# British HIV Association/British Association for Sexual Health and HIV/British Infection Association Adult HIV Testing Guidelines 2020

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[a]From September 2016 to June 2018
[b]From June 2018 to November 2019

# Contents

# 1 Executive summary

The elimination of human immunodeficiency virus (HIV) transmission in the UK is now considered to be an achievable ambition. To attain this target all individuals living with undiagnosed HIV will need to be offered testing and commenced on antiretroviral therapy (ART). The early initiation of ART, regardless of CD4 cell count, has clear benefit for the individual (with avoidance of morbidity and mortality), their partners (avoidance of transmission by having an undetectable viral load) and public health (reduced community viral load and HIV transmissions). Although significant progress has been made in the UK, with falling HIV incidence and near universal ART coverage in those diagnosed, there remains a significant proportion who are undiagnosed (7% in 2018), present late (43% in 2018) [1], and continue to experience morbidity and mortality and contribute to the ongoing transmission of HIV.

These guidelines include a number of recommendations regarding HIV testing. The approaches described need to be adopted and adapted based on local HIV prevalence data, populations and services. Not all approaches are relevant in all areas (e.g. seroprevalence-based testing). In areas of lower prevalence some approaches (e.g. indicator condition testing, risk groups and home sampling/testing) become increasingly important to ensure all those at risk are offered/able to request a test. However, in areas of high and extremely high prevalence, the other approaches should also be instigated in order to widen the potential reach of testing those with undiagnosed HIV. While cost-effectiveness of testing programmes is relevant for some approaches (e.g. indicator condition testing and high local seroprevalence), it should not be universally applied as the cut-off threshold for testing programmes as we work towards the elimination of HIV. All stakeholders should engage in devising a comprehensive approach best suited to their local situation.

Given the clear benefits of treatment, both for the individual and public health, more needs to be done to ensure that all those living with HIV are diagnosed promptly and can rapidly access treatment and care. Those who test negative but remain at risk should have equitable access to combination prevention (including condoms, health promotion and pre-exposure prophylaxis [PrEP]). All testing programmes must ensure they have robust results governance processes and easily accessible pathways to either HIV treatment and care services or prevention services for those at ongoing risk. In some instances (e.g. in emergency departments) this may be provided most effectively in partnership (e.g. with local sexual health services).

All healthcare workers should be able to offer an HIV test in their setting. Lengthy pre-test discussion is not required. Individuals should be made aware that they will be tested for HIV and informed how they will receive their result; for many clinical settings, opt-out testing* is the most effective method to increase testing coverage. Community testing, self-sampling and self-testing may increase access to testing for specific groups.

HIV testing is recommended for:

- People belonging to groups at increased risk of exposure to HIV, including men who have sex with men (MSM) and their female sexual partners, black Africans, people who inject drugs (PWID), sex workers, prisoners, trans women and people from countries with high HIV seroprevalence and their sexual partners;
- People attending health services whose users have an associated risk of HIV, including sexual health services, tuberculosis (TB), hepatitis and lymphoma clinics, antenatal clinics, termination of pregnancy services and addiction and substance misuse services;
- All people presenting with symptoms and/or signs consistent with an HIV indicator condition;
- People accessing healthcare in areas with high (>2/1000; if undergoing venepuncture) and extremely high (>5/1000; all attendees) HIV seroprevalence;
- Sexual partners of an individual diagnosed with HIV.

An annual test is recommended for PWID, sex workers and MSM, and more frequently for those reporting higher risk behaviours or those also belonging to other groups.

Self-testing and sampling and community testing should be provided for at-risk groups and in areas of high seroprevalence to increase testing uptake and frequency.

HIV testing programmes should employ a universal (i.e. non-targeted) opt-out approach when comprehensive coverage is desirable.

The window period for fourth-generation serological HIV testing is 45 days; this has been revised in light of published evidence.

Barriers to testing include HIV stigma and reluctance to offer testing by healthcare professionals. Normalisation of HIV testing by integration into routine practice and education and training of healthcare workers are recommended to address these barriers; however, larger-scale interventions are likely to be required to have a meaningful impact on societal stigma and discrimination.

## 1.2 Main changes included in the present guidelines

- Indicator condition testing recommendations now have a broader evidence base;
- New recommendation to offer testing in emergency departments in areas with high/extremely high HIV seroprevalence;
- Recommendation for testing based on local diagnosed HIV seroprevalence now divided into two categories (high and extremely high) with different recommendations, in line with National Institute for Health and Care Excellence (NICE) guidance;
- Change to the window period for fourth-generation serology to 45 days.

*Opt-out testing means that attendees are informed that they will be automatically tested unless they actively decline.

# 2 Introduction

The UK government has recently committed to the elimination of HIV transmission by 2030 [2]. To achieve this, individuals living with undiagnosed HIV infection will need to be identified through testing and commenced on ART, thereby eliminating the risk of further onward transmission. Those identified as being at ongoing risk of infection will require combination prevention (including condoms, frequent sexually transmitted infection [STI] and HIV testing, behavioural interventions and PrEP) to significantly reduce their risk of acquiring HIV infection.

HIV treatment guidelines universally acknowledge the benefits of immediate ART, regardless of CD4 cell count, for an individual's health. Individuals who are diagnosed promptly can expect a near-normal life expectancy. Furthermore, with an undetectable viral load on ART, people living with HIV do not transmit the virus to their sexual partners. This is referred to as treatment as prevention (TasP) and underpins the public health message: U=U (undetectable = untransmittable).

Implementation of these approaches has resulted in significant reductions in the number of new HIV diagnoses for almost all groups in the UK. HIV testing is the gateway both for accessing effective treatment and for combination prevention, but improvements are required to ensure that all individuals can benefit equally.

The term 'HIV' refers to HIV-1 throughout these guidelines, unless HIV-2 is specified.

## 2.1 UK epidemiology

In 2018, there were an estimated 103,800 (95% credible interval 101,600–107,800) people living with HIV in the UK, of whom 93% were diagnosed and 97% were on ART. Of those individuals accessing care with a viral load result in 2018, 97% had an undetectable viral load [1]. Among adults receiving specialist HIV outpatient care in the UK in 2018, there were no significant differences in the proportions receiving ART by gender, ethnicity, age or mode of HIV acquisition (range 95–99%). Rates of viral suppression were similarly high [1]. With 7% of people with HIV living with undiagnosed infection, the main area where progress is needed therefore is testing.

There has been a significant decline in new HIV diagnoses in the UK in the past few years from a peak of 6278 in 2014 to 4453 in 2018 [1]. This decline, while evident in both MSM and black African populations, is most marked among MSM, particularly in London. The decline in new HIV diagnoses reflects a decrease in incidence, which began in 2012, and is most likely to be due to increases in testing, repeat testing and prompt initiation of ART (i.e. TasP). More recently PrEP has contributed to the continuing decline. Significant differences are observed in the most affected populations in testing coverage and rates, and consequent late presentation; these vary by ethnicity, age and locality [1]. It is therefore essential that planning of interventions to increase HIV testing is done in the context of the local epidemic to achieve maximum impact without risk of stigmatising potentially vulnerable communities. Monitoring and evaluation of such programmes should be carried out to assess effectiveness and inform future adaptations. With expansion of testing settings to non-specialist services, time to linkage to HIV specialist care will be an important metric to monitor.

## 2.2 Overarching principles

HIV testing should be voluntary and confidential, with easy, equitable and free access.
Individuals should be aware they are being tested for HIV and that testing is voluntary; they should be informed how their result will be managed. Lengthy pre-test discussion is not required. How much additional information is provided will vary to an extent based on the setting, the purpose of testing and the individual being offered a test. How information is delivered should be adapted to the circumstances. Basic information should include how results can be accessed, the advantages of testing, availability and effectiveness of treatments, prevention and the window period. Not all situations will require all this

information, which in many cases can be provided in written form (leaflet or website link). The General Medical Council (GMC) provides guidance on obtaining consent for any medical investigation and this should be adhered to regardless of setting [3].

HIV-related stigma continues to be reported and feared by people living with HIV, compounded for some by pre-existing stigma based on actual or perceived membership of different social groups (e.g. groups based on gender identity, religion, class, ethnicity and sexuality). HIV testing, including the offer of a test, can have similar associations for both individuals and healthcare workers. Easy, equitable, non-discriminatory access to HIV testing in all settings should be available to all individuals who wish to test or for whom testing should be recommended.

All patient-related information and testing behaviour and outcome data should be kept according to information governance standards and national legislation, regardless of setting.
Similarly, robust results governance should be in place for all testing programmes, regardless of setting. In some settings this may be more effectively provided in collaboration with another service (e.g. local sexual health service). In all settings, irrespective of who is delivering the testing, there should be clear, agreed pathways to HIV treatment and care services delivering timely linkage to care. For those who test negative and remain at risk there should be clear pathways/signposting to prevention services.

### 2.2.1 Cost-effectiveness

An undiagnosed prevalence of 0.1% is consistently considered to be cost-effective for HIV screening [4]. The evidence shows a greater cost-effectiveness in settings and populations where the undiagnosed prevalence is higher. In antenatal settings, a lower threshold of 0.0075% has been estimated, due to the large extended lifetime costs of an infant acquiring HIV vertically [5]. The estimated prevalence of undiagnosed HIV in England in 2018 was 0.016% (95% confidence interval [CI] 0.012–0.024%) among those aged 15 to 74 years. Thus, universal population testing in the UK is not supported by cost-effectiveness evidence. Estimates of the undiagnosed prevalence of HIV vary by at-risk population and geography, therefore testing is recommended for all patients in high and extremely high prevalence areas and those in high-risk groups elsewhere because the undiagnosed prevalence is likely to be much higher than in the general population. It is worth noting that since this evidence was published, the cost of HIV treatment has decreased and life expectancy has increased leading to a likely downward revision of the cost-effectiveness threshold.

The cost-effectiveness threshold for testing programmes can be applied where relevant (e.g. high/ extremely high areas and indicator condition testing), however with the current focus on elimination of HIV transmission it should not be seen as restrictive where there is an identified need for testing, and all individuals meeting the recommended criteria should be offered a test.

## 2.3 Guideline development process

These guidelines were jointly commissioned by the British HIV Association (BHIVA) Guidelines Subcommittee, the British Association for Sexual Health and HIV (BASHH) Clinical Effectiveness Group and the British Infection Association (BIA). The guideline development process followed BHIVA's guideline development manual (www.bhiva.org/GuidelineDevelopmentManual), applying the modified GRADE system for the assessment, evaluation and grading of evidence and the development of recommendations [6,7]. The Co-chairs of the writing group, who were nominated by BHIVA, BASHH and BIA, nominated a writing group of experts. In addition, members of all three organisations were invited to volunteer to join the writing group by an open process of self-nomination. Community groups representing people living with HIV were invited to nominate representatives via the Community Advisory Board (UK-CAB).

The scope, purpose and guideline topics that were identified as requiring an update from the previous guidelines were agreed by the writing group. Questions concerning each topic were agreed and a systematic literature review undertaken by an information scientist. Details of the search questions (including the definition of populations, interventions, comparators and outcomes) and the search

strategy can be found on the BHIVA website (https://www.bhiva.org/file/5dfcdefd0eb5d/Testing-guidelines-literature-search-strategy.pdf). The literature searches for the 2020 guidelines covered the period from January 1998 to January 2017 and included abstracts from selected conferences between January 2014 and January 2017. For each topic and healthcare question, evidence was identified and evaluated by writing group members with expertise in the field. Using the modified GRADE system (taking into consideration that these guidelines are public health guidelines and thus reliant on different forms of evidence), members assessed and graded the quality of evidence for predefined outcomes across studies and developed and graded the strength of recommendations. All writing group members received training in the use of the modified GRADE criteria before assessing the evidence. Grade reflects the strength of the evidence of the recommendation to the healthcare worker.

Where the evidence is strong (e.g. 1A) we use the term recommend, indicating the healthcare worker should in almost all situations follow this recommendation. Where evidence is less robust we use the term suggest.

The guidelines were published online for public consultation for 6 weeks and external peer review was sought.

The writing group included patient representatives who were involved in all aspects of the guideline development.

# 3 Who should be tested

## Recommendations

1) People belonging to groups at increased risk of exposure to HIV

- HIV testing should be routinely recommended to the following individuals (all Grade 1A):
  - MSM;
  - Female sexual contacts of MSM;
  - Black Africans;
  - People reporting current or prior injecting drug use;
  - Sex workers;
  - Prisoners;
  - Trans women;
  - People from a country with high diagnosed seroprevalence (>1%)*;
  - People reporting sexual contact with anyone from a country with high diagnosed seroprevalence regardless of where contact occurs;
  - Individuals known to have/have had a mother living with HIV and who do not have documented HIV negative status (see guidance from the Children's HIV Association [CHIVA]: https://www.chiva.org.uk/files/3114/2738/8429/dont-forget.pdf).

- HIV testing should be considered for the following individuals (Grade 2D):
  - Trans men.

*For an up-to-date list see [8].

2) People attending certain healthcare settings

- HIV opt-out testing is recommended for all patients attending the following settings (Grade 1C):
  - Sexual health services;
  - Addiction and substance misuse services;
  - Antenatal services;
  - Termination of pregnancy services;
  - Healthcare services for hepatitis B and C, TB and lymphoma.

- Individuals commencing chemotherapy or immunosuppressive or immunomodulatory therapy should be offered an HIV test in line with relevant NICE/speciality guidelines (GPP).

3) People presenting with symptoms and/or signs consistent with an HIV indicator condition

- All individuals presenting to any healthcare provider in any healthcare setting with an indicator condition should be recommended to have an HIV test (Grade 1C–2D; 1D for AIDS-defining conditions)*. See Appendix 1 for indicator condition tables, including by specialty (Table 3).

- Individuals who decline on first offer should have at least one repeat offer made at a subsequent visit (Grade 1D).

- Services providing HIV testing should have adequate results governance and agreed documented transfer to care pathways (Grade 1D).

*See explanatory notes in the evidence review below.

4) All patients accessing primary and secondary healthcare in areas of high and extremely high HIV seroprevalence, including emergency departments.

- Routine HIV testing is recommended for all individuals who have not previously tested who are (Grade 1B):
  - Accessing healthcare in areas of high HIV prevalence (2–5 per 1000) and undergoing venepuncture;
  - Accessing healthcare in areas of extremely high HIV prevalence (>5 per 1000), whether or not they are undergoing venepuncture for another indication.

For local prevalence rates see https://www.hiv-lens.org/.

Recommendations for repeat testing should be based on clinical judgement and risk assessment; for example, emergence of an indicator condition or ongoing risk.

5) Sexual partners of those with diagnosed HIV (Grade 1A)
All sexual partners of an individual diagnosed with HIV should be offered and recommended an HIV test (see BHIVA/BASHH/NAT HIV partner notification for adults: https://www.bhiva.org/HIV-partner-notification-for-adults). Repeat testing may not be indicated for monogamous partnerships if subsequent episodes of sexual contact were known to be protected by TasP (i.e. the person living with HIV was on ART with a maintained undetectable viral load). Repeat testing will also be influenced by other potential risk behaviours of the person without HIV.

These guidelines do not cover children (see https://www.chiva.org.uk), blood donors, transplant donors and recipients or renal dialysis patients; the relevant Department of Health and Social Care guidance should be followed [9].

## Evidence review

### *Specific groups*

Applying the cost-effectiveness threshold of undiagnosed HIV prevalence of 1 per 1000, the recommendation for testing specific populations is underpinned by the following estimated undiagnosed prevalence in 2018 (aged 15–74 years) for:

- MSM: 0.681% (95% CI 0.403–1.257%); the corresponding figures in London and elsewhere in England were 0.714% (95% CI 0.375–1.441%) and 0.643% (95% CI 0.306–1.393%);
- Black African men and women: 0.165% (95% CI 0.128–0.217%); 0.136% (0.088–0.217%) among men and 0.189% (95% CI 0.151–0.235%) among women;
- PWID: 0.089% (95% CI 0.019–-0.266%) [10].

Currently there are no UK seroprevalence data available on trans people.

### *Antenatal services*

Uptake of HIV screening among women who attend for antenatal care is very high (>99%). While positivity remains low (0.013%) [11], this uptake rate is deemed cost-effective when considering the benefit to both the mother and the unborn child.

A review confirmed the cost-effectiveness of universal antenatal HIV screening, as well as rescreening in the late gestation period, in both developed and developing countries [5]. Universal antenatal screening for HIV in Australia where the prevalence of the unscreened population ranges between 0.02% and 0.001% was found to be cost-effective using cost information from 2001–2002. Taking into account the costs of HIV testing, the additional antenatal and delivery care necessitated, training of healthcare staff and lifetime medical care for infants who acquired HIV vertically, the authors concluded that universal HIV screening was cost-effective at or above an undiagnosed HIV prevalence of 0.0043% (no cost ratio per quality-adjusted life year [QALY] provided). Similarly, in the USA, the cost-effectiveness of antenatal screening was found to be high in populations with an undiagnosed prevalence as low as 0.0075% in 2000 (cost ratio per QALY was not provided) [12].

### *High and extremely high prevalence areas*

Geographical targeted testing aims to reduce the number of individuals living with HIV who are unaware of their infection in geographical areas where undiagnosed prevalence is high (set at >1 per 1000 based on previous US studies) and overcomes the need to target HIV testing to any specific population, potentially preventing further stigmatisation of these populations. However, undiagnosed prevalence cannot be accurately measured and available estimates do not provide local level data. By contrast, Public Health England (PHE) has accurate measures of the diagnosed prevalence available for small areas. To better tailor thresholds to more effectively identify those at increased risk of late diagnosis, PHE performed a k-median cluster analysis to model diagnosed HIV prevalence distribution in local authorities in England as part of the development of the 2016 NICE HIV testing guidelines [13]. This produced three strata based on prevalence of diagnosed HIV: low (<2 per 1000), high (2–5 per 1000; 50 local authorities based on 2016 data) and extremely high (>5 per 1000; 20 local authorities based on 2016 data). When the model was applied to national late HIV diagnosis data, two-thirds of late HIV diagnoses were found to occur in high and extremely high prevalence local authorities. This suggests that successful application of this guidance could potentially impact on two-thirds of late diagnoses nationally. PHE produces the strata data, based on the national HIV surveillance data each year [11].

### *Indicator conditions*

An indicator condition is any medical condition associated with an undiagnosed HIV seroprevalence ≥1 per 1000. This may be due to either shared transmission routes with HIV (e.g. hepatitis B and C) or dysregulated immunity.

There are two categories:

1. Conditions that would be AIDS defining in an individual living with HIV (category 1; see Appendix 1, Table 1).
2. Non-AIDS-defining conditions associated with an undiagnosed HIV seroprevalence ≥1 per 1000 (category 2; see Appendix 1, Table 2).

The strength of the recommendation in category 2 is divided on the basis of the available evidence:

- The strength of the recommendation is Grade 1C for those conditions that have been demonstrated unequivocally as having an undiagnosed HIV seroprevalence ≥1 per 1000 in prospective studies, where previously undiagnosed HIV infection was either a primary or secondary outcome of an HIV testing intervention.
- The strength of the recommendation is Grade 1D or 2D for those indicator conditions considered by experts to be highly likely to be associated with undiagnosed HIV seroprevalence rates ≥1 per 1000. For 1D recommended indicator conditions, a variety of data sources have been used to inform this strength of recommendation, ranging from large-scale case–control studies using national and other large data registries in primary and secondary care to retrospective observational studies and audits. For 2D recommendations, only poor-quality evidence or expert opinion exists, or existing poor-quality data have failed to demonstrate an association with a prevalence >1 per 1000. We suggest that HIV testing is done in these conditions as an important differential, even if the prevalence is <1 per 1000.

# 4 Frequency of HIV testing

## Recommendations

All individuals having an HIV test should undergo repeat testing at the appropriate time interval if the current test does not adequately cover the window period for a high-risk sexual contact (see Section 7 Testing technology).

- An annual test is recommended for (Grade 1C):
  - PWID;
  - Sex workers (those who fall into other risk categories such as MSM and trans women should test more frequently);
  - Sexually active MSM (as a minimum; other than those with one long-term mutually exclusive partner).

- MSM reporting any of the following should test every 3 months:
  - Condomless anal intercourse with partner(s) of unknown or serodifferent HIV status, where the contact is not known to be virologically supressed (i.e. not protected by TasP), over the last 12 months (Grade 1B);
  - Multiple or anonymous partners since the last HIV test (Grade 1C);
  - More than 10 sexual partners, over the last 12 months (Grade 1B);
  - Drug use during sex in the last 6 months (Grade 1B for methamphetamine or inhaled nitrites; Grade 1C for GHB/GBL, ketamine or other novel psychoactive substances).

- MSM should be offered repeat HIV testing at follow-up attendance after treatment for syphilis, or anogenital gonorrhoea or chlamydial infection (Grade 1C).

- Three-monthly HIV testing should be routinely offered as part of monitoring for PrEP (Grade 1B).

- Systematic recall strategies should be considered for those who are eligible for but decline PrEP (Grade 1C for MSM and trans women and Grade 1D for other populations).

- The provision of home-based self-sampling and testing can increase testing frequency in MSM and may benefit all at-risk groups (Grade 1B for MSM).

- SMS text reminders should be used to increase re-attendance and HIV testing rates in MSM and others at elevated risk (Grade 1C).

- Regular, repeat HIV testing should form part of an integrated risk-reduction strategy aimed at reducing behavioural risk (Grade 1A for MSM; 1C for other groups).

## Evidence review

There are few data to support recommendations on routine testing frequency in groups with elevated HIV incidence and prevalence other than in MSM, so in most groups repeat testing should be triggered by the identification of individual behavioural risk factors, symptoms suggesting seroconversion, or the identification of indicator conditions.

A retrospective review of 31,469 heterosexual patients of a diverse range of ethnicities attending London sexual health services found that of 4584 retested for HIV within 12 months of an initial negative test only one retested positive [14]. Thus, it may be the case that testing more frequently than annually in heterosexuals, in the absence of specific clinical concerns, is of limited utility. Cost-effectiveness studies support annual testing in UK heterosexual populations at a prevalence of 0.8% [14-16].

Testing 3-monthly is cost-saving in high-risk MSM [17,18]. A cost-effectiveness study of MSM and PWID found that HIV testing for MSM was cost-saving or cost-effective over a 1-year period for both 6-month compared with annual testing and quarterly compared with 6-month testing using either fourth-generation serology or point-of-care testing.

Testing PWID every 6 months compared with annually was moderately cost-effective over a 1-year period with a fourth-generation test, whereas testing with rapid, point-of-care tests (POCTs) or quarterly was not cost-effective [18].

A study of female sex workers in Victoria, Australia demonstrated that it was not cost-effective to test sex workers for HIV more frequently then every 40 weeks [19].

The rationale for testing frequency recommendations in MSM is detailed in the UK national guidelines on the sexual health of MSM [20]. Stratification of risk for HIV infection in MSM is based on several international sources including US Centers for Disease Control PrEP guidance [21] and supporting observational evidence [22]. HIV incidence varied by the rate of incident syphilis in the iPrEx study of HIV PrEP [23]. In a study of 301 MSM diagnosed with a bacterial STI in a London clinic recalled at 3 months for retesting (of whom 206 attended), 29 MSM per 100 person-years of follow-up were diagnosed with a new STI and there were five new cases of HIV [24]. In 2015, a total of 25,321 gay and bisexual men were diagnosed with an anogenital bacterial STI within specialist sexual health services in England; 43% of these men received an HIV test (at the same sexual health service) during the following year with an overall positivity rate of 2.8% [25]. The high rates of HIV acquisition observed in MSM in the deferred arm of the PROUD trial of PrEP [26] and in the control arm of the ANRS IPERGAY study [27] suggest that MSM and trans women meeting UK eligibility criteria for PrEP provision, but who are unable or do not wish to take PrEP, should receive particular attention for active recall HIV testing strategies which may include interval self-sampling and testing.

Australian MSM offered self-testing plus clinic-based testing versus clinic-based testing alone in a randomised trial had a mean of 4.2 HIV tests per year versus 1.9 (relative risk 2.08; 95% CI 1.82–2.38; $P<0.0001$) [28]. An Australian randomised controlled trial of rapid HIV testing versus conventional serology in MSM who had had an HIV test in the preceding 2 years showed an increase in uptake of initial tests but no significant difference in the incidence of repeat testing [22].

SMS text message reminders significantly increased re-attendance for HIV testing in UK [29] and Australian MSM [30]. Findings from UK studies suggest that SMS text reminders may be more effective in MSM than other risk groups but effectiveness is highly dependent upon physician prompts, such as automatic clinic recall for testing [31].

# 5 Community and self-testing/sampling

## Recommendations

- Self-testing and sampling should be made available to at-risk groups and in areas of high seroprevalence to increase testing uptake and testing frequency (Grade 1B).

- Community testing increases testing rates in at-risk groups and should be provided or commissioned as part of local HIV testing programmes (Grade 1B).

Disproportionately affected populations report significant barriers associated with healthcare facility-based testing, including inconvenience, confidentiality concerns and fear of stigma [32]. Increasing early and repeat HIV testing among high-risk populations is key in reducing the time from infection to treatment initiation [32,33].

HIV self-testing (administering the test and interpreting the result at home), self-sampling (collecting a sample at home, posting to a clinic/laboratory and receiving the results at a later date) and outreach community testing (HIV tests administered in fixed, community-based sites, or as part of outreach activities, with no fixed site) all offer alternatives to testing within sexual health services and other medical settings. The proportion of HIV diagnoses made outside sexual health services has increased year on year over the last decade [25].

Community-based testing and self-administered tests, although delivered on a smaller scale than facility-based testing, demonstrate high acceptability, may increase HIV testing uptake among key populations and deliver comparable reactivity rates to facility-based screening [25]. Community-based tests may be provided by community peers, however strong clinical governance frameworks must be used to ensure high-quality services. In terms of self-administered tests, more research is needed to strengthen the evidence regarding value for money and linkage to care.

## Evidence review

In Europe, evidence for HIV self-sampling and self-testing is limited to a small number of countries (UK, Belgium, France, Spain and the Netherlands) with no studies available from Eastern Europe. Most studies relevant to the UK context focus on MSM and there are limited data on self-sampling and self-testing in other key groups or the general population.

Most HIV self-sampling and self-testing in the UK has been based on online request platforms.

### *Self-testing*

To date, five blood-based self-tests have been approved (CE marked) in Europe [34]. All have a sensitivity and specificity of greater than 99% and are either second- or third-generation assays. To be lawfully sold and advertised in the UK, HIV self-test kits need to be CE marked by the manufacturer to ensure the test meets regulatory requirements. They can be ordered online or purchased in some high-street pharmacies [35]. Oral fluid self-tests are not yet available in the UK. However, in countries where available, they are the primary preferred type of self-test. Blood-based tests are preferred by some groups including those MSM who test frequently and PWID [36,37].

Results of self-administered tests are considered 'reactive'* when they indicate the presence of HIV antibodies or antigens. As there is a small possibility of a false-positive result, a single rapid diagnostic test is not sufficient to diagnose HIV and confirmatory laboratory testing is **required.**

*****Reactive results refer to the first HIV-positive test result prior to a confirmatory test for diagnosis.

Populations that may benefit from HIV self-testing include those with a high prevalence of HIV, vulnerable populations who may be less likely to access testing and those who test frequently due to ongoing risk.

HIV self-testing is highly acceptable among different groups and in different settings [38]. The most commonly cited benefits of self-testing are ease, convenience, privacy, immediacy, anonymity and not needing to visit a healthcare facility [39].

A systematic review and meta-analysis of oral fluid self-tests in men demonstrated a two-fold increase, compared to standard HIV testing services, in testing uptake, testing frequency and likelihood of an HIV diagnosis with no evidence of harm and minimal increase in risk-taking behaviour [40]. Another systematic review found little evidence of adverse events associated with self-testing, such as adverse emotional reactions, inter-partner violence, coerced testing, psychosocial or mental health issues, suicide or self-harm [39]. Self-reported barriers to self-testing include cost, fear of carrying out the blood test, interpreting the outcome or having a reactive test result without any immediate personal support. Concerns about accuracy, user error, lack of experience with self-testing and awareness of the availability of a self-testing option are also reported [39,41]. While self-testing can facilitate regular HIV testing, the second- and third-generation tests have a longer window period than fourth-generation tests, which could mean that a recent HIV infection is missed.

Where reported, the HIV self-test positivity rates have been high [42]. An internet-based self-test scheme targeted at UK MSM and black African individuals yielded a new HIV diagnosis rate of 0.83%; around 20% had not previously tested for HIV, 99% described the process as ‘easy’ and 98% would use the service again. Of the 92% who were contactable, all reported confirmatory testing and engagement with HIV services [43]. Reported linkage to care rates following self-testing vary globally, from 20–100% [39]. In one systematic review, the majority of participants reported the intention to link into care following performing a self-test, particularly if the result was reactive; however, the evidence of actual linkage into care is limited and further research is required [39].

A small, randomised study in the USA of emergency department attendees who declined an HIV test demonstrated higher subsequent HIV testing among individuals provided with an HIV self-test kit compared with those who were only offered advice [44].

### *Self-sampling*

Since 2015, a national self-sampling service has been offered to key populations in England using a fourth-generation assay. The service was routinely commissioned by 55% of local authorities at some point during the period November 2015 to October 2017. The service distributed over 122,000 kits with a 57% return rate, yielding a reactive rate of 1.14% at a cost of £950 per reactive test result. The programme engaged individuals who had never previously tested for HIV (29% of returned kits and 29% of reactive tests) [45]. One London-based study found that 88% of MSM who received a reactive result from an HIV self-sampling kit were linked to care [46].

Internet-based self-sampling services are important for providing testing access in rural areas, where individuals may otherwise have to travel far to attend clinic. The services are convenient and confidential, can be accessed 24 hours a day and there is no need to attend a clinic to obtain the test. Self-sampling is considered acceptable by users, though some have found that obtaining a blood sample is challenging. Some users report concerns about confidentiality, test accuracy and lack of access to support from healthcare worker [42].

A small UK study investigating HIV self-sampling in a service that switched from mini-tube (MT) to dried blood spot (DBS) samples demonstrated significantly better processing rates for DBS at 98.8% versus 55.7% for MT samples ($P<0.001$), driven primarily by inadequate MT blood volume. False-reactive rates were also higher for MT samples (5.4% *vs* 0%) [47].

### *Community-based testing*

In a systematic review of community-based HIV testing, six cluster randomised trials (performed in Africa, Thailand and China) met the inclusion criteria. Community-based HIV testing reached all target groups at higher coverage than facility-based testing, increased simultaneous testing of partners, lowered high-risk behaviour and facilitated earlier HIV diagnosis [48]. Community pharmacies are well placed to provide and normalise HIV testing. Studies have shown that offering rapid POCTs in these settings is feasible, acceptable and cost-effective [49,50].

A survey of community-based voluntary counselling and testing services in 32 EU countries found that there is wide heterogeneity; just over half the services were included in national strategic plans, and most were MSM-focused and primarily peer-driven [51]. In a study of more than 3000 community-based rapid HIV tests in MSM in Denmark, there were 37 new diagnoses and 36 of those newly diagnosed were linked to care and virally suppressed after a median of 8 months; 12% had never previously tested for HIV [52]. A small study in Uganda demonstrated that peer-based HIV self-test distribution yielded high rates of test uptake [53].

# 6 Testing approach

## Recommendations

- In a broad range of healthcare settings, HIV testing programmes should employ a universal (i.e. non-targeted) opt-out approach when the local prevalence of undiagnosed HIV means that testing is cost-effective or where 100% testing coverage is desirable (e.g. sexual health clinics and antenatal services) (Grade 1C).
- Clear, unambiguous communication should be used when establishing opt-out testing in any setting to ensure that both patients and staff understand what is meant by the term opt-out (GPP).

Opt-out testing* aims to increase coverage and normalise HIV testing.

## Evidence review

Opt-out models of testing in acute care settings have been shown to be acceptable, feasible and, with appropriate resources, sustainable. This approach addresses the key barriers, with better coverage and sustainability across a range of different healthcare settings [54-60].

Opt-out testing is accepted as standard practice in antenatal and sexual health clinics and is highly effective [61].

Opt-in models of testing suffer from low test offer rates despite the high acceptability to patients [62-64]. Interventions to increase offer rates in opt-in models (e.g. staff education and paper and computer prompts) can lead to increased test rates but are difficult to sustain in acute care settings and over the long term [65-68].

Offering home sampling and testing kits for HIV may increase the frequency of testing in certain patient groups but does not suit all individuals [69].

Point-of-care testing is acceptable and effective in some areas but may not be practical or appropriate for use in busy urgent care settings. It has been highlighted as a barrier to widespread HIV testing in these settings [70].

*Opt-out testing means that attendees are informed that they will be automatically tested unless they actively decline.

# 7 Testing technology

### Recommendations

- We recommend that clinic policies and patient information regarding the HIV test window period should be based on 99th percentile estimates; where a test is undertaken sooner than this time interval, window period data should be used to counsel patients as to the likelihood of a false-negative result (GPP).
- We recommend that the following window periods are applied when utilising these tests (Grade 1A):
    - Fourth-generation laboratory tests, 45 days;
    - Third-generation laboratory tests, 60 days;
    - All POCTs (including Determine HIV-1/2 Ab (third generation), INSTI HIV-1/2 Test and the OraQuick Rapid HIV-1/2 antibody Test), 90 days.
- Confirmatory testing should be undertaken according to locally determined pathways in liaison with local virology teams (GPP).
- Molecular assays (viral RNA or proviral DNA) are not recommended for routine diagnosis though this may change as evidence and/or assay approvals evolve (Grade 1B).
- We recommend molecular assays for diagnostic uncertainty (e.g. primary HIV or indeterminate serology on PrEP) via locally determined pathways in liaison with local virology teams (Grade 1B).

There are two methods for routine HIV testing: (i) laboratory-based tests performed on samples obtained through venepuncture; and (ii) self-sampling, self-testing and rapid POCTs which can be performed in the clinic, in the community setting or as a home test.

The window period of a test can be defined as the time interval between exposure to infection and accurate detection of that infection; the window period ends when HIV can be detected consistently by the test in question [71]. Knowledge of window periods guides clinicians to offer the appropriate test, at the most appropriate time, and to advise patients accordingly. Factors governing the window period include characteristics of the virus, the test and the exposed individual's immune response [71]. HIV tests have evolved considerably since the start of the epidemic, yielding progressive reduction in window periods over time [72] (see Appendix 2 for definitions of HIV tests).

Consensus guidelines recommend fourth-generation HIV laboratory tests with venous sampling as the first-line choice, with POCTs also available (which are largely third-generation tests) [13,72-74]. Confirmatory testing should be undertaken according to locally determined pathways in liaison with local virology teams.

We do not recommend molecular assays (viral RNA or proviral DNA) as part of routine diagnostic algorithms though this may change as evidence and/or assay approvals evolve.

We suggest the use of molecular assays in cases of diagnostic uncertainty (e.g. primary HIV or indeterminate serology on PrEP) via locally determined pathways in liaison with local virology teams.

### Evidence review

A literature review revealed two recent studies that specifically addressed window periods for different HIV screening tests and the implications for interpreting results and counselling patients.

Taylor *et al.* [75] reviewed data from commercial and literature-reported seroconversion panels to calculate the window period for third- and fourth-generation tests and calculate the probability of a false-negative test result during the window period. For third-generation tests the cumulative probability of a

false-negative HIV test result was 5%, 1% and 0% by 40, 85 and 99 days post-exposure, respectively, and for fourth-generation tests the corresponding intervals were 34, 42 and 50 days. Rapid POCTs were excluded from this analysis and are expected to have longer window periods than laboratory-based investigations.

Delaney *et al.* [71] evaluated 20 US Food and Drug Administration (FDA)-approved HIV immunoassays against the Aptima HIV-1 RNA test (the only HIV-1 nucleic acid test approved for diagnosis by the FDA) using 222 longitudinal samples from 25 HIV seroconvertors in the USA. Time between detection of HIV RNA and reactive immunoassay results was combined with simulated eclipse period (time from exposure to HIV RNA detection) data to estimate the window period for each test. The median window period data for each type of screening test are presented in Table 1 including 99th percentile values (i.e. the number of days post-exposure by which time 99% of HIV infections would yield a reactive result).

**Table 1** Estimated median, interquartile range (IQR) and 99th percentile window period by test type

| **Type (no. of inclusive tests)** | **Median (IQR), days** | **99th percentile, days** |
|---|---|---|
| Antibody/antigen laboratory (4) (fourth-generation laboratory test) | 17.8 (13.0–23.6) | 44.3 |
| IgG/IgM-sensitive laboratory (3) (third-generation laboratory test) | 23.1 (18.4–28.8) | 49.5 |
| IgG-sensitive rapid screening (6) (third-generation POCT) | 31.1 (26.2–37.0) | 56.7 |
| IgG-sensitive supplemental (2) | 33.4 (28.5–39.2) | 58.2 |
| Western blot (viral lysate) (1) | 36.5 (31.0–43.2) | 64.8 |

The authors concluded that 99% of HIV infections would be identified by fourth-generation tests by 45 days post-exposure, and most by 50 days post-exposure using third-generation tests. All tests were capable of detecting infection by 90 days post-exposure.

### *Atypical results on ART*

Post-exposure prophylaxis, PrEP and early ART initiation in acute infection can blunt the HIV antibody response [71] yielding non-reactive, atypical or non-progressive HIV serology in a setting in which the HIV viral load is likely to be undetectable. BHIVA/BASHH guidelines on the use of HIV PrEP [76] recommend that atypical test results in individuals taking, or after recent, PrEP should be discussed with a regional expert and investigated further for possible seroconversion and the Antiviral Unit of PHE Colindale should be informed (non-identifying information sent to csuqueries@phe.gov.uk).

Diagnosing breakthrough HIV infections on PrEP is challenging and may involve multiple tests including western blot, RNA and proviral DNA molecular assays [76]. Any sudden increase in the level of reactivity in a repeat sample in a diagnostic assay, even if still below the negative cut-off, should be considered suspicious and monitored. Anyone with atypical HIV tests on PrEP should undergo repeat testing 4 and 8 weeks after PrEP cessation. See boxes 1 and 2 for more information.

**Box 1** Atypical HIV results: what to look for

| | |
|---|---|
| 1 | Low signals near to cut-off in screening assays (including either just below or below cut-off) |
| 2 | Seroreversion on follow-up specimens |
| 3 | Discrepant results between assays |
| 4 | Slow development of antibody/antigen signals in subsequent samples |
| 5 | Weak and/or incomplete banding patterns on line immunoassay or western blot |

**Box 2** HIV tests available at Reference Laboratory Services at PHE Colindale

| | |
|---|---|
| 1 | Wide range of assays (non-standard commercial and in-house enzyme-linked immunosorbent assays, proviral DNA and novel sequencing) |
| 2 | Western blot to determine antibody-specific responses |
| 3 | Collation of test results from a variety of platforms to determine PrEP interference with particular assays |
| 4 | Referral to clinic specialising in atypical serological responses to HIV infection (difficult diagnoses) |

# 8 Barriers to HIV testing and interventions to address them

## Recommendations

- Any doctor, nurse or other health professional should be competent to offer an HIV test (GPP).
- An opt-out HIV testing approach should be adopted where appropriate in order to address some of the barriers to HIV testing (Grade 1C).
- Education and training should be provided to all healthcare workers who may be expected to act on these guidelines (Grade 1C).
- The offer of an HIV test should be integrated into routine practice to normalise HIV testing (GPP).

## Evidence review

### *Barriers to testing*

Barriers to HIV testing can occur at various levels including policy, health system, healthcare provider and individual.

Barriers to testing at the structural, policy, legal and organisational levels:
1) Access to services
Barriers to access may include the geographical distance to a testing venue, necessitating expenditure of time and money [77-79], limited or inappropriate service opening hours, length of waiting time and the time taken to receive test results [71]. Individuals may also be concerned about testing for HIV in relation to their immigration status [78,80] or for fear of prosecution for reckless transmission [81].
2) Testing environment
Consideration should be given to making the testing environment accessible and conducive to testing. This may be more acute for marginalised, young or vulnerable patient populations. A lack of cultural sensitivity can result in perceived stigma, leading to non-attendance [78,79]. Trans people report gaps in provider competence relating to HIV testing [82].
3) Service capacity
Services and staff report insufficient time, staff and training to expand HIV testing [83].
4) Cost
A lack of funding or reimbursement [83] may act as a disincentive to implementation of testing.

Barriers to testing at a healthcare provider level:
1) Clinicians may lack the relevant knowledge and skills to effectively offer an HIV test to an individual for whom it is indicated.
2) Non-HIV specialist physicians may be unaware of who to test and when and the benefits of testing to the individual [83].
3) Lack of relevant communication skills and ability to undertake risk assessment [84].
4) Lack of skill in relation to rapid POCTs.

Barriers to testing at the individual level:
1) Lack of awareness, or the perception of being at low risk of HIV: individuals may have never tested despite risk of exposure, they may assume on-going negative status following a negative test result, or they may not have sought healthcare for relevant symptoms.
2) Fear of a positive result: due to cultural or psychosocial factors, particularly if stigma is anticipated, individuals may fear testing for HIV due to concerns relating to disclosure and risks to their confidentiality, or for fear of rejection or discrimination in the home, workplace or healthcare setting. Fear of HIV illness or dying may underpin reluctance to test for HIV. These concerns will be fuelled by lack of knowledge of the impact of treatment, including benefits to the individual with regard to prevention of transmission, and of the ability to obtain insurance.

### *Interventions to overcome barriers and to increase testing*

Various interventions to introduce and expand HIV testing have been assessed. The most acceptable and effective example of routine HIV testing has been the adoption of universal HIV testing in antenatal clinics in the UK and Ireland. This is offered on a true opt-out basis as part of routine care. The uptake is near universal with over 99% coverage [1] and this together with appropriate management of the pregnant woman has directly led to the near elimination of vertical transmission of HIV in the UK [85].

Routine opt-out HIV testing as part of a sexual health screen for patients attending sexual health clinics has been similarly successful and is highly acceptable to patients and staff [85,86].
Despite these examples, the rollout of routine HIV testing in other clinical settings has been less successful [25,67,87]. Efforts to introduce HIV testing routinely in services for TB, lymphoma and hepatitis have had mixed results [88-90].

Testing of patients attending medical services such as emergency departments and acute medical admissions units in areas of high prevalence have demonstrated that patients have few objections to the offer of a test and when offered the uptake is high [61,88]. It was demonstrated in an area of high prevalence in North London that overall individual practice HIV testing rates increased by 16% for each additional general practitioner who attended a brief educational intervention, and that this increase was sustained over 8 years of observation [91]. However other studies have shown no effect [92,93].
Some studies employed extra staff to request consent from patients for testing. Although this was initially successful, as it addressed capacity, competence and confidence concerns, it was not sustainable in the longer term after the conclusion of the study [67].

A more robust approach has been to integrate HIV testing into routine investigations so that the offer of the test becomes normal practice with no additional resource required [61,94]. This helps to normalise HIV testing, making the test part of the routine work up for all patients with no special consent required beyond that required for any routine blood test.

Some of the structural and service-related barriers can be addressed by applying current agreed standards (GPP), including BASHH Standards for the Management of STIs, 2019 (https://www.bashh.org/about-bashh/publications/standards-for-the-management-of-stis/) and BASHH Recommendations for Integrated Sexual Health Services for trans, including non-binary, people (http://www.gpone.wales.nhs.uk/sitesplus/documents/1000/bashh-recommendations-for-integrated-sexual-health-services-for-trans-including-non-binary-people-2019pdf.pdf).

# 9 Testing where the patient lacks capacity to consent

Legislation in England, Wales and Scotland provides a framework for decision-making on behalf of adults aged 16 years and over who lack capacity to make decisions on their own behalf (including the unconscious patient). The Mental Capacity Act 2019 applies to England and Wales. In Scotland, the Adults with Incapacity (Scotland) Act 2000 applies, for which there is a separate British Medical Association (BMA) guidance note. In Northern Ireland, common law applies.

Persons lack capacity if, at the time the decision needs to be made, they are unable to make a decision because of a mental disorder or are unable to communicate their decision. Key points to consider when assessing capacity:

1) The assessment of capacity relates to the specific issue in question, in this case consent to HIV testing.

2) Start from the presumption that the patient has capacity to make this decision.

3) Consider whether patients understand what decision they are being asked to make and can assess the information relevant to the decision; do they understand the consequences of making a choice?

4) Take all possible steps to help patients make a decision for themselves (e.g. provide information in an accessible form such as drawings). If a patient is judged to lack capacity to consent to an HIV test, consider whether this is temporary or permanent. If temporary, testing should be deferred until the patient regains capacity, unless testing is immediately necessary to save the patient's life or prevent a serious deterioration of their condition.

5) If the lack of capacity is, or is likely to be, permanent, a decision should be sought from any person with relevant powers of attorney or the requirements of any valid advance statements should be followed.

6) If the patient has not appointed an attorney nor left a valid advance statement, HIV testing may be undertaken where this is in the best interests of the patient (England and Wales) or is necessary and of benefit to the patient (Scotland).

Guidance on assessing capacity is published by the GMC and the BMA [95]. Advice on how to assess appropriate treatment of patients who lack capacity is available in the relevant statutory codes of practice for Scotland and Northern Ireland [96].

If consciousness is regained the patient should be told of the test result as soon as practicable.

If a patient dies, a decision should be made on disclosure according to the circumstances (e.g. others at risk and previously disclosed wishes).

# 10 List of abbreviations

| | |
|---|---|
| AIDS | Acquired immunodeficiency syndrome |
| ART | Antiretroviral therapy |
| BASHH | British Association for Sexual Health and HIV |
| BHIVA | British HIV Association |
| BIA | British Infection Association |
| BMA | British Medical Association |
| CHIVA | Children's HIV Association |
| CI | Confidence interval |
| DBS | Dried blood spot |
| FDA | Food and Drug Administration |
| GBL | Gamma butyrolactone |
| GHB | Gamma hydroxybutyrate |
| GMC | General Medical Council |
| HIV | Human immunodeficiency virus |
| Ig | Immunoglobulin |
| IQR | Interquartile range |
| MSM | Men who have sex with men |
| MT | Mini-tube |
| NICE | National Institute for Health and Care Excellence |
| PHE | Public Health England |
| POCT | Point-of-care test |
| PrEP | Pre-exposure prophylaxis |
| PWID | People who inject drugs |
| QALY | Quality-adjusted life year |
| STI | Sexually transmitted infection |
| TasP | Treatment as prevention |
| TB | Tuberculosis |
| UK-CAB | Community Advisory Board |

# Appendix 1. Indicator conditions

**Table 1** AIDS-defining conditions in people living with HIV

| Category | Condition |
|---|---|
| **Neoplasm** | Cervical cancer<br>Non-Hodgkin lymphoma<br>Kaposi's sarcoma |
| **Bacterial infection** | *Mycobacterium tuberculosis*, pulmonary or extrapulmonary<br>*Mycobacterium avium* complex or *Mycobacterium kansasii*, disseminated or extrapulmonary<br>Mycobacterium, other species or unidentified species, disseminated or extrapulmonary<br>Pneumonia, recurrent (two or more episodes in 12 months)<br>Salmonella septicaemia, recurrent |
| **Viral infection** | Cytomegalovirus retinitis<br>Cytomegalovirus, other (except liver, spleen, glands)<br>Herpes simplex, ulcer(s) >1 month/bronchitis/pneumonitis<br>Progressive multifocal leukoencephalopathy |
| **Parasitic infection** | Cerebral toxoplasmosis<br>Cryptosporidiosis diarrhoea, >1 month<br>Isosporiasis, >1 month<br>Atypical disseminated leishmaniasis<br>Reactivation of American trypanosomiasis (meningoencephalitis or myocarditis) |
| **Fungal infection** | *Pneumocystis carinii* pneumonia<br>Candidiasis, oesophageal<br>Candidiasis, bronchial/tracheal/pulmonary<br>Cryptococcosis, extrapulmonary<br>Histoplasmosis, disseminated/extrapulmonary<br>Coccidioidomycosis, disseminated/extrapulmonary<br>Talaromycosis (penicilliosis), disseminated |

**Table 2** Evidence grading for HIV indicator conditions (where HIV test is recommended), defined by having an undiagnosed HIV prevalence of at least 1 per 1000

| Indicator condition | Strength of recommendation (1/2) | Grade of evidence (A–D) | Reference |
|---|---|---|---|
| Sexually transmitted infection | 1 | C | [24,97,98] |
| Malignant lymphoma | 1 | C | [99-103] |
| Anal cancer/dysplasia | 1 | C | [98,102] |
| Cervical dysplasia | 1 | C | [98,102,104] |
| Herpes zoster | 1 | C | [98,103] |
| Hepatitis B or C (acute or chronic) | 1 | C | [102,103,105] |
| Unexplained lymphadenopathy | 1 | C | [102,106] |
| Mononucleosis-like illness | 1 | C | [102,103,107,108] |
| Community-acquired pneumonia | 1 | C | [98,102,103,109] |
| Unexplained leukocytopenia/ thrombocytopenia lasting >4 weeks | 1 | C | [98,102,103] |
| Seborrhoeic dermatitis/exanthema | 1 | C | [102,110,111] |
| Peripheral neuropathy | 1 | C | [102,103,106] |
| Severe or atypical psoriasis | 1 | C | [102] |
| Mononeuritis | 1 | D | [112] |
| Unexplained weight loss | 1 | D | [97,113-115] |
| Unexplained oral candidiasis | 1 | D | [103,113] |
| Hepatitis A | 1 | D | [103,113,116] |
| Unexplained fever | 1 | D | [113,117] |
| Candidaemia | 2 | D | |
| Visceral leishmaniasis | 2 | D | |
| Primary lung cancer | 2 | D | [102] |
| Invasive pneumococcal disease | 2 | D | |
| Oral hairy leukoplakia | 2 | D | |
| Guillain–Barré syndrome | 2 | D | |
| Subcortical dementia | 2 | D | |

| | | | |
|---|---|---|---|
| Multiple sclerosis-like disease | 2 | D | [112] |
| Unexplained chronic diarrhoea | 2 | D | |
| Unexplained chronic renal impairment | 2 | D | |

**Table 3** AIDS-defining conditions in people living with HIV and indicator conditions by specialty

| Specialty | AIDS-defining conditions in people living with HIV | Indicator conditions |
|---|---|---|
| Dentistry | | |
| | Kaposi's sarcoma | Oral hairy leukoplakia<br><br>Unexplained oral candidiasis |
| Dermatology | | |
| | Herpes simplex, ulcer(s) >1 month<br><br>Kaposi's sarcoma | Exanthema<br><br>Herpes zoster<br><br>Seborrhoeic dermatitis<br><br>Severe or atypical psoriasis |
| Ear, nose and throat | | |
| | | Mononucleosis-like illness<br><br>Oral hairy leukoplakia<br><br>Unexplained lymphadenopathy<br><br>Unexplained oral candidiasis |
| Gastroenterology /hepatology | | |
| | Cryptosporidiosis diarrhoea >1 month<br><br>Isosporiasis >1 month<br><br>Candidiasis, oesophageal | Anal cancer/dysplasia<br><br>Hepatitis A<br><br>Hepatitis B or C (acute or chronic)<br><br>Unexplained chronic diarrhoea<br><br>Unexplained weight loss |
| General practice/emergency medicine | | |
| | Symptomatology fitting any of the listed conditions | Symptomatology fitting any of the listed conditions |
| Genitourinary medicine | | |
| | Herpes simplex, ulcer(s) >1 month | Sexually transmitted infections |
| Haematology | | |
| | Lymphoma | Unexplained leukocytopenia/ thrombocytopenia >4 weeks<br><br>Unexplained lymphadenopathy |
| Infectious diseases /internal medicine | | |
| | *Mycobacterium avium* complex or | Candidaemia |

| | | |
|---|---|---|
| | *Mycobacterium kansasii*, disseminated or extrapulmonary<br><br>Mycobacterium, other species or unidentified species, disseminated or extrapulmonary<br><br>Salmonella septicaemia, recurrent<br><br>Cytomegalovirus, other (except liver, spleen, glands)<br><br>Herpes simplex, ulcer(s) >1 month/ bronchitis/pneumonitis<br><br>Atypical disseminated leishmaniasis<br><br>Reactivation of American trypanosomiasis (meningoencephalitis or myocarditis)<br><br>Cryptococcosis, extrapulmonary<br><br>Histoplasmosis, disseminated/extrapulmonary<br><br>Coccidioidomycosis, disseminated/extrapulmonary<br><br>Talaromycosis (penicilliosis), disseminated | Herpes zoster<br><br>Invasive pneumococcal disease<br><br>Mononucleosis-like illness<br><br>Oral hairy leukoplakia<br><br>Unexplained chronic renal impairment<br><br>Unexplained fever<br><br>Unexplained lymphadenopathy<br><br>Unexplained oral candidiasis<br><br>Unexplained weight loss<br><br>Visceral leishmaniasis |
| Nephrology | | |
| | | Unexplained chronic renal impairment |
| Neurology | | |
| | Progressive multifocal leukoencephalopathy<br><br>Cerebral toxoplasmosis | Guillain–Barré syndrome<br><br>Mononeuritis<br><br>Multiple sclerosis-like disease<br><br>Peripheral neuropathy<br><br>Subcortical dementia |
| Oncology | | |
| | Cervical cancer<br><br>Non-Hodgkin lymphoma<br><br>Kaposi's sarcoma | Anal cancer/dysplasia<br><br>Malignant lymphoma<br><br>Primary lung cancer<br><br>Unexplained lymphadenopathy<br><br>Unexplained weight loss |

| | | |
|---|---|---|
| Obstetrics and gynaecology | | |
| | | Cervical dysplasia |
| Opthalmology | | |
| | Cytomegalovirus retinitis | |
| Primary care | | |
| | Symptomatology fitting any of the listed conditions | Symptomatology fitting any of the listed conditions |
| Respiratory | | |
| | Pneumonia, recurrent (two or more episodes in 12 months)<br><br>*Mycobacterium tuberculosis*, pulmonary or extrapulmonary<br><br>*Pneumocystis carinii* pneumonia<br><br>Candidiasis, bronchial/tracheal/ pulmonary | Community-acquired pneumonia<br><br>Invasive pneumococcal disease |

# Appendix 2. HIV tests: definition

| | |
|---|---|
| First generation | Based on viral lysate antigens to detect HIV antibodies (e.g. western blot) |
| Second generation | Utilise synthetic peptide or recombinant protein antigens with/without viral lysates to detect HIV immunoglobulin (Ig)G antibodies |
| Third generation | Synthetic peptide or recombinant protein antigen-based tests detect IgM and IgG antibodies with increased sensitivity during early seroconversion |
| Fourth generation | Combination third-generation assays to detect IgM and IgG antibodies, and monoclonal antibodies to detect p24 antigen |

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