INDICATOR CONDITION GUIDED HIV TESTING – PROGRESS AND CHALLENGES

A Sullivan
Malta, February 2016
HIV Indicator Condition Guided Testing

Indicator conditions are conditions associated with an excess risk of being HIV-positive

Opportunistic healthcare focused strategy

Routine HIV testing is cost effective when the undiagnosed HIV prevalence in the target group >0.1%

Included in a number of testing guidelines but very variable implementation
> 300 delegates from 53 countries of WHO Europe Region
To identify strategies for overcoming obstacles to optimal testing and earlier care
Indicator Condition guided testing
Recommended actions:
- Produce evidence on prevalence and missed opportunities for testing
- Completion of Indicator Disease Guidance

NOV 2007
SEP 2009 – FEB 2011
HIV Indicator Diseases Across Europe Study – Phase 1

Pilot study (2009-2011)
Routine test offer to all 18-65 year olds of unknown HIV status presenting for care of an Indicator Condition
17 sites in 14 European countries

Results

HIV tests
3588 patients
66 new HIV diagnoses

HIV prevalence 1.8%
95% CI 1.4 - 2.3

Potential missed opportunities in preceding 5 years
20% previous potentially HIV-related presentations
23% had more than one presentation

11% hospitalised
71% AIDS diagnosis or infection
# Results – HIV diagnoses per Indicator Condition

<table>
<thead>
<tr>
<th>Condition</th>
<th>HIV test</th>
<th>HIV +</th>
<th>Prevalence (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>3588</td>
<td>66</td>
<td>1.84 (1.42-2.34)</td>
</tr>
<tr>
<td>STI</td>
<td>764</td>
<td>31</td>
<td>4.06 (2.78-5.71)</td>
</tr>
<tr>
<td>On-going mononucleosis-like illness</td>
<td>441</td>
<td>17</td>
<td>3.85 (2.26-6.10)</td>
</tr>
<tr>
<td>Leuco/thrombocytopaenia</td>
<td>94</td>
<td>3</td>
<td>3.19 (0.66-9.04)</td>
</tr>
<tr>
<td>Herpes Zoster &lt;65 yrs old</td>
<td>207</td>
<td>6</td>
<td>2.89 (1.07-6.21)</td>
</tr>
<tr>
<td>Seborrheic dermatitis</td>
<td>97</td>
<td>2</td>
<td>2.06 (0.25-7.24)</td>
</tr>
<tr>
<td>Hepatitis B/C</td>
<td>1099</td>
<td>4</td>
<td>0.36 (0.10-0.93)</td>
</tr>
<tr>
<td>Cervical or anal dysplasia</td>
<td>542</td>
<td>2</td>
<td>0.37 (0.04-1.32)</td>
</tr>
<tr>
<td>Malignant lymphoma</td>
<td>344</td>
<td>1</td>
<td>0.29 (0.01-1.61)</td>
</tr>
</tbody>
</table>
Barriers to testing

Clinician barriers identified within the study

- motivation of colleagues in other specialties to deliver testing
- time pressure on service delivery
- skills - education and training of staff
Table 1: Definitions of indicator conditions and recommendations for HIV testing

1. Conditions which are AIDS defining among PLHIV*

- **Neoplasms:**
  - Cervical cancer
  - Non-Hodgkin lymphoma
  - Kaposi's sarcoma

- **Bacterial infections**
  - Mycobacterium Tuberculosis, pulmonary or extrapulmonary
  - Mycobacterium avium complex (MAC) or Mycobacterium kansasii, disseminated or extrapulmonary
  - Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
  - Pneumonia, recurrent (2 or more episodes in 12 months)
  - Salmonella septicaemia, recurrent

- **Viral infections**
  - Cytomegalovirus retinitis
  - Cytomegalovirus, other (except liver, spleen, glands)
  - Herpes simplex, ulcer(s) >1 month/bronchitis/pneumonitis
  - Progressive multifocal leuencephalopathy

- **Parasitic infections**
  - Cerebral toxoplasmosis
  - Cryptosporidiosis diarrhoea, >1 month
  - Isosporiasis, >1 month
  - Atypical disseminated leishmaniasis
  - Reactivation of American trypanosomiasis (meningoencephalitis or myocarditis)

- **Fungal infections**
  - Pneumocystis carinii pneumonia
  - Candidiasis, oesophageal
  - Candidiasis, bronchial/ tracheal/ lungs
  - Cryptococcosis, extra-pulmonary
  - Histoplasmosis, disseminated/ extra pulmonary
  - Coccioidiomycosis, disseminated/ extra pulmonary
  - Penicilliosis, disseminated

2a. Conditions associated with an undiagnosed HIV prevalence of >0.1 %**

- Sexually transmitted infections
- Malignant lymphoma
- Anal cancer/dysplasia
- Cervical dysplasia
- Herpes zoster
- Hepatitis B or C (acute or chronic)
- Mononucleosis-like illness
- Unexplained leukocytopenia/ thrombocytopenia lasting >4 weeks
- Seborrheic dermatitis/exanthema
- Invasive pneumococcal disease
- Unexplained fever
- Candidaemia
- Visceral leishmaniasis
- Pregnancy (implications for the unborn child)

2b. Other conditions considered likely to have an undiagnosed HIV prevalence of >0.1%

- Primary lung cancer
- Lymphocytic meningitis
- Oral hairy leukoplakia
- Severe or atypical psoriasis
- Guillain–Barré syndrome
- Mononeuritis
- Subcortical dementia
- Multiplesclerosis-like disease
- Peripheral neuropathy
- Unexplained weightloss
- Unexplained lymphadenopathy
- Unexplained oral candidiasis
- Unexplained chronic diarrhoea
- Unexplained chronic renal impairment
- Hepatitis A
- Community-acquired pneumonia
- Candidiasis

3. Conditions where not identifying the presence of HIV infection may have significant adverse implications for the individual's clinical management despite that the estimated prevalence of HIV is most likely lower than 0.1%.

- Conditions requiring aggressive immuno-suppressive therapy:
  - Cancer
  - Transplantation
  - Auto-immune disease treated with immunsuppressive therapy
  - Primary space occupying lesion of the brain.
  - Idiopathic/Thrombotic thrombocytopenic purpura

* Based on CDC and WHO classification system [46]
** References in appendix 2

Updates to the table based on future evidence of HIV prevalence in indicator conditions under 2b can be found at www.hiveurope.eu
HIDES 2 - Audit

Audit of HIV testing in Indicator Conditions
Retrospective from May 2013, n=100 or 12 months

Tuberculosis, non-Hodgkins lymphoma, anal and cervical Ca
hepatitis B and C, oesophageal candidiasis

49 audits from 23 centres, representing 7037 patients

The median test rate

<table>
<thead>
<tr>
<th>Region</th>
<th>%</th>
<th>IQR</th>
</tr>
</thead>
<tbody>
<tr>
<td>All audits</td>
<td>72</td>
<td>32–97</td>
</tr>
<tr>
<td>North</td>
<td>44</td>
<td>22–68</td>
</tr>
<tr>
<td>South</td>
<td>68</td>
<td>21–98</td>
</tr>
<tr>
<td>Central</td>
<td>78</td>
<td>30–91</td>
</tr>
<tr>
<td>East</td>
<td>99</td>
<td>86–100</td>
</tr>
</tbody>
</table>
HIDES 2
2012 - 2014

Routine offer of HIV test to patients (18-65 yrs) presenting with indicator condition

**Primary endpoint:** demonstration of previously undiagnosed HIV infection >0.1% in each indicator condition (IC)

150 surveys were performed, across 42 clinical centres in 20 countries across four regions of Europe

<table>
<thead>
<tr>
<th>Disease Area</th>
<th>Indicator Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malignancies</td>
<td>Lymphoma</td>
</tr>
<tr>
<td></td>
<td>Cervical dysplasia or cancer (CIN II and above)</td>
</tr>
<tr>
<td></td>
<td>Anal dysplasia or cancer (AIN II and above)</td>
</tr>
<tr>
<td></td>
<td>Primary lung cancer</td>
</tr>
<tr>
<td>Viral infections</td>
<td>Hepatitis B infection</td>
</tr>
<tr>
<td></td>
<td>Hepatitis C infection</td>
</tr>
<tr>
<td></td>
<td>Hepatitis B &amp; C co-infection</td>
</tr>
<tr>
<td></td>
<td>Ongoing mononucleosis-like illness</td>
</tr>
<tr>
<td>Haematological disorders</td>
<td>Leucocytopenaemia and / or thrombocytopenaemia</td>
</tr>
<tr>
<td></td>
<td>Lymphadenopathy</td>
</tr>
<tr>
<td>Dermatological</td>
<td>Severe psoriasis</td>
</tr>
<tr>
<td></td>
<td>Seborrhoeic dermatitis</td>
</tr>
<tr>
<td>Other</td>
<td>Pneumonia (hospitalised)</td>
</tr>
<tr>
<td></td>
<td>Peripheral neuropathy</td>
</tr>
</tbody>
</table>

disease
Results

Total number | 9471
Male | 54%
Median age | 37 yrs (IQR 29 – 49 yrs)
White | 86.6%
Previous HIV test | 14.4%

HIV positive test | 235
HIV prevalence | 2.5% [95%CI 2.2 – 2.8]

Median CD4 count | 200 cells/µl [IQR 65 – 390]
Late presenters | 143 71.9%
Hx of HIV-associated symptoms | 61 28.2%
HIV prevalence by indicator condition

- Tested: 73 734 401 722 1881 84 1751 299 1126 1339 588 276 53 144
- HIV+: 7 39 16 32 61 2 41 6 13 13 4 1 0 0

- 95% CI > 0.1
- 95% CI < 0.1

- Hep B & C
- Mononucleosis
- Lymphadenopathy
- Leuco / thrombocytopenia
- Pneumonia
- Neuropathy
- Hep C
- Seborrhoeic dermatitis
- Hep B
- Cervical dysplasia / cancer
- Lymphoma
- Psoriasis
- Anal dysplasia / cancer
- Lung cancer

- 95% CI > 0.1
- 95% CI < 0.1

- 0.1% and LL 95%CI>0.1%
HIDES 2 extension

INF MONO extension to June 2015
European primary care centres and acute hospitals from HIDES 2

Number 1248
HIV positive 74
Prevalence 5.9 (4.6 – 7.2)*

*(95% confidence limit)
Indicator Conditions Guidelines

Table of Indicator Conditions and HIV testing recommendations have been updated according to the findings in HIDES 2.

Unexplained Lymphadenopathy
Community-acquired pneumonia
OptTEST

EU funded programme to increase HIV testing and access to treatment and care
Denmark
Czech Republic, Estonia, France, Greece, Poland, Spain, United Kingdom
Belarus, Georgia, Ukraine
Ireland, Netherlands

HIV Indicator Condition testing
  Hepatitis B and C
  Pneumonia
  Infectious Mononucleosis-like syndrome
Transfer to Care
Cost Effectiveness
Stigma and Legal barriers
Indicator Condition guided HIV testing

Strategic pack
- slide set
- specialty guideline review
- missed diagnosis review and cost burden analysis
- business case proforma

Interactive service design module
- staff roles and responsibilities
- care pathways (incl transfer to care)
- test selection
- results governance

Staff training module
- interactive
- testing scenarios
- assessment

Resource pack
- patient support
- evidence, guidelines

Quality Improvement methodology (PDSA, SPC) to increase coverage

Co-funded by the 2nd Health Programme of the European Union
There are different ways to offer an HIV test. HOW will the HIV test be offered to your patients?

Will your offer of an HIV test be presented to the patient as "Opt-out" or "Routine offer"?

- Opt-out: The patient is notified that the HIV test is always performed as part of routine investigations and he/she needs to inform the staff if he/she chooses not to test.
- Routine offer: The patient is offered an HIV test and he/she is required to agree to test.

HIV testing is voluntary - the patient should provide informed consent. Is verbal consent sufficient in your setting, or are there requirements to document a patient's consent? If so, where and by whom?

Now please answer the questions on the right.
PLANNING

Who will offer an HIV test?

In your service, are there any restrictions on which members of staff can offer an HIV test?

Offering an HIV test should be within the competence of any health care professional.

There is no need for special counselling skills beyond those required for routine clinical practice. Additional training can be found in Tool 3 (education and training for staff).

Are there opportunities to involve other health care workers or other members of the team in HIV testing - phlebotomists, health care assistants, receptionists etc.?

Consider which members of staff could offer an HIV test (with additional education/training/support)

Now please answer the questions on the right
# Checklist

**OptTEST WP5 Tool 2 – Checklist to support planning for introduction of indicator-condition guided HIV Testing**

### Key groups to involve in the planning:

<table>
<thead>
<tr>
<th>Your team</th>
<th>Lab team</th>
<th>HIV Team</th>
<th>Your patients</th>
</tr>
</thead>
</table>

### Points to Consider

<table>
<thead>
<tr>
<th>Points to Consider</th>
<th>Your Plan for your Service – Based on your Tool 2 Responses</th>
<th>Any Further Action Needed to complete planning?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Planning – Offering an HIV test in your service</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HOW will the HIV test be offered to your patients?</td>
<td>ROUTINE OFFER</td>
<td></td>
</tr>
<tr>
<td>(• Routine offer or • Opt-out?)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are you required to document <strong>CONSENT</strong> to an HIV test?</td>
<td>DON'T KNOW → →</td>
<td>“Don’t know” response = ACTION: Discuss with your local HIV and/or local information governance team.</td>
</tr>
<tr>
<td>(• Yes – where and by whom? • No, • Don’t know)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WHO can currently offer an HIV test to your patients?</td>
<td>DOCTOR, NURSE</td>
<td></td>
</tr>
<tr>
<td>(• Doctor, • Nurse, • Physician’s Assistant, • Health Care Assistant, • Phlebotomist, • Other – if Other please give details of other staff groups) [56]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WHO could offer an HIV test with additional training/education/support?</td>
<td>HEALTH CARE ASSISTANT</td>
<td></td>
</tr>
<tr>
<td>(• Doctor, • Nurse, • Physician’s Assistant, • Health Care Assistant, • Phlebotomist, • Other – if Other please give details of other staff groups) [56]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>When are patients’ <strong>CONTACT DETAILS</strong> verified?</td>
<td>WHEN OBTAINING CONSENT</td>
<td></td>
</tr>
<tr>
<td>(• At reception, • When obtaining consent, • When taking blood sample, • Other – if Other, please give details) [57]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-test discussion / Patient information leaflet (PIL)</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Will you use a patient information leaflet in your service?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(• Yes- see additional question below, • No) [58]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Example of a patient information leaflet

HAVING AN HIV TEST IN THE HEPATITIS CLINIC
Chelsea and Westminster Hospital Foundation Trust

INFORMATION FOR PATIENTS

HIV (the human immunodeficiency virus) is a virus that affects the immune system and causes AIDS if left untreated.

HIV is now a manageable infection with medication. Successful treatment depends on identifying the infection at an early stage.

There are some conditions that occur more frequently in people with HIV infection, including Hepatitis B and C.

We are now routinely offering HIV tests to all people with these conditions, as recommended by National Guidelines.

Most people with these conditions will not have HIV infection, but we think it is worthwhile that everyone takes the test.

During your assessment by the Hepatology team, you will be asked if you agree to have an HIV test. We will conduct this test on a blood sample. You can ask any questions you may have, and you do not have to have the test. Declining to have an HIV test will in no way affect the care you receive.

The test looks for the presence of antibodies (proteins produced by you) and antigen (virus) in the blood that may indicate whether or not you are infected with HIV.

The HIV test result may be "negative," which means you do not have HIV infection, or "reactive" which means you require further tests to see whether or not you have HIV infection. Any patient with a "reactive" test result will be asked to attend the John Hunter Clinic at Chelsea and Westminster for further tests.

Taking an HIV test is confidential. Taking the test, and testing negative, has NO implications for insurance or mortgage applications.

If you feel you have been at risk of acquiring HIV infection in the past 3 months you should test today, and then repeat the test at 3 months. We can help arrange for you to do this.

Receive your test result:

If your result is reactive – or we need to contact you for any other reason (for example technical problems with your sample) – you will be contacted by a member of our Health Advisor Team at the John Hunter Clinic for Sexual Health.

It is essential that you verify with reception that the telephone/mobile number on our system is the correct contact number for you.

Negative results will be available two weeks after testing. You can obtain this result in one of the following two ways:

Send an email to chelewest.testing@nhs.net including the following information – your name, date of birth, hospital number and state ‘Please send me my HIV test result’

Or call our answerphone on 020 3315 6123 and leave your name, date of birth, hospital number, contact telephone/mobile number and state ‘Please call me back about my HIV test result’

February 2016

Please keep this leaflet for your reference.

Date attended: ___ / ___ / 201_

Result due by: ___ / ___ / 201_
2. EXAMPLE OF TESTING PATHWAY IN ACUTE MEDICAL ADMISSION UNIT OR INPATIENT WARD-
HIGHLIGHTING OPPORTUNITIES FOR HIV TESTING AND PROVISION OF PATIENT INFORMATION

LEAFLET (PIL)

INFORMATION LEAFLET (PIL)

- Patient admitted to AMU/Ward
- Initial observations and bloods are taken by nurse/healthcare assistant
- Patient clerked by clinician
- Initial observations and bloods are taken by nurse/healthcare assistant
- Patient reviewed by Consultant/admitting on post - take ward round
- Subsequent planned venupuncture - Doctor, Nurse Phlebotomist, healthcare assistant
- Patient admitted to a ward or discharged

If none of the opportunities to give PIL or offer an HIV test are taken before patient sees the clinician - the clinician can initiate discussion with patient, offer test and take blood.
We will now take you through the steps to produce your own pathway, asking you to identify where there are the opportunities for HIV testing.

Enter the role corresponding to the staff member the patient would encounter at each step of the pathway against each number below. Entering a zero against a number will remove that part of the pathway.

If your pathway is much more complex please click here to go to a proforma you can adapt.

1 =
2 =
3 =
4 =
5 =
6 =

While it will be technically possible to generate a personalised pathway via these webpages, we don't have that functionality available at the moment. Please enter below the names of staff the patient would encounter as they travel through your service:

1 =
2 =
3 =
4 =
5 =
6 =

Update pathway
Online Staff Training module

HIV testing in indicator conditions

- Introduction
- Check your knowledge
- Why test for HIV?
- The test
- Giving test results
- Assessment

Key: Not Started Started Complete

Zoom
HIV testing in indicator conditions

HIV indicator conditions

You can see the list of indicator conditions associated with each specialty by clicking on the buttons below. We recommend that you click on your own specialty at least. Alternatively you can click here to see the full list of indicator conditions.

- Respiratory/Pulmonology
- Neurology and neurosurgery
- Dermatology/genitourinary medicine
- Gastroenterology/hepatology
- Oncology
- Gynecology/Obstetrics
- Haematology
- Infectious Diseases/Internal medicine
- Rheumatology
- Ophthalmology
- Ear Nose Throat
- Nephrology
HIV testing in indicator conditions

You can see the list of indicator conditions associated with each specialty by clicking on the buttons below. We recommend that you click on your own specialty at least. Alternatively you can click here to see the full list of indicator conditions.

Yellow: Conditions which are AIDS defining among PLHIV - strongly recommend testing.

Blue: Conditions associated with an undiagnosed HIV prevalence of >0.1% - strongly recommend testing. Other conditions considered likely to have an undiagnosed HIV prevalence of >0.1% - offer testing.

Green: Conditions where not identifying the presence of HIV infection may have significant adverse implications for the individual's clinical management despite that the estimated prevalence of HIV is most likely lower than 0.1% - Offer testing.

Specialty: Dermatology/dermatovenereology/genitourinary medicine

- Kaposi’s sarcoma
- Herpes Simplex ulcer(s)
- Atypical disseminated leishmaniasis
- Penicilliosis, disseminated
- Seborrheic dermatitis/exanthema
- Herpes zoster
- Sexually transmitted infections
- Hepatitis B or C (acute or chronic)
- Severe or recalcitrant psoriasis
- Candidaemia
- Candidiasis
Offering an HIV test - Jean Luc

Would you like to have an HIV test? We could do one for you today.

If the doctor offers an HIV test to the patient in the following way, how do you think this might make the patient feel?

Write your thoughts below and then click 'Confirm'
Offering an HIV test - Jean Luc

Would you like to have an HIV test? We could do one for you today.

If the doctor offers an HIV test to the patient in the following way, how do you think this might make the patient feel?

Write your thoughts below and then click ‘Confirm’

Why does she want me to have an HIV test?
Offering an HIV test - Jean Luc

Would you like to have an HIV test? We could do one for you today.

Why is she suggesting a test? Does she think I have HIV?

Why should I be more at risk of HIV than anyone else?

How dare she suggest I might be at risk of HIV?
HIV testing in indicator conditions

Giving a positive HIV test result - Elena, Peter and Joseph

Patients' responses to a positive HIV test result can vary greatly. Here are some examples of how you could give a positive result in ways that will help them understand and process this information.

*Click on the audio buttons to listen.*

You can click here to read Elena's history  You can click here to read Peter's history  You can click here to read Joseph's history

You can click here to view the audio transcript  You can click here to view the audio transcript  You can click here to view the audio transcript

+ ZOOM
OptTEST site numbers

- Total number of tests
- Total number of positives
- Total number of sites
- Total number of sites and positive

Graph showing the increase in total number of tests, total number of positives, and total number of sites over time from Jan - Mar 2015 to Jul - Sep 2016.
OptTEST results

HIV positivity 1.5%

Preliminary linkage to care data
57 patients; 3 known positive (not engaged with care at time of testing)
Data available 46
Linked to care 38 82%
Not linked 8 4 PWID (2 of whom also new HCV)
  2 foreign born; left the country

Stage (n=30)
  CD4 cell count 11-1041 cells/µL
  Median 338 cells/µL
  Late Diagnosis 16 53%

2 had CD4 count reported but not linked to care
Challenges

Motivation of colleagues in other specialties

Operational
  time pressure
  staff experience

Staff skills
HIV specific concerns: stigma, targeting, dealing with positive results

Cost
Missed diagnosis review and cost burden analysis
Business case proforma
Outcome data

Sustainability
Business case proforma
Outcome data
Other challenges

Stigma and legal barriers – OptTEST work stream
website: http://legalbarriers.peoplewithhiv.europe.org

Individuals’ awareness
  public education
  patient and community organisations
  disease specific organisations

Infectious mononucleosis-like syndrome
  raise awareness especially in high risk groups
  PIL development with EATG
The website (www.opttest.eu)

Optimising testing and linkage to care for HIV

About OptTEST
Newsletters
Presentations

News:

OptTEST Newsletter #9
Read about OptTEST national Continuum of Care meetings in Greece and Poland, national cost-effectiveness seminars in France, Spain and Estonia - and other activities and upcoming events here.

Cost-effectiveness
WP6 presented results at a national level meeting in Estonia on the 19th December. The meeting took place in the Ministry of Social Affairs. The aim was to introduce the methods and