HIV Point of Care Testing in Practice

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HIV

- **Significant disease burden**
  - Some 37.8 million people are living with HIV worldwide
  - 77,400 in the UK
  - 7,734 people were newly infected in the UK in 2007
  - The incidence continues to rise, especially in women

- **Linked to other sexually transmitted diseases**
  - 2 to 5-fold increased risk of acquiring HIV infection when syphilis is present
  - HIV virus is transmitted more readily in people with untreated STDs

- **Contributes substantially to the increase in other infectious disease epidemics** such as TB in the developed world

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HIV screening objectives:

- To foster earlier detection of HIV infection
  - To optimise prognosis
  - To link people to clinical and prevention services
  - To increase risk reduction, thereby reducing onward HIV transmission
CONTEXT

- **DoH, National Sexual Health and HIV Strategy (2001)**
  - reduce transmission of HIV & STIs
  - increasing uptake of HIV testing

- **DoH, Choosing Health, (2004)**
  - improve access to services, especially in hard to reach groups
  - plurality of providers

- **EU 2007**
  - Increased earlier diagnosis of HIV
  - Increased availability of HIV testing

- **PCTs: key commissioning priorities**
  - Reduce inequalities in health and well-being
  - Prevent and reduce the transmission of infectious disease e.g. HIV
  - Improve the experience of people who use our services
  - Improve access to health services

- **PCT performance indicators**
  - reduction in late HIV diagnoses

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BASHH / BHIVA / BIS recommendations

- Any health care provider in UK should have skills to perform HIV test
- No specific training required
Who should be offered an HIV test?

- Universal (opt out) HIV testing
- Where HIV prevalence in the local population exceeds 2:1000
- Routinely offered in certain situations
WHY BOTHER?

EARLIER DIAGNOSIS!

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Why?

- In UK, 31% adults (about 22,000) with HIV are unaware of their infection.
- Up to 50% of HIV transmission is thought to be facilitated by those unaware of their status.
- If HIV positive:
  - access to care & medicines
  - reduction in onward transmission
  - patient empowerment by knowing status.

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To reduce HIV-related morbidity and mortality it is essential that HIV is diagnosed as early as possible

- High proportion of patients with advanced HIV infection present to primary care in the 12 months prior to eventual diagnosis
- Missed opportunities for prompt diagnosis in primary and secondary care
- Diagnosis too late for effective treatment is the most important factor explaining HIV-related death in the UK.
  - Late diagnosis accounts for 35% of HIV-related deaths.
- One third (40% in black Caribbeans and black Africans but 35% MSM) of new patients have a CD4 count < 200 cells/mm³ at initial presentation.
- 8% are diagnosed for 1st time with AIDS.
What is the effect of late diagnosis?

- Patients do less well than
  - Those who delay treatment
  - Start treatment at an ideal time
- Poorer virological response
- More likely to die within 1\textsuperscript{st} year of diagnosis
Challenges

- ‘Hard to reach’ populations
  - Health seeking behaviour
  - Stigma
  - Immigration issues
- Patient barriers to HIV testing
  - Perception of own risk & HIV status
  - Reluctance to visit GU clinic
  - Anxiety & fear
    - Waiting for results
    - Venepuncture
    - Positive result
      - Discrimination if positive
      - Concern about relationship
  - Failure to return/pick up result

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Which test?

Two methods in routine practice

- Venepuncture – lab based screening assay
  - 3rd generation (Ab tests)
  - 4th generation (Ag/Ab tests)
- Rapid point of care test (POCT). from either a finger prick or mouth swab sample
Why Point of care HIV testing?

- Improves detection of undiagnosed HIV infection by
  - increasing the capacity of sexual health services
  - removing barriers which discourage HIV testing among people at risk.
- Can help
  - Diagnose individual infection
  - Prevent mother-to-child transmission
  - Monitor HIV prevalence
  - Screen blood donations
Advantages of HIV POCT

- Easily-performed by any member of the healthcare team who need not be medically trained.
- Results are in one patient visit
  - Removes the need to trace patients who fail to return for results
  - Reduces the number of appointments needed.
  - Reduces the anxiety associated with waiting for results
  - Allows patients to access testing with minimum disruption to their work or social lives.
- Less invasive than standard HIV testing.

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- Can be performed quickly and simply without the need for laboratory equipment.
- Suitable for outreach and community settings
- Can be carried out by any trained health worker / fieldworker
Previously tested for HIV?

No - 22%
- Why not?
  - anxiety over a positive result 20%
  - fear of test procedure /blood test 14%
- 85% preferred receiving same day HIV test results
- 40% would have attended for a test sooner if a non invasive POCT had been available.
Patient’s Views

75% patients preferred the OraQuick swab to having a blood test

PERCEIVED BENEFITS OF HIV POC TEST

- Reduced anxiety of waiting 90%
- Quick and easy to do 87%
- Could do it by myself 59%
- No need to return for results 28%
- Avoid blood test 5%
Point of care tests already commonly used in sexual health settings

- Pregnancy tests
- Urinalysis
- Blood Glucose
- Microscopy of urethral, cervical, rectal samples for gonococcal and non-gonococcal urethritis
Point of Care HIV Testing

- Post Exposure Prophylaxis (PEP)
- Hard-to-reach patients
- Outreach services
- Antenatal care
- Primary care
- Detection of HIV seroconversion

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Which HIV POCTs are commonly used in the UK?

- Determine® HIV-1/2
- INSTI™ HIV Antibody test
- OraQuick® ADVANCE™ Rapid HIV-1/2 Antibody Test

All of these devices are CE marked.

New!

- Determine® HIV-1/2 Ag/Ab Combo

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Determine® HIV-1/2 Ag/Ab Combo

- Can identify HIV infection through detection of the HIV-1 p24 antigen before the presentation of antibody response.
- Simultaneous detection of two marker types reduces the “window period” by several days when compared to third generation test.
- Detects HIV 2 – 20 days earlier compared to Determine® HIV-1/2.
- Sensitivity - 92.2% in Primary HIV Infection.
Kinetic of HIV markers during infection (Adapted from Pilcher et al, 2004 and ANAES report, 2000)
Determine® HIV-1/2

- Prick finger using safety lancet
- Use capillary tube to take sample
- Apply sample to test strip
- Add buffer solution

Negative
Reactive

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Add 1 to 2 drops of blood to the Sample Diluents.

Pour the diluted sample into the Membrane Unit.

Re-suspend the Colour Developer and add it to the Membrane Unit.

Add the Clarifying Solution.

**INSTI™ HIV-1/HIV-2 Rapid Antibody Test**

*Bringing excellence to life*
Results in 60 Seconds or Less

One Dot  Two Dots  No Dots
NEGATIVE  POSITIVE  INVALID

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OraQuick® ADVANCE™ Rapid HIV-1/2 Antibody Test

The kit

Patient self – swabs gums

Place the test pad into vial of developer solution

Reactive Negative

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### The Manufacturers’ Data

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<th>Product</th>
<th>Sensitivity</th>
<th>Specificity</th>
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<tr>
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HIV Rapid tests in GU clinics
- Acceptable
- Feasible
- High proportion of previously untested patients
- Those most at risk of HIV in GU clinics may decline serological testing but will accept rapid tests

HIV Rapid tests in outreach services
- Acceptable
- Feasible
- High proportion of previously untested patients
- Those most at risk of HIV in GU clinics may decline testing there; but will attend other settings

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What does HIV POCT screening involve?

- Communication with the patient, an interactive process to assess risk, recognition of specific behaviours, identification of persons at risk and obtaining informed consent.
- A rapid HIV test undertaken by a trained member of staff – a simple, non invasive procedure, results in 2 - 20 minutes.
- Further counselling to link the patient to the essential, appropriate care and/or prevention counselling.
Advantages

- Cost effective: streamlines HIV testing process
- Potential increase in PbR revenue
  - Increase new: follow up ratio
  - POCT service attractive to new clients
- Cost savings associated with the reduction of use of unnecessary PEP
- Patient preference
- Fewer clinic visits
- Reduces need to chase up patients who fail to return
- Improves proportion of patients who keep their first HIV appointment
- Easy to perform, increased job satisfaction
- Reduction in late diagnosis

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Disadvantages

- Reduced specificity and reduced sensitivity versus current 4th generation laboratory tests.
- False negatives in early infection
- All positive results must be confirmed by serological tests as there will be false positives, particularly in lower prevalence populations

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Setting up an HIV POCT service – the clinician’s point of view

- Pathology involvement from the outset - benefit from expertise in
  - purchase of devices
  - training
  - Interpretation of results
  - troubleshooting
  - quality control
  - quality assessment
  - health and safety

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European Guidelines

- Sites should be overseen by CPA accredited laboratory
- Robust quality assurance programme
- Same strict quality assurance principals as practised by laboratory
  - SOP
  - EQA process
  - Audit
    - SOP
    - Documentation
    - Training
    - Internal/external quality standards
    - Validation of samples

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Challenges

- Integrating MHRA and other guidelines with clinical practice
- Working together – equal partners?...Or not?
  - Differing priorities
  - Different levels of experience and expertise
  - Level of detail
    - SOP
    - Audit
    - CRA

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Tell me again – Why HIV POCT?

- more effective patient centred care
- faster clinical decisions
- better health outcomes
- lower healthcare costs
Since we have used the rapid HIV test, we have found a massive increase in our HIV diagnosis.

The Determine HIV test in the laboratory is very simple and gives sensitive and specific result. Furthermore the test has been successfully implemented outside the laboratory setting by non-laboratory staff in a Point of Care testing scenario.

Some clients have visited the service just because we now offer the rapid test.
It’s quick and easy to do. It gives a clear indication early on about your HIV status, and there’s no more waiting a for the result to come through the next day, as it is ready after 15 minutes. It’s comfortable because it’s done by the individual.

Doesn’t make me feel ill and nervous beforehand from (the) thought of a needle.

Alleviates stress and anxiety of blood tests...

This will definitely encourage more people to have HIV tests.

You don’t have to worry about your blood being taken out.
Thanks to

- Karen Moir GU POCT Coordinator BLT
- Merle Symonds Principal Heather Advisor BLT
- Maria Sampson Pathology Manager BLT
- Julia Spring POCT Coordinator BLT

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