Where do we diagnose HIV? Monitoring new diagnoses made in non-traditional settings in England, Wales and Northern Ireland

Short title: Setting of HIV diagnosis in EW&NI

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ABSTRACT

Objectives: To describe ten-year trends in HIV diagnosis setting and explore predictors of being diagnosed outside of a sexual health clinic (SHC).

Methods: Analyses of national HIV surveillance data were restricted to adults (aged ≥15) diagnosed 2005-2014 in England, Wales and Northern Ireland. Logistic regression identified factors associated with diagnosis outside a SHC (2011-2014).

Results: Between 2005 and 2014, 63,599 adults were newly diagnosed with HIV; 83% had a diagnosis setting reported. Most people were diagnosed in SHCs (69%) followed by: medical admissions/accident and emergency (A&E) (8.6%), general practice (6.4%), antenatal services (5.5%), outpatient services (3.6%), infectious disease units (2.7%) and other settings (4.0%). The proportion of people diagnosed outside SHCs increased from 2005-2014, overall (27-32%) and among MSM (14-21%) and black African men (25-37%) and women (39-52%) (all trend p<0.001). Median CD4 increased across all settings but was highest in SHCs (384 cells/mm^3) and lowest in medical admissions/A&E (94 cells/mm^3). Predictors of being diagnosed outside SHCs included: acquiring HIV through heterosexual contact (adjOR 1.99; 95%CI: 1.81-2.18) or injecting drug use (3.28; 95%CI: 2.56-4.19) (ref: MSM), being diagnosed late (<350 cells/mm^3) (2.55; 95%CI: 2.36-2.74) (ref: diagnosed promptly) and being of older age at diagnosis (35-49: 1.60, 95%CI: 1.39-1.83; ≥50: 2.48, 95%CI: 2.13-2.88) (ref: 15-24).

Conclusions: The proportion of HIV diagnoses made outside of SHCs has increased over the past decade in line with evolving HIV testing guidelines. However, late diagnosis remains high, indicating further expansion of testing is necessary, as many people may have had missed opportunities for earlier diagnosis.

INTRODUCTION

In 2016, 89,400 people were living with HIV in England, with 10,400 unaware of their infection.(1) Timely diagnosis of HIV is of major public health importance, ensuring the full benefit of treatment and minimising the risk of onward transmission.(2, 3) Whilst there has been a decline in late presentation over time, 42% of adults were diagnosed late (CD4<350 cells/mm^3) in 2016 in the United Kingdom (UK) and 23% were severely immunocompromised (<200 cells/mm^3) at the time of diagnosis.(1)

In an effort to reduce the number of people undiagnosed and late presentation of HIV, a number of testing guidelines and public health policies have been developed over the past ten years. In 2008, the national HIV testing guidelines released by the British HIV Association (BHIVA) recommended expanding testing outside of specialist sexual health clinics (SHCs) in areas of high prevalence (>2/1,000 population aged 15-59).(4) These guidelines, endorsed in 2011 by the National Institute of Clinical Excellence (NICE),(5, 6) advocate routine HIV screening for all new registrants in general practice (GP), general medical admissions to hospital and community-based targeted testing of key risk groups, such as men who have sex with men (MSM) and black Africans. In 2016, NICE and Public Health England (PHE) further developed testing guidelines to include recommendations for testing in primary and secondary care for people with HIV clinical indicator conditions and co-infections, such as tuberculosis and viral hepatitis.(7) In 2017, NICE published quality standards on HIV testing to further encourage uptake, recommending testing for hospital admissions, accident and emergency (A&E) attendees and people having blood taken in hospital in areas of extremely high HIV prevalence (≥5/1,000 population).(8) The standards further recommend that an HIV test should be offered in GPs in areas of extremely high prevalence during patient registration or when performing a blood test if an HIV test has not been performed in the past 12 months.

Routine HIV testing outside of traditional settings (SHCs and antenatal care) has been established to be operationally feasible and acceptable to both patients and providers.(9) A BHIVA audit comparing the setting of diagnosis in a sample of people diagnosed in the UK found that there had been a significant increase in the proportion of people diagnosed outside of SHCs over time (2003: 19% vs. 2009: 33%).(10) However, a survey of sexual health commissioners in 2012, found less than a third (31%) had commissioned testing in new GP registrants and only one in seven (14%) among medical admissions.(11) Furthermore, a recent study showed less than half (45%) of people diagnosed with hepatitis B or C were tested for HIV within six months of diagnosis.(12)

Comprehensive national public health monitoring of people newly diagnosed with HIV in the UK provides a unique opportunity to assess where people are first diagnosed, how this has changed over time and the impact of testing policies on place of diagnosis and late diagnosis rates. Here, we explore ten-year trends in HIV diagnosis setting in England, Wales and Northern Ireland and identify predictors of diagnosis outside of a SHC.

METHODS

Data sources

In the UK, new diagnoses of HIV are reported to PHE annually by laboratories and clinicians from a variety of settings as part of the national surveillance programme. Multiple mechanisms to report new diagnoses ensure a high completion rate with minimal reporting delay. Information is collected on demographics, including sex, age, ethnicity, country of birth, probable exposure, setting of diagnosis and first CD4 count and date after diagnosis. Data are cleaned, validated, de-duplicated and stored in the HIV and AIDS New Diagnoses and Deaths (HANDD) database.(13)

To maximise the completeness of setting of diagnosis, new diagnosis data were linked to data collected as part of the Sentinel Surveillance of Blood Borne Virus Testing (SSBBV), which collects information on BBV testing from 23 participating laboratories in England, covering approximately 40% of all diagnostic testing.(14) Following linkage, SSBBV contributed information on diagnosis setting for 5.4% (n=3,427) of people. HANDD data were also linked to the HIV and AIDS Reporting System (HARS), a dataset of all people attending for HIV care following diagnosis, which provided setting of diagnosis for a further 11% (n=6,735). Linking between datasets was based on deterministic and probabilistic matching of pseudo-anonymised identifiers such as Soundex (algorithm for indexing names), date of birth, sex, clinic number, geography and site of diagnosis.

Data were extracted from HANDD in April 2016, matched to SSBBV in May 2016 and to HARS in November 2016. Data from Scotland were excluded as information on diagnosis setting is not routinely reported to PHE.

Population

Adults (≥15 years at diagnosis) diagnosed in England, Wales and Northern Ireland between 2005 and 2014 were included in analyses.

Categorising setting of diagnosis

Setting of diagnosis was grouped into six categories: SHCs, antenatal services, outpatient services (e.g. hepatology, tuberculosis, fertility etc.), medical admissions and A&E, infectious disease (ID) units (both inpatient and outpatient), GP and other. Other settings included diagnoses made in prisons, blood services, drug misuse services, community organisations and non-specified medical settings. Medical admissions were grouped with diagnoses from A&E due to small numbers. All women diagnosed during pregnancy were categorised as antenatal.

Statistical analyses

Statistical analyses and data management were carried out using STATA v13 (College Station, Texas, USA). In descriptive analyses, proportions were calculated excluding missing data unless explicitly stated otherwise. Chi-squared test for trend was used to assess changes over time in the proportion of people diagnosed in each setting for everyone and for MSM and black African men and women separately to investigate the impact of HIV testing guidelines (significance level: $p<0.05$). Spearman's test for correlation was used to investigate trends in CD4 count at diagnosis over time.

Logistic regression was used to identify factors associated with being diagnosed outside SHCs for the most recent years (2011-2014). Women diagnosed in antenatal services were excluded from these analyses as antenatal services are a well-established setting for HIV testing (>98% uptake)(12) and including these diagnoses would overestimate the association between sex and the outcome. Variables found to be significant in univariate analysis were included in a backward stepwise model selection process based on $p>0.05$ as a threshold for removal.

RESULTS

Setting of first HIV diagnosis

Between 2005 and 2014, 63,599 adults were first diagnosed with HIV in England, Wales and Northern Ireland (range: 5,712-7,398 diagnoses/year) and 83% (52,923) had a setting of diagnosis reported. The difference between those with setting data reported and those with data missing can be seen in Supplementary Table 1. Characteristics of people missing setting of diagnosis were similar to those with a site of diagnosis reported overall, with the exception of being slightly older at diagnosis, mostly diagnosed in London and had a higher proportion of missing ethnicity and exposure information.

Over the ten year period, the majority of people were diagnosed in SHCs (69%; 36,620) followed by: medical admissions/A&E (8.6%; 4,546), GP (6.4%; 3,403), antenatal services (5.5%; 2,932), outpatient services (3.6%; 1,878) and ID units (2.7%; 1,434). There were 2,110 people diagnosed in other settings, including 224 people diagnosed in prisons, 202 in blood/transfusion services, 64 in drug misuse services and 30 in haemophilia services. The remaining 4.0% of people diagnosed in other settings were diagnosed by community organisations, outreach services or other medical services not specified.

Changes in diagnosis setting over time by key population subgroups are shown in Figure 1a-d and Supplementary Table 2. Throughout 2005-2014, SHCs remained the main source of new HIV diagnoses, accounting for over 65% of all diagnoses annually. However, both the proportion and absolute number of people diagnosed in SHCs declined over the decade from 72% (4,658/6,438) in 2005 to 68% in 2014 (3,406/4,973) (p<0.001). This decline was also seen in diagnoses from ID units (2.3% (147) in 2005 to 1.8% (89) in 2014 (p<0.001)) and antenatal services (7.5% (481) to 2.8% (137) (p<0.001)). In contrast, the proportion of diagnoses in other medical settings rose significantly: 7.5% (485) to 9.3% (462) in medical admissions/A&E (p<0.001), 3.9% (251) to 8.1% (403) in GP (p<0.001) and 2.7% (177) to 4.8% (238) in outpatient services (p<0.001). Fewer than 50 diagnoses/year were made in A&E alone prior to 2011; from 2011 onwards, diagnoses increased, accounting for >1.0% of all diagnoses each year.

This shift in diagnoses to other non-SHC sites was observed among MSM and black African men and women (Figure 1b-d). This shift was less marked among MSM, of whom 86% (1,849/2,159) were diagnosed in SHCs in 2005 compared to 79% (2,105/2,675) in 2014 (p<0.001) (Figure 1b). In comparison, the proportion of black African men diagnosed in SHCs dropped 12% (p<0.001), all black African women 13% (p<0.001) and non-pregnant black African women 20% (p<0.001), over the decade. Among black African women, 19% (391/2,089) of diagnoses were made in antenatal services in 2005 compared to 13% (77/580) in 2014 (p<0.001).

CD4 count at diagnosis by setting

CD4 count at diagnosis was available for 83% (52,765) of adults diagnosed between 2005 and 2014, with availability improving over time. Median CD4 count at diagnosis overall was 345 cells/mm^3 [interquartile range (IQR): 168-531] and was highest among people diagnosed in SHCs (384 cells/mm^3 [IQR: 220-566]), followed by antenatal services (348 cells/mm^3 [IQR: 215-500]), other diagnosis settings (323 cells/mm^3 [IQR: 150-510]), GP (293

cells/mm^3 [IQR: 124-480]), outpatient services (231 cells/mm^3 [IQR: 95-413]), ID units (215 cells/mm^3 [IQR: 60-415]) and medical admissions/A&E (94 cells/mm^3 [IQR: 24-277]).

Over the decade, CD4 count at diagnosis increased (r_s=0.113; p<0.001), most notably in SHCs (r_s=0.167; p<0.001) where median CD4 count rose from 328 cells/mm^3 [IQR: 174-498] in 2005 to 468 cells/mm^3 [IQR: 302-659] in 2014 (Figure 2). CD4 count among diagnoses from GP also increased significantly (r_s=0.054; p<0.005), with median counts rising from 241 cells/mm^3 [IQR: 101-437] in 2005 to 333 cells/mm^3 [IQR: 144-531] in 2014. In medical admissions/A&E, median CD4 count remained very low (2005: 99 cells/mm^3 [IQR: 25-292]; 2014: 119 cells/mm^3 [IQR: 30-304]). There was no clear trend over time in CD4 count at diagnosis among diagnoses in antenatal services and ID units.

Setting of diagnosis among key population groups

Setting of diagnosis among people diagnosed in recent years (2011-2014) by sex, age, ethnicity, HIV exposure and CD4 count at diagnosis is shown in Figure 3 and Supplementary Table 3. Non-pregnant women were significantly more likely than men to be diagnosed in GP (11% (464/4,344) vs. 7.3% (1,060/14,530) (p<0.001)), outpatient services (7.8% (337) vs. 4.0% (583) (p<0.001)) and medical admissions/A&E (13% (564) vs. 7.3% (1,389) (p<0.001)). After SHCs, older adults (>50 years at diagnosis) were most frequently diagnosed in medical admissions/A&E (20%; 595/2,973).

Black African and black Caribbean populations were significantly more likely to be diagnosed outside of SHCs than people of other ethnicities (p<0.001). In recent years, one in eight black Africans (554/4,714) and black Caribbeans (65/559) were diagnosed in medical admissions/A&E. Likewise, one in nine black Africans (11%; 509) and one in 10 black Caribbeans (9.7%; 54) were diagnosed in GP.

MSM were more likely to be diagnosed in SHCs than other risk groups (80% (8,019/10,043) of MSM vs. 55% (4,415/8,007) of heterosexuals and 50% (180/359) of people who inject drugs (PWID)) (p<0.001). In contrast, PWID were the group most likely to be diagnosed outside a SHC, particularly in medical admissions/A&E (15% (54) of PWID vs. 6.5% (654) of MSM and 13% (1,061) of heterosexuals) and other settings (14% (52) vs. 4.0% (399) of MSM and 4.5% (358) of heterosexuals) (all p<0.001). Of the 52 PWID diagnosed in other settings, 35% (18) were diagnosed in prison, 35% (18) in drug misuse services and 31% (16) in other non-specified settings.

Compared to those diagnosed promptly (CD4 count ≥350 cells/mm^3 at diagnosis), people diagnosed late were more likely to be diagnosed outside SHCs, most often in medical

admissions/A&E (19%; 1,364/7,122 vs. 3.8%; 355/9,350) (p<0.001). Late diagnosis was 43% (7,122/16,669) overall from 2011-2014 and highest in medical admissions/A&E (79%; 1,364/1,719), followed by ID units (66%; 203/309), outpatient services (65%; 502/774), GP (55%; 731/1322), antenatal services (51%; 292/574), other settings (48%; 345/713) and SHCs (36%; 4,209/11,782).

Factors associated with being diagnosed outside a SHC

After model selection and adjustment in multivariable analysis (Table 1), being diagnosed outside a SHC was associated with: acquiring HIV through heterosexual contact (adjusted odds ratio (adjOR): 1.99; 95% confidence interval (CI): 1.81-2.18) or injecting drug use (adjOR: 3.28; 95% CI: 2.56-4.19), being diagnosed late (adjOR: 2.55; 95% CI: 2.36-2.74) and with older age at diagnosis. While ethnicity significantly contributed to the overall model, no one individual ethnic group had significantly increased odds of being diagnosed outside a SHC.

DISCUSSION

This study is the first to comprehensively describe where people are diagnosed with HIV in England, Wales and Northern Ireland. Over the past ten years, there has been a shift in diagnosis setting, with an increasing proportion of people being diagnosed outside of specialist SHCs. This shift must be considered in the context of the updates to national HIV testing guidance advocating for expanded testing and the availability of new technologies for HIV testing across clinical and community settings.(4-8)

HIV testing has been scaled up across a variety of settings in recent years.(12) In 2016, over one million people were tested for HIV in SHCs in England alone.(12) Testing in SHCs has risen steadily, including a 47% increase among MSM from 2010-2015.(15) Testing for HIV has also been scaled up over time in non-traditional, non-SHC, settings. Between 2008 and 2012, testing outside SHCs accounted for one third of all tests performed and the number of individuals tested in GP increased 1.6-fold.(16) There have been a number of initiatives to reduce undiagnosed HIV infection through opt-out testing in A&E,(17, 18) targeted testing of people presenting with HIV-indicator conditions to outpatient services or GP (9) and testing in community settings using rapid test kits.(19-22) Targeted testing to high-risk populations, outside of SHCs, has also been a common testing strategy applied in recent years, particularly for MSM and black African men and women.(20, 23, 24) Universal testing of women through the UK antenatal screening programme, established in the late 1990s, has reduced mother-to-child transmission to 0.27%.(25) The decline we observe in the

proportion of diagnoses made in antenatal services is due to a reduction in diagnoses among black African women born abroad overall; this is most likely because of changes in migration.(26, 27) The number of new diagnoses among women who probably acquired HIV in the UK has remained relatively stable over time, suggesting no change in incidence.(1)

Our finding of an increase in diagnoses outside of SHCs is consistent with the scale-up in testing coverage described above. However, positivity rates can vary across different settings and populations, ranging from 0.5% in GP to 2.5% in prisons and 0.7% in black African men and women to 1.2% among MSM.(12) Economic evaluations have found testing in antenatal services, primary care and expanded annual testing of risk groups to be cost effective in the UK.(28-30) One study, in a large London hospital, found opt-out emergency department screening was cost-saving.(31)

Despite increases in the volume of HIV testing over the past decade and evidence for cost effectiveness, a systematic review of adherence to HIV testing guidelines suggests that only 27% of patients eligible for testing receive a test, with low-levels of provider offer being the driving factor.(32) Furthermore, evidence suggests over a quarter of local authorities in England did not commission any primary HIV prevention or testing in 2016/2017.(33) Late diagnosis is still a significant concern, with 43% of people diagnosed from 2011-2014 presenting with a CD4 <350 cells/mm^3. Median CD4 counts among people diagnosed in GP and outpatient services have risen over time but were relatively low compared to median CD4 among people diagnosed in SHCs. This highlights potential missed opportunities for earlier testing, as the majority of these individuals will have been living with HIV-infection for at least 3-5 years prior to diagnosis.(1) The lower median CD4 count among people diagnosed in hospital/A&E is likely due to universal screening occurring at some sites,(18) as well as patients presenting with HIV-related symptoms. A 2010 BHIVA audit found a quarter of new diagnoses had a missed opportunity for earlier diagnosis.(10) Routine offer to all attendees to health care settings is likely to increase uptake and yield of previously undiagnosed persons at an earlier stage of infection. There is evidence that rate of provider offer could be increased through education of medical staff, particularly junior doctors and medical students,(34-37) or the use of electronic testing prompts and clinical decision making tools.(38, 39)

HIV self-sampling and self-testing are also key strategies that can be used for earlier diagnosis. Self-sampling involves self-collection of a blood or saliva sample using a testing kit, which is then posted to the laboratory for testing. Results are delivered by phone, text or online. In contrast, in self-testing, the individual collects the sample using a testing kit and the results are available almost immediately.(40) These initiatives aim to reach people who

do not attend health services and may be at the highest risk for acquiring HIV. In 2014, the national self-sampling project was launched and self-testing was legalised in the UK.(41, 42) Since their introduction, tens of thousands of people have purchased HIV self-testing kits (26,723 in 2016) and ordered and returned free self-sampling kits (22,085 in 2016).(12)

In this study, we identified predictors of diagnosis outside of SHCs: acquiring HIV through heterosexual contact or injecting drug use compared to sex between men, older age at diagnosis and late presentation of HIV. MSM in the UK primarily access SHCs for their sexual healthcare, are more likely to test more frequently and to be diagnosed in SHC than other groups.(43-45) In addition, MSM who attend non-SHC services are less likely to be offered an HIV test.(43) There is also a wealth of evidence that older people are more likely to access health care services, such as GP and A&E, for age-related conditions, providing more opportunities for HIV testing.(46, 47) Older persons are also more likely to be diagnosed late (48); this is due both to not feeling at risk and not being offered a test.(49)

There are a number of limitations to these analyses. Firstly, this is a retrospective study and analysis was restricted to the data collected as part of routine surveillance. We do not collect data on indicator conditions at diagnosis or records of previous attendances to healthcare to identify missed opportunities for diagnosis. Given the coding system in place from 2005-2014, we were not able to differentiate diagnoses made in the community or through self-testing or self-sampling; these would have been captured in the "other setting" category. Though, reporting changed in 2015 to enable this distinction to be monitored going forward, with the recognition that reporting of a previous positive test in the community or through self-testing/self-sampling requires not only the patient to disclose this previous test, but for the clinician to record the information. Secondly, there may be some misclassification of diagnoses made in outpatient/inpatient settings. SSBBV does not directly collect information on whether a diagnosis was made in an inpatient/outpatient setting, only whether the diagnosis was provided in secondary care in hospital. Hospital department address information provided to SSBBV was used to infer setting of diagnosis and cross-checked with other data sources where possible; though, as SSBBV contributed information on only 5.4% of diagnoses and inpatient/outpatient were a subset of these (~300 diagnoses across all years), we think the impact on the analysis is minimal. Another limitation is the inability to classify 17% of diagnoses over the ten years by setting. This may be due to incomplete linkage between the datasets due to issues with identifier completeness. However, we have included a description of the differences between people with and without a reported setting (Supplementary Material - Table 1) and given the relatively high median CD4 count among people with an unknown setting of diagnosis, it is likely we are underestimating diagnoses in

SHCs. Finally, whilst it would have been ideal to be able to present positivity rates instead of number of diagnoses in each setting, denominator information on the number of HIV tests performed was not available. This limits our ability to evaluate the implementation and success of NICE guidelines in obtaining high positivity rates in areas outside of SHCs. SSBBV and the genitourinary medicine activity dataset (GUMCAD) provide testing information for a subset of people; SSBBV covers 40% of testing in the general population and GUMCAD covers all testing in SHCs.(12) However, there is currently no comprehensive surveillance of HIV testing across all settings in the UK.

CONCLUSIONS

Since the availability of the first HIV testing guidelines in the UK a decade ago, non-traditional settings have played an increasingly important role in diagnosing people with HIV particularly in primary and secondary health care settings. Universal offer and recommendation of an HIV test in these settings is feasible and effective in diagnosing persons who are not regular attendees at SHCs and those who do not feel they are at risk of HIV. The continued number of people diagnosed in medical admissions/A&E with the low CD4 counts at diagnosis represents evidence of missed opportunities for testing in particular. Close monitoring and evaluation of where HIV diagnoses are made can guide future testing implementation. Future research will explore the impact of the 2016/2017 UK HIV testing guidelines and determine the contribution of community testing, self-testing and self-sampling strategies in diagnosing people with HIV.

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