COMPETING INTEREST OF FINANCIAL VALUE > £1,000:

David Chadwick: none declared
Late HIV Diagnosis: 
Pilot Review Process to Identify 
Missed Opportunities for Testing

David Chadwick
# Late Presenters and Missed Opportunities for Testing

<table>
<thead>
<tr>
<th>Authors</th>
<th>Population</th>
<th>Results</th>
<th>Sub-group risk/common missed presentations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Byrne 2017 <em>(BHIVA national audit 2016)</em></td>
<td>773 (CD4&lt;200)</td>
<td>46% had clear missed opportunity for testing (mostly clinician-related)</td>
<td>35% diagnosed as inpatient; in 2 years prior to diagnosis 60% attended GP; 37% clinic; 18% admitted); few recent arrivals in UK</td>
</tr>
<tr>
<td>Ellis 2011 <em>(BHIVA national audit 2011)</em></td>
<td>580 (CD4 &lt;350)</td>
<td>25% had clear missed opportunity for testing</td>
<td>Diarrhoea, weight loss, STIs, blood dycrasia, lymphadenopathy</td>
</tr>
<tr>
<td>Tominski <em>et al</em> <em>(HIV Medicine 2017)</em></td>
<td>270 (CD4&lt;350)</td>
<td>21% had clear missed opportunity for testing</td>
<td>Lymphopaenia, thrombocytopenia, weight loss oral candida, zoster.. (higher risk heterosex men and women)</td>
</tr>
<tr>
<td>Burns <em>et al</em> <em>(AIDS 2008)</em></td>
<td>263 Africans (50% CD4&lt;200) in London 2004-6</td>
<td>82% not offered HIV test</td>
<td>In years prior to diagnosis 76% attended GP; 38% clinic; 15% admitted</td>
</tr>
<tr>
<td>Corbett <em>et al</em> <em>(HIV Medicine 2017)</em></td>
<td>42 (median CD4-281)</td>
<td>60% missed opportunities</td>
<td>66% had blood dyscrasias (81% of late presenters) in past 5 yrs; 65% missed opp. in primary care</td>
</tr>
</tbody>
</table>
What is the likely impact on patients of missed opportunities for testing in UK?

- In 2016, of 5,164 newly-diagnosed patients with HIV, around 2,066 were diagnosed late (CD4<350) and 1,084 very late (CD4<200) \(^1\)

- Assuming 50% of these had missed opportunities (MO) for testing, late diagnoses (CD4<350) were preventable in up to 1,033 Patients

- That year around 300 patients presented with AIDS within 3 months of diagnosis – probably 150 were preventable \(^2\)

- There were also 594 deaths related to HIV infection, and around 300 in patients recently diagnosed. Of these deaths around 150-200 were likely preventable \(^2\) if previous opportunities to test hadn’t been missed

---

2. Extrapolated from Croxford et al. Lancet Public Health 2017 2(1), e35–e46, Jan 2017
Late HIV diagnosis (CD4<350 at diagnosis) by HIV service provider

- 127 trusts in England received newly-diagnosed adults in 2014
- 40% of these adults had a CD4<350 at diagnosis
- 34% (43/127) trusts were below the England benchmark

All trusts: 40%
British HIV Association: Recording and investigation of late HIV diagnoses: good practice position statement

Background and rationale
This paper provides advice to improve clinical practice with the aim of diagnosing HIV infection at the earliest possible opportunity. Often people with HIV infection present to clinical services but remain undiagnosed because they are not offered an HIV test, including those presenting with indicator conditions which should prompt testing. This requires improvement because:

BHIVA Standards of Care for People Living with HIV 2013 states in relation to standard 1:

All HIV services should undertake a review of all patients presenting to care with advanced immunosuppression (CD4 count <200 cells/mm$^3$ or AIDS diagnosis), with “look back” of previous engagement with health care services. A summary should be provided to commissioners to aid greater understanding for interventions which can be implemented to reduce late diagnosis annually.
National Pilot of Late Diagnosis Review Process

Why haven’t we been doing structured reviews of patients with late HIV diagnoses who suffer harm?

• Lack of recommended national process which is clearly defined
• Lack of good access to health record data....
• ? Stigma/embarrassment/confidentiality...
• Apportioning blame....
Background to Late Diagnosis Process

• 2016: BHIVA National Audit shows continued problem with late diagnosis and MOs (50% of cases)
• 2017: A&S subcommittee discuss development of formal review process as commissioned standard
• Late 2017: LDP proposal sent to HIV CRG
• April 2018: LDP process approved, subject to pilot process demonstrating feasibility
• July-December 2018: Pilot LDP process in 16 centres
Pilot process for reviewing late HIV diagnoses
(July – December 2018)

CD4<200 or AIDS in new patient?

- No → No further investigation
- Yes

Patient been in UK > 2 months and either (i) suffered some harm (due to delayed diagnosis) or (ii) have AIDS?

- No → No further investigation
- Yes

Preliminary investigations* suggests missed opportunities for testing (2/12 – 5yrs ago)

- No → No further investigation
- Yes

Clear or likely missed opportunities for testing found and definite, serious harm resulted from delayed diagnosis?

- No → Serious Learning Event
- Yes

* From medical notes, other electronic records (e.g. NHS Spine/Path data) and patient history...

SI Report with full RCA & report to PHE and commissioners
NPSA/NRLA Harm Grading System

For this process, harm suffered to be put in 1 of 3 categories:

- **Minor (Grade 0/1)** – ‘0’ means no harm (asymptomatic)
- **Intermediate (Grade 2/3)**
- **Major (Grade 4/5)**

**Table:**

<table>
<thead>
<tr>
<th>Consequence score (severity levels) and examples of descriptors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Domains</strong></td>
</tr>
<tr>
<td>Impact on the safety of patients, staff or public (physical/psychological harm)</td>
</tr>
<tr>
<td>Minimal injury requiring nonminimal intervention or treatment</td>
</tr>
<tr>
<td>No time off work required</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
## Outcome process for late diagnoses

<table>
<thead>
<tr>
<th>Delayed diagnosis; no evidence of missed opportunity(ies) for testing</th>
<th>No or minimal Harm (0/1) Demonstrated</th>
<th>Some Harm (2/3) Demonstrated (‘AE’-equivalent)</th>
<th>Serious Harm (4/5) Demonstrated (‘SAE’-equivalent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delayed diagnosis &amp; <em>possible</em> missed opportunity(ies) for testing</td>
<td><em>Letter to relevant service</em></td>
<td><em>Letter to relevant service</em></td>
<td><strong>Serious Learning Event (SLE)</strong></td>
</tr>
<tr>
<td>Delayed diagnosis &amp; <em>definite</em> missed opportunity(ies) for testing</td>
<td><em>Letter to relevant service</em></td>
<td><strong>Serious Learning Event (SLE)</strong></td>
<td><strong>Serious Incident (RCA)</strong></td>
</tr>
</tbody>
</table>
Review process for reviewing previous healthcare episodes

- Case-notes review – both inpatient/outpatient episodes
- Pathology system: e.g. ICE plus OpenNet function
- Summary Care Record (NHS Spine) – GP prescriptions
- Other electronic health record systems...
- Patient recall of accessing healthcare..
For each healthcare episode identified:

- Was there a possible missed opportunity for testing (as per BHIVA 2008 testing guidelines)?

- If so, after further review:
  - Possible or likely/definite?
  - Date of episode
  - Location of episode (e.g. GP, inpatient, clinic...)
  - Source of data: notes, pathology system (e.g. ICE), NHS Spine (SCR), patient’s own recall.
  - Specific details e.g. indicator condition vs risk factor etc....
Where on the spectrum of ‘harm’ does late diagnosis of HIV lie?

**NHS definitions of incidents and harm**

*Serious Incident (SI) – requiring RCA*
Serious Incidents include acts or omissions in care that result in either unexpected or avoidable death, unexpected or avoidable injury resulting in serious harm.

*Patient safety incident (PSI) – potentially requiring SLE*
A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care – i.e. any harm that does not qualify as a serious incident

Around 16% of all SIs notified in NHS are in due to delayed diagnosis or missed diagnosis
Deaths: Serious Incidents and Root Cause Analyses (RCA)

• Deaths with clear (i.e. definite) missed opportunities to test apparent are Serious Incidents requiring an RCA

• If patient died, and clear missed opportunities were found, the Coroner should also be informed: you need to state that you believe it very likely the delayed diagnosis led to death

• I’m not aware of any such incidents being reported, but the Coroner has duty to investigate all deaths where deficiencies of health care are suspected: ideal outcome should be an inquest

• In theory if the inquest found that the death was likely preventable (i.e. with earlier testing and treatment – cART), a Regulation 28 report should be issued after a narrative verdict.
Serious Learning Events (SLE) and Root Cause Analyses (RCA)

• If local clinical lead (e.g. GP) decides there was a MO to test, they should write a local action plan aiming to prevent MOs occurring.

• For RCAs, they should also fill in the Contributory Factors section.

• Once template is returned, and potentially multiple responses amalgamated, HIV clinician should review the responses and comment – essentially on whether you think action plan is reasonable.

• Need for duty of candour – patient or NoK informed of process.
Example Case for Late Diagnosis Review

- May 2017 - 45 year-old white female admitted to local DGH with SOB & weight loss
- No apparent risk factors for HIV infection.
- Clinical presentation – pneumocystis pneumonia (confirmed on BAL) – treated IV co-trimoxazole
- HIV test positive; CD4 - 121
- Required ventilation on ICU – but developed large PE
- Died of cardiogenic shock 3 weeks post admission
Approach to ‘look-back’ for potential missed opportunities for testing: example case

- Medical records – only secondary care potentially relevant was Neurosurgery (back pain with MRI – 2014) and thyroid lump investigated 2012

- Partner questioning: couldn’t remember much except several GP visits including shingles and glandular fever in past 3 years

- Electronic records: NHS Spine & Pathology system......
### Allergies and Adverse Reactions

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Certainty</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>26 Nov 2014</td>
<td>Sensitivity to AMITRIPTYLINE HYDROCHLORIDE, drowsy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16 Oct 2009</td>
<td>No known allergies</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Acute Medications (For the 12 month period 02 May 2016 to 02 May 2017)

<table>
<thead>
<tr>
<th>Type</th>
<th>Date</th>
<th>Medication Item</th>
<th>Dosage Instructions</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Medication</td>
<td>Prescribed: 02 May 2017</td>
<td>Salbutamol 100micrograms/dose inhaler CFC free</td>
<td>inhale 2 doses as needed</td>
<td>200 dose</td>
</tr>
<tr>
<td>Acute Medication</td>
<td>Prescribed: 13 Dec 2016</td>
<td>Miconazole 20mg/g oromucosal gel sugar free</td>
<td>use 4 times/day</td>
<td>15 gram</td>
</tr>
<tr>
<td>Acute Medication</td>
<td>Prescribed: 07 Dec 2016</td>
<td>Benzydamine 0.15% oromucosal spray sugar free</td>
<td>use every 3 hrs</td>
<td>30 ml</td>
</tr>
<tr>
<td>Acute Medication</td>
<td>Prescribed: 07 Sep 2016</td>
<td>Ketorolac 0.5% eye drops</td>
<td>one drop 3 times/day</td>
<td>5 ml</td>
</tr>
<tr>
<td>Acute Medication</td>
<td>Prescribed: 31 Aug 2016</td>
<td>Aciclovir 800mg tablets</td>
<td>take one 5 tablet times/day</td>
<td>35 tablet</td>
</tr>
</tbody>
</table>

### Current Repeat Medications

No relevant information available for this category.

---

*Note: The circled medication is specified for Herpes Zoster (Shingles).*
Summary of possible/probable missed opportunities for testing

2. Prescription aciclovir (?) shingles – August 2016
3. Glandular fever-like illness - August 2015
4. Thrombocytopenia & atypical lymphocytes in 2015/2016
5. Vaginal discharge – July 2014 (?)
6. CIN-2 – July 2012
Outcome under LDP system

1. Notify as likely Serious Incident on DATIX: delayed diagnosis with fatal outcome
2. Discuss with Patient Safety Team
3. Discuss with Coroner
4. Start RCA process – send review forms to GP practice
5. Inform her partner of process
6. Final report would hopefully lead to processes to improve testing in primary care
Outcomes & Benefits of Process

• Regional/National data – may indicate specific areas of suboptimal testing practice, with potential for targeted interventions

• Formal learning exercise for clinicians concerned – useful for appraisal/reflection (and QIP activity for you!)

• Confidence we are learning from MOs and transparency for patient/family

• New Quality Dashboard indicator
Challenges of Process

• Yet another thing to do......

• Access to medical records and electronic systems

• Making a call on MOs – possible vs definite....?

• **Blame culture** - rather a learning process to improve patient safety

• Explaining system to and engaging Trust/Organisation’s Patient Safety Team
Summary

• Late diagnosis of HIV remains common (40%) and significant numbers of patients suffer harm due to missed opportunities to test.

• We need a paradigm shift to viewing late/very late diagnoses, where MOs to test are apparent, as episodes of diagnostic error and preventable harm.

• If the pilot Late Diagnosis Process is successful, routine reviews of all very late diagnoses (CD4<200) will become a commissioned standard.
Acknowledgements

BHIVA LDP Group
Andrew Freedman
Lucy Garvey
Philippa Matthews
Ben Cromarty
Mark Gompels
Fiona Burns
Ann Sullivan
Ben Cromarty
Vanessa Apea
Other members of A&S subcommittee

Public Health England
Valerie Delpeche
Adamma Aghaizu
Caroline Lowndes

NHS England HIV CRG
Mas Chaponda
Ian Williams
Other members of Data Subcommittee
Workload Implications

- 50 new patients (per year)
- 10 new patients CD4<200 or AIDS
- 3-5 No Action (minimal harm/no MOs)
- 3-5 Minor/intermed. Harm with MO (letter to service re. MO)
- 1-3 Sig. harm and MO (RCA or SLE)

MO – Missed opportunity(ies) to test
Further circumstances when a death should be referred to the Coroner are if:

- the body is unidentified;
- the death is due to malnutrition or exposure / hypothermia;
- the death may be due to acute alcohol poisoning (but not chronic addiction);
- the death may be due to lack of medical care;
- the death occurs within 24 hours of admission to hospital (unless the admission was purely for terminal care);
- in the event of a stillbirth there is any doubt whether the child was born alive (e.g. the foetus breathed or exhibited other signs of life);
- the deceased was receiving any form of war pension or industrial disability pension (however irrelevant the disability may appear to be) unless the death can be shown to be wholly unconnected;
- there are any other unusual or disturbing features to the case;
- Careful consideration should be given to reporting a death where there is, or is likely to be, an allegation or complaint of:
  
  (i) medical / nursing mismanagement; and / or
  
  (ii) inappropriate treatment; and / or
  
  (iii) the death is the subject of a (serious) untoward incident investigation.

There is no legal requirement to report a death in this situation, but careful thought should be given as to whether the Coroner needs to be made aware of the circumstances surrounding the death.