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HCV RNA and Antigen Detection for Diagnosis of Acute Hepatitis C Among MSM on PreP

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BACKGROUND

- High incidence of HCV infection has been reported among high risk MSM [1, 2].
- Current guidelines recommend that these individuals should be screened at least once a year with ALT and anti-HCV antibody [3].
- **Our aim was to assess the sensitivity of different tests for early diagnosis of acute hepatitis C in high risk MSM.**

METHODS

Population and samples

- **High risk MSM** enrolled in the ANRS IPERGAY PreP trial blinded and open phases
- Follow-up visits : screening, M1, M2 and every 2 months
- Stored sera at each visit

Sreening for Hepatitis C

- **ALT at each visit**
- **3rd Generation (3thG) HCV antibody immunoassay** (EIA 3thG)
  - ✓ At the **screening visit** and **every 6 months**
  - ✓ If ALT > 2.5 times the upper limit of normal (ULN)

POSITIVE 3thG EIA
➔ *Diagnosis of acute hepatitis C*

Evaluation of the sensitivity of HCV diagnostic tests

- At the **visit of diagnosis**
- At the **previous visit** *(using stored sera)*

INDIRECT tests **Anti-HCV antibody**	DIRECT tests **HCV antigen & RNA**
• EIA 3thG ARCHITECT HCV Ab® (Abbott) 	• EIA ARCHITECT HCV Ag® (Abbott) : reactive > 3,00 fmol/L
• *OraQuick*® HCV test (Orasure) 	• Cobas® HCV test (Roche) 
• *TOYO*® HCV test (Nephrotek) 	• Xpert HCV Viral Load (Cepheid) 

RESULTS

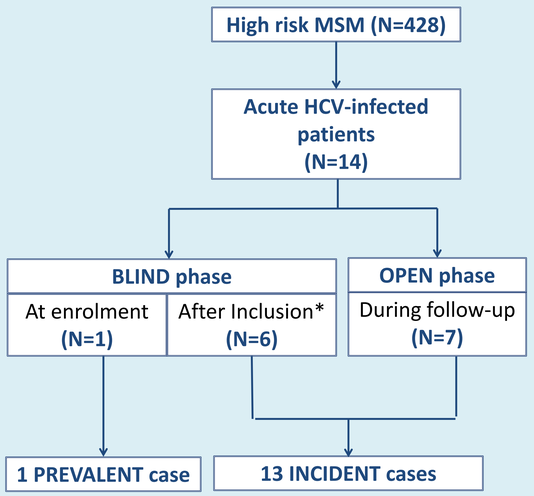

FIGURE 1. Flow-chart. Description of the number of HCV-infected patients diagnosed (based on trial HCV serology) during the ANRS IPERGAY PreP trial. * One patient was HIV-HCV co-infected

- During the study period (from March 5, 2012 to June 30, 2016), 428 participants were enrolled with a **median follow-up of 2.1 years (IQR: 1.5-2.8)**
- **14 patients were diagnosed with HCV** infection including **one co-infected with HIV**
- One case was diagnosed at enrollment and 13 during follow-up
- **HCV incidence was 1.40 per 100 person-years (95%CI: 0.74-2.39)**.
- **Genomic analysis** at diagnosis identified the following genotypes
  - **Type 1 : N=6** patients (43%)
  - **Type 3 : N=1** patients (7%)
  - **Type 4 : N=7** patients (50%)

Patients characteristics at HCV diagnosis	N=13†
Partners in last two months	**25** [16; 40]
Sexual acts in the past 4 weeks *(NA = 2)*	**15** [8; 20]
Condomless receptive anal sex (last sexual act / past 4 weeks) *(NA = 1)*	**11/12**
CHEMSEX * (during last sexual act)	**7/13**
Bleeding (after last sexual act) *(NA = 3)*	**1/10**
Fisting (during last sexual act) *(NA = 3)*	**2/10**
Sexually transmitted infections **	**5/13**

TABLE 1. Characteristics of patients at hepatitis C diagnosis (N=13).
Risk factors for hepatitis C were collected during the last two months or the last four weeks before hepatitis C diagnosis visit (data are presented as median or n/N evaluated)
† 1 participant with no data at HCV diagnosis
* CHEMSEX: use of ecstasy / cocaïn / GHB.GBL / ketamine / crack / heroin / speed / LSD / mephedrone or slam;
** Anal Chlamydia (N=4), syphilis (N=1).
IQR=interquartile range; NA: not available.

Test		Visit of diagnosis (N=14)		Prior visit (N=13*)	
		Number of positive tests / number of sera tested	Sensitivity (95% CI)	Number of positive tests /number of sera tested	Sensitivity (95% CI)
EIA 3thG HCV Ab®		**14/14**	**100%** (77-100)	**0/13**	
Anti-HCV antibody rapid tests	*OraQuick*®	**13/14**	**93%** (66-99)	**0/9**	**0%** (0-34)
	TOYO®	**11/14**	**79%** (49-95)	**0/9**	**0%** (0-34)
EIA HCV Ag® *(UI/ml)*		**13/13** (median[IQR]: 938 [12-5 274])	**100%** (75-100)	**8/9** (median[IQR]: 13 475 [2 936-33 351])	**89%** (52-100)
HCV RNA Tests *(cp/mL)*	Cobas® HCV test	**14/14** (median[IQR]: 1 539 693 [10 414-3 415 663])	**100%** (77-100)	**11/13** (median[IQR]: 1 935 372 [71 036-10 900 000])	**85%** (55-98)
	Xpert HCV viral load	**13/13** (median[IQR]: 903 500 [115 643-4 600 000])	**100%** (75-100)	**8/8** (median [IQR]: 1 545 000 [28 475-3 712 000])	**100%** (63-100)
Increased ALT *(UI/mL)*		**13/13** (median[IQR]: 451 [103-597])	**100%** (75-100)	**3/12** (median[IQR]: 291 [83-381])	**25%** (2-57)

TABLE 2 : Sensitivity of the different tests available for acute HCV infection diagnosis at the visit of diagnosis and during the prior visit. Prior visit occurred within a median delay of 2 months earlier (IQR: 1,5-2). Among 12 patients who were tested during prior visit with both HCV RNA (Roche) and ALT, 7 had an HCV RNA detectable and no increased ALT (p=0.008, McNemar's test)
* 1 participant with no previous visit data

CONCLUSION

- **The HCV antigen immunoassay and plasma HCV RNA test were positive within a median of 2 months before the detection of antibodies and ALT elevation**, when patients were asymptomatic and had no increased ALT in the majority of cases
- These tests **should be used in high risk MSM for early diagnosis of acute HCV infection** and prevention of transmission.

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References [1] Urbanus et al. Trends in hepatitis C virus infections among MSM attending a sexually transmitted infection clinic; 1995-2010. *AIDS* 2014; 28(5):781-90. [2] Vanhommerig et al. Risk factors for sexual transmission of hepatitis C virus among HIV-infected MSM: a case-control study. *Open Forum Infect Dis* 2015; 2(3) [3] Hepatitis C guidance: AASLD-IDSA recommendations for testing, managing, and treating adults infected with hepatitis C virus. *Hepatology.* 2015 ; 62(3):932-54.

Acknowledgments
This trial was funded by the French National Agency for Research on AIDS and Viral Hepatitis (ANRS), the CTN (Canadian Trial Network), the "Fonds Pierre Bergé pour la prevention", the SIDACTION and the Bill and Melinda Gates Foundation. It was conducted with the support of Gilead Sciences (donation TDF-FTC). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of this poster.