Alternative HIV testing strategies: are we ready?

J. Deblonde
BREACH symposium
27th November 2015
HIV TESTING
KNOWING YOUR HIV STATUS
Outline

- State-of-the-art testing strategy
- HIV services
- HIV testing figures
- International recommendations

- Are we ready for … ?
  - Decentralised & demedicalised HIV testing
  - HIV self-testing
State-of-the-art testing strategy

I. Immunoassay (mostly type ELISA)
   - Screening for antibodies
   - & screening for antigen, if 4th generation test
   - On venous blood
   - In a clinical laboratory

II. If reactive, then a confirmation strategy in an Aids Reference Laboratory
As an alternative …

I. Simple and rapid antibody screening assay
   - Point-of-care test
   - 3rd generation test – window period: 3 months
   - First screening result
   - Venal puncture, a finger prick or a mouth swab sample

II. Reactive rapid test needs a confirmation strategy ~ the state-of-the-art HIV testing strategy
HIV testing services

- General practitioners and specialists
- 3 screening centres – Antwerp, Brussels, Liège
  - For specific groups: free and anonymous testing
- Decentralised HIV testing projects
  - Collaboration NGOs, CBOs & ARC/ARL
HIV testing in Belgium: some figures

• High and relatively stable testing rate
  ○ 2014: 697,684 tests
  ○ 62 tests per 1000 inhabitants

• More testing in the 25-34 age group
  ➢ 164 tests per 1000 inhabitants

• More testing among women
  ➢ 73 tests per 1000 women versus 51 tests per 1000 men

• GPs versus specialists: each +/-50%
International recommendations 2015

- WHO guidelines on HIV testing services
- ECDC evidence brief on HIV testing in Europe

• Diagnosing the undiagnosed & linkage to care = priority

• Diversification of HIV testing services
  o Clinical settings
  o Non-clinical settings – trained lay providers
  o Self-testing
Definition and rationale

• Testing in non-clinical settings:
  o Bars, parties, schools, workplace …

• To reach those who may otherwise not test for HIV

• Rapid test (3\textsuperscript{rd} generation) – first screening

• Cost-effectiveness
  o Key-affected populations
  o Geographic areas with largely undiagnosed HIV infection

• Involvement of non-medical staff = lay providers
HIV test on another person = medical act

KB (AR) nº78 from 10/11/1967: performing an HIV test on another person is a medical act:

- can only be done by a medical doctor
- with the informed consent of the patient (based on Law from 22/08/2002 on Patients Rights)
Quid decentralised & demedicalised HIV testing?

- The law allows for **decentralised** HIV testing
  - A medical doctor **can perform** a test outside a clinical setting
  - If the test used is in conformity with the Belgian law

- The law does not provide for **demedicalised** HIV testing
  - Advice Superior Health Council to amend the KB nº78
  - Minister of Health investigates how to adapt the law
  - Further organisation + financing = regional competence
SHC advice: what does it say?

- “Test for triage” approach: orientation test

- Implementation and evaluation
  - Overarching approach
  - Steering committee
  - Data collection

- Quality framework
  - Training
  - For both medical and non-medical actors
  - Aids Reference Centres
SELF-TESTING
Definition and rationale

• Self-test or home test

• Rapid test – first screening result

• To test self-collected specimen
  o Blood spot
  o Oral fluid

• To interpret the results without the help of trained (health) staff

• An opportunity to test discretely and conveniently
HIV self-testing ≠ medical act

The HIV self-test is intended for personal use

- KB n°78 from 10/11/1967 is not applicable

- The right to self-determination: you can perform any test on yourself!
Quality control HIV self-tests

Quality control on the commercialization of HIV self-tests in the EU:

- Directive 98/79/EC
- Belgium: KB 14/11/2011
- Notified Body tests the performance, the labelling and directions of use of the HIV self-test
CE labelled HIV self-tests

• Only HIV self-tests with a CE label can be legally sold in the EU

• Once a CE label obtained, the test can circulate freely in the EU

• On the condition that the test is accompanied by a leaflet in the respective languages of the countries where it is sold
HIV self-testing in UK and France

**United Kingdom**
- Since 6/04/2014: lawful to sell HIV self-testing kits
- 27/04/2015: launch BioSure HIV Self-Test®
- Only available to UK residents à £29.95
- Sale: hivselftest.co.uk

**France**
- 28/04/2014: launch Autotest VIH®
- 15/09/2015: available in pharmacies or through the websites of pharmacies
- Price setting: 20 à 30€
What is the situation in Belgium?

• No legal barriers for the HIV self-test
• No CE-labelled HIV self test available
• Information leaflet for health professionals & prevention associations (to be validated)
• Information for target groups
  o www.seksualiteit.be
  o www.preventionsida.org
• Belgian Competent Body for In Vitro Diagnostic Medical Product (WIV-ISP)
National HIV testing strategy

HIV Plan, action 38: need for a national HIV testing strategy covering the topics

- Who can test?
- Whom to test?
- Where to test?
- When to test?
- How to test?
- Monitoring & evaluation
Acknowledgments

Katrien Fransen (ARL Antwerp, ITM)
Anne-Françoise Gennotte (CHU Saint Pierre)
Françoise Lequarré (ARC Liège)
Thierry Martin (Plateforme Prévention Sida)
Sandra Vandeneynde (SENSOA)
WIV-ISP colleagues

THANK YOU!