

PRoF Award abstract – Call 2015

Swab 2 Know :

Low threshold online HIV testing

1. Research Outline

Acronym	S2K
Project name in English	Swab 2 Know
Pitch (1 sentence)	Developing an HIV-testing strategy using oral fluid samples and online communication of test results for high risk populations in Belgium.
Executive summary (max. 10 lines)	<p>We implemented an innovative HIV test strategy in order to decrease the burden of undiagnosed HIV infections among males who have sex with males and sub-Saharan African migrants. The HIV test was performed on oral fluid. Participants chose either to have a test package sent to a Belgian address of their choice or to provide a sample during an outreach session. The results of the tests were made available on a secured website. This website was also meant to provide information on HIV and sexually transmitted infections (STI). All participants with a reactive result were invited to undergo a confirmation test for HIV. Emergency phone counselling is provided to the participants with reactive results. Linkage to care for participants with confirmed HIV infection was ensured by follow-up by phone contact.</p>

2. Cause and context of the research

The number of new HIV infections remain each year worryingly high in Belgium. Men who have sex with men (MSM) and sub-Saharan African migrants (SAM) are the two most represented groups in the population of persons with newly detected HIV infection. According to the last report from the Institute of Public Health, these two groups account for nearly 60% of all new HIV infections in Belgium

The prevalence of HIV infection in these two groups is also much higher than in the general population. Recent research in Flanders found HIV prevalence rates among MSM varying from 1,5% to 14.5% according to the setting. 15% of them were previously unaware of their diagnose. It is estimated that this undiagnosed population is mostly fueling the HIV epidemic and should be the target of increased detection strategies. Beside raising awareness to test, it is also important to design alternative testing strategies that will be able to pick up those previously undiagnosed HIV infections. Allowing early diagnosis of HIV infection is not only important for the individual (early start of antiviral treatment and thereby less evolution to AIDS phase) but also for the public health. It is much more difficult to transmit HIV among persons where the infection is under control.

Voluntary counselling and testing is the classical strategy to detect HIV infection. Nevertheless several barriers to HIV testing have been described (Deblonde J, Eur J Public Health 2010). Therefore alternative strategies should be explored especially among the high risk groups. These include rapid tests, community based testing, self-testing etc...

This project has been developed against this background to improve HIV detection in high risk group with specific emphasis on linkage to care for newly diagnosed HIV infections.

3. Innovation results achieved

Our project started with the modification of a classic ELISA test used for the detection of HIV infection in blood samples. Our team developed and validated a method to use this test on oral fluid (Fransen K. J Virol Methods 2013).

The swab2know project is proposing this test as a self-sampling strategy (the participant takes his/her own sample) where the test is still performed in the laboratory. A specific research protocol has been written. This protocol has been approved by the Institutional review board (IRB) of the Institute of Tropical Medicine and by the Ethical Committee of the University Hospital of Antwerp. This project has also been reviewed and endorsed by the “Vlaams Agentschap Zorg en Gezondheid - Team Preventie” for population research (“bevolkingsonderzoek”).

The oral fluid sample can be collected either at home or during outreach sessions. In the home sample option, the participant order a test package on the website and send the sample back to the laboratory with the provided prepaid envelope. We also offer tests during outreach sessions where a team of outreachers visit venues and propose the test to visitors on the spot. All tests are performed at the AIDS reference laboratory of the Institute of Tropical Medicine. A quality control is performed beside the HIV test, it consist of a measure of immunoglobulins to ensure the sample is effectively oral fluid. After validation, the result of the test is uploaded on a secured website within the five workdays, the participant can recollect the result with a personal account and the unique sample code. The website is monitored to ensure that the participants are picking up their results. When participants do not pick up their results after several days, they are motivated to do so by standardized text and mail messages. In case of a positive results the participants is called within 24 hours of collecting the result to offer emergency counselling and answers question. The participants are motivated and guided to undergo a confirmation test on blood.

In the last two and half years we performed 1912 tests. 975 tests were requested online through the website, 98% of the participants collected their results. 987 tests were collected through outreach activities, 83% of the participants collected their results.

Here follows an in-depth analysis of the tests realized among the MSM group. Those data have recently been submitted for publication. The data of the SAM group are currently under review and will be soon thoroughly analyzed.

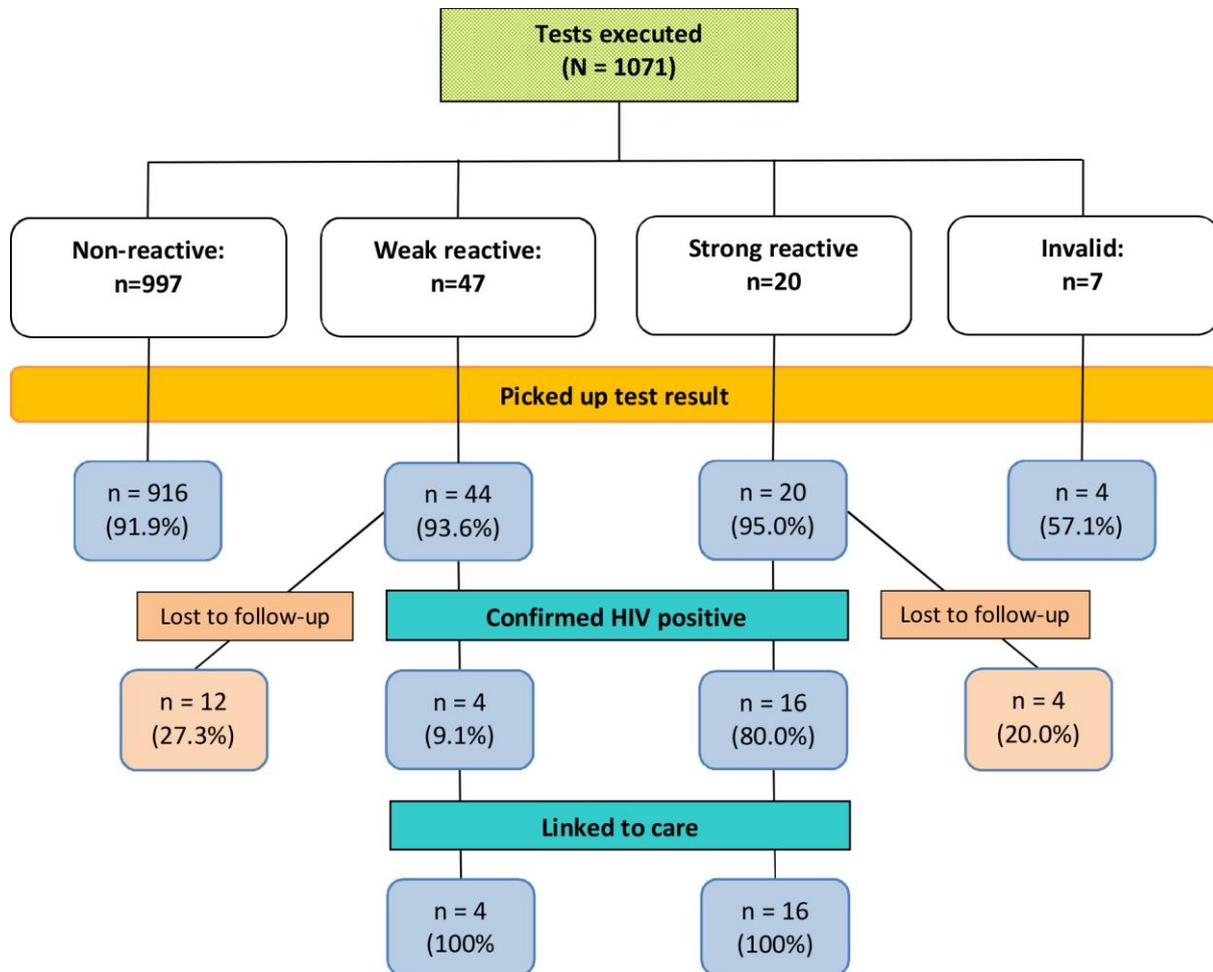
Data from 1071 tests from 898 MSM were used for this analysis. 430 samples (40.2%) were ordered online by 289 participants. 641 samples (51.6%) from 609 men were collected during outreach sessions. These sessions were organized in sauna's/bathhouses (5 sessions), fetish scene (4 sessions), dancing/discotheque (8 sessions), during World Outgames in Antwerp targeting athletes and supporters (3 sessions), and other gay events (3 sessions).

Description of the participants:

	Online (N = 430)	Outreach (N = 641)	P-value
Age (mean 95% CI)	34.3 (33.4 – 35.3)	33.4 (32.5 – 34.3)	.25
Sexual contacts with n(%)			.07
Men	397 (92.3)	524 (91.0)	
Men and women	30 (7.0)	52 (9.0)	
Women *	3 (0.7)	0 (0.0)	
Having a GP n (%)	389 (90.5)	558 (87.2)	.10
Never tested for HIV n (%)	43 (10.0)	111 (17.3)	.001
Number of sexual partners in past 3 months mean (95% CI)	3.23 (2.75 – 3.70)	7.18 (6.10 – 8.26)	<.001

* All participants reporting sexual contacts with women answered 'transgender' on the question for gender

Flowchart of the main study result:



Overall, 20 participants were known to be confirmed newly diagnosed with HIV, all of them were linked to care. This represents 2.2% of all participants tested (n=898). Six newly diagnosed participants ordered their sampling kit online which put the new HIV infection rate in this group at 2.1% (6/289 participants); while 14 were detected during outreach sessions (new HIV infection rate: 2.3%; 14/609 participants). This difference is not statistically significant ($p=0.83$).

An additional benefit of the project was that three partners from participants were newly diagnosed with HIV.

Of the 983 participants who collected their test results, 388 (39.5%) filled in a post-test survey. The vast majority of them (371; 95.6%) reported being very satisfied with the process while 17 (4.4%) experienced mixed feelings taking part in the project. Whereas 48 (12.4%) reported they would consider taking part again, most of the respondents (n=337; 86.9%) reported they would do so without any doubt. Three respondents (0.8%) reported

that they would 'not to participate again' in the future. One had been diagnosed with HIV through the project, which makes future participation redundant.

This first analysis shows encouraging results with a high level of satisfaction from the participants in this project. Above all we were able to diagnose a high number of new HIV infection with this method. And all newly infected patients have been successfully linked to care and put under regular follow-up.

To our knowledge this approach of combining self-sampling, HIV test on oral fluid and result delivery through a secured website is unique. We are aiming to extend this methodology in other countries through an European project aiming at improving early diagnosis of HIV infection among high risk groups (<https://eurohivedat.eu/>).

We are thinking of several possible improvements for this project depending on funding. We consider adding testing for other STI's beside HIV, eg hepatitis C virus on oral fluid or Chlamydia trachomatis/Neisseria gonorrhoea on genital self-samples. The development of an automated counselling and risk assessment tool on the website will allow a better selection of the participants and better information delivery. The development of an app or a mobile website would allow to reach participants through mobile phone.

4. Link to the PRoF values

- a) **Minimal comfort:** in this project, attention has been put to decrease as much as possible the burden of the HIV test for the participant. The test is non invasive (oral fluid), is performed at the request of the participant (self-sampling at home or during outreach activities). The result is picked up by the participants through a website at their best convenience.
- b) **Privacy:** respecting the privacy of participants is an absolute requirement for this project. By disclosing the result of the test on the website, the initiative is left to the participant to collect the result. He/she can do this in respect of his/her privacy. Although the privacy of the participants is protected, the project does not allow full anonymity. We link the participant account with an e-mail address and we ask a phone number in order to allow follow-up if needed.
If the participant order a test by internet, he/she has to disclose a name and address in order to deliver the test package. In order to increase privacy and avoid the package to be sent to an address, test packages are also available and distributed through our partners (see below).
- c) **Security:** The data are not stored on the website but in two separate databases. On one side the participant identifier and on the other side the test results. The website is secured by means of the Secure Sockets Layer-protocol, and holds a security certificate provided by Belnet. The level of security is comparable to PC banking.
- d) **Anti-loneliness:** This aspect is not straightforward in our project. Performing self-sampling may be seen as a lonely act. Moral distress may occur when a participant learns the test result by consulting a secured website. We monitor the pick up of all reactive results on the website. The nurse of the study, a social nurse by training and proficient in counselling HIV positive patients, calls all participants with a reactive result within 24h of result pickup. This allow to reduce the potential burden of having to cope alone with the consequences of a reactive test. This is also much appreciated by the participants and leads to a high number of participants undergoing a confirmation test and a high linkage to care for the participants with a confirmed HIV infection.
- e) **Non stigmatising solutions:** Targeting risk populations may seem stigmatising in some way. We absolutely want to focus on the two target groups of MSM and SAM in this project. Our website is designed in a way to inform potential visitors on HIV and STI's and the importance to get tested for these conditions. The HIV test is dedramatized, several test options are presented beside the oral fluid test.
- f) **Inter generational:** this project is targeted to specific populations (SAM and MSM) not to a specific age category. Attention has been put to develop a tool requiring a minimum of health and computer literacy.
- g) **Respect:** this project has been developed in way to respect the autonomy of the participant. The website has been developed to disclose information in a non-judgemental way. The participant may decide for whatever reason no to collect their result on the website. Our project is followed up closely by the IRB of the Institute of

Tropical Medicine. Because of the potential ethical issues, in relation with most of the PRoF values, we provide six-monthly report to the IRB.

- h) **Flexibility**: it is obvious that this aspect is one of the major asset of the project. Several options are presented to the participants. Either they choose to have a test package to be sent to a Belgian address of their choice. Either they choose to be tested during an outreach session (date and place disclosed on the website and through partners). In both test modalities the result is made available on the website within five workdays. The participant decide when and where they consult the website to pickup their result.

5. Applicable IPR rules

At the moment there are no IP issues raised in this project. The project is also currently developed as a research protocol and not as a commercial project.

The adaptation of the HIV test from blood to oral fluid sample has been made on the basis of a commercially available assay. The method used to adapt the test has been described in a scientific publication in order to allow other research groups to reproduce the test.

The website has been developed with commercial softwares by our IT partners.

The swabs used to collect oral fluid are commercially available (Oracol® MMD, Worcester, England).

The domain names “swab2know.be” and “swab2know.eu” have been registered.

6. Information on the partners

- a) Institute of Tropical Medicine,
 - The AIDS reference laboratory (ARC), Department of Clinical Sciences. They developed and validated the oral fluid test. They perform the HIV tests on oral fluid within this project.
 - The AIDS reference center (ARC), Department of Clinical Sciences. They are coordinating the project and ensure the daily administrative processing of the test requests (both online requests and outreach sessions). They are responsible for the linkage to care of the participants with reactive results.
 - The HIV-SAM project is responsible for the contact with the SAM population. They take care of the outreach sessions in this population.
 - The IT department is in charge of the technical aspects of the project.

- b) All Directions (www.alldirections.be), a Flemish SME specialized in database and internet applications, realized the website interface and the project databases together with the IT department of the Institute of Tropical Medicine.

- c) Sensoa (www.sensoa.be), the Flemish expertise center on STI and HIV, has contributed to the development of the project, is in charge of the contacts with the MSM population. They are providing support for the outreach sessions in this population.

- d) Boysproject (<http://www.boysproject.be/>) is organising test sessions in their walk-in house for male commercial sex workers and during outreach session in this population.

- e) The Health Services of the Flemish Brabant Province is distributing swabs through a network of MSM organisations in their province.

- f) The City of Antwerp is providing financial support



Addendum: Contact information

Eric Florence, MD, PhD

Department of Clinical Sciences

Institute of Tropical Medicine

Nationalestraat 155

B-2000 Antwerpen

Tel: +32-3-2476465

eflorence@itg.be