

Use of 3 HIV testing methods in French primary care setting: ELISA laboratory screening versus two rapid finger-stick HIV tests, under five minute (INSTI) and under 30 minute (VIKIA) tests

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Daïana Papadima^{1,2}, Raphaël Gauthier^{2,3,4}, François PrévotEAU du Clary^{2,5}, Jean-Pierre Aubert^{2,3,4}, Stéphane Bouée^{2,6},
Guillaume Conort^{2,7}, Jean-Michel Livrozet^{2,8}, Jean-Michel Peter^{2,12}, Olivier Taulera^{2,9}, Alain Wajsbrot^{2,10}, Catherine Majerholc^{2,3,4,11}

¹ Département de Médecine Générale, Université Louis Pasteur Strasbourg, France
² Groupe d'études et recherche ville-hôpital : 75 rue du Ruisseau, Paris, France
³ Univ Paris Diderot, Sorbonne Paris Cité, Dept Med Gen, F-75018 Paris, France
⁴ EA Recherche Clinique Coordonnée Ville-Hôpital, Méthodologies et Société (REMES), F-75018 Paris, France
⁵ Hôpital La Grave, Hôpitaux de Toulouse, France
⁶ Cemka Eval, 43 Boulevard du Maréchal Joffre, 92340 Bourg-la-Reine, France

⁷ Département de Médecine Générale, Université de Bordeaux, France
⁸ Service des maladies infectieuses et tropicales, Hôpital Edouard Herriot, Lyon, France
⁹ Hôpital Saint Louis, Paris, France
¹⁰ Médecine Générale, Hôpital d'Avignon, France
¹¹ Service de médecine interne, Hôpital Foch, Suresnes, France
¹² Groupe Hospitalier Mulhouse Sud-Alsace, France

Background

- In 2009, French national guidelines recommended widespread routine HIV screening, reinforcement of regular targeted screening of at-risk groups and/or depending on circumstances. Promotion of rapid point of care HIV tests (RHT) to expand HIV screening began.
- Five years later, unpromising results: low increase in HIV testing, persistence of hidden HIV epidemics (around 29 000 people unaware being HIV+)
 - Studies led in the emergency room setting¹ showed a low feasibility of the mass screening strategy;
 - The missed opportunities study² showed that MDs could employ targeted screening based on risk groups and/or clinical signs.
 - The Morlat experts' group report³ and the GPs National Council⁴ insist on risk factor based screening
- RHT feasibility and interest in French general practice, little amount of data:
 - DEPIVH: Good acceptability but limited feasibility of rapid HIV testing (VIKIA) in GPs office due to time restriction, technical difficulties and staff training⁵,
 - Efficient strategy in Guyane (highest HIV prevalence in France) with financial support from social security⁶,
 - The joint screening of HIV, HBV and HCV after appropriate training of motivated GPs improved testing rates, even after a short period, particularly within at-risk groups⁷.
- Hypothesis: simultaneously offering GPs 3 screening tools from which to choose could help establish the most suitable HIV screening strategy for general practice and hence diminish hidden HIV epidemics.
- We designed a new study titled DEPIVH 2. In addition to VIKIA RHT, we introduced the immediate answer RHT – INSTI test and left the possibility of using Elisa blood tests.

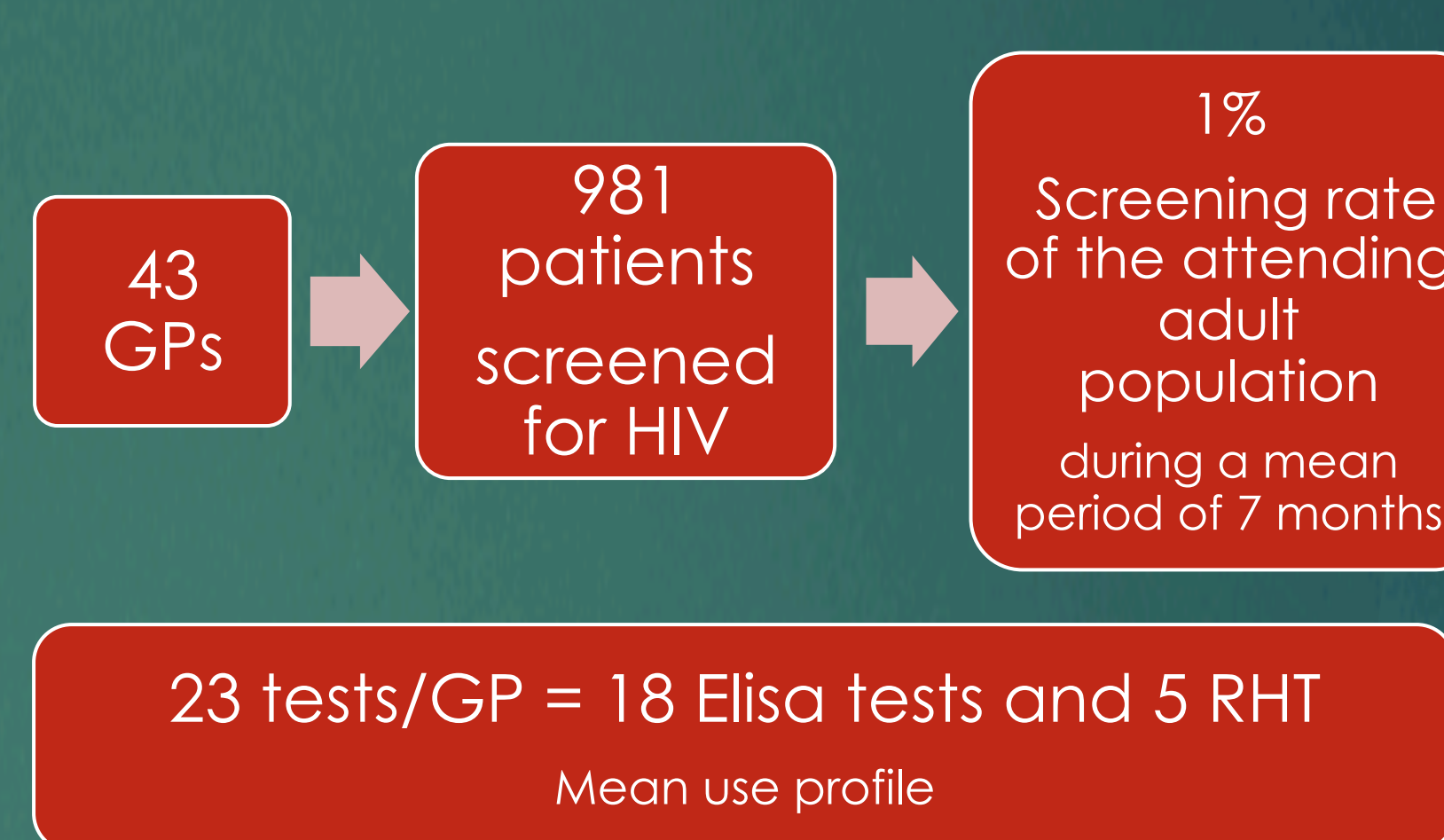
Methods

- National prospective interventional study led in French GPs offices between December 2013 and December 2014.
- Primary outcome:** to assess the use of 3 screening methods in French GPs current HIV screening practice:
 - ELISA test prescription,
 - immediate answer RHT INSTI (Nephrotek),
 - or 30 min delayed answer RHT VIKIA (BioMérieux).
- Adult patients over 18 YOA of unknown HIV status that visited their physician were eligible for study.
- HIV testing was performed following spontaneous patient request, routine physician recommendation, or on a targeted basis.
- Secondary endpoints:
 - Screening rate of population with unknown HIV status consulted during the study period,
 - Screening circumstances and reasons for the choice of the screening method,
 - Investigators satisfaction regarding RHT and problems encountered

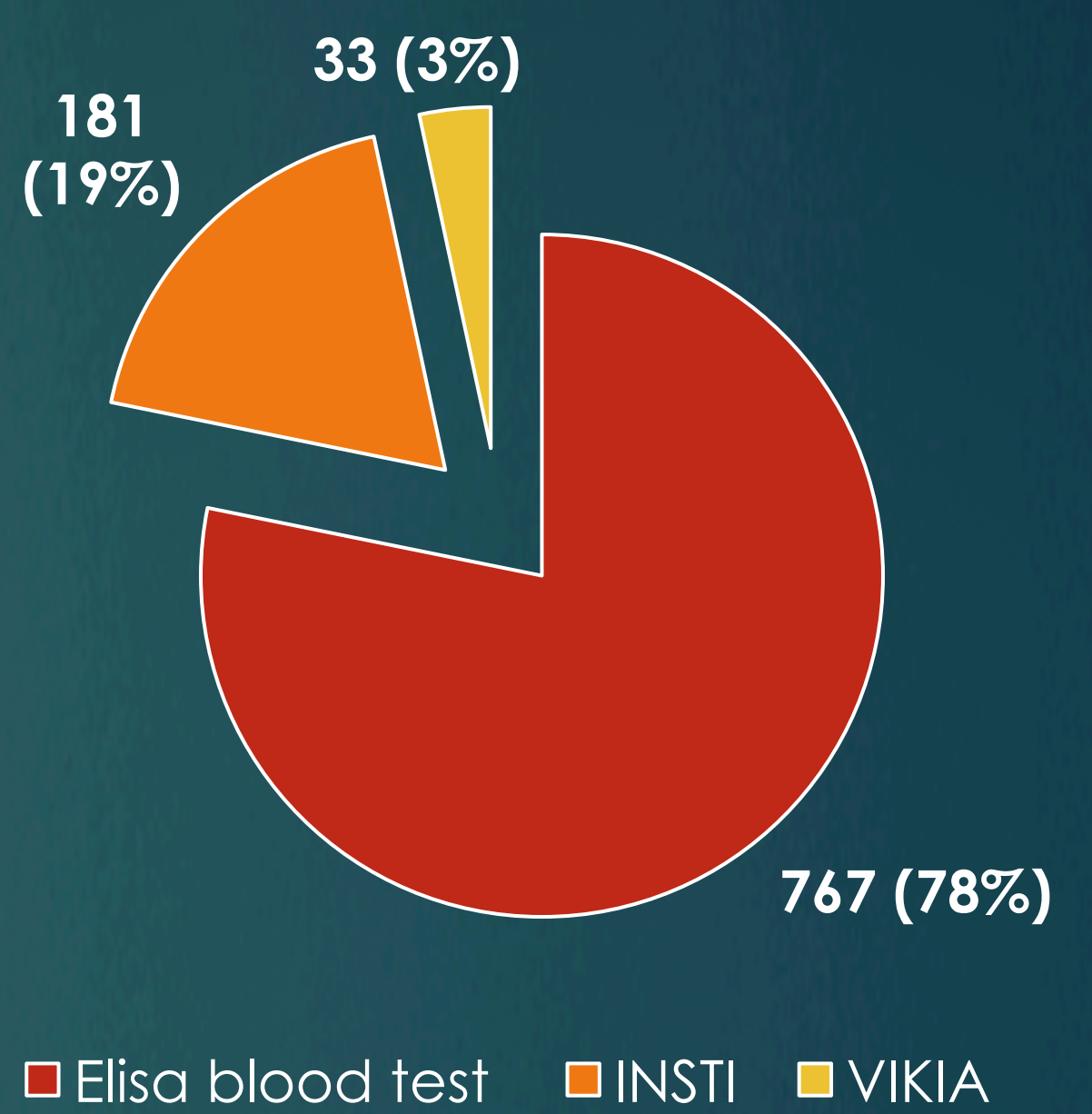


VIKIA

INSTI



Use of each screening method



Investigators

43 GPs, mean age 46 years old,
48.8% women,
One-third in practice since 2009

Medical activity of the GPs	N= 43
Practice area	
Urban area	38 (88.4%)
Suburban area	4 (9.3%)
Rural area	1 (2.3%)
Part time clinic hours	
Yes	17 (43.6%)
No	22 (56.4%)
UNK	4
No of patients attending their practice last month	
Total no of respondents	36 (83.7%)
Mean (standard deviation)	318.5 (125.7)
No of HIV+ adult patients attending their practice last month	
Total no of respondents	37 (86%)
Mean (standard deviation)	18.0 (38.2)
Total no of HIV+ adult patients being followed by the GP	
Total number of repondants	36 (83.7%)
Mean (standard deviation)	55.3 (119.1)

UNK – unknown

Patients demographic characteristics and screening data

Population: screened attending patients with unknown HIV status.	Elisa Blood Test n= 767 (78.2%)	RHT n=214 (21.8%)		Total n=981(100%)	p-value
		Vikia n=33	INSTI n=181		
Gender					
Female	433 (56.5%)	102 (47.7%)	535 (54.5%)		0.0224 (e)
Male	334 (43.5%)	112 (52.3%)	446 (45.5%)		
Age (years)					
Mean (SD)	34.8 (12.0)	33.7 (11.9)	34.5 (12.0)		0.2431 (b)
Previous HIV screening history?					
Yes	499 (67.3%)	154 (72.0%)	653 (68.4%)		0.2003 (e)
No	242 (32.7%)	60 (28.0%)	302 (31.6%)		
UNK	26	--	26		
Date of previous HIV test					
1983-1993	3 (0.6%)	4 (2.7%)	7 (1.1%)		
1994-2004	28 (7.0%)	10 (6.9%)	38 (6.2%)		
2005-2009	70 (15.0%)	12 (8.1%)	82 (13.3%)		
2010-2014	368 (78.4%)	121 (82.3%)	489 (79.4%)		
Who initiated the screening procedure?					
GP	469 (62.0%)	51 (23.9%)	522 (53.7%)		
Patient	71 (9.4%)	61 (28.6%)	132 (13.6%)		
Both	216 (28.6%)	101 (47.5%)	317 (32.7%)		<0.0001 (e)
UNK	11	1	12		
Reason for HIV screening.					
Routine test	557 (75.0%)	123 (60.3%)	680 (71.8%)		
Risk factor	159 (21.4%)	77 (37.7%)	236 (24.9%)		<0.0001 (e)
Clinical signs	27 (3.6%)	4 (2.0%)	31 (3.3%)		
UNK	24	10	34		

UNK – unknown; (b) Student Test, (e) CHI2 Test

HIV test results

Test results	Elisa Blood Test n=767 (78.2%)	RHT n=214 (21.8%)	TOTAL n=981 (100%)
Positive	5 (0.7%)	4 (1.9%)	9 (0.9%)
Negative	641 (83.6%)	203 (95.3%)	844 (86.0%)
Invalid	--	6 (2.8%)	6 (0.6%)
Unrecovered	120 (15.7%)	0	120 (12.5%)
UNK	1	1	2

UNK – unknown

9 newly diagnosed HIV infection (NDHI):

- 7 men and 2 women,
- Mean age: 37 years old,
- Tested after GPs' offer or in mutual agreement with patient,
- Mainly after targeted screening: 4 MSM and 5 migrants, 2/3 had previous screening history,
- With potentially HIV clinical signs (4/9) and comorbidities (2 with chronic HBV and one with chronic HCV).

The 3 patients with medical history and regular follow-up for chronic hepatitis were diagnosed by RHT point of care.

All NDHI were confirmed and all patients were linked to care.

NDHI were done by 5 GPs, in cities of Paris, Toulouse, Lyon and Marseille:

- 4 GPs have part time clinic duty in the follow-up of patients suffering from chronic viral infections,
- Mean number of patients HIV+/month during the study ~ 78,
- Screening rate – 3% (3 times higher than the global study screening rate).

Reasons for choosing Elisa blood test or RHT :

- < 3 months HIV exposure: 19% of Elisa blood tests vs 25% of RHT.
- Possible HIV primary infection or HIV clinical signs: 2.9% of Elisa blood tests and RHT.
- Opportunity to combine blood tests: 85.8% of Elisa tests.
- Opportunity of performing an RHT: 68.4% of RHT.
- Rapidity of test result: 43.4% of RHT.
- Certainty of having the test done and the result delivered: 15.1% of RHT.
- Fear of venous blood sampling: 11.8% of RHT.

Conclusions

- Giving GPs several HIV testing methods led to significant screening activity.
- Elisa blood test was the most frequently chosen screening method, mainly by physicians, in order to combine with other blood analysis.
- RHT were done primarily on patient demand or after collective agreement.
- RHT INSTI was preferred due to its rapid result delivery.
- Most of the tests were routine screening procedures.
- 28.2% were targeted
 - mainly based on HIV risk factors,
 - in lesser degree on HIV clinical signs.
- A significant part of RHT (~40%) was performed in targeted screening .
- The significant part of the unfulfilled Elisa blood tests emphasizes RHT point of care as an alternative screening tool.

9 new diagnoses of HIV infection were made (0.9% of 981 tests):

- By RHT as well as Elisa blood test;
- After targeted screening: MSM and migrants;
- 5 diagnosed in Toulouse in « an acces to care » GPs practice;
- By 5 GPs, among whom, 4 are frequently confronted with HIV epidemics.

One third of GPs are aware of the importance of HIV screening:

- The role of additional medical intervention in follow-up of HIV positive patients;
- Recent office practice after 2009 (year of the release of the current guidelines by National Health Authority) ~ more up to date.

Rapid HIV tests used by GPs working in high HIV prevalence areas in France:

- Are a useful screening tool that expand on the repertoire of HIV tests,
- Are well-accepted by MDs,
- Allow the diagnosis of new HIV infections.

They should be considered and promoted by healthcare authorities.

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³ Professeur Philippe Morlat, CNS et ANRS. Prise en charge médicale des personnes vivant avec le VIH. Actualisation 2014 du rapport 2013 112 p. Online: http://www.sante.gouv.fr/IMG/pdf/experts_vih_actualisations2014.pdf.

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