The impact of clinical research in an Irish HIV cohort

S O’Dea, Research Nurse
Why is it important to detect asymptomatic, often self-limiting microbial colonization in HIV+ MSM??

Transmission & acquisition

Recent trends in high risk sexual practices

Undetected reservoir
STIs in Ireland

2010

Figure 2. Crude incidence rate* of sexually transmitted infections (<1,000 notifications per year) by year, 1995-2011

- **GN**
  - M: 478
  - F: 151

- **Syphilis**
  - M: 451
  - F: 165

**Syphilis resurgence in Dublin, Ireland.**

Mulligan E, Middle F.
St James’s Hospital, Centenary Medicine and Infectious Diseases, Dublin, Ireland. eavan@acceler.ie

- 381 (86.8%) cases occurred in MSM.

Where known, 126/421 (28.7%) occurred in HIV-positive patients

- Background
- Aims
- Study A
- Study B
- Discussion
- Conclusion
New HIV diagnosis

2011

New HIV diagnoses by year of diagnosis and probable route of transmission (2000 to 2011). hpsc.ie

HIV in Ireland 2011 Report - hpsc.ie
Newly diagnosed HIV+: MSM vs Hetro

2011

<table>
<thead>
<tr>
<th>Ever diagnosed with</th>
<th>MSM</th>
<th>Hetero</th>
<th>IDU</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlamydia</td>
<td>10</td>
<td>4</td>
<td>-</td>
<td>14</td>
</tr>
<tr>
<td>Gonorrhoea</td>
<td>10</td>
<td>1</td>
<td>-</td>
<td>11</td>
</tr>
<tr>
<td>Syphilis</td>
<td>36</td>
<td>6</td>
<td>-</td>
<td>42</td>
</tr>
</tbody>
</table>
557 HIV infected adults:
*incident STIs* (excluding trich.)

- MSM: 94%
- STI: 6%

MSM diagnosed with STI by 6 months:

- No STI: 80%
- STI: 20%

Mayer et al. 2012

**MSM: HIV+ vs HIV-**

Sti’s in MSM in previous 12 months:

- **HIV negative/untested MSM**: 7.1%
- **HIV+ MSM**: 34.7%

Schmidt AJ et al. 2011

Self-reported history of sexually transmissible infections (STIs) and STI-related utilization of the German health care system by men who have sex with men: data from a large convenience sample. *BMC Infectious Diseases 2011*

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SuNN Study 2010, USA

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Mayer et al. 2012

Risk factors

Age

Any history of STI

>2 Sex partners

CD4 count

Use of same sex toys

Meeting on the internet

Enema use before sex

Marijuana use
Risk factors

Denial of risk behavior does not exclude asymptomatic anorectal sexually transmitted infection in HIV-infected men.


School of Medicine, University of California San Diego, San Diego, California, United States of America.
STUDY A: Aims

1. Assess the prevalence of asymptomatic STIs in HIV+ MSM in presenting for routine HIV care.
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2. Assess risk factors for asymptomatic STIs in this cohort.
**STUDY A: Aims**

1. Assess the prevalence of asymptomatic STIs in HIV+ MSM in presenting for routine HIV care.

2. Assess risk factors for asymptomatic STIs in this cohort.

**STUDY B**

3. Implement changes to improve asymptomatic STI screening allowing early intervention.
STUDY A: Methods

• Following consent a pharyngeal swab, rectal swab and urine specimen was collected from each participant.

• Testing for Gonorrhoea (Gc) and Chlamydia (CT) was performed using validated nucleic acid amplification techniques (NAAT).

• Participants completed a self-administered questionnaire and additional information was collected from medical records.

• Statistical analysis was performed using SPSSv19.
STUDY A: Results

50 Asymptomatic HIV+ MSM

Positive STI on this screen
8
(2 with 2 concurrent STIs = 10 STIs)

Negative STI on this screen
42
**STUDY A: Results**

50 Asymptomatic HIV+ MSM

Positive STI on this screen
8

Negative STI on this screen
42

- 8 positive patients
- 10 STIs detected
  - Gc rectal & pharyngeal
  - CT rectal sites only

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Background  |  Aims  | Study A  | Study B  | Discussion  | Conclusion
STUDY A: Previous STI

50 Asymptomatic HIV+ MSM

Positive STI on this screen vs Negative STI on this screen

Previous STI

- Previous STI 87.5%
- No previous STI 12.5%

VS

Previous STI

- Previous STI 81%
- No previous STI 19%
STUDY A: Condom use

50 Asymptomatic HIV+ MSM

Positive STI on this screen

Negative STI on this screen

Condom use

Always 37.5%
Sometimes 62.5%

Always 40%
Sometimes 48%
Unknown 7%
Never 5%

Condom use

Always
Sometimes
Never
Unknown
STUDY A: HAART & Viral load

50 Asymptomatic HIV+ MSM

Positive STI on this screen

Negative STI on this screen

HAART & VL

25% Virally suppressed 75%

21% Virally suppressed 76%

HAART & viral load <40 Not on HAART

HAART & viral load >40 Not on HAART

Background I Aims I Study A I Study B I Discussion I Conclusion
STUDY A: HAART & Viral load

50 Asymptomatic HIV+ MSM

Positive STI on this screen

HAART & VL

Virally suppressed 75%

25%

• Rectal Gc & CT
• Rectal Gc

HAART & viral load <40
Not on HAART

Negative STI on this screen

HAART & VL

Virally suppressed 76%

21%

HAART & viral load <40
Not on HAART

HAART & viral load >40
Not on HAART

Background | Aims | Study A | Study B | Discussion | Conclusion
**STUDY A:** Number of sexual partners in 1 yr

<table>
<thead>
<tr>
<th>Number of Partners</th>
<th>Positive STI on this screen</th>
<th>Negative STI on this screen</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2 - 3</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>&gt; 4</td>
<td>25</td>
<td>0</td>
</tr>
</tbody>
</table>

**STUDY A:**

- **Background**
- **Aims**
- **Study A**
- **Study B**
- **Discussion**
- **Conclusion**
STUDY A: Age

- Previous STI
- HAART & VL
- Condom use
- Numbers of sexual partners
- Country of origin

- Age - Younger age [29 vs 40 years, p<0.001]

> independent predictor of positive STI screen
STUDY B: Implementing changes

All HIV+ MSM attending outpatients for routine HIV care between July & September 2012 were offered a full sexual health screen regardless of last previous screen which, unique to this clinic and to Ireland, implemented self-screening.
**Self rectal swabbing: sensitivity & specificity**

*Alexander S et al. 2008*

*Self-taken pharyngeal and rectal swabs are appropriate for the detection of Chlamydia trachomatis and Neisseria gonorrhoeae in asymptomatic men who have sex with men. Sex Transm Infect. 2008;*

<table>
<thead>
<tr>
<th>272 MSM</th>
<th>sensitivity</th>
<th>specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rectal Gc (nurse)</td>
<td>94.9%</td>
<td>90.1%</td>
</tr>
<tr>
<td>Rectal Gc (patient)</td>
<td>92.3%</td>
<td>87.9%</td>
</tr>
<tr>
<td>Rectal CT (nurse)</td>
<td>80.0%</td>
<td>99.6%</td>
</tr>
<tr>
<td>Rectal CT (patient)</td>
<td>91.4%</td>
<td>98.2%</td>
</tr>
</tbody>
</table>

No significant difference in sensitivity or specificity was observed between the nurse-taken and the patient-taken rectal swabs for either GC or CT.
**Self rectal swabbing: acceptability**

Rectal swabs were acceptable to 82% participants.

Wayal S et al. 2009

*Self-sampling for oropharyngeal and rectal specimens to screen for sexually transmitted infections: acceptability among men who have sex with men.* Sex Transm Infect 2009

Patients indicated that they would like to be offered testing in future...

Soni and White. 2011

*Self-screening for Neisseria gonorrhoeae and Chlamydia trachomatis in the human immunodeficiency virus clinic--high yields and high acceptability.* Sex Transm Dis. 2011
Self rectal swabbing

1. Sit down as if having a bowel movement, insert swab 3-4 centimeters.
2. Tense the swab and move from side to side.
3. Place swab in tube and seal.

INSTRUCTIONS FOR GENERAL PRACTITIONERS ON PATIENT SELF COLLECTION OF ANAL SPECIMENS TO TEST FOR GONORRHOEA AND CHLAMYDIA INFECTIONS IN GAY MEN

WHY SELF COLLECTION?

Patients, particularly those who are asymptomatic, are more likely to use testing services if the specimen collection has been made easy and acceptable. Many patients are reluctant to have their deferred examination confirmed by a screening test that involves a visible and potentially uncomfortable procedure. Self-collection of specimens can also benefit the user by allowing the examination to be limited and screening for gonorrhoea and chlamydia is required.

WHEN IS SELF COLLECTION APPROPRIATE?

Self-collection and screening are only acceptable for asymptomatic men. It may be acceptable in individuals who are at risk of infection through safer sex, or individuals who are at risk of infection through injection drug use.

INFORMATION FOR PATIENTS

The placement of the swab in the anal canal to collect the specimen is crucial in the safety and quality of the analysis results. Monitoring the patient’s language or language of the patient’s language is important. It is not necessary to get the patient’s consent to perform the test. In general, the language of the patient who can understand it is important.

ANAL SPECIMEN PREPARATION

1. Open the swab and insert it.
2. Insert the swab into the anal canal.
3. Insert the swab into the anal canal.
4. Insert the swab into the anal canal.
5. Insert the swab into the anal canal.
6. Insert the swab into the anal canal.

YOUR VERBAL ADVICE TO PATIENTS

1. Sitting technique
2. Standing technique
3. Lying technique

STIs in Gay Men Action Group

STUDY B: Implementing changes

Self screening

71 HIV+ MSM participated

- self rectal swab.
STUDY B: Results

Self screening

71 HIV+ MSM participated

- self rectal swab.
- 11% (8) pts positive
STUDY B: Results

Self screening

71 HIV+ MSM participated

- self rectal swab.
- 11% (8) pts positive
# OTHER STUDIES: STIs in HIV+ MSM

<table>
<thead>
<tr>
<th>Study</th>
<th>Prevalence of STIs</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erbolding 2000 &amp; Chen JL 2003 In Baker 2009</td>
<td>4-11%</td>
<td></td>
</tr>
<tr>
<td>Defraye A et al 2011</td>
<td>8.8%</td>
<td>Belgium</td>
</tr>
<tr>
<td>gunter Rieg 2008</td>
<td>14%</td>
<td>USA</td>
</tr>
<tr>
<td>Heiligenberg 2012</td>
<td>16%</td>
<td>Netherlands</td>
</tr>
<tr>
<td>Soni &amp; white 2011</td>
<td>17.4%</td>
<td>UK</td>
</tr>
<tr>
<td><strong>Our study 2012: Nurse led</strong></td>
<td>16%</td>
<td>Ireland</td>
</tr>
<tr>
<td><strong>Our study 2012: Self swab</strong></td>
<td>11%</td>
<td>Ireland</td>
</tr>
</tbody>
</table>
## Current Guidelines

<table>
<thead>
<tr>
<th>Organization</th>
<th>Guidelines</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>BHIVA 2008</td>
<td>Annual offer of a full sexual health screen (regardless of reported history)</td>
<td></td>
</tr>
<tr>
<td>CDC 2011</td>
<td>More frequent STD screening (i.e., at 3–6-month intervals) is indicated for:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Pharyngeal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Anal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Urethral</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Serology</td>
<td></td>
</tr>
<tr>
<td></td>
<td>More frequent testing: 3-6 monthly testing is recommended for men who</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• have episodes of unprotected anal sex</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• have more than 10 partners in the past six months</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• participate in group sex or use recreational drugs during sex</td>
<td></td>
</tr>
</tbody>
</table>
Non-urethral sites

SJH GUIDE

Nurse swabs 2012

Self swabs 2012

Rectal 60 %

Rectal 70 %
Non-urethral sites

GMHS 2011

461* STI diagnosis

Chlamydia
- Urethral: 25%
- Non-urethral: 75%
- Non-urethral: 80%

Gonorrhea
- Urethral: 15%
- Non-urethral: 85%
- Non-urethral: 85%

http://www.hse.ie/eng/services/Find_a_Service/Sexualhealth/Gay_Men’s_Health_Service/Research_Reports/gmhsannualreports.html
Non-urethral sites

GMHS 2011

461* STI diagnosis

Chlamydia

- Urethral: 25%
- Rectal: 66.5%

Gonorrhea

- Urethral: 15%
- Rectal: 39%

Rectal: 53%

http://www.hse.ie/eng/services/Find_a_Service/Sexualhealth/Gay_Men’s_Health_Service/Research_Reports/gmhsannualreports.html
Non-urethral sites: Barriers

8 large HIV clinics in 6 US cities
1334 HIV-infected MSM  2004-2006

<table>
<thead>
<tr>
<th>STI screen</th>
<th>Screening rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>syphilis</td>
<td>66.0% - 75.8%</td>
</tr>
<tr>
<td>Rectal CT</td>
<td>2.3% - 8.5% *</td>
</tr>
<tr>
<td>Rectal &amp; Pharyngeal Gc</td>
<td></td>
</tr>
</tbody>
</table>

* despite moderate to high positivity among specimens from asymptomatic patients during this period of 3.0%-9.8%.

STD screening of HIV-infected MSM in HIV clinics.

Division of Sexually Transmitted Disease Prevention, Centers for Disease Control and Prevention, Atlanta, GA 30333, USA. khoover@cdc.gov

Changes in health care

Pregnancy test

Blood glucose

BP

Self Swab
Limitations

- Small sample number
- Reliance on self-reporting regarding behaviours and sexual history
- Unknown reasons for declining screen
- Unknown rate of STIs in those that declined screen
Conclusions

1. The **high prevalence** of asymptomatic STIs in HIV+ MSMs is concerning.

2. Younger age was the only significant variable associated with a positive STI screen in our study. This is particularly concerning as it indicates that **young HIV infected MSM continue to practice high risk sexual behaviours despite access to counselling and education.** This high risk group should be targeted at both a national and departmental level.

3. The high prevalence of **non-urethral infections** emphasises the importance of screening at these sites.

4. **Self screening** in asymptomatic individuals is an effective method of **reducing barriers** and improving the sexual health care provided to this population. It is **an effective method for detecting STIs and has a high acceptability** among patients.
Thank you