

Point-Of-Care Testing and Diagnostics for HCV Infection: Have we Reached a Single-Visit Diagnosis?

Pr Karine Lacombe,
INSERM UMR-S1136, IPLESP
SMIT St Antoine, AP-HP
Sorbonne Université



Why should we think « out of the box » in terms of HCV screening?



High efficacy
Optimal safety
Short duration

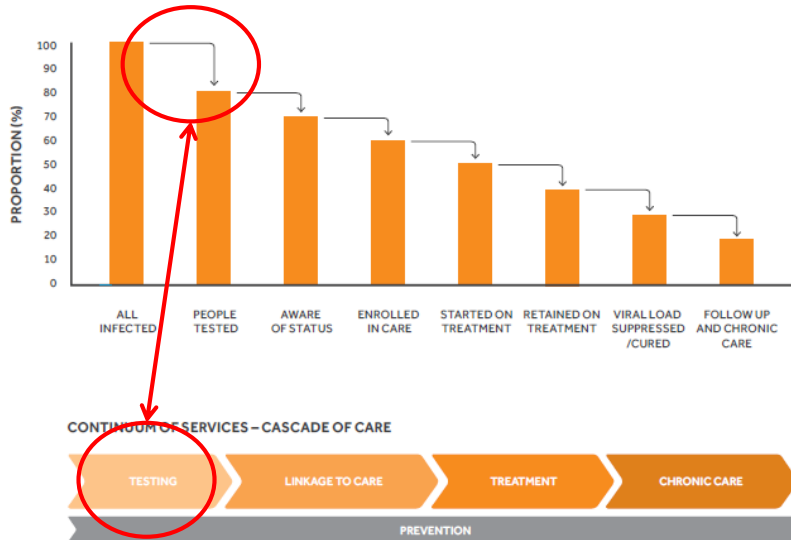


GLOBAL HEPATITIS REPORT,
2017



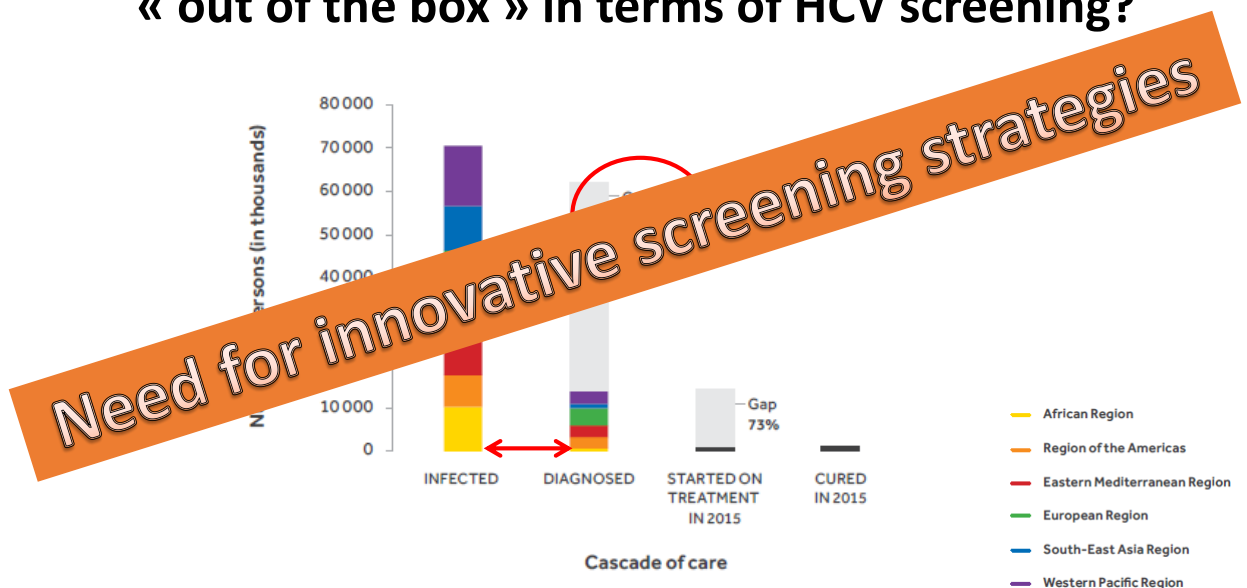
HCV elimination
By 2030

Why should we think « out of the box » in terms of HCV screening?



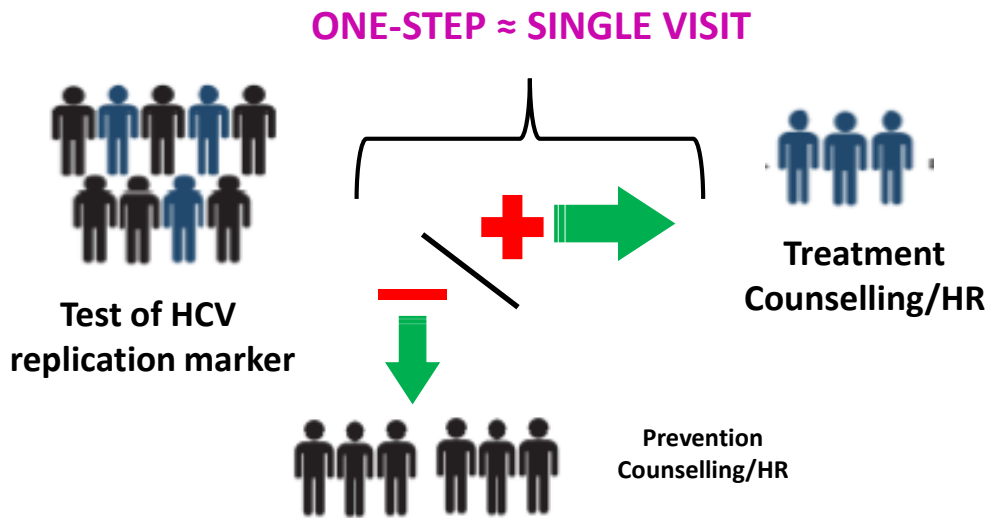
3

Why should we think « out of the box » in terms of HCV screening?



Definition:

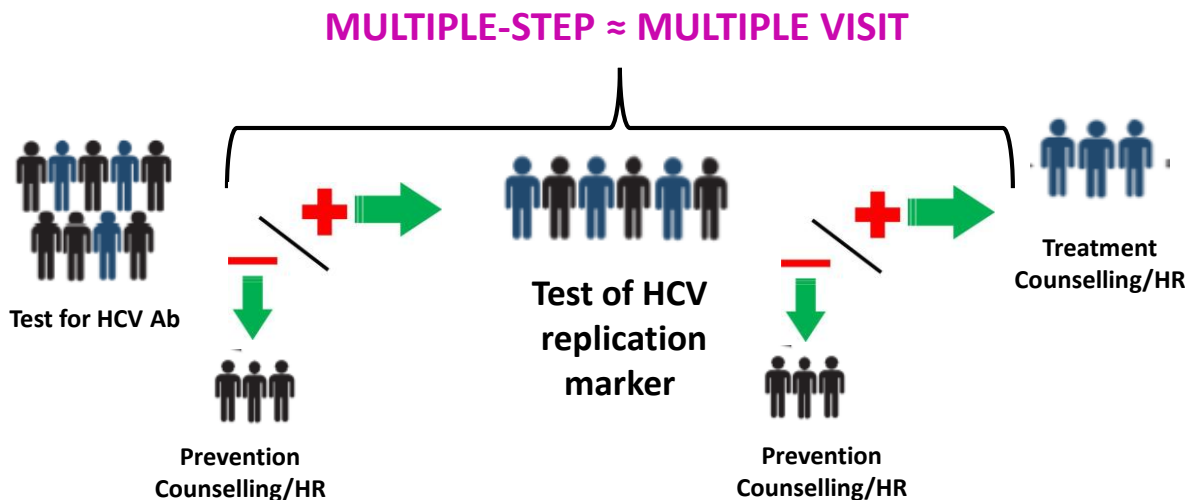
« single-visit » *versus* « multiple visits »



5

Definition:

« single-visit » *versus* « multiple visits »



Definition #2:

« Point-of-Care » *versus* « Laboratory-centered »

Def. « POC »



Def. « Lab.centered »



“POC testing is defined as testing performed close to or near the patient, i.e. where healthcare is provided outside of traditional centralised laboratories »

Chevaliez S, J Hepatol 2018

7

Innovative diagnostic tools for « single visit »

8

NAT POC devices

GenXpert



- Small (23cm)
- Light weight (1kg)
- Rechargeable battery
- Wireless connection
- Limit detection : 40UI
- Limit quantification: 1000UI
- CE marked and WHO prequal.

GenDrive



- Limit semi-quantification: 1000UI

Others



Abbott/Alere



Samba semi-Q

Developed for HIV
adapted for HCV

Chevaliez S. J Hepatol 2018

9

HCV core Ag based devices

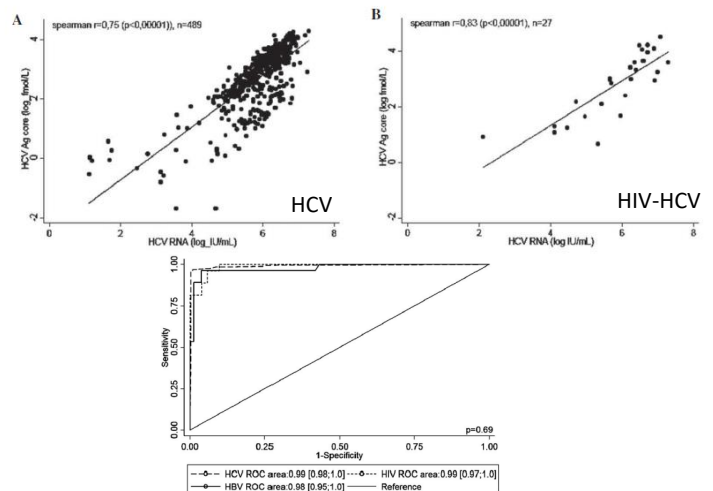


Figure 3. ROC curves of the performance of cAg quantification for the diagnosis of chronic hepatitis C in HCV mono-infected, HIV-infected and HBV-infected patients.

Duchesne, J Int AIDS Soc 2017

10

POC HCV core Ag: still under development



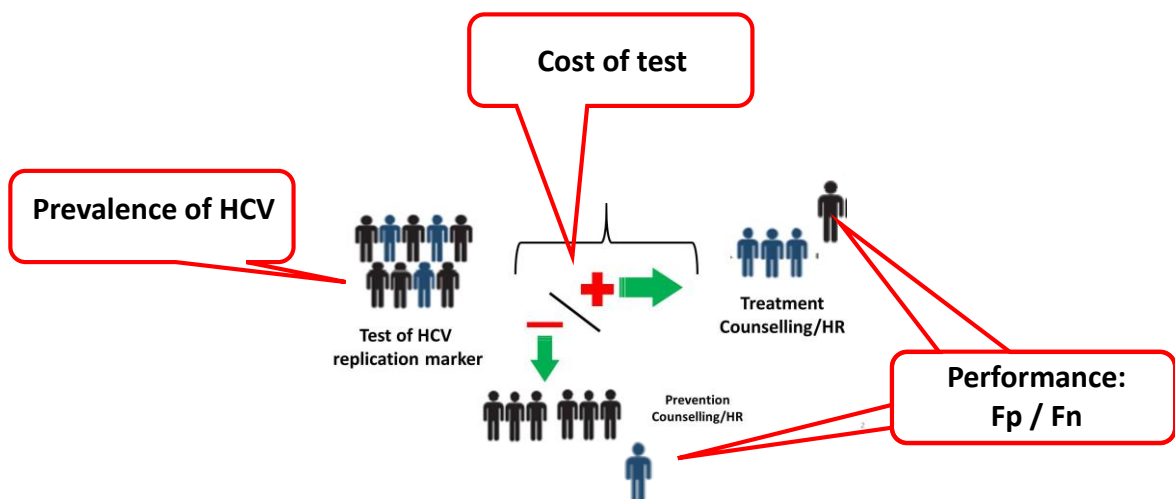
Chembio Diagnostics Announces Collaboration with FIND to Develop
Hepatitis C Virus Point-of-Care Diagnostic Test

And also innovative diagnostic strategies based on
microfluidics sampling and fluid actuation, and sensing
based on piezo-electric resonator

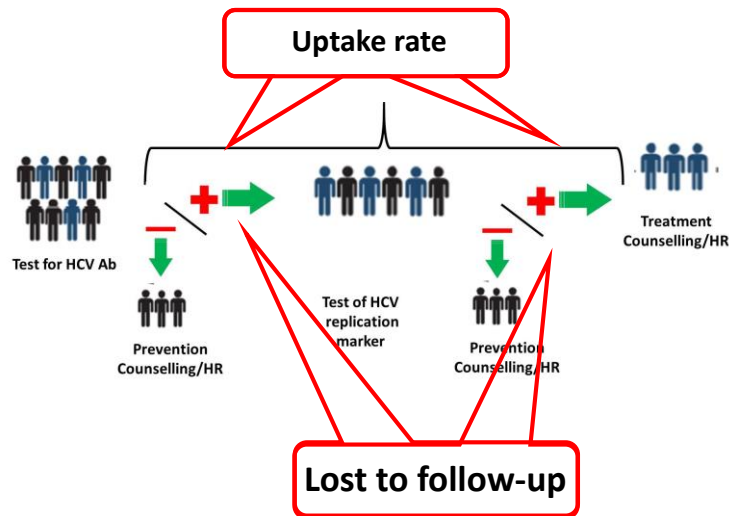
Duchesne, J Viral Hepat 2018

11

Issues around « one-visit » / « two-visit » diagnosis



Issues around « one-visit » / « two-visit » diagnosis



13

Issues around POC v. lab tests

Def. « POC »



Def. « Lab.centered »



Microsampling

14

Dried Blood Spots, old and new



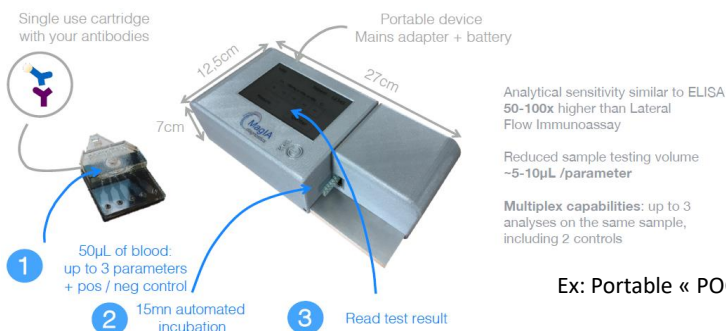
- High performance for HCV-Ab and HCV-RNA
- Lower performance for HCV cAg
- Storage constraints after transportation

Chevaliez S. J Hepatol 2018

15

Exploring new ways of testing: « integrated » HIV-HBV-HCV screening

- 2018 EASL recommendation to enhance the 3 viruses screening in at-risk population
- Also a recommendation in the French general population for screening 3 viruses once in a lifetime (AFEV 2018)



Ex: Portable « POC » ELISA device from MAGIA

16

Exploring new ways of screening: « self-testing »



79 \$ in the USA !

Guisse et al. BMC Infectious Diseases (2018) 18:281
<https://doi.org/10.1186/s12879-018-3185-7>

BMC Infectious Diseases

RESEARCH ARTICLE

Open Access



A qualitative assessment of the acceptability of hepatitis C remote self-testing and self-sampling amongst people who use drugs in London, UK

Andy Guisse^{1,2*}, T. Charles Witzel³, Sema Mandal^{4,5}, Caroline Sabin^{5,6*}, Tim Rhodes^{1,5}, Anthony Nardone^{4,5} and Magdalena Harris¹

- Concept of remote testing acceptable, although evidence of tension associated with outcomes: value of autonomy, fear of dealing with positive result in isolation / linkage to care

17

Wrap-up summary

- Reaching the goal of HCV elimination by 2030 implies acting on all steps of the HCV continuum of care
- 1st step = screening with urgent need for a change in the model of HCV screening
- One-step or two-step strategy ? Choice influenced by
 - Cost of tests
 - Technologies
 - Performance (FP – FN)
 - Prevalence of infection
 - Uptake rate of screening
 - Lost to follow-up rate
- Cost-efficacy analysis essential to drive screening policies
- Impact on the continuum of care as a whole should be evaluated (from screening to cure), and not only impact of screening rates

18

Thank you!



Lea Duchesne

Maud Lemoine

**François Lamoury/Francesco Marinucci / Elena Ivanova
and the FIND hepatitis team**