



Blood-borne viruses opt-out testing in emergency departments in London: Good practice guidance

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This work builds on the actions of pioneering NHS Trusts who have successfully implemented HIV opt-out testing in emergency departments as well as piloted expanding to include blood-borne viruses. The commitment and dedication of the teams at these sites in driving forward opt-out testing in emergency departments cannot be underestimated and this programme would not have been possible without their consistent effort and hard work.

We would like to acknowledge key partners who have been fundamental in the expansion of HIV and blood-borne virus testing in emergency departments, through their work in campaigning, raising awareness, surveillance, funding pilot programmes, and including opt-out testing in national guidance, including: British Association of Sexual Health and HIV, British HIV Association, British Infection Association, Royal College of Emergency Medicine Elton John Aids Foundation, Fast Track Cities London, Hepatitis C Trust, National AIDS Trust, Terrence Higgins Trust, UK Health Security Agency and Office for Health Improvement and Disparities.

The identification of dedicated resources for the expansion of blood-borne virus testing in emergency departments in areas of high prevalence is testament to the importance of this work and the incredible progress that London is making towards eliminating blood-borne viruses.

Introduction

Blood borne virus opt-out testing in emergency departments in London

From April 2022, emergency departments (ED) in London will be funded to provide routine blood borne virus (BBV) testing for HIV, hepatitis B and hepatitis C, in everyone aged 16 years and over who is having a blood test, unless they opt-out.

Purpose

The purpose of these guidelines is to support implementation of routine BBV opt-out testing in London EDs in a consistent manner that maximises uptake and linkage to care. These guidelines are informed by national guidance and models of good practice.

Background

In November 2021, £20 million funding was identified by NHS England and NHS Improvement to implement ED opt-out HIV testing in high-prevalence local authorities as part of the national <u>HIV Action Plan</u>. All London Trusts meet the prevalence criteria and have been included. Funding was additionally secured in March 2022 to include testing for hepatitis B and hepatitis C. London's BBV opt-out testing in EDs will launch in April 2022 and is expected to run for three years.

Context

London has made significant progress towards elimination goals for BBVs and reducing preventable BBV deaths and the stigma associated with BBVs; however, many people living with one or more of these BBVs remain undiagnosed or are diagnosed at a late stage. This is despite widely available, safe, effective and free treatments for BBVs. More needs to be done to expand testing to identify people living with BBVs earlier and EDs have a key role to play.

Opt-out ED testing is an effective strategy to identify people living with undiagnosed BBVs and to support diagnosed people who have disengaged from care to reengage. ED opt-out BBV testing supports the national <u>HIV Action Plan</u>'s commitment to end new HIV cases in England by 2030 (aligned to the <u>World Health</u> <u>Organisation (WHO)</u> and <u>UNAIDS</u> global HIV strategies), WHO viral hepatitis elimination goals and a more inclusive and population-focused approach to elimination programmes.

Routine BBV testing in EDs builds on HIV opt-out testing in EDs, which has been successfully implemented in several London EDs, and is supported by <u>Fast Track</u> <u>Cities London</u>, London HIV Community Advisory Group, London HIV Clinical Forum, <u>Terrence Higgins Trust</u>, <u>National AIDS Trust</u>, <u>National Institute of Clinical Excellence</u> (NICE), <u>Royal College of Emergency Medicine (RCEM)</u>, the <u>British HIV Association</u> (BHIVA), <u>British Association of Sexual Health and HIV (BASHH) and British Infection</u> <u>Association (BIA)</u>. Inclusion of hepatitis B and hepatitis C testing in routine BBV testing in EDs is supported by <u>UK Health Security Agency</u> (UKHSA), <u>Office for</u> <u>Health Improvement and Disparities</u> (OHID), <u>Hepatitis C Trust</u>, the <u>London Joint</u> <u>Working Group on Substance Use and Hepatitis C</u>, the National Strategic Group on Viral Hepatitis and London Hepatitis C Operational Delivery Networks (ODNs).

Good Practice Principles

1 Governance and oversight

Blood borne virus (BBV) opt-out testing in emergency departments (ED) should be implemented by each London Integrated Care System (ICS) with engagement of all relevant providers and specialty teams. This would include, at a minimum: ED, HIV, sexual health, hepatology, pathology, community organisations, IT, electronic patient records (EPR) and data/ business intelligence.

There should be senior management and leadership oversight at each site with named leads for each specialty area. Each site should develop their own standard operating procedure (SOP). SOPs should include end-to-end clinical pathways and data process flows, with clear lines of responsibility and accountability for key elements, including: public facing communications, the testing process, staff training, Pathology, IT, results management, linkage to care, data collection, reporting, monitoring, audit and evaluation.

2 Emergency department

Opt-out BBV testing should be normalised and considered part of routine care for people who are attending ED and having blood tests.

BBV opt-out testing should have minimal impact on ED staff efficiency and patient flow in the department and should ideally be delivered by existing ED staff.

All ED staff should be provided with training, including clear and simple messaging such as:

"All adults are now routinely tested for HIV, hepatitis B and C unless they opt-out."

The training should ensure that all ED staff feel confident to carry out routine opt-out BBV testing, understand the rationale behind testing and how to signpost to further information.

EDs may wish to identify and train BBV testing champions to lead on updates and training, maintain momentum and support ED staff with opt-out testing.

Every effort should be made to secure accurate patient contact details in ED to ensure that people with reactive or positive results can be contacted.

3 Opt-out testing

Routine BBV testing in EDs should be implemented using an opt-out approach. Key points in the implementation of the opt-out strategy include:

- All adults attending ED who are having blood tests for any reason should be routinely tested for BBVs unless they opt out.
- People should be informed about opt out BBV testing, including the option to optout and how to do so, but pre-test counselling or consent is not required.
- People should be informed using clearly visible and accessible written information that is displayed throughout the ED (see Section 4).
- There is no expectation on ED staff to provide additional verbal information or reminders about BBV testing, but should they wish to do so, it may be helpful to include standard phrasing in staff training, for example:
 "We now routinely test everyone for the common viruses: HIV, hepatitis B and hepatitis C along with the other blood tests you are having in A&E. *If you would prefer not to have these tests done today, you can opt out."*
- The decision to opt-out should be recorded in the person's medical record.
- If someone opts out, they should be signposted (for example, through publicfacing information) to other ways to access BBV testing and support, including local sexual health clinics and home testing providers.
- BBV testing for someone who is unconscious or lacks capacity should be undertaken if it is in their best interests, in accordance with GMC guidance.

Why use BBV opt-out testing in EDs?

Unlike opt-in testing, opt-out testing does not require a person to expressly agree to undergo a test. Instead, they are notified that testing will be performed unless they explicitly decline.

An opt-out strategy considers BBV testing as a routine part of medical care for all adults (16 and over) attending EDs in London, a region with high rates of prevalent infection and new diagnoses of BBVs. Expansion of opt-out testing can include an implied consent approach, which is recommended by this guidance and has been successfully implemented in several London EDs in high areas of HIV prevalence, including Kings College Hospital and Croydon University Hospital. To minimise operational barriers to HIV testing in these busy ED departments, patients who are undergoing blood tests for any reason are made aware that they will be tested for HIV via clearly displayed and accessible banners, posters and leaflets, with the opportunity to opt out. In this way, people attending ED are informed about BBVs, how the test will be carried out, how they will be notified and that they are tested

unless they specifically opt-out. Pre-test counselling is not required. Instead, counselling resources are focused on people who have a reactive or positive result.

There is a strong rationale for adopting an opt-out approach to BBV testing in areas of high prevalence instead of a risk-based or opt-in approach. Systematic review evidence shows that opt-out programmes can increase uptake when compared to opt-in. Routine opt-out testing reduces both patient and staff anxiety associated with BBV testing, fosters earlier diagnosis and treatment, and thereby reduces onward transmission and is likely to be cost effective. Making BBV testing routine for all patients normalises the process and is expected to reduce the stigma associated with a risk-based testing approach. An opt-out strategy for BBV testing is important to address health inequalities by reaching groups, such as those from ethnic minorities, who may be disproportionately affected both by higher rates of some BBVs and stigma associated with BBV testing or diagnosis. Finally, opt-out testing provides a valuable opportunity to re-engage with people who have previously been diagnosed with a BBV but who are not accessing treatment or care.

Precedent for opt-out BBV testing already exists in NHS antenatal services, sexual health clinics, prisons and testing of all healthcare workers. Opt-out HIV testing has been successfully implemented in many EDs and acute medical admissions units in England. Several EDs have also successfully piloted opt-out BBV testing for HIV, hepatitis B and hepatitis C.

Where opt-out testing is not applicable

Opt-out BBV testing is a population level testing programme and is therefore not applicable where there is concern that a patient's presentation in ED is BBV-related. Where someone presents with a condition that is suspected to be related to HIV, hepatitis B or hepatitis C, including HIV seroconversion and acute hepatitis, expedited BBV diagnostic testing and early involvement of HIV/ID/hepatology specialists is advised.

Similarly, if someone attending ED, or the clinician seeing them, is concerned that they are particularly at risk for a BBV (for example, due to the patient disclosing a recent risk), then there should be clear signposting to the relevant specialist service. This could be to the local sexual health clinic, or other relevant service, to ensure that they are offered full diagnostic testing and appropriate support, including prevention counselling, discussion about BBV testing window periods and any need for repeat testing.

4 Public facing information

Key messages about BBV testing, and how to opt-out, should be displayed prominently in the ED, particularly in waiting areas and phlebotomy areas.

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At the minimum, public-facing communications should include clear messaging on the following:

- a. The opt-out nature of ED BBV testing and to speak to a member of staff if they wish to opt-out or discuss testing further
- b. BBV care and treatment is safe, effective and free from the NHS
- c. BBV results are confidential
- d. How results will be provided ("no news is good news")
- e. How to seek further information.

Ensuring accessibility of information

Information should be available in a range of accessible formats, including posters, banners and leaflets, digital and paper options, translations in at least the five most spoken languages and paper large print versions. There should be specific provision of accessible public-facing information for people who are blind or partially sighted.

A range of pan-London public-facing communications materials will be made available for sites to use, should they wish.

5 Pathology

For the purposes of this guideline BBV testing refers to testing to detect current infection with HIV, hepatitis B and Hepatitis C.

The recommended tests are as follows:

- HIV: 4th generation HIV antibody/antigen test
- Hepatitis B: Hepatitis B surface antigen
- Hepatitis C: Hepatitis C antibody with reflex RNA testing on the same sample if antibody positive. For sites that are unable to provide hepatitis C antibody with reflex RNA testing on the same sample, testing for hepatitis C with hepatitis C antigen would be an acceptable alternative.

Failsafe automatic reporting of all non-negative results should be set up to report to all relevant parties as agreed in local SOPs (for example, HIV/Hepatology/Infectious Diseases), with clear protocols to ensure that all non-negative results are actioned.

6 Working with EPR systems

In Croydon University Hospital, the HIV team worked closely with the local EPR team to develop electronic alerts, automatic EPR requests and laboratory ordering algorithms that allowed them to achieve and sustain very high uptake rates of HIV opt-out testing in their ED. Learning from the Croydon approach has informed the following recommendations:

- BBV tests should be automatically added when any blood test is requested in ED. This removes the need for staff to manually add on an BBV testing. An automated system message such as: "Added by system as part of ED BBV Testing" may be included.
- Opting out of BBV testing should be recorded on the person's medical record.
- Recording of opt-out should automatically block ordering of BBV tests (including individual BBV tests) or generate a prompt for ED staff to deselect BBV tests from the order set.
- Sites may wish to include the option to record the reason for opting out for example, the person reports that they are already aware that they are living with a BBV.
- Recording opt-out should generate a problem or condition on the person's medical record including the date of decline, for example: "*BBV Testing Declined* 11/2/22".
- The opt-out triggered block on BBV testing should be automatically deleted after an appropriate period – six months is recommended. This means that BBV testing would automatically be blocked for six months following the person's initial opt out, and if they attend the ED after six months, they would again need to optout.
- Repeat testing: EPR should block repeat BBV testing within an agreed period 12 months is recommended. There must be an option for the clinician to override this if earlier repeat testing is indicated (for example, new clinical or risk-based indication).
- Clinical and pathology teams should work with EPR teams to develop appropriately cautious wording to accompany reporting of an initial non-negative BBV result on EPR. This should highlight that repeat testing is always required to confirm a diagnosis and that non-negative results are managed by specialist teams.

7 Communicating results to patients

Public-facing information should state that patients will only be contacted if they have a reactive or indeterminate result, or, if agreed locally, because there is a quality control issue – for example, an underfilled sample.

Local SOPs should specify when the patient should expect to hear from the results team(s) in the event of a non-negative result: 14 days is recommended.

Local SOPs may wish to develop appropriately cautious wording for local patient communications to reflect that while the intention is to test everyone and that every effort will be made to contact patients in the event of a non-negative result, the following caveats may apply:

- in a small number of cases there may be BBV tests that are undertaken in ED but are not processed due to technical issues or human error
- if a patient's details are incorrect or the patient is not able to respond to attempts to contact them, then there may be a delay in notifying them.

As stated in '<u>Section 3. Opt-Out Testing</u>': if a patient attends ED and is particularly concerned about BBVs and testing, then they should be signposted to specialist services – such as the local sexual health clinic for dedicated counselling, testing and follow up.

8 Management of negative results

A "no news is good news" approach for negative results is recommended. This means that the patient does not need to be informed in the event of a negative result.

9 Management of non-negative BBV test results

ICSs should support ED, pathology and specialist clinical services to work jointly to agree on clear lines of responsibility and accountability for management of non-negative BBV results at each site.

ED staff are not expected to manage non-negative results from BBV testing, nor are they expected to inform or counsel people about a reactive test result. All nonnegative results should be automatically reported to and managed by the relevant specialist teams (HIV/Sexual Health/Hepatology/hepatitis C ODNs) who will notify the individual, organise confirmatory testing and facilitate linkage to care and support. Local SOPs should build on existing pathways for management of non-negative BBV results and should be suitable to manage the expected increased volumes of results generated by ED testing and additional considerations specific to ED testing.

Failsafe automatic reporting of all non-negative results should be set up to report to all relevant parties (for example, HIV/Hepatology/Infectious Diseases/ ED) with clear protocols to ensure that all non-negative results are actioned.

If an individual has a reactive BBV test in ED and re-presents to ED before the results team has been able to inform them, then ED should discuss with the relevant specialist team to ensure the individual is informed during that ED attendance.

Inpatient teams should be informed if a patient has a reactive BBV test in ED and is subsequently admitted to hospital.

Each site should develop a robust results management SOP that includes end-toend processes for recall, confirmatory testing, linkage to appropriate care and support services, and management of quality control issues. It should be clear in local SOPs the points at which clinical responsibility is transferred between different teams. SOPs should be informed by national standards for the care of people living with HIV, hepatitis B and hepatis C.

10 Quality control issues

Local protocols should be developed for instances where a blood sample has been taken but BBV testing cannot be performed (for example, underfilled samples). In this case it is recommended that the individual is notified and signposted to services where they can access a repeat test – such as, the local sexual health clinic and/ or to home testing services.

11 Resource allocation

Adequate resources should be allocated for the following key areas:

- staff training in EDs
- ED testing
- pathology
- results management (including data entry, monitoring, reporting, audit and evaluation)
- follow up (including peer support).

There should be adequate resource allocated to notify and engage people identified by ED BBV testing who have an existing BBV diagnosis but who have been lost to follow-up. It should be acknowledged that this group may require additional support.

12 Signposting to prevention / further support services

ED departments should offer information on how to access local sexual health services, providers of home sexual health and HIV testing, and sources of information and support around BBVs.

The following websites may be useful:

- The NHS website https://www.nhs.uk/service-search/sexual-health signposts to local sexual health clinics, contraception and pregnancy services and help following a sexual assault.
- Information on where to get an HIV test can be found on the www.nhs.uk
- Free postal test for HIV and syphilis test kits are available from <u>https://freetesting.hiv</u>
- Advice and support about HIV can be found on the Terrance Higgins Trust website <u>www.tht.org.uk</u> and the National AIDS Trust website <u>www.nat.org.uk</u>
- Advice and support about hepatitis C can be found on the Hepatitis C Trust website: <u>http://hepctrust.org.uk</u>
- Advice and support about hepatitis B can be found on the British Liver Trust website: <u>https://britishlivertrust.org.uk</u>

13 Peer support and community involvement

Peer support is an integral part of high-quality BBV care. People differ in their emotional and psychological reaction to a positive BBV diagnosis and will require a range of community and peer-support services. These can be vital to adjustment to their diagnosis, as well as supporting long-term condition management and adherence, and should therefore be integrated into their care and treatment. Particular attention should be given to vulnerable groups who may be at greatest risk of being lost to follow up or not engaged in services.

ICSs should ensure that services for newly diagnosed people work with local community organisations and national groups to ensure that community and peer support is offered to all individuals who have a positive BBV diagnosis identified through ED testing. This offer should be co-produced with community organisations and integrated into the care and treatment pathway, in line with <u>national standards</u> for peer support, <u>NICE guidance</u>, <u>BHIVA standards</u>, and include the NHS England and Improvement commissioned hepatitis C peer support. ICSs may wish to consider the use of peer and community support to help newly engaged people engage with services for initial evaluation.

14 Data collection, reporting, monitoring and evaluation

ICSs should work with sites to ensure robust processes and resources are in place to support data collection and reporting for the purposes of clinical care, programme assurance, audit, service evaluation and national surveillance.

Data recorded by sites should include the following minimum set of core monitoring metrics. This is not intended to be an exhaustive list and will vary according to the BBV.

Core monitoring metrics for sites undertaking BBV opt-out testing

- BBV testing as a proportion of people attending ED who are having blood tests
- numbers of reactive tests
- proportion of reactive tests that are true positive results
- proportion of people with a positive test who are newly diagnosed and those who had previously been diagnosed
- proportion of those previously diagnosed who are in care vs. lost to follow up
- proportion of people with a reactive test who are contacted
- proportion of people with a reactive test who are offered peer/ community support
- time to linkage to care
- time to starting treatment (acknowledging that not all people, particularly people living with HBV will start treatment)
- demographic data (age, ethnicity, gender and so on).

Data considerations for macro-level monitoring and surveillance

Macro-level monitoring of the programme by UKHSA and NHSEI will be mainly through existing centralised data collection systems and data linkage to follow the person's care pathway. The systems include:

- NHSD HES Emergency Care Dataset (ECDS) for ED attendees and blood tests
- UKHSA national BBV testing, diagnosis, care monitoring surveillance systems (e.g. Sentinel Surveillance of BBV testing (SSBBV)
- Second Generation Surveillance Systems (SGSS) for new diagnoses of notifiable organisms such as hepatitis B and hepatitis C

- HIV and AIDS Reporting System (HARS)
- HIV and AIDS New diagnoses database (HANDD)
- National HCV Treatment Monitoring Registry

To support macro level monitoring and surveillance, data leads at sites should ensure:

- accurate and consistent reporting to these systems, particularly NHSD HES / ECDC and UKHSA SSBBV
- laboratories are part of the SSBBV network
- agreed, standardised reporting metrics should be used.

In addition to core metrics, measures for audit, monitoring equity, economic evaluation and quality assurance will be considered and introduced.

Bespoke data collection may be necessary for some indicators that are not part of existing centralized systems – for example, proportion of people contacted with their result, and method of contact – unless these can be captured through site-specific / ICS systems and reported centrally.

Monitoring data will also feed into an evaluation of the programme, encompassing clinical/public health, economic and implementation optimization, that will be led by UKHSA in co-production with sites and stakeholders.