Evaluation of the Xpert® HCV viral load fingerstick assay in the harm reduction setting in Catalonia, Spain

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Disclosures

- Verónica Saludes has received travel sponsorship from Gilead and Cepheid.

Background/aims

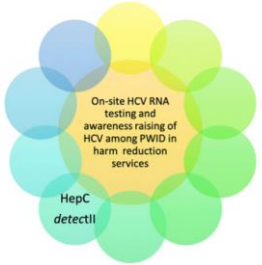
- **Catalonia** has a wide **network of harm reduction services,** (~6,000 PWID/year) offering **rapid HCV-Ab testing**.

HepC*detect* II Study (2016-17):

On-site HCV-RNA screening using dried blood spots (DBS)

⇨ 59% prevalence of viremic infection

⇨ Suboptimal linkage to care and antiviral therapy.



Hepatitis C: new models of care for drugs services. EMCDDA 2019

- **Aim:**
  - To evaluate the clinical performance and effectiveness of a one-step, HCV-RNA point-of-care (**RNA-PoC**) testing strategy in **fingerstick blood** among PWID recruited at a drug consumption room (DCR) in Barcelona.

Methods

N=100 current PWID (05-2018 to 02-2019)

- ≥18 years of age
- Injected drug use (previous 6 mo.)
- Not under HCV treatment

Ab-PoC testing
(TürkLab)

RNA-PoC (DCR):

RUO version of the **Xpert® HCV Viral Load Fingerstick**

100 µl of whole blood
LOD: 13-35 IU/mL
60 min

Remote validation of results in the central lab

- Results delivery and preferences
- Referral to care

Reference assay (central lab):

Xpert® HCV Viral Load

1000 µl of plasma
LOD: 4 IU/mL
105 min

- Discordant results: HCV Real Time (Abbott; LOD: 12 IU/mL)
- HCV genotyping by sequencing
- HIV serology testing (Ag/Ab)

CE-IVD. In Vitro Diagnostic Medical Device. Not all tests available in all countries. Not available in the U.S.

Results

Excellent agreement (κ=0.979)

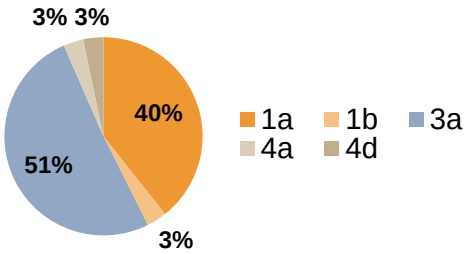
	95% CI
– **98.4% sensitivity**	91.5-99.7%
– **100% specificity**	90.6-100%

		Xpert VL (plasma)		
		Detectable	Undetectable	Total
Xpert FS (whole blood)	Detectable	62	0	62
	Undetectable	1*	37	38
	Total	63	37	100

**Pos <10 IU/mL in plasma (pos <12 IU/mL by Abbott)*

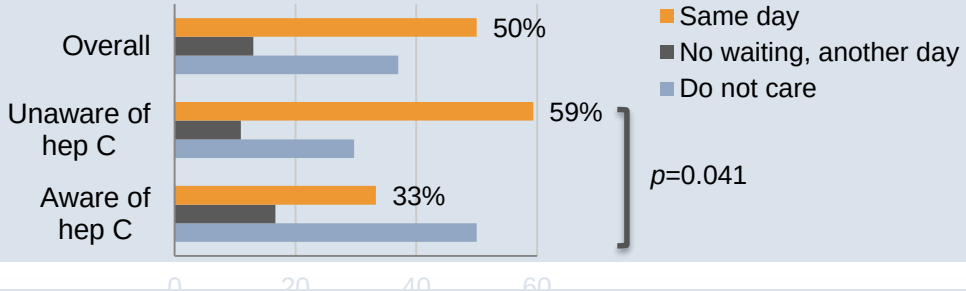
63% prevalence of viremic infection:

- 3.2% pos <10 IU/mL
- 3.2% Ab-POC negative
- 25.4% HIV/HCV co-infected
- HCV genotypes:



Delivery of FS assay results:

- In **100**% of cases (same-day delivery in 80%)
- **PWID preferences:**



- **54.8%** of viremic cases **became aware of it**
- **Referral to care in all required viremic cases** (96.8%)

Conclusions/implications

- The RNA-POC diagnosis strategy **increased PWID awareness on HCV status** and allowed for the **timely and reliable identification of treatment candidates**.

- **Local cost-effectiveness studies** should be performed to establish whether this RNA-POC test could either substitute the Ab-POC test (**one-step strategy**) or complement it (**reflex two-step strategy**) in the harm reduction setting.

- This study has contributed to an ongoing decentralized **“test and treat” pilot intervention** in this DCR.

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