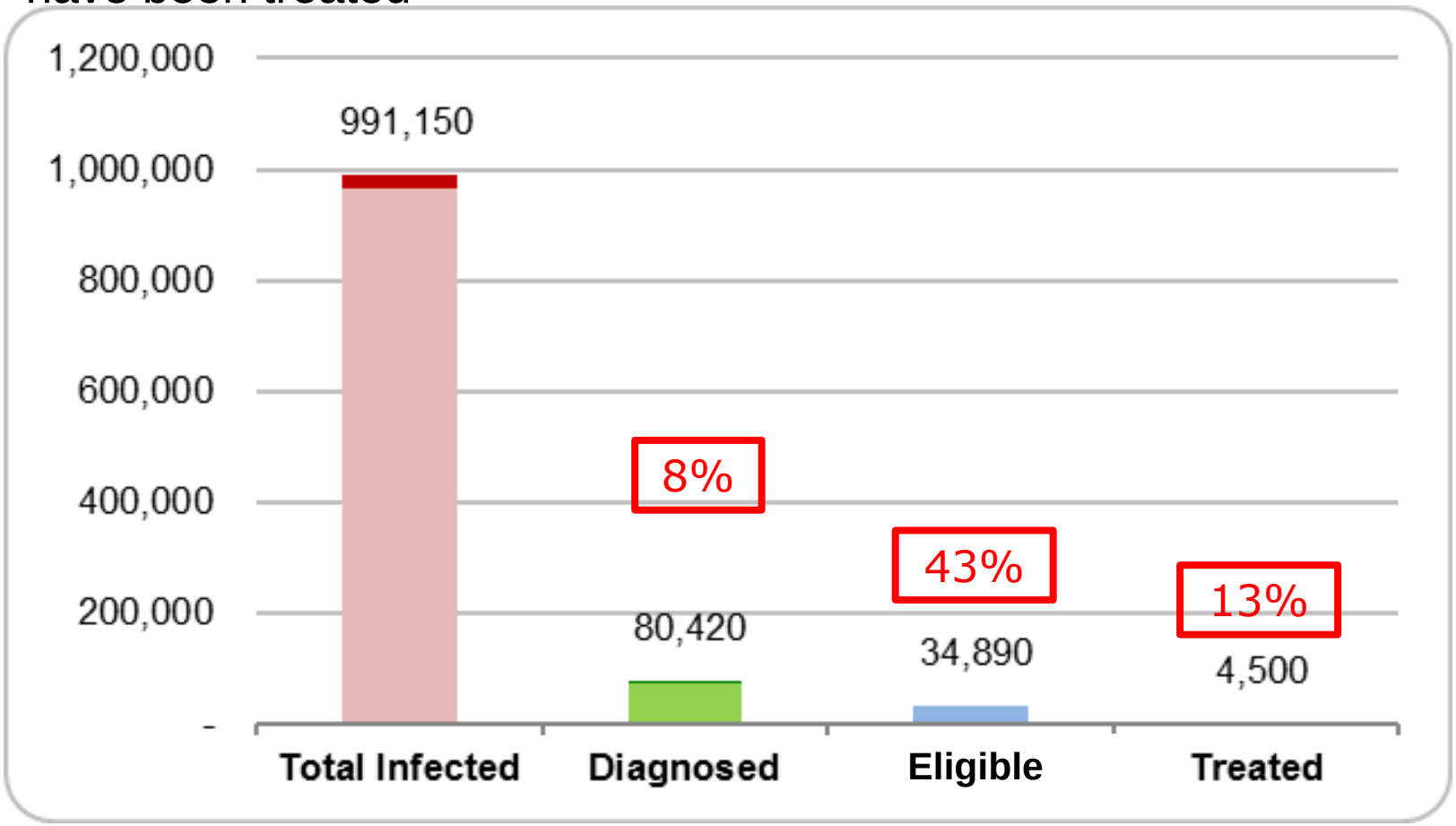



- Prevalence of HCV among:
  - General population: 0.4%-1.7% - North; 1.0%-4.3% - South
  - Injecting drug users: 30%-97.2%
- Viral hepatitis - third leading cause of deaths in Viet Nam [1]

1. *Lancet* 2015; 385: 117–71

# Cascade of HCV diagnosis and treatment in Vietnam – Estimated of diseases burden 2017

- In 2016, only 4,500 patients out of over 990,000 estimated to be infected have been treated

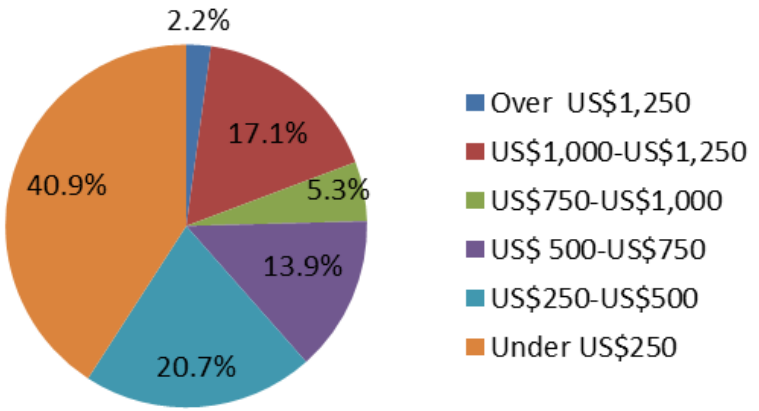



- Morbidity and mortality due to hepatitis C projected to increase, if intervention is not strengthened

# Contributors to limited accessibility of HCV diagnosis and treatment in Vietnam

- Lack of awareness in general population
- Unavailability of screening tests at district & provincial levels
- Unavailability of HCV confirmatory tests outside of the national level and a few provinces
- Limited awareness and capacity among healthcare workers at all levels
- Complex guidelines/procedures (genotype test, HCV RNA Viral Load, etc.)
- High costs of diagnosis & treatment
  - Unaffordable DAA prices
  - Not yet covered by health insurance

**Willingness to Pay for Treatment at Varying Price Levels***




N=416

**Only 25% of patients can afford US$750 for 12w tx course**

*Rapid assessment on willingness to pay in Hai Duong Provincial Hospital

# Study objectives

- To evaluate the treatment outcome of direct-acting antivirals on patients with HCV mono-infection and on patients with HCV/HIV co-infection
- To evaluate the decentralization model of HCV treatment and care from national to provincial and district levels.

# Agenda

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# Study design and methods

- Patient inclusion criteria:
  - Age 18 and above
  - Patients who are anti-HCV positive and HCV RNA positive
  - HCV/HIV co-infected patients: all patients, regardless of fibrosis level
  - HCV mono-infected patients:
    - Liver fibrosis from F3 (using Fibroscan test or APRI score)
    - With metabolic disorders: diabetes, hypertension, etc.
- Patient exclusion criteria:
  - Patients whom HCV treatment is contraindicated, according to the national guidelines (severe sepsis, heart failure, pregnancy, etc…)
- Demographic and clinical data of individual patients was collected prospectively from paper records
- Data calculation and analysis: all HCV/HIV co-infected patients initiated on DAAs from June to Dec 2017 with SVR12 results by 31 March 2018

# Study design and methods (cont.)

**Treatment regimen: Daclatasvir + Sofosbuvir ± Ribavirin**

- Based on national guidelines on HCV diagnosis and treatment
- **Daclatasvir (Daklinza) 60mg and 30mg**: *free for patients*
- **Sofosbuvir 400mg:** OOP by patients at negotiated price from a local distributor



**5 treatment sites at:**

- National level (1x): Nat. Hosp. of Tropical Diseases
- Provincial level (3x): Dong Da Hospital – Ha Noi, Provincial General Hospital in Nam Dinh, Provincial HIV/AIDS Center in Hai Duong
- District level (1x): Nam Tu Liem District Health Center

Duration: 6/2017-12/2018

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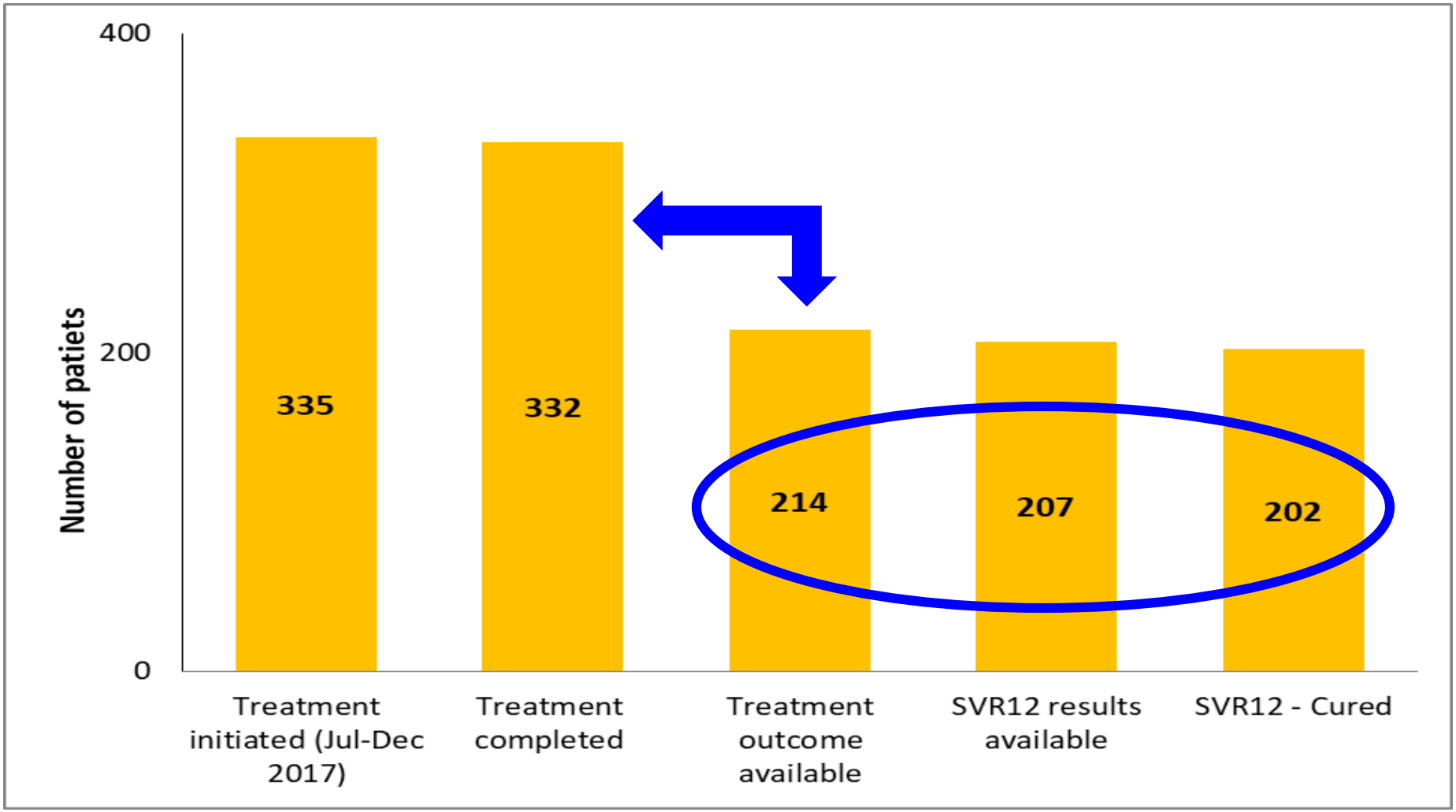
# Cascade of care among HCV/HIV co-infection (as of 31 March 2018)



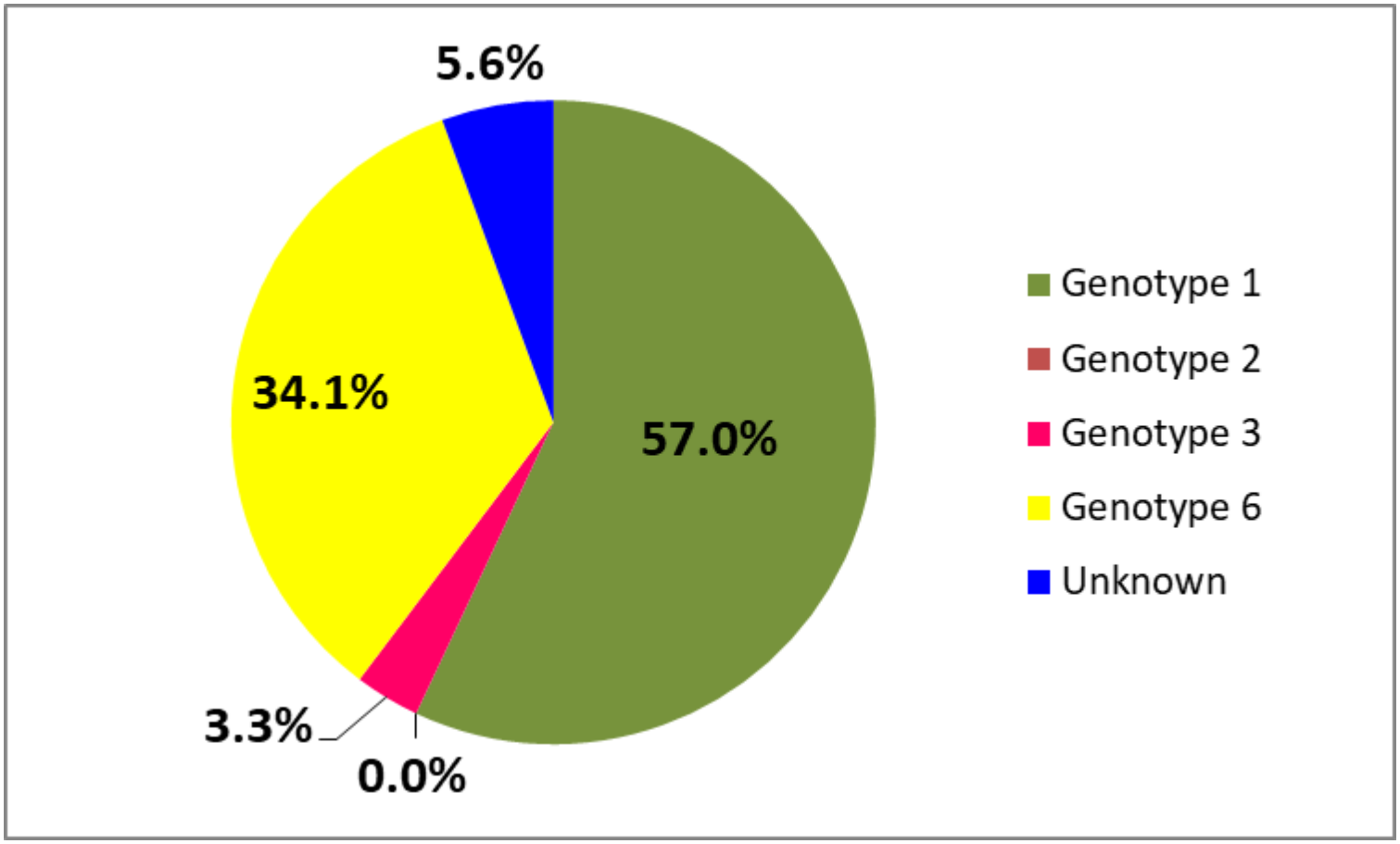
# Demographic information (N = 214)

| Characteristics | Participants, N (%) |
|---|---|
| Age | Median Age 40.0; IQR: 37.0-43.0 |
| Male | 200 (93.5%) |
| Female | 14 (6.5%) |
| Injecting Drug User | |
| Yes | 140 (65.4%) |
| Fibrosis level | |
| No Fibrosis | 169 (79.0%) |
| Compensated Cirrhosis | 41 (19.1%) |
| Decompensated Cirrhosis | 4 (1.9%) |
| Treatment Facility Level | |
| National | 95 (44.4%) |
| Provincial | 65 (30.4%) |
| District | 54 (25.2%) |
| ART patients using EFV | 177 (82.7%) |

# Demographic information (N = 214) (cont.)

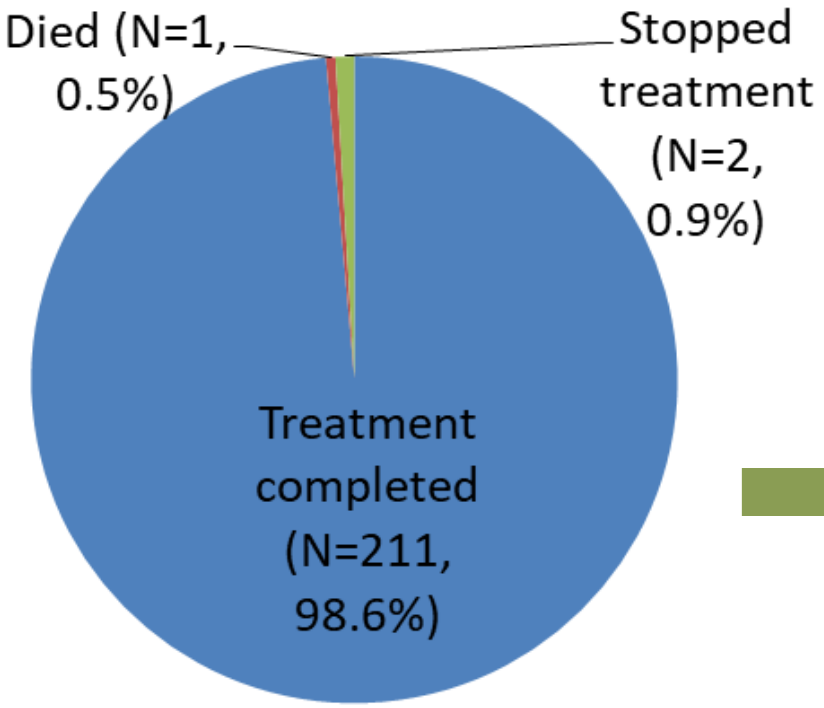
| Characteristics | Participants, N (%) |
|---|---|
| Prior experience of HCV treatment | |
| Yes | 9 (4.2%) |
| Pre-treatment signs & symptoms | |
| Yes | 64 (29.4%) |
| HBsAg positive | |
| Yes | 10 (4.7%) |
| Treatment regimen | |
| SOF+DCV | 188 (87.9%) |
| SOF+DCV+RBV | 26 (12.1%) |
| Treatment duration | |
| 12 weeks | 201 (93.9%) |
| 24 weeks | 12 (5.6%) |

# Genotype breakdown (N = 214)

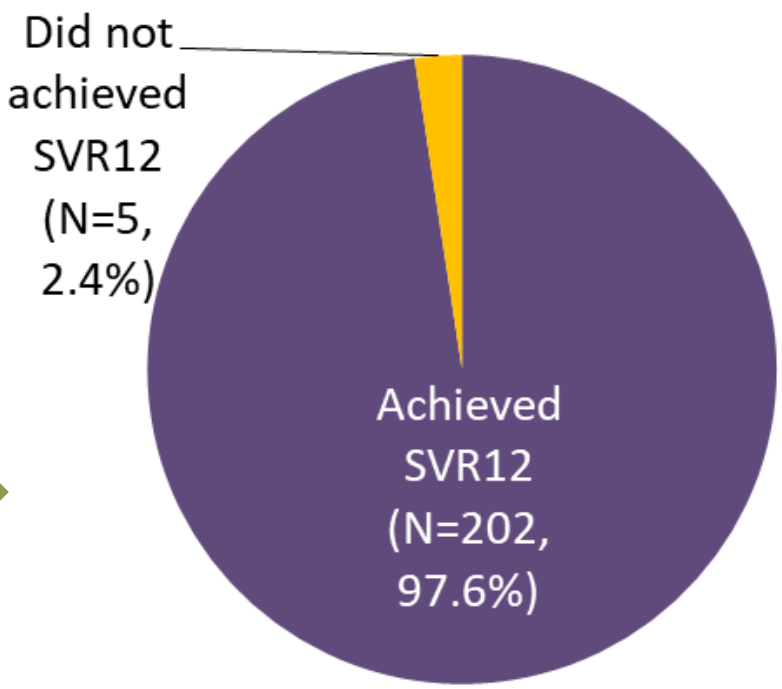


# Treatment outcome and SVR12 results

**Treatment Outcomes (N=214)**

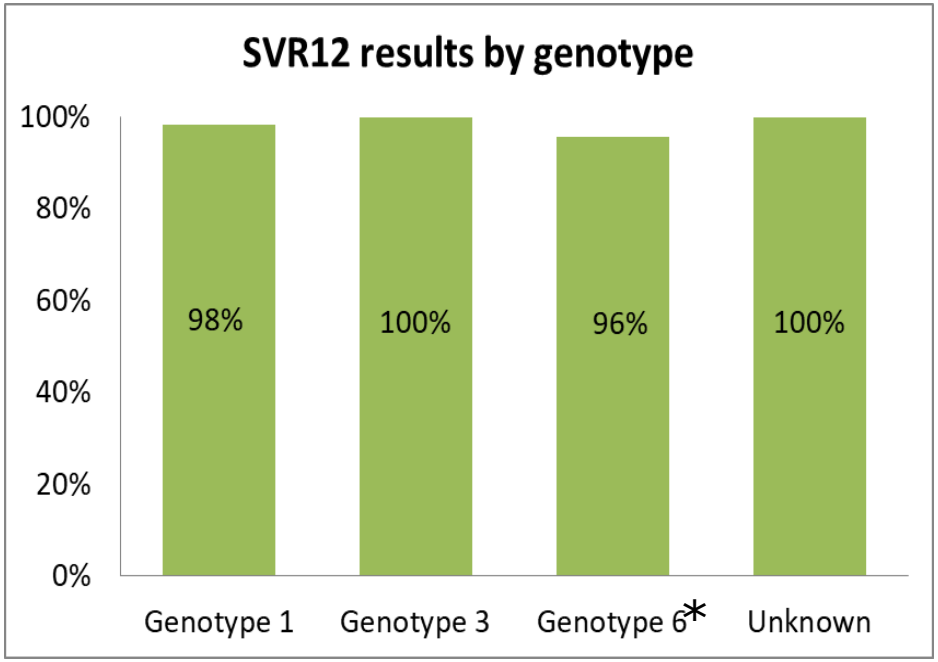


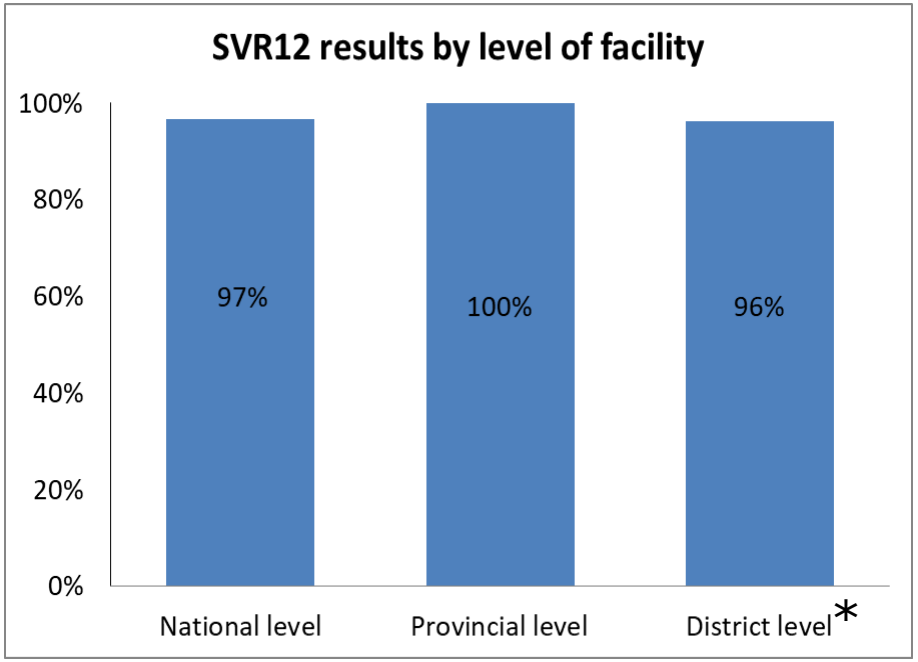

**SVR12 Results (N=207)**




- 1 patient died due to the end-stage liver diseases
- 2 patients stopped treatment due to financial difficulties
- 4 patients can’t afford SVR12 test

# SVR12 results by different genotype and level of facilities




- SVR12 results are high across all genotypes and all patient populations
- No statistically significant difference of SVR12 results by genotype or level of healthcare facility (using Fisher's exact test)



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# Conclusions

- Preliminary results of pilot program show a very high cure rate (98%) using SOF+DCV±RBV to treat HCV/HIV co-infected patients

- No significant difference in cure rate observed among:
  - Patients initiated on treatment at national, provincial or district level facilities ➔ decentralization of DAA treatment at district level is feasible
  - Patients with genotype 6 vs. other genotypes ➔ results adds to the limited publication of using SOF+DCV in genotype 6 patients

- Many patients did not return promptly for SVR12 testing after treatment completion (36%)

# Limitations

- Study results might be affected by patient's out-of-pocket expenditures
  - Unaffordable diagnostic/monitoring tests (for genotyping & SVR12 tests) and treatment cost (even with negotiated price reduction) is the largest barrier for patients to access testing and treatment
  - Complex insurance referral/procedures is another barrier resulting in patients loss between treatment completion and SRV12 testing

# Acknowledgements


- National Hospital of Tropical Diseases
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- Nam Tu Liem District Health Center in Ha Noi
- Hai Duong Provincial HIV/AIDS Center
- Nam Dinh Provincial General Hospital
- Global Hepatitis Team – Clinton Health Access Initiative