



# Change in deferrals for men who have sex with men: Assessing the risk of HIV transmission by transfusion

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# Plan

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Part I: HIV epidemiology among MSM in France

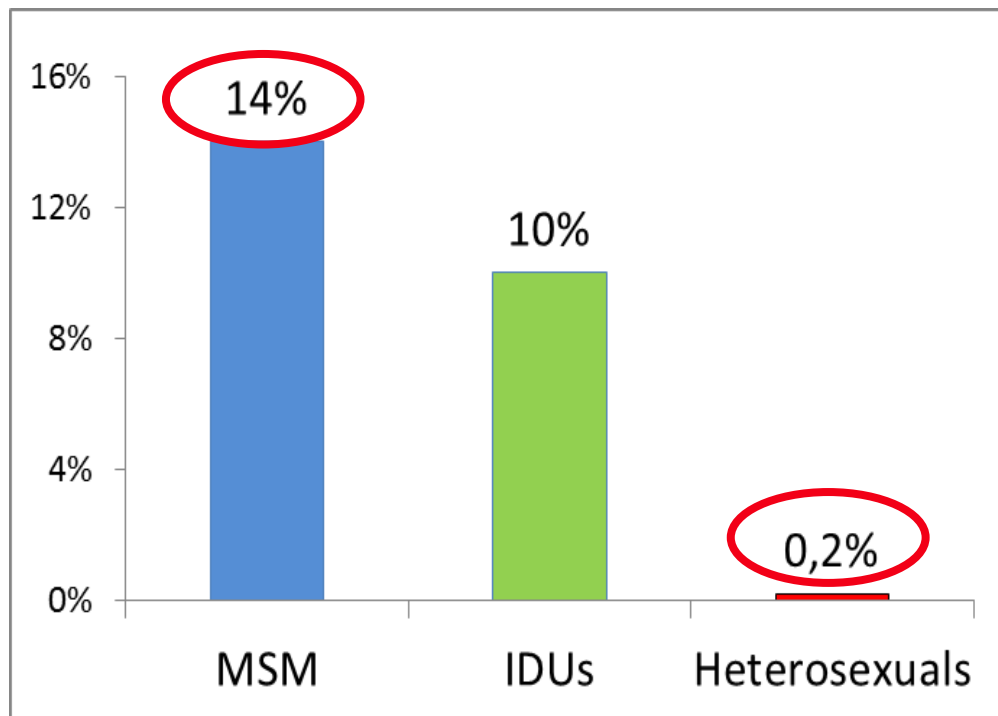
Part II: MSM and blood donations – HIV risk assessment

Part III: Monitoring the change in the blood donor selection criteria

# Part I: HIV epidemiology among MSM in France

## HIV prevalence

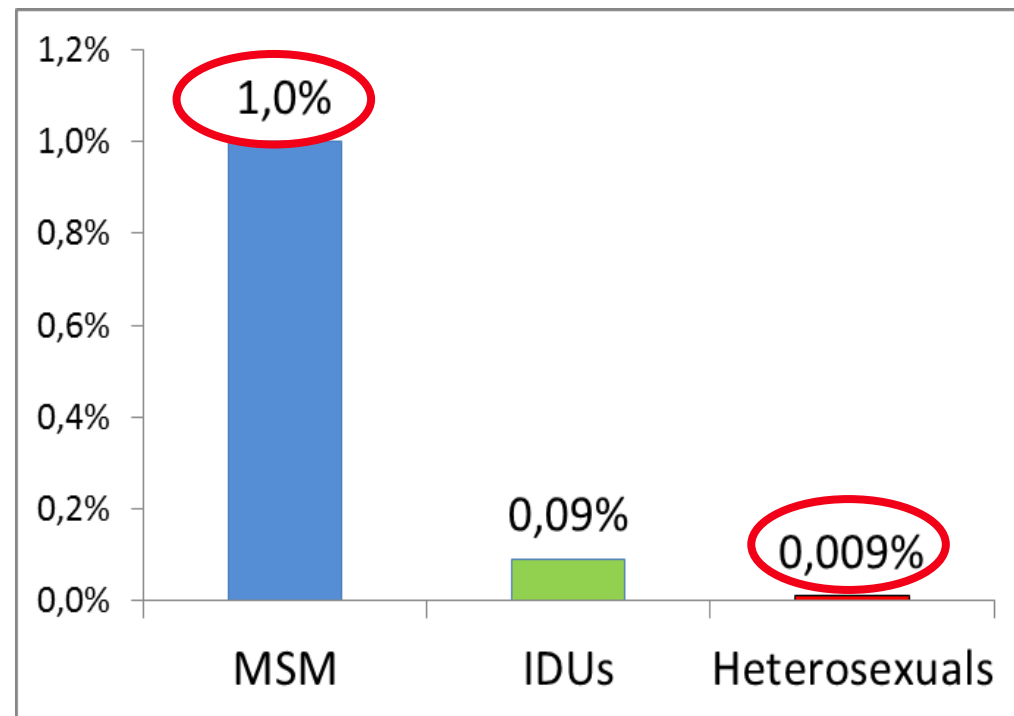
➔ 70-fold higher than in heterosexuals



Source: InVS - 2015

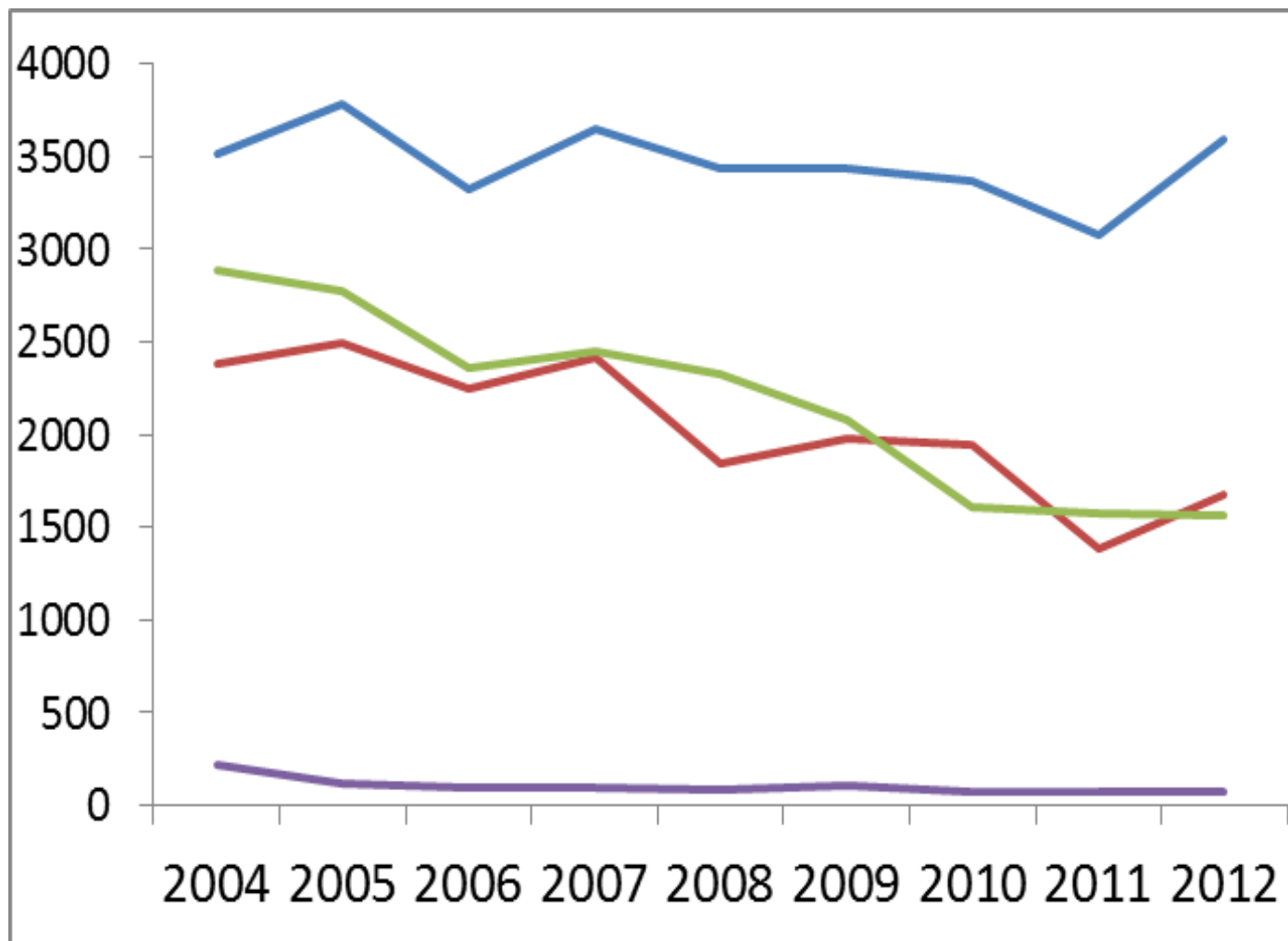
## HIV incidence

➔ 115-fold higher than in heterosexuals



Source : S. Le Vu et al. Lancet Inf. Dis. 2010

# HIV incidence trends per transmission category France, 2003-2012



MSM

French-born heterosexuals

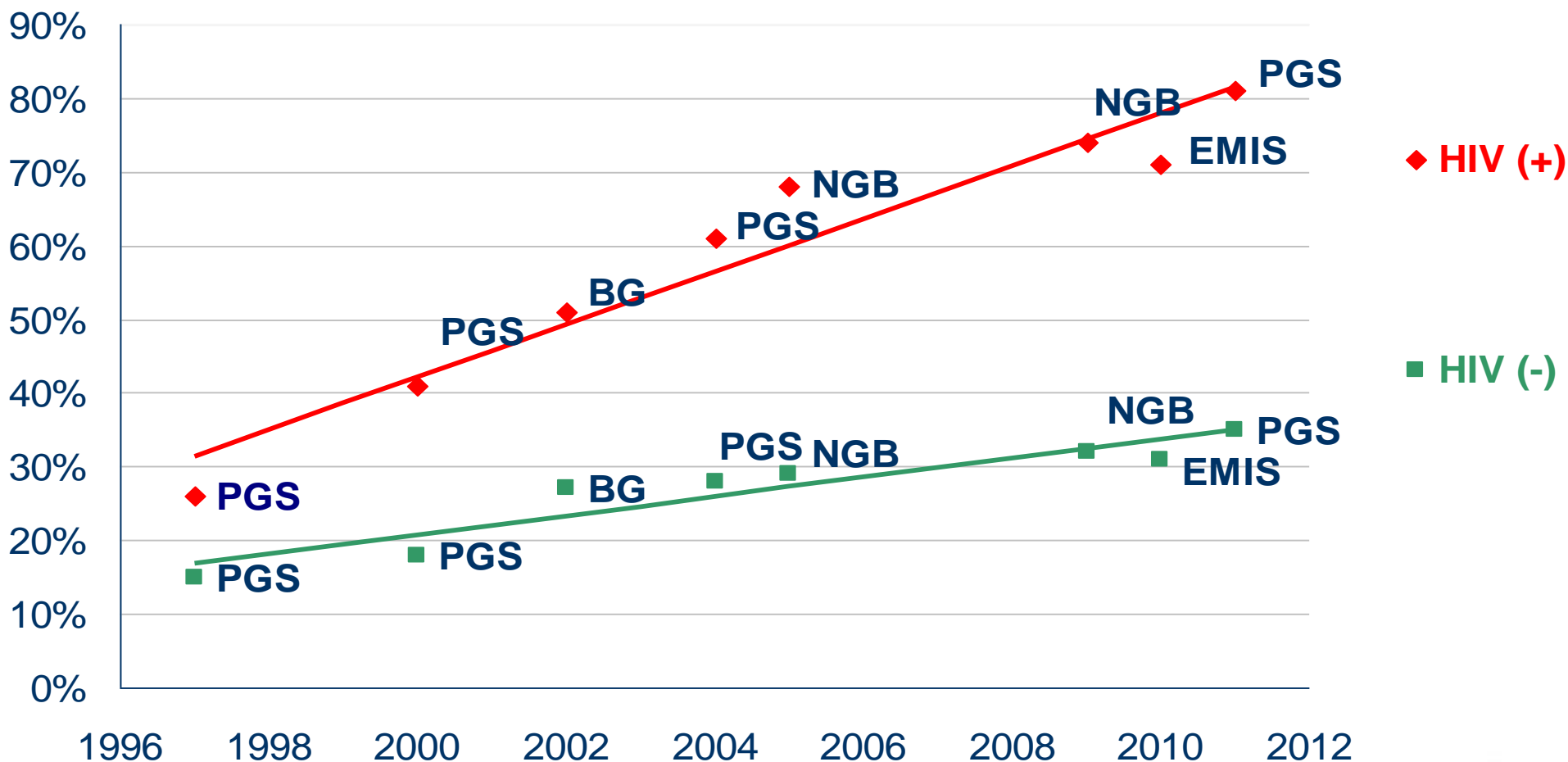
Foreign-born heterosexuals

IDU

Source : S. Le Vu et al. *Lancet Infectious Dis.* 2010 – Update until 2012

# Sexual behaviours of MSM: risk increases

At least one unprotected anal intercourse with a casual partner within the last 12 months



PGS: Press Gay Survey - BG: Baromètre Gay – NGB: Net Gay Baromètre - EMIS : European MSM Internet Survey

# Part I: conclusion

- ➔ MSM is the most affected population by HIV compared to other populations
- ➔ HIV transmission remains very high among MSM
  - 3 600 new infections in 2012, which corresponds to 1% incidence
  - Incidence does not decrease between 2003 and 2012
  - Sexual risk behaviors increase over time...
- ➔ In this context, the decision to change the criteria of blood donor selection for MSM was not easy....

# Part II: MSM and blood donations

## HIV risk assessment

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### Background

In France MSM have been permanently excluded from blood donation since 1983

- This selection criterion is the subject of debate and controversies
- This measure is not fully respected since some men do not report, during the pre-donation interview, they have had sex with men

➔ May to November 2015: Consultation of stakeholders organized by the Ministry of Health

**Results of HIV risk assessment made in that context are presented here**

# Objectives of the HIV risk assessment

- 1 - To estimate the fraction of risk of HIV transmission by transfusion associated with the lack of compliance of MSM with the current criterium (permanent deferral) and to estimate the rate of non compliance
- 2 - To assess the impact on the residual risk of HIV of two strategies
  - **1<sup>st</sup> strategy:** Men would donate blood and be deferred if they report more than one male sexual partner in the last 12 months\*
  - **2<sup>nd</sup> strategy:** Men would be deferred for 12 months after the last sexual contact with a man.

\* Pillonel et al. Vox Sanguinis 2011



# Current residual risk of transmitting HIV by transfusion France, 2011-2013

HIV Residual Risk = HIV Incidence Rate among repeat blood donors  
x (Window Period/365)

HIV incidents cases 2011 to 2013	Number of Donor-Years	Incidence rate per 10 <sup>5</sup> D-Y (95% CI)	Window period (in days)	HIV Residual Risk (95% CI)
24	2,710,846	<b>0.89</b> (0.58 – 1.34)	12	<b>1/3,450,000 donations</b> (0 - 1/11,000,000)

→ This corresponds to less than one donation infected with HIV per year in France

# Fraction of the current HIV residual risk attributed to MSM France, 2011-2013

Of the 24 HIV incident cases observed during the study period: 22 men, 2 women

During the post-donation medical interview, the mode of contamination was identified:

- 15 MSM
- 9 heterosexuals (7 men, 2 women)

- Despite the permanent exclusion of MSM: two third (15/24) of the HIV residual risk is attributable to MSM who do not comply with the permanent deferral
- Therefore, if all MSM had abstained from donating blood during the study period, the risk would have been 1 in 9,000,000 donations, a 2.6 fold reduction in the residual risk (1/3,450,000).

# Assessment of the rate of non-compliance of MSM with the permanent deferral France, 2011-2013

## 1 – Non-compliance of MSM donors found to be HIV positive

Non-compliance rate =  $\frac{\text{\# of HIV infections among MSM new donors}}{\text{\# of MSM living with HIV, but undiagnosed}}$  =  $\frac{5 \text{ (on average each year)}}{9200^*}$   
**(first-time donors)**

→ MSM non-compliance rate for new donors = 0.054%

Non-compliance rate =  $\frac{\text{\# of new HIV infections among MSM repeat donor}}{\text{\# of new HIV infections among MSM but undiagnosed}}$  =  $\frac{7 \text{ (on average each year)}}{2220^{**}}$   
**(repeat donors)**

→ MSM non-compliance rate for repeat donors = 0.32%

## 2 - Non-compliance of MSM calculated over the entire male blood donor population

**Best-case scenario:** Non-compliance of HIV neg MSM = Non-compliance of HIV pos MSM → **0.36%**

**Worst-case scenario:** MSM give blood at the rate of the male general population → **3.75%**

→ "Truth" is between the two, with a central value for the rate of 2.1%

\* Supervie et al. AIDS 2014 \*\* From HIV case reporting InVS

# Non-compliance in other countries

(surveys among blood donors)

Author	Journal	Year	Country	Study period	N	% of non-compliance	
						lifetime	≤ 12 months
Sanchez	Transfusion	2005	US	1998	25,168 men	2.4%	0.4%
Goldman	Transfusion	2011	Canada	2008	18,108 men	1.4% in FTD 1.0% in RD	0.5% in FTD 0.1% in RD
Custer	Transfusion	2015	US	2013	3,183 men	2.6%	-
Romeijn	ISBT	2015	Pays-Bas	2014	18,137 men	1.4%	-
Seed	Vox Sang	2014	Australia	2012-13	14,473 men	-	0.23% 0.16% in FTD 0.24% in RD
Davison	ISBT	2015	UK	2013	65,500	-	0.4%

FTD = first time donors, RD = repeat donors

Non-compliance rate to lifetime exclusion in France 2011-13: **2.1%** [0.36%-3.75%]

# Impact of the 1<sup>st</sup> strategy in which men would only be deferred if they have had more than one male sexual partner in the last 12 months

(estimates updated from Pillonel et al Vox Sanguinis 2011)

2011-2013 Period	# of HIV incident cases	Residual Risk		% of variation	
		1/n donations	# of HIV+/year		
Current estimate	24	1/3,450,000	< 1	—	
Other donors only (Current less 15 MSM)	9	1/9,000,000	~ 0.3	- 62 %	
<b>Risk impact</b>	<b>Best-case scenario<sup>1</sup> (9+12)</b>	<b>21</b>	<b>1/3,900,000</b>	<b>~ 1</b>	<b>- 13 %</b>
	<b>Worst-case scenario<sup>2</sup> (9+108)</b>	<b>117</b>	<b>1/700,000</b>	<b>~ 4</b>	<b>X 4,5</b>

<sup>1</sup> HIV incidence among MSM = 0,07% (Blood donors) <sup>2</sup> HIV incidence among MSM = 1% (general population of MSM)

## Impact of the 2<sup>nd</sup> strategy in which men would be deferred for 12 months after the last sexual contact with a man (2011-2013)

- If compliance to this strategy was perfect, the HIV residual risk attributable to MSM would be zero (1 year > duration of the silent window period)
  - **HIV residual risk = 1/9,000,000**
- Using published estimates of non-compliance among repeat donors: 0.1%\* to 0.4%\*\*

This strategy would result in an overall HIV residual risk :

from **1 in 6,000,000 donations (with 0.1%)** → **1.7 times lower than the current risk**

to **1 in 3,300,000 donations (with 0.4%)** → **close to the current risk**

\* Goldman et al, *Transfusion* 2011 \*\* Sanchez et al, *Transfusion* 2005

## Part II: conclusion (1)

→ Two third of the current risk was attributed to MSM

This result was supported by HIV NAT yield observations (2001 to 2014):

19 of the 21 donors found HIV-RNA positive/HIV-Ab negative were men, of whom more than half were MSM (10 MSM / 6 heterosexuals / 3 unknown)

→ These findings raised the question of changing the permanent deferral for MSM in France

## Part II: conclusion (2)

- Changing to a temporary deferral for MSM who report more than one male sexual partner in the last 12 months, would probably increase the risk of transfusion-transmission of HIV
- However, this estimate does not take into account a change in compliance of MSM linked to a modification of the deferral criterion
- As some MSM currently consider “life-time deferral” discriminatory, they give blood while hiding their sexual orientation
- A less stringent criterion could perhaps be perceived to be more equitable and could enhance responsibility
- As it was not possible to verify this hypothesis, the health authorities have not retained this proposition



## Part II: conclusion (3)

- A change from lifetime exclusion to 12-month deferral after the last male-to-male contact does not seem to increase the risk of transfusion-transmitted HIV in France
- Thus, this last criterion has been chosen in agreement with a large majority of stakeholders: November 4<sup>th</sup> 2015, the Minister of Health announced that **MSM could give blood from June 2016, provided they have not had sex with men in the last 12 months before donation.**

In addition to this 12 month criterion, MSM can donate plasma (quarantined plasma) if they have had only one partner in the last 4 months (same as heterosexuals)

Nevertheless, the impact on blood safety of these new blood donor selection criteria needs to be assessed...

## Part III: Monitoring the change in the blood donor selection criteria

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1. National surveillance of blood donors
2. Sociological survey among blood donors found HIV positive
3. Quantitative compliance survey among the blood donor population

# 1. National surveillance of blood donors

This surveillance (beginning in 1992) permits to monitor changes in blood donor selection criteria

- HIV prevalence: evolution of the number of donors found HIV+ among new donors
- HIV incidence: evolution of the number of seroconversion among repeat donors, HIV-NAT yield cases and recent HIV cases detected by the test for recent infection
- Risk factors for HIV infection (obtained during the post-donation medical interview)
- Residual risk estimates
- Fraction of the HIV residual risk attributed to MSM
- Assessment of non-compliance with the 12-month deferral of MSM donors found HIV+
- Impact on other markers (Syphilis, HBV, HCV)

## 2. Sociological survey among blood donors found HIV positive

As compliance is a key parameter, a sociological study among donors found to be HIV positive at the time of donation, was conducted in 2015

**Objective:** To explore knowledge, attitudes and motivations of donors found HIV positive

**Methods:** Qualitative interviews of 32 donors and ethnographic observations in blood donation units

This in-depth qualitative approach of the situation of donors found to be HIV positive will allow us to understand the social context of blood donation and elements leading to non-compliance

This should improve the pre-donation medical interview and, therefore, the blood safety

→ Results will be available mid-2016

→ This study could be extended after changes in blood donor selection criteria

### 3. Compliance survey among the blood donor population

#### Objectives:

- To estimate the rate of non-compliance (ie failure to disclose a risk during the pre-donation interview which would lead to deferral)
- To assess knowledge, attitudes and motivations among blood donors who appear as non-compliant with donor selection criteria
- To assess the attitude of donors in case of shortening the deferral length for MSM (6, 4 months)

#### Methods:

- Anonymous, unlinked online questionnaire among a representative sample of donors
- Invitation to donors by email with URLs for information web page and questionnaire
- Information for donors on InVS website

→ Implementation of the study in 2017

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