1st INHSU Regional Conference on Hepatitis Care in Substance Users:

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Diagnostics and point-of-care technologies to enhance HCV testing and treatment

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Hepatitis C:
the « Test and Treat » revolution

Adapted from J. Grebely, 2018

Point-Of-Care tests: from antibodies to NAT detection

BLOOD/LIQUIDS COLLECTION

- Phlebotomy
- Dried blood spots
- Capillary / cravicular

ANTIBODY DETECTION

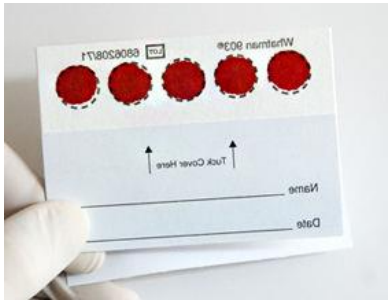
- Centralised lab
- Rapid test
- Point-Of-Care test

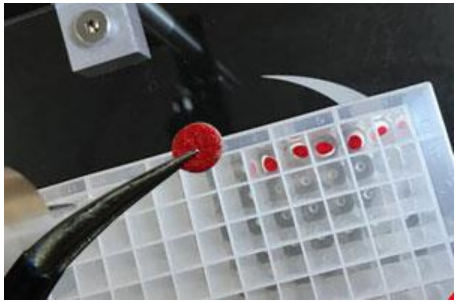
HCV cAg / NAT DETECTION

- Centralised lab
- Point-Of-Care RNA / cAg

Dried blood spots

- **PWID in Vietnam (Ho Chi Minh City):** viremia detection using DBS for HCV-RNA and HCV cAg (86 subjects)
  - 92% for HCV-RNA
  - 87% for HCV cAg
- **PWID in Tanzania (Dar-Es-Salaam):** viremia detection using DBS for HCV-RNA and HCV cAg (153 subjects)
  - 99,1% for HCV-RNA
  - 76,7% for HCV cAg





Point-Of-Care antibody detection

MDM dropping center, Temeke district (Dar-Es-Salaam, Tanzania): screening with OraQuick, SD Bioline)[1]

		HCV positive			HIV and HCV positive		
		n	%	(95% CI)	*n*	%	(95% CI)
PWID	Male	64	27.7	(22.0–34.0)	35	15.2	(10.8–20.4)
	Female	10	27.8	(14.2–45.2)	10	27.8	(14.2–45.2)
	All PWID	74	27.7	(22.4–33.5)	45	16.9	(12.6–21.9)
NIDUs	Male	0	0.0	(0.0–2.9)[a]	0	0.0	(0.0–2.9)[a]
	Female	3	8.1	(1.7–21.9)	2	5.4	(0.7–18.2)
	All NIDUs	3	1.8	(0.4–5.3)	2	1.2	(0.1–4.4)

Analyzer

One droplet
50 µl

Multiplex
6 analyses

Fast
15-20mn

2 Kits

HIV/HCV
early detection

HBV
treat or vaccine

Multiplex HIV/HCV and HBV MagIA test solution

[1]Bowring, IJDP 2013

Capillary NAT Point-Of-Care

- OAT center within Muhimbili National Hospital (Dar-Es-Salaam, Tanzania)

n = 188	Reference test: Xpert® HCV VL plasma assay (cut-off 4 IU/mL)		
Index test: Xpert® HCV VL Fingerstick assay (cut-off 40 IU/mL)	HCV RNA quantifiable	HCV RNA negative	Total
HCV RNA quantifiable	109	1	110
HCV RNA negative	1	77	78
Total	110	78	188

Note: Xpert® HCV viral load (VL) Fingerstick assay; sensitivity 109/110 (99.1%), specificity 77/78 (98.7%).

Mohamed Z, Liver Int 2019

Why screening is not enough: necessity for cost-efficacy analysis

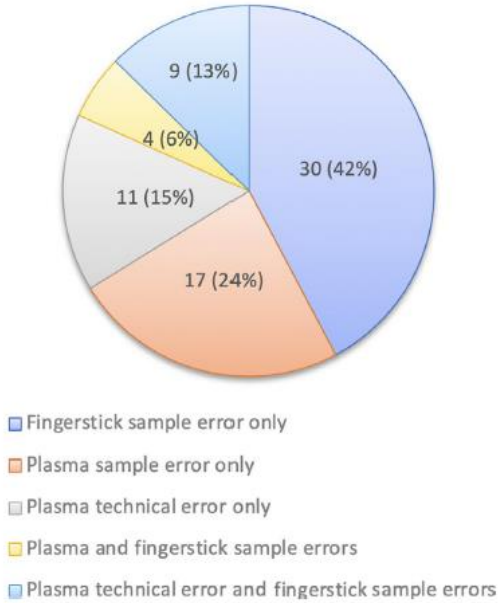


FIGURE 2 Breakdown of testing errors for both Xpert® HCV RNA plasma and Fingerstick assay (n = 71). HCV, hepatitis C virus; VL, viral load

- **From the cohort study in a dropping center in Tanzania[1]**: out of 220 PWID where fingerstick and plasma HCV(RNA testing were performed ➔ 71 blood samples resulted in testing errors

- **From a cohort study in a consumption room in France[2]**: out of 90 PWID where DBS and fingerstick HCV-RNA testing was performed ➔ 83 with valid fingerstick and 84 with valid DBS

[1]Mohamed Z, Liver Int 2019. [2]Chevaliez, *submitted*

Cost-effectiveness analysis of screening the PWID community in Dakar

Strategy	Testing sequence		
1 (ref.)	Anti-HCV Ab (lab – serum)	→	RNA (lab – serum)
2	Anti-HCV Ab (lab – DBS)	→	RNA (lab – DBS)
3	Anti-HCV Ab (POC)	→	RNA (lab – serum)
4	Anti-HCV Ab (POC)	→	RNA (lab – DBS)
5	Anti-HCV Ab (POC)	→	RNA (POC)
6	Anti-HCV Ab (lab – sérum)	→	HCV cAg (lab – serum)
7	Anti-HCV Ab (lab – DBS)	→	HCV cAg (lab – DBS)
8	Anti-HCV Ab (POC)	→	HCV cAg (lab – serum)
9	Anti-HCV Ab (POC)	→	HCV cAg (lab – DBS)
10	RNA (POC)		
11	HCV cAg (lab – serum)		
12	HCV cAg(lab – DBS)		

- **Rate of coverage :**
  test lab –sérum *versus*
  tests lab – DBS ou POC (1st test)
- **Rate of lost-to-follow-up :**
  test lab –serum *versus*
  tests lab – DBS or POC (2nd test)

Cost-effectiveness analysis of screening the PWID community in Dakar

- **Current testing sequence:** ven. lab HCV-Ab + ven. lab HCV-RNA
- **Cost-effective sequence ([HCV]P of 38,4%):**
  - Ab rapid test + HVC-RNA POC (98,4% of correct diagnosis)
  - Ab rapid test + ven. lab HCV-RNA (99,8% of correct diagnosis)
- **Sensitivity analysis:**
  - If [HCV]P of 55,5%:
  - If price of HCV-RNA POC cartridge < 9,78€:
  - If price of HCV-Ab rapid test > 10,41 €:

HCV-RNA POC more cost-effective

Duchesne L, IJDP 2019. Lepretre A, JIAS 2015

Budget analysis: cost-effective does not mean affordable…

Countries and strategies	Millions euros	% GDP	% of national health expenditures
Cameroon			
S_5 : Ab_POC → RNA_POC	37,3	0,12	17,0
S_4 : Ab_POC → RNA_lab_DBS	55,6	0,18	25,2
Côte d'Ivoire			
S_5 : Ab_POC → RNA_POC	36,1	0,09	7,8
S_4 : Ab_POC → RNA_lab_DBS	39,1	0,10	8,4
Senegal			
S_5 : Ab_POC → RNA_POC	22,9	0,14	10,3
S_4 : Ab_POC → RNA_lab_DBS	24,4	0,15	10,9

Duchesne L, *submitted*

Where do we stand in the future?
Time for frugal innovation in diagnostics

Device (product or service) characterized by its simplicity, that is to say a low technological intensity and a low cost (financial, institutional) aiming to meet a still unmet need while guaranteeing a high degree of quality for his user

Tran and Ravaud *BMC Medicine* (2016) 14:102
DOI 10.1186/s12916-016-0651-1

BMC Medicine

COMMENTARY Open Access

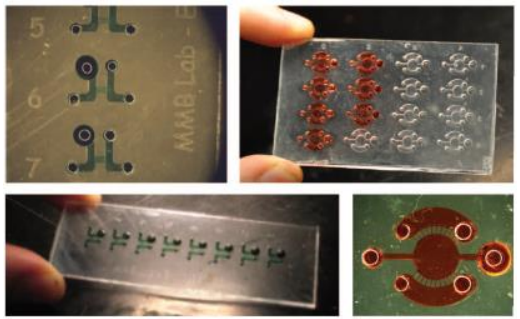
Frugal innovation in medicine for low resource settings

Viet-Thi Tran[1,2,3*] and Philippe Ravaud[2,3,4,5]

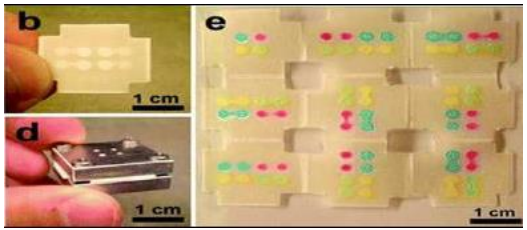
Microfluidic systems: the future ?

- Processing, amplification and detection of genetic material = long process
- Challenge: integrating all steps into « all in one »
- Microfluidics: using the physical properties of micro / nano conducts to separate particles that interfere with specific reagents
- Needs+++ for development in diagnostics

Thermoplastics



Paper (3D structure)



Thank you !