British HIV Association (BHIVA), British Association for Sexual Health and HIV (BASHH), British Infection Association (BIA) and Royal College of Emergency Medicine (RCEM) joint working group: rapid guidance on opt-out blood-borne virus testing in high-prevalence and extremely high-prevalence acute medical settings and emergency departments

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Introduction

In late 2022 BHIVA established a working group to develop a rapid guidance statement on the model of consent for opt-out testing for blood-borne viruses (BBVs; HIV, hepatitis B virus [HBV] and hepatitis C virus [HCV]) in emergency departments (EDs) and other acute medical settings. Routine opt-out HIV (with HBV and syphilis) testing has been the standard of care in antenatal services since 2000 and has been successfully piloted in several EDs across the UK over the past decade. The success of opt-out testing in EDs in finding new cases of HIV and people who had been previously diagnosed but were no longer in care led to a commitment from the UK government to expand opt-out HIV testing to all EDs in the highest HIV prevalence areas, as part of the national HIV Action Plan [1]. The rapid expansion of opt-out HIV testing in EDs has led to a pressing need for further guidance on opt-out testing to supplement the existing BHIVA/BASHH/BIA HIV testing guidelines [2].

This interim guidance is intended to assist EDs in high-prevalence (>2/1000) and extremely high-prevalence (>5/1000) areas, and other facilities managing people who present for urgent care (e.g. urgent treatment centres and same day emergency care), in developing processes for routine opt-out testing for BBVs including HIV and in reaching high coverage. It could also be used as a model for other healthcare settings. The guidance has been endorsed by the RCEM Quality in Emergency Care Committee. It is expected that an interim update to the BHIVA/BASHH/BIA HIV testing guidelines in 2024 will incorporate this guidance.

Given the successful experience of many EDs in using opt-out BBV testing, we propose a set of best practice recommendations for sites setting up similar testing processes. This guidance has been developed with a working group including ED consultants, HIV and Infectious Disease consultants and community representatives.

Summary of recommendations

1. **Governance and practical implementation**

For implementation of a routine opt-out BBV testing system in EDs we recommend referring to the NHS Blood-borne viruses opt-out testing in emergency departments in London: good practice guidance (section 1) [3] (Grade 1C).

2. **Training of staff in EDs**

All members of staff in EDs require training on the opt-out testing process, including how to provide further information on tests and how people attending EDs may receive test results (GPP).

3. **Publicity in EDs**

Posters/banners and leaflets on opt-out testing should be available with clear instructions on how to opt-out of tests and, where possible, how/where to obtain test results. If departments operate a policy of not informing people attending EDs if the results are negative, this should be made clear in the publicity. Links to translations in the most commonly spoken languages other than English among people attending the hospital should be made available (GPP).

4. Situations in which opt-out testing may not be appropriate

There are some situations in which opt-out testing for BBVs may not be appropriate. We recommend referring to the 2020 RCEM best practice guideline [4] and the 2020 BHIVA/BASHH/BIA HIV testing guidelines [2] for further guidance (GPP).

5. Provision of reactive results

EDs should not be expected to manage results arising from BBV testing. Pathways for results management should be co-designed with the relevant local specialist services (genitourinary medicine [GUM]/sexual health clinics, HIV, infectious diseases or hepatology), with these specialist services taking responsibility for managing all results (including indeterminate results and those with a sample error, e.g. underfilled or mislabelled samples) and the onward care of people attending EDs (Grade 1C).

6. Monitoring and evaluation of services

Units should evaluate the effectiveness of opt-out testing via audits, service evaluations and national surveillance (GPP).

Background and rationale

Since the late 2010s, it has been increasingly common for EDs in high-prevalence areas (for HIV and other BBVs) of the UK to include opt-out HIV testing for all adults where blood is taken. In Europe, opt-out HIV testing has been defined by the EuroTEST initiative as: "consent based on pre-test information, provided by posters, information leaflets or videos, displayed in waiting rooms that HIV and/or blood-borne virus testing is included in routine blood testing or a medical intervention package, effectively given by allowing someone to draw blood from the arm but without prior specific discussions about which conditions are being tested for and without the requirement for explicit oral or written consent" [5]. Opportunistic opt-out testing for BBVs is based on extensive evidence that testing in UK EDs is effective in identifying undiagnosed BBV infections and people known to be living with BBVs who are no longer accessing care [6-8]; it is also supported by European Centre for Disease Control guidance on BBV testing [9]. Testing in EDs and other acute medical settings is also consistent with National Institute for Health and Care Excellence, RCEM and BHIVA/BASHH/BIA testing guidelines for areas of high HIV prevalence [2,4,10] and follows the highly successful model of antenatal testing for BBVs and syphilis [11]. Expanded BBV testing will contribute to national and World Health Organization goals of ending HIV transmission and eliminating HCV infection by 2030 [12,13].

As part of the HIV Action Plan [1], NHS England allocated £20 million towards opt-out HIV testing in EDs in areas of extremely high HIV prevalence in England in late 2021; subsequently HCV elimination programmes have supported integrated BBV testing in EDs. In practice, in EDs implementing opt-out testing, high coverage is achieved by widely displaying written information clearly in waiting rooms and treatment areas via posters and other materials which state that these tests will be done routinely in those having a blood test unless someone opts out. Implementation of opt-out testing

was first piloted in some EDs involved in the Going Viral project in 2014 [14] and has been formalised as part of the 2022 Blood-borne viruses opt-out testing in emergency departments in London: good practice guidance [3] or by consultation with a trust's ethics committee. Where opt-out testing has been implemented, training of ED staff has included where to direct people with concerns about undergoing BBV tests. There are clear pathways for specialist services (GUM/sexual health clinics, HIV, infectious diseases or hepatology) to take responsibility for all results management and onward care of all people diagnosed with BBVs through ED testing.

A pilot study of this approach in an ED in Leeds (2018–2019) identified 247 people with HCV, 128 people with HBV and 124 people with HIV, out of 33,816 tests [6,15]. The majority of these people were already known to be living with BBVs but were not engaged in care at the time. A recent analysis of the first year of the NHS England ED programme of testing in areas of extremely high HIV prevalence showed that there were 5068 positive HIV tests, of which 4400 were people already in care, 341 were new diagnoses and 208 were people previously diagnosed and not currently in care; status was not yet known for 119 [16].

The ethical framework for opt-out HIV/BBV testing largely follows the widely accepted precedence in antenatal testing, which has an uptake of over 99% and has effectively eliminated vertical HIV transmission in the UK. Historically, due to the sensitive nature of HIV testing, the General Medical Council (GMC) guidance was that explicit consent for a test was required, however this resulted in exceptionalism of HIV testing [17]; there was not the same requirement for other BBV tests, including HBV and HCV. Since 2008 the GMC has removed explicit references to HIV testing in its guidance on consent [18], thereby incorporating it within the general guidance. There are several reasons why the original GMC approach was questioned and the case for continued exceptionalism of HIV is widely felt to be no longer valid and potentially harmful [19]. First, HIV and other BBVs are now fully treatable (with a potential cure for HCV), and people normally have a very good prognosis with treatment. Moreover, treatment eliminates onward sexual transmission. Second, there is substantial evidence that such exceptionalism has been and remains a clear barrier to testing among both patients and healthcare providers; this inevitably has led to missed opportunities for testing, and later diagnoses when prognosis is poorer, healthcare costs are higher and further transmission of infections occurs.

The HIV Commission (2020), led by non-governmental organisations and including community representation, made a strong argument in favour of normalising HIV testing in order to end late diagnosis and onward transmission [20]. While formal evaluations of people's experiences of ED opt-out testing are ongoing and yet to be published, a number of case studies in the NHS England London ED programme report [3] indicate the likelihood of high acceptability of the process. Moreover prior to initiation of the Leeds ED project, 200 people attending the ED were asked to complete a survey about the concept of 'notional' consent for BBV tests, and 83% agreed that it was acceptable [15].

Literature search

We conducted a literature search and evidence review and found few publications related to opt-out, assumed, implied or notional consent for HIV or BBV testing; these terms are all consistent with

the European AIDS Clinical Society definition of opt-out testing. The Leeds project and a similar programme at St George's Hospital in London appear to be the only published studies from departments in which this form of consent was routinely implemented [6,15,21]. One UK study published in 2017 investigating the attitudes of clinicians and the public to such forms of BBV testing consent in any setting showed that both groups preferred a reminder about testing at the point of blood being taken [22]. Another study in a UK ED where this was implemented identified a large number of people with HIV who were not engaged in care, with high numbers of these people subsequently engaging in care [8]. In two studies assessing staff and service users' attitudes to opt-out BBV testing in EDs (with a mandated verbal reminder to people about testing), a number of issues relating to processes and perceptions of testing were identified [6,23]. A further systematic review of ED-based BBV testing showed general acceptability but a need for improved linkage to care for those testing positive [24]. A recent update on the NHS England ED testing programme highlighted further challenges with linking new diagnoses to care [25].

Given the paucity of literature and evidence to inform recommendations, it was the view of the working group that use of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for evaluation was limited. Hence recommendations given in this guidance are mostly good practice points (GPP), based on the experience of clinicians working in EDs and HIV/viral hepatitis services in participating centres, of healthcare professionals working in other settings in which BBV testing is carried out, and of representatives of community/service user organisations.

Recommendations

1. Governance and practical implementation

In terms of the logistics and governance of implementing an opt-out BBV testing system in areas of high/extremely high HIV prevalence, we recommend referring to the NHS Blood-borne viruses opt-out testing in emergency departments in London: good practice guidance (section 1) [3]. We recommend establishing a named lead for the ED service with sufficient time allocated to contribute to setting up the service, providing training and monitoring outcomes following implementation. Trusts should take measures to minimise the risk of people attending ED believing that they have been tested for BBVs when they have not been tested. These measures may include maximising test uptake and clear patient-facing information about the testing process, and maximising exposure to opt-out information.

Given the risk of people believing incorrectly that they have been tested (when coverage of BBV testing in EDs is low), we recommend that pathology ordering systems include automated BBV testing requests. Typically this will automatically include all three BBVs (as a bundle) with any blood test ordered in the ED, for example linked to a full blood count or renal function test request. We also recommend that automatic HCV RNA testing of samples reactive for HCV IgG is built in and that test ordering systems have processes to avoid re-testing within 12 months.

Individual units should decide with pathology laboratories whether tests can be conducted on a serum (biochemistry) sample, which is the simplest option, or whether a separate serum sample is

required. The latter (preferred) option has the advantage of being able to support more additional (confirmatory) tests (e.g. HCV RNA or confirmatory HIV tests) for reactive or indeterminate samples.

2. Training of staff in EDs

It is important to ensure that all members of staff in EDs are aware of the opt-out testing process, how to ensure testing is avoided when the person opts out and who to refer people to when they require more information or in-depth discussion. Moreover, staff should be advised to remind people attending EDs about testing if they cannot read or understand the posters or have insufficient knowledge of written English (and any of the other translations). Training should be provided to new members of staff and during junior doctor induction and to those responsible for phlebotomy, who may be asked questions about the testing. Training should include discussion of when reminders about tests are appropriate and when testing may not be appropriate as well as situations in which a pre-test discussion with the person about BBVs is needed (see below).

3. Publicity in EDs

Highly visible posters, banners or electronic screen displays and accessible leaflets on opt-out testing in areas in which blood is taken should be the minimum requirement for EDs. These should provide clear instructions on how to opt-out of tests and, where possible, how and where to obtain test results. If departments operate a policy of not informing service users if the results are negative, this should be stated. Links to translations of patient information materials in commonly spoken languages other than English should be made available; it is anticipated that a national website incorporating translations of this information in many languages will be available with links from 2024. These materials should have clear instructions on how to opt out of tests. Information on BBV testing should also be incorporated into generic ED patient information leaflets, which could be accessed online or via a QR code.

4. Situations in which opt-out testing may not be appropriate

There are some situations in which opt-out testing for BBVs may not be appropriate; this is further discussed in the RCEM best practice guideline [4] and the 2020 BHIVA/BASHH/BIA HIV testing guidelines [2]. Such situations will include where someone presents with a condition suggesting that HIV/BBV infection is likely, in which case a pre-test discussion should ideally take place; however, this concern should not prevent BBV tests being ordered. In a person who is unconscious or lacks capacity to opt in or opt out, BBV testing should be undertaken if in the best interests of the person, in accordance with GMC guidance (paragraphs 88 and 89) [18]. It is considered generally to be in the person's best interest to be included in, rather than excluded from, BBV testing programmes as attending an ED in an area with high HIV prevalence constitutes a higher risk of HIV than that of the general UK population.

5. Provision of reactive results

A designated department or departments should be responsible for handling all results (to include indeterminate results and those with a sample error, e.g. underfilled or mislabelled samples). This will normally be a local GUM/sexual health clinic or HIV, infectious disease or hepatology unit, rather than the ED itself, and may be in a different trust/organisation. Departments should be aware that people with underfilled or mislabelled samples may believe they have been tested, when testing was

not possible. A 'no news is good news' approach for negative results is pragmatic and acceptable, or (where possible) an automated system for providing negative results is recommended. People should be informed about reactive (or 'non-negative') results according to local standard operating procedures, which will normally involve contact by telephone or other applications. We encourage relevant services to involve community support groups in assisting and supporting people diagnosed in EDs in engaging with HIV and viral hepatitis services.

6. Monitoring and evaluation of services

It is important that units evaluate the effectiveness of opt-out testing via audits, service evaluations (ideally including acceptability to service users) and national surveillance. Suggested metrics for such evaluations are provided in section 14 of the NHS good practice guidance [3]. Services are recommended to evaluate the effectiveness of teaching and training on BBV testing and ensure all staff feel confident and well supported.

Conclusion

Given the rapid development of opt-out BBV testing in EDs over the past few years, the purpose of this guidance is to provide some assistance to organisations currently testing and those starting a testing programme. We anticipate this approach becoming more common and future BHIVA/BASHH/BIA HIV testing guidelines providing further guidance on opt-out testing within EDs and other facilities where it may be appropriate.

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