2014 European Guideline on HIV Testing

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Presentation Plan

- Purpose and aim of the guideline
- What is new in the guideline and what is the rationale behind the change?
- What do we expect?

Guidelines

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2014 European Guideline on HIV testing

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Abstract

Testing for HIV is one of the cornerstones in the fight against HIV spread. The 2014 European Guideline on HIV Testing provides advice on testing for HIV infection in individuals aged 16 years and older who present to sexually transmitted infection, genito-urinary or dermato-venereology clinics across Europe. It may also be applied in other clinical settings where HIV testing is required, particularly in primary care settings. The aim of the guideline is to provide practical guidance to clinicians and laboratories that within these settings undertake HIV testing, and to indicate standards for best practice.

Purpose of the guideline

- To provide advice on testing for HIV infection in individuals aged 16 years or older who present to STI, genito-urinary (GU) or dermato-venereology (DV) clinics across Europe.

Aim of the guideline

- To provide practical guidance to clinicians and laboratories that in these settings undertake HIV testing and to indicate standards for best practice.

Changes in content

- The setting redefined
  - to include STI, GU and DV clinics
  - primary care also mentioned

Benefits and harms of HIV testing

- Emphasis on adverse effects of HIV diagnosis on sexual and risk taking behavior
- Negative implications

Benefits of HIV testing

- Early diagnosis and early onset of ART
  - Life expectancy and QoL improved[1-5]
  - Risk of HIV transmission decreased[6]
  - Sexual and needle sharing behaviors significantly reduced[7-13]

1 Kitahata MM, et al. N Engl J Med 2009

2 May M, et al. BMJ 2011

3 Kranzer K, et al. J Acquir Immune Defic Syndr 2013

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5 Soria A, Lazzarin A. J Acquir Immune Defic Syndr 2007

6 Cohen MS, et al.. N Engl J Med 2011

7 Desenclos J-C, et al. AIDS 1993

8 Kamb ML, et al. JAMA 1998

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10 Allen S, et al. AIDS 2003

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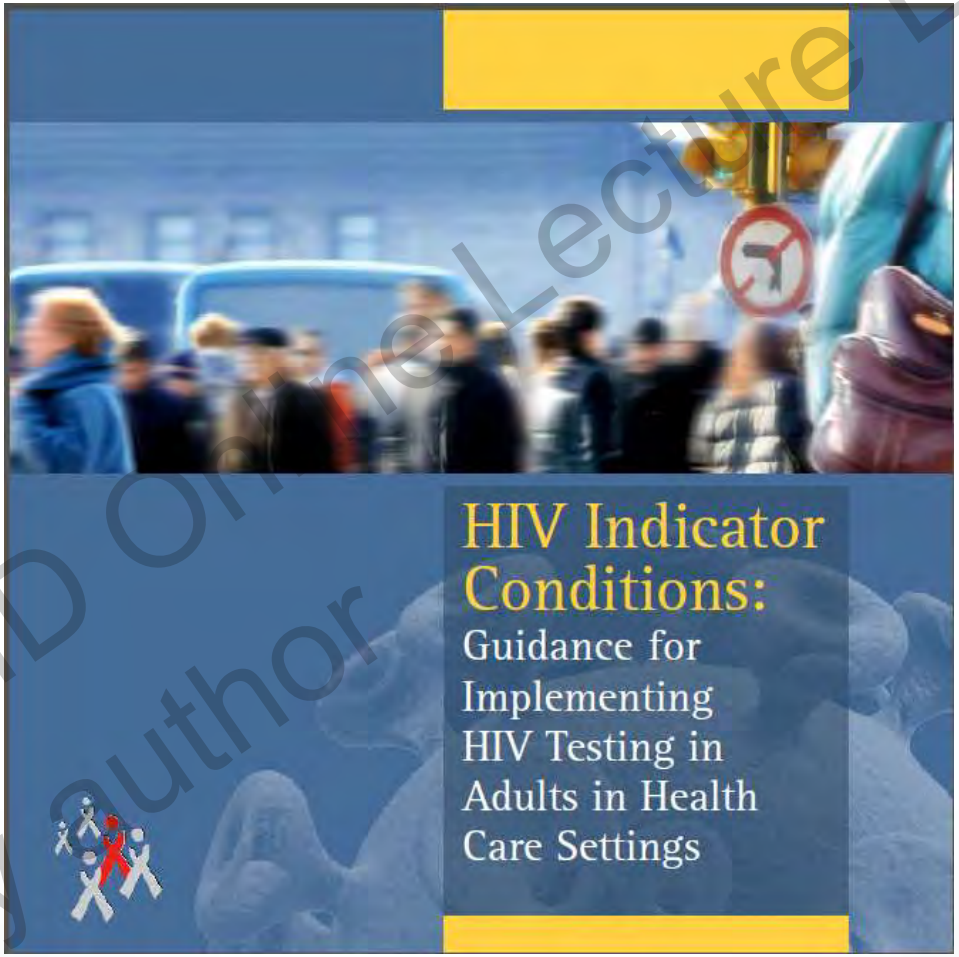

When to consider testing

- Testing frequency
  - Every 12 months seems reasonable unless specific aspects of risk behaviour warrant more frequent testing (eg. Every 3-4 mo)
  - Testing frequency should be based in part on the level of risk and requires a dialogue between the provider and the patient, which will require test history and any risk behaviours.

Pre-test Assessment

- Shortened and simplified
- Introduction paragraph
  - Importance of informed consent
  - Assessment of the window period
- Components of pretesting assessment
  - Obtain HIV testing history
  - Offer testing for other STIs
  - Offer PEPSE if indicated and available

Other Subheadings

- Individuals who may require more in-depth pretest discussion
  - Deleted
- Informed consent
- Testing without informed consent
- Confidentiality
  - the use of a number or a false name may be an option «where available» for individuals who decline HIV testing due to concerns about confidentiality

Samples

- Samples other than venous blood should be subjected to rigorous training and quality assurance

2008 Guideline

- Testing for HIV
  - Type of test
  - Confirmation of positive results
  - Quality control

2014 Guideline

- Recommendations for the laboratory
  - HIV screening and confirmatory tests
    - Screening serology test
    - Confirmation of reactive serology results
    - Confirmation of indeterminate/equivocal screening results
    - Recent HIV infection
    - Quality control

Screening serology test

- Strong emphasis on the use of fourth generation assays that simultaneously test for anti-HIV antibodies and p24 antigen as screening tests

Confirmation of reactive serology

- Confirmatory algorithms may vary. Generally they include at least one additional antibody or antibody/antigen serology test that employs a different platform from the initial screening test.
- It may be replaced by testing a plasma sample for HIV-1 RNA, provided the viral load is >1000 c/mL. In patients with a lower or undetectable VL a second serum sample should be collected for repeat serological testing.

Confirmation of indeterminate results

- False reactivity/early HIV infection
- All patients with an initial indeterminate result should undergo repeat testing 1-2 weeks later
- When there is strong suspicion of recent infection HIV-1 RNA or (in some cases p24 antigen) may be tested

Recent HIV infection

- NAATs are not recommended for screening
- Suspected primary infection but negative serology→HIV RNA testing
  - HIV RNA (+)→ Show seroconversion 1-2 wks later
  - Low RNA values→ interpret with caution
- NAATs not available/affordable→repeat serology 1-2 wks later

Quality control

- Where a national accreditation scheme is not available, testing should be undertaken only under approved (eg., CE) tests under a strict quality assurance program; quality assurance results should be made available for inspection where required.

Interpreting negative test results

1. Sickinger E. J Clin Microbiol 2004
2. Gürtler R. J Virol Methods 1998
3. Taylor D. Int J STD AIDS 2014
4. Speers D. J Clin Microbiol 2005
5. Meier T J Clin Virol 2001
6. Miedouge M. J Clin Virol 2011
7. Ly TD. J Virol Methods 2004
8. Ly TD. Virol 2012
9. Maylin S. Intervirology. 2014

- Earlier detection of HIV with 4th gen assays[1-3]
- Variability in analytical sensitivity of assays[6-8]
- Second diagnostic window[4-5]
- Recent HIV infection may be missed[9]

Interpreting negative test results

- Person received PEP
- Patient very anxious and requires further reassurance
- Impaired ability to develop antibodies
- Microbiologically proven simultaneous acute infection with another viral pathogen (CMV, HCV)

Point-of-care Tests

1. Greenwald JL. Curr Infect Dis Rep 2006
2. Wesolowski LG. AIDS 2006
3. Chetty V. J Clin Virol 2012
4. Faraoni S. J Clin Virol 2013
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8. Pavie J. PLoS One 2010
9. Katz DA. BMC Res Notes 2012
10. Ng OT. PLoS One 2012
11. Pant Pai N. PLoS Med 2013

- Reduced sensitivity[1-6]
  - False negative results
- PPV reduced in low prevalence settings[7]
- More variation in assay performance and sensitivity for POC tests that use other samples[2,8]
- Obtain a blood sample
- Self-testing for HIV[9-11]

What do we expect?

- Guidelines are not strict rules, they include recommendations
  - Evidence based
  - Expert opinions
- Uptake of recommendations by HCP or healthcare seekers variable

An audit highlighting a lack of awareness of the UK national guidelines for HIV testing, 2008

L Mitchell MRCP DipGUM, **S A Bushby** MRCP DipGUM DipHIV **and M Chauhan** MD FRCOG

Department of GUM, Sunderland Royal Hospital, Sunderland, UK

- Awareness of HCPs on UK guidelines (2008)
  - 67% unaware of new guidelines
  - 26% aware but did not read
  - 3% aware and read
- Mean barrier for HIV testing is
  - lack of training (63%)
  - concerns about pre-test discussion (60%)
  - concerns about consent (40%)

Int J STD AIDS 2011

HIV testing: getting the message across—a survey of knowledge, attitudes and practice among non-HIV specialist physicians

Ewan Hunter.[1] Meghan Perry.[2] Clifford Leen.[2] Nikhil Premchand[1]

- Awareness of non-HIV physicians regarding HIV testing in patients with indicator diseases
  - 88% unaware of BHIVA guidelines
- Most common perceived barriers
  - low-risk population (48%)
  - lack of patient acceptance (35%)
  - consent process/pretest counselling (33%)

Postgrad Med J 2012

- Promotion
- Encouragement and training
- Follow-up

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