Memorandum of Understanding

between

NHS ENGLAND

and

UK HEALTH SECURITY AGENCY

in relation to

EVALUATION OF THE EMERGENCY DEPARTMENT OPT OUT BLOOD BORNE VIRUS TESTING PROJECT

Clause

ANNEX

THIS AGREEMENT is dated _____

PARTIES

(1) **NHS ENGLAND** of Quarry House, Quarry Hill, Leeds, LS4 7UE ("**NHS England" or "NHSE"**).

(2) **UK HEALTH SECURITY AGENCY** of 17 Smith Square London SW1P 3JR ("**UKHSA")**

1. BACKGROUND

1.1 NHS England and UKHSA have agreed to work together on the project detailed in 0 (the "**Project"**).

1.2 The parties wish to record the basis on which they will collaborate with each other on the Project. This Memorandum of Understanding ("**MoU"**) sets out:

(a) the key objectives of the Project;

(b) the principles of collaboration;

(c) the governance structures the parties will put in place; and

(d) the respective roles and responsibilities the parties will have during the Project.

1.3 The Project will commence on 01/02/2023 and expire on 31/03/2025.

2. KEY OBJECTIVES FOR THE PROJECT

2.1 The parties shall undertake the Project to achieve the key objectives set out in 0 to this MoU (the "**Key Objectives"**).

2.2 The parties acknowledge that the current position with regard to the Project and the contributions already made (financial and otherwise) are as detailed in the 0C to this MoU.

3. PRINCIPLES OF COLLABORATION

3.1 The parties agree to adopt the following principles when carrying out the Project (the "**Principles"**):

(a) collaborate and co-operate. Establish and adhere to the governance structure set out in this MoU to ensure that activities are delivered and actions taken as required;

(b) be accountable. Take on, manage and account to each other for performance of the respective roles and responsibilities set out in this MoU;

(c) be open. Communicate openly about major concerns, issues or opportunities relating to the Project;

(d) learn, develop and seek to achieve full potential. Share information, experience, materials and skills to learn from each other and develop effective working practices, work collaboratively to identify solutions, eliminate duplication of effort, mitigate risk and reduce cost;

(e) adopt a positive outlook. Behave in a positive, proactive manner;

(f) adhere to statutory requirements and best practice. Comply with applicable laws and standards including procurement rules, data protection and freedom of information legislation.

(g) act in a timely manner. Recognise the time-critical nature of the Project and respond accordingly to requests for support;

(h) manage stakeholders effectively;

(i) deploy appropriate resources. Ensure sufficient and appropriately qualified resources are available and authorised to fulfil the responsibilities set out in this MoU. In particular the parties agree to make the contributions detailed in Annex C to this MoU and will ensure any key personnel detailed in Annex C are willing and able to provide the input expected of them; and

(j) act in good faith to support achievement of the Key Objectives and compliance with these Principles.

4. PROJECT GOVERNANCE

4.1 The following guiding principles are agreed. The Project's governance will:

(a) provide strategic oversight and direction;

(b) be based on clearly defined roles and responsibilities at organisation, group and, where necessary, individual level;

(c) align decision-making authority with the criticality of the decisions required;

(d) be aligned with Project scope and each Project stage (and may therefore require changes over time); and

(e) provide coherent, timely and efficient decision-making.

4.2 The parties will form a board to provide overall strategic oversight and direction to the Project ("the "Emergency Department Blood Borne Virus (ED BBV) Testing Evaluation Advisory Group").

4.3 The terms of reference of the ED BBV Testing Evaluation Advisory Group are set out in Annex C to this MoU.

5. ROLES AND RESPONSIBILITIES

5.1 The parties shall undertake the roles and responsibilities set out in Annex D to this MOU to deliver the Project, based on the proposal submitted and attached as Annexe E.

6. ESCALATION

6.1 If either party has any issues, concerns or complaints about the Project, or any matter in this MoU, that party shall notify the other party and the parties shall then seek to resolve the issue by a process of consultation. If the issue cannot be resolved within fourteen (14) days, either party may escalate the matter to the ED BBV Testing Evaluation Advisory Group, which shall decide on the appropriate course of action to take.

6.2 If either party receives any formal inquiry, complaint, claim or threat of action from a third party (including, but not limited to, claims or requests for information made under the Freedom of Information Act 2000) in relation to the Project, the matter shall be promptly referred to the ED BBV testing Evaluation Advisory Group. Each party shall use reasonable endeavours to consult with the Collaborators' Board before any action is taken in response to any such inquiry, complaint, claim or action but for the avoidance of doubt, such action may be taken without consultation with the ED BBV testing Evaluation Advisory Group where the recipient of the inquiry, complaint, claim or action considers it reasonable to do so, for example where an urgent response is required. The parties shall each provide all reasonable assistance to the other, including but not limited to the provision of information in a timely manner, in order for the other party to deal with any inquiry, complaint, claim or action.

7. INTELLECTUAL PROPERTY

7.1 For the purposes of this MoU the term "Intellectual Property Right" shall have the following meaning:

patents, rights to inventions, copyright and related rights, moral rights, trade marks and service marks, business names and domain names, rights in get-up, goodwill and the right to sue for passing off, rights in designs, rights in computer software, database rights, rights to use, and protect the confidentiality of, confidential information (including know-how and trade secrets) and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.

7.2 The parties intend that any Intellectual Property Rights created in the course of the Project shall vest in the party whose employee created them.

7.3 Where any Intellectual Property Right vests in either one of the parties in accordance with the intention set out in clause 7.2 above, that party shall grant an irrevocable, royalty-free, non-exclusive licence to the other party to use that intellectual property for the purposes of the Project.

8. CONFIDENTIAL INFORMATION

8.1 "Confidential Information" means any information which has been designated as confidential by either party in writing or that ought to be considered as confidential (however it is conveyed or on whatever media it is stored) including information the disclosure of which would, or would be likely to, prejudice the commercial interests of any person, trade secrets, Intellectual Property Rights and know-how of either party and all Personal Data and special categories of personal data within the meaning of the Data Protection Act 2018. Confidential Information shall not include information which:

(a) was public knowledge at the time of disclosure (otherwise than by breach of this clause 8);

(b) was in the possession of the receiving party, without restriction as to its disclosure, before receiving it from the disclosing party;

(c) is received from a third party (who lawfully acquired it) without restriction as to its disclosure; or

(d) is independently developed without access to the Confidential Information.

8.2 Except to the extent set out in this clause or where disclosure is expressly permitted elsewhere in this MoU, each party shall:

(a) treat the other party's Confidential Information as confidential and safeguard it accordingly; and;

(b) not disclose the other party's Confidential Information to any other person without the owner's prior written consent.

8.3 Clause 8.2 shall not apply to the extent that:

(a) the law requires such disclosure by the party making the disclosure, including any requirements for disclosure under the Freedom of Information Act 2000, or the Environmental Information Regulations 2004; and

(b) the information is contained in the MoU and is to be disclosed under the Government's Transparency policy.

8.4 A party may only disclose the other party's Confidential Information to its staff who are directly involved in the provision of the Project and who need to know the information, and shall ensure that its staff are aware of and shall comply with these obligations as to confidentiality.

8.5 Each party shall not, and shall procure that its staff do not, use any of the other party's Confidential Information received, otherwise than for the purposes of the Project.

8.6 Nothing in this MoU shall prevent a party from disclosing the other party's Confidential Information:

(a) for the purpose of the examination and certification of its accounts; or

(b) for any examination pursuant to Section 6(1) of the National Audit Act 1983.

8.7 Nothing in this clause 8 shall prevent either party from using any techniques, ideas or know-how gained during the performance of the MoU in the course of its normal business to the extent that this use does not result in a disclosure of the other party's Confidential Information or an infringement of Intellectual Property Rights.

9. PUBLICITY

A party shall not make any public statement, announcement or communication relating to the existence or performance of the MoU or the relationship between the parties without the other party's prior approval in writing, which shall not be unreasonably withheld.

10. TERM AND TERMINATION

10.1 This MoU shall commence on the date of signature by both parties and shall expire on completion of the evaluation project.

10.2 Either party may terminate this MoU by giving at least three months' notice in writing to the other party.

10.3 On termination of this MoU by either party, in the event that UKHSA (in the reasonable opinion of NHS England) has failed to carry out its responsibilities under this MoU, NHS England shall be entitled to recover all or part of any funds paid to UKHSA under this MOU by issuing a written request stating how much UKHSA is liable to repay to NHS England. On receipt of any such written request, UKHSA shall return the requested sum to NHS England within ten (10) business days of receipt of the request.

10.4 Termination of this MoU shall not affect the continuing rights, remedies or obligations of the parties.

11. VARIATION

This MoU, including the Annexes, may only be varied by written agreement of NHS England and UKHSA.

12. ASSIGNMENT

Outside of this agreement, which includes the limited and defined subcontracting to the University of Bristol, neither party shall assign, transfer, mortgage, charge, subcontract, delegate, declare a trust over or deal in any other manner with any or all of its rights and obligations under this MoU without the prior written consent of the other party (such consent not to be unreasonably withheld or delayed).

13. COSTS AND LIABILITIES

13.1 Except as otherwise provided, the parties shall each bear their own costs and expenses incurred in complying with their obligations under this MoU.

13.2 The parties agree to share the costs and expenses arising in respect of the Project between them in accordance with 0 to this MoU.

13.3 Both parties shall remain liable for any losses or liabilities incurred due to their own or their employees' actions and neither party intends that the other party shall be liable for any loss it suffers as a result of this MoU.

14. STATUS

14.1 Unless otherwise stated, this MoU is not intended to be legally binding, and no legal obligations or legal rights shall arise between the parties from this MoU. The parties enter into the MoU intending to honour all their obligations.

14.2 Nothing in this MoU is intended to, or shall be deemed to, establish any partnership or joint venture between the parties, constitute either party as the agent of the other party, nor authorise either of the parties to make or enter into any commitments for or on behalf of the other party.

Signed for and on behalf of NHS England

DocuSigned by:
[redacted]
0E4D3AEB7E0A4BC...

Name: .....

Full Name: [redacted] .....

Position: .....

Job Title/Role: [redacted] .....

Date: .....

Date Signed: 23 May 2023

Signed for and on behalf of UKHSA

DocuSigned by:
[redacted]
DA4ECD056714444...

Name: .....

Full Name: [redacted] .....

Position: .....

Job Title/Role: [redacted] .....

Date: .....

Date Signed: 11 May 2023

CONTACT POINTS

For NHS England

Name:	[redacted]
Office address:	NHS England, Quarry House, Quarry Hill, Leeds, LS4 7UE
Tel No:	[redacted]
E-mail Address:	[redacted]

For UKHSA

Name:	[redacted]
Office Address:	UKHSA 61, Colindale Ave London, NW9 5EQ
Tel No:	[redacted]
E-mail Address:	[redacted]

Annexe A. The Project

Project overview

To undertake monitoring and evaluation to optimise the emergency department blood borne virus opt-out testing programme in terms of individual and public health benefits as well as value for money. This will take a three-pronged evaluation approach: combining public health monitoring, economic evaluation (both collecting mainly quantitative data) as well as implementation optimisation / behavioural science research (collecting mainly qualitative data).

The Key Objectives

Three key objectives have been identified:

- Evaluate the implementation of ED opt-out BBV testing to provide recommendations to guide optimisation and standardisation and any future roll-out of ED testing in lower prevalence sites.
- Evaluate the ED opt-out testing programme, comparing different models of delivery using mainly quantitative data (and mixed methods) implementation optimisation / behavioural science research (collecting mainly qualitative data).
- Undertake cost effectiveness analysis of hepatitis and HIV testing in EDs comparing different models of opt-out, contacting patients and linkage to care.

The existing position and contributions already made

The Emergency Department Blood Borne Virus (ED BBV) opt out testing project was launched in April 2022. 33 of the 34 targeted emergency departments have currently implemented BBV testing. The inclusion of any additional emergency departments in the Project will be subject to clause 11.

Annexe B. ED BBV testing Evaluation Advisory Group: Outline Terms of Reference

1. PURPOSE

1.1 The ED BBV testing Evaluation Advisory Group will provide expert input on all aspects of the evaluation, particularly with regards to clinical activities

1.2 Each party shall delegate to its representative on the ED BBV testing Evaluation Advisory Group such authority as is agreed to be necessary in order for the ED BBV testing Evaluation Advisory Group to function effectively in discharging the duties within these Terms of Reference. Each party shall ensure that its representative has the relevant delegated authority.

2. RESPONSIBILITIES

2.1 The overarching objectives of this group are to:

(a) Provide expertise and intelligence on relevant issues affecting ED opt-out testing and other work ongoing in the sector to inform the direction of the ED-opt out evaluation.

(b) Support and provide guidance to the evaluation project to meet its aim and objectives and/or suggest a means by which these can be amended if required.

(c) Review and provide feedback on evaluation outputs including the formal evaluation reports.

(d) Provide recommendations for future work on the basis of the evaluation reports.

3. ACCOUNTABILITY

3.1 The group's advice will inform the work of the ED BBV testing Operational Group (comprised of NHSE, UKHSA and University of Bristol members) which reports to the National ED BBV testing steering group.

4. MEMBERSHIP AND QUORUM

4.1 The ED BBV testing Evaluation Advisory Group will comprise membership from NHSE, UKHSA, University of Bristol and key stakeholders representing clinical and advocacy groups for HIV and hepatitis.

4.2 The ED BBV Testing Evaluation Advisory Group will be chaired by NHSE, UKHSA and University of Bristol on a rotating basis.

5. CONFLICTS OF INTERESTS

Any group member with a conflict of interest against any agenda item must declare it prior to the meeting so a decision can be made as to whether the individual in question can attend that meeting.

6. FINALISATION OF TERMS OF REFERENCE

These Outline Terms of Reference are not final, and it is the intention of the Parties that they shall be finalised and incorporated into this Agreement as soon as possible.

Annexe C. ED BBV testing Operational Group: Outline Terms of Reference

1. PURPOSE:

1.1 The operational group will provide guidance for the evaluation of the ED opt out programme and ensure that the deliverables laid out in the MoU between UKHSA and NHSE are achieved.

2. RESPONSIBILITIES:

2.1 The operational group is responsible to the National ED BBV advisory group.

3. OBJECTIVES

3.1 The operational group will have the following objectives:

a. Provide strategic direction to the evaluation project
b. Review progress against objectives and key milestones
c. Ensure that adequate resources are available to the project
d. Review and provide feedback to the final evaluation plan
e. Review data, challenges and successes within the project and feed back to the ED BBV Advisory group and solicit expert input where required.

4. MEMBERSHIP

4.1 The operational group will consist of the below named people:

Organisation	Name
UKHSA	[redacted]
UKHSA	[redacted]
UKHSA	[redacted]
UKHSA	[redacted]
UKHSA	[redacted]
NHSE	[redacted]
NHSE	[redacted]
NHSE	[redacted]
NHSE	[redacted]
NHSE	[redacted]
NHSE	[redacted]
NHSE	[redacted]
Clinician	[redacted]
UoB	[redacted]
UoB	[redacted]

4.2 In the event of someone not being able to attend they may nominate a replacement.

4.3 Others may be op-opted to the group if UKHSA and NHSE agree such a need arises.

5. MEETINGS

5.1 This group operates as a working group.

5.2 Meetings will be cochaired by a representative each from UKHSA and NHSE

5.3 Papers will be circulated at least two working days in advance of meetings by the secretariat.

5.4 The agenda will be set by the cochairs but the standard agenda is expected to include:

- Introduction
- Review of minutes and actions arising from last meeting
- Update of collaboration with UoB for optimisation and economic evaluations
- Any escalated actions
- Recent activity
- Planned activity
- Changes to risks
- AOB
- Date of next meeting

6. DECLARATION OF CONFLICTS OF INTEREST

6.1 Any group member with a conflict of interest against any agenda item must declare it prior to the meeting so a decision can be made as to whether the individual in question can attend that part of the meeting.

7. TIMELINES AND OUTPUTS

7.1 The intention of the public health evaluation of the ED program is to produce:

(a) Public health evaluation

(b) 6-monthly indicator reports

(c) 12-month evaluation - summer 2023

(d) 24-month evaluation – summer 2024

(e) End of program evaluation - summer 2025

(f) Optimisation evaluation (sub-contracted to Bristol)

(g) Health economic evaluation

Annexe D. Contributions

NHS England will contribute to UKHSA to deliver the following as outlined in table 1to a maximum of £400,000 (including overheads, but excluding applicable VAT). UKHSA will sub-contract to University of Bristol.

Table 1: deliverables and costs

Deliverables	Year	Delivered by	Cost
Undertake one year evaluation report	2023/24	UKHSA	£77,710.50
Preparation of qualitative research protocol	2023/24	UoB	£64,919.50
Analysis plan for health economic protocol	2023/24	UoB	£57,370
Price			£200,000
Final evaluation report	2024/25	UKHSA	£77,710.50
Qualitive analysis report	2024/25	UoB	£64,919.50
Health economics report	2024/25	UoB	£57,370
Price			£200,000
Total exclusive of applicable VAT			£400,000

NHS England staff from the ED BBV testing project team, Hepatitis C Elimination programme and BI teams will engage with the evaluation team to inform the evaluation and offer advice.

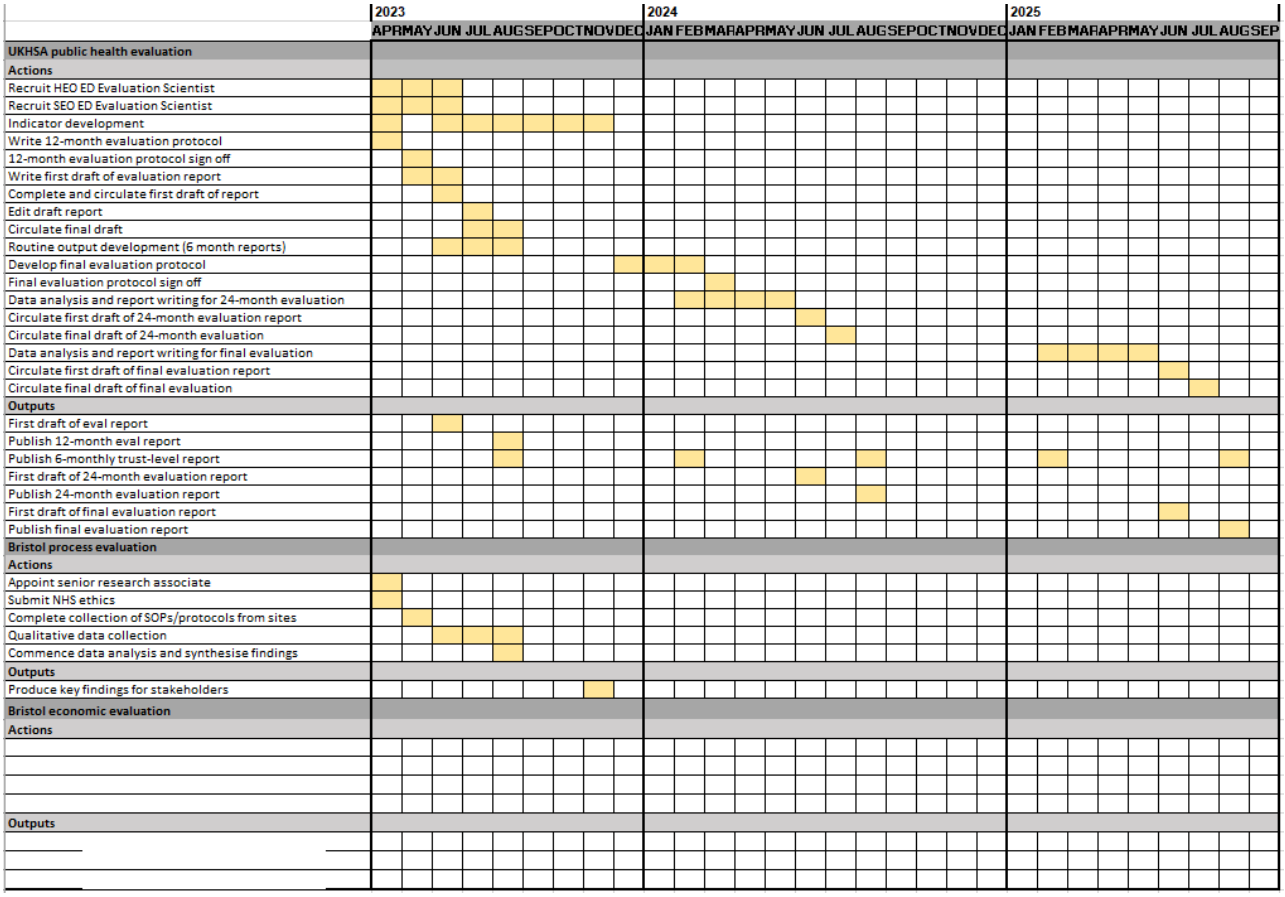
UKHSA will contribute senior management time for the oversight and supervision of this evaluation work over the full duration of the project.

Annexe E. Roles and Responsibilities

Key Objective 1 – Evaluate the implementation of ED opt-out BBV testing to provide recommendations to guide optimisation and standardisation and any future roll-out of ED testing in lower prevalence sites.		
Action	Party Responsible	Deadline
Phase 1: To describe and compare the different strategies and approaches of sites to implement BBV testing in EDs. The existing standard operating procedures (SOP) will be reviewed together with, protocols and patient materials across the 33 sites (28 London, 3 Manchester, Salford, Brighton, Blackpool). Phase 2: To examine the facilitators and barriers to embedding implementation ED opt-out BBV testing, focus group conduct focus group discussions and in-depth interviews with ED staff, target patient populations and stakeholders will be undertaking.	UKHSA will subcontract this to University of Bristol.	describe the different strategies and approaches of sites to implement BBV testing in EDs, (delivery dates as per Gantt chart below)
Key Objective 2 – Evaluate the ED opt-out testing programme, comparing different models of delivery		
Action	Party Responsible	Deadline
1. Standardised data collection and monitoring throughout the programme 2. Analysis of first twelve months 12-15 months 3. Analysis of first 24 months	UKHSA	Interim analysis of first 12 months due summer 2023, 24 month analysis due August 2024, evaluation 30-36 months, due August 2025.

4.Final evaluation 30-36 months to inform any commissioning decisions regarding continued delivery of service beyond 3 years.		
Key objective 3: Undertake cost effectiveness analysis of hepatitis and HIV testing in EDs comparing different models of opt-out, contacting patients and linkage to care.		
Data from the ED testing programme will be used in existing cost-effectiveness models of ED testing to parameterize testing prevalence or yield, test costs, costs for following up new diagnoses and linking to care, and intervention effects (contact rates, linkage to care and subsequent treatment rate) in the different settings	UKHSA will subcontract this to University of Bristol.	Analyses carried out 30-36 months.

Gantt chart of deliverables



Bristol Economic evaluation dates to be confirmed as they become available.

Annexe E. LONDON OPT-OUT HIV/HEPATITIS TESTING IN EMERGENCY DEPARTMENTS PROJECT - EVALUATION PROPOSAL

Executive Summary

To undertake monitoring and evaluation to optimise the opt-out testing programme in terms of individual and public health benefits as well as value for money, a three-pronged evaluation approach is recommended: combining public health monitoring and evaluation, economic evaluation (both collecting mainly quantitative data) as well as implementation optimisation / behavioural science research (collecting mainly qualitative data).

The total costs for 5 research posts (with varying FTE and duration over the 3 years), based with co-supervision either in UKHSA, University of Bristol or University College London, and working collaboratively with NHSE and clinical sites, will be approximately £400,000 (including overheads, but excluding VAT).

Background

In November 2021 £20 million funding was identified by NHSE nationally to ensure ED implementation of opt out blood borne virus testing in sites meeting high prevalence as part of the national HIV Action Plan published in 1/9/2021. All London Trusts and some other trusts in Brighton, Manchester, Southampton meet the prevalence criteria. The programme launches in April 2022 and is expected to run for 3 years. Testing will be done only on those patients who have blood tests, which ranges from 20-50% of ED attendees.

Working towards HIV and hepatitis elimination

The HIV Action Plan has a commitment to end new HIV cases in England by 2030 and meet interim targets by 2025 (aligned to the WHO global HIV strategy). While focus is on HIV, the programme will likely include opt-out hepatitis B virus (HBV) and hepatitis C virus (HCV) testing, in support of efforts to meet WHO viral hepatitis elimination targets and goals, and a more inclusive and population-focused approach to elimination programmes.

NICE guidance

NICE guidance recommends that people are offered an HIV test when having a blood test when attending an emergency department (ED) in areas of high HIV prevalence, and to all ED attendees in areas of extremely HIV prevalence. NICE have not yet recommended HBV or HCV testing in areas of high prevalence (partly because regional prevalence estimates have been difficult to derive). However recent studies of hepatitis testing in EDs have indicated this may be a useful strategy as part of broader efforts to increase diagnoses and linkage to care and treatment.

Addressing inequalities and stigma

A key component of the HIV Action Plan and WHO viral hepatitis elimination strategy is to reduce stigma and tackle inequalities in healthcare access and health outcomes experienced by PLWHIV and people with hepatitis C and hepatitis B. ED testing can provide the setting to do so. This is particularly the case for hepatitis B and C, which predominantly affect marginalised groups- with HCV burden mainly in people who inject drugs, people who experience homelessness, and migrants; and for HBV, mainly

immigrant communities who may not be able to navigate the system. ED offer a point of contact for groups at increased risk of blood borne virus (BBV) who may be less likely to engage with other health services. Furthermore opt-out testing can normalise BBV testing if it becomes part of the routine patient pathway and obviates the need to ask about stigmatising risk factors /behaviours.

Individual and public health benefits

The benefits of opt-out testing in EDs are clear in terms of identifying HIV infection early, identifying people with HIV not currently engaging in treatment, supporting access into treatment, and preventing onward transmission. Similarly, for HCV early diagnosis improves cure rates and holistic whole person benefits in risk behaviour reduction, as well as halting progression to cirrhosis and liver cancer; modelling indicates a treatment as prevention effect. While there is no cure for HBV, early diagnosis facilitates managed care and treatment which can be long term, with the aim of viral suppression to reduce liver disease progression to cirrhosis and transplants. For all BBVs reducing late diagnoses is key to maximising individual and population benefits in terms of morbidity and mortality, especially premature mortality for HCV.

Evaluation and Implementation Research

Research gaps and needs

Published studies of opt-out testing pilots or programmes in EDs are mainly on HIV and done in the USA. However, more recently there have been several projects in England, mainly in London, for hepatitis C, B and HIV testing, including economic evaluations. Studies look at the prevalence of HIV/hepatitis (via unlinked anonymised methodology), test uptake, test positivity, and linkage to care. Unlike HIV testing where patient acceptability is quite high, there are few studies on HBV and HCV testing with a qualitative methodology and behavioural insights lens. Moreover, monitoring and evaluation (M&E) metrics (using quantitative data) are not standardised, and detailed descriptions of the intervention are not given, so it is difficult to compare interventions and outcomes. The proposed studies/ service evaluations outlined below aim to fill those gaps and provide relatively real-time evidence to optimise ED opt out testing as a case-finding and linkage to care initiative to support elimination strategies and goals. Findings may be used together with other information generated by UKHSA to assess the relative importance of ED HIV and hepatitis testing against other forms of identifying new diagnoses in the run up to elimination targets, particularly for ED HIV testing and the 2030 elimination target.

National Institute of Health Research (NIHR) Health Protection Research Units (HPRUs) in partnership with UKHSA.

Researchers based at the NIHR Health Protection Research Unit in Behavioural Science and Evaluation at the University of Bristol and NIHR Health Protection Unit in BBV/ STI at University College London, in partnership with UKHSA, have considerable experience in:

(1) social and behavioural science and qualitative studies, specifically in optimising implementation of healthcare programmes and complex interventions where system / structural and individual behavioural factors are at play.

(2) monitoring and evaluation –data collection of operational monitoring metrics and standardised data collection for longer term quantitative /mixed methods evaluation, using/process/outputs approach including data items for economic analyses; also utilising UKHSA's unique legal permission for collecting surveillance data with personal identifiers and capabilities in surveillance epidemiology, large dataset record linkage, and programme evaluation.

(3) economic evaluations of the cost effectiveness of complex interventions and specifically in HIV / hepatitis opt-out testing and linkage to care in ED

The research and M&E infrastructure that is established will also allow us to undertake further responsive projects to those outlined below during the course of the opt-out testing programme, if needs are identified, e.g. unlinked anonymous monitoring to get a better handle on the prevalence of hepatitis or other BBV (e.g. HTLV) in the locality, and further qualitative studies to get patient perspectives to get insights as to why some diagnosed patients dis-engage from care.

Evaluation Governance

To provide guidance and scrutiny for the below outlines, a small Advisory group can be established with representation from stakeholders including: NHSEI, ICS, participating trusts (ED, lab and BBV clinicians), UKHSA, HPRU, Hep C Trust and LJWG. This advisory group will help to place this project and associated evaluations within that landscape ensuring that it compliments other developments in HIV, HBV and HCV and feeds into overarching strategic workplans.

Proposal outlines (with costs)

(1) Implementation optimisation

Justification

There have been several opt-out testing pilots in EDs with large variations in uptake of testing and linkage to care; highest for HIV, followed by HBV then HCV. In addition, some studies have shown that individuals diagnosed in ED have previously been diagnosed but dis-engaged in care or lost to follow up. Some concern has also been raised about the acceptability of assumed consent for HIV testing. The variation in linkage to care and disengagement are likely multifactorial in cause, and could reflect the nature of the populations affected, organisational, operational, and patient and staff barriers, most of which are potentially modifiable. Furthermore, ED testing provides an opportunity to identify and re-engage those people living with HIV/HBV/HCV who have disengaged from treatment. The root causes of non-engagement and poor linkage to care have not yet been investigated nor rapidly implementable solutions adopted, despite the potential for improving the yield and impact during the ED programme runtime.

Researchers based at the NIHR Health Protection Research Unit in Behavioural Science and Evaluation at the University of Bristol have considerable experience in rapidly developing brief interventions to successfully support implementation, by co-producing

intervention processes and materials with the intended users. Previous successful applications of this approach include interventions to reduce antibiotic prescribing across 6 EU countries and in 36 UK hospitals and the Germ Defence website designed to help reduce household transmission of Covid-19 which had over 600,000 engaged users.

Proposed Rapid Optimisation Approach

Aim: to evaluate the implementation of ED opt-out BBV testing to provide recommendations to guide optimisation and standardisation and any future roll-out of ED testing in lower prevalence sites.

Phase 1: To describe and compare the different strategies and approaches of sites to implement BBV testing in EDs we will review use of existing standard operating procedures (SOP), protocols and patient materials across the 32 sites (27 London, 3 Manchester, Salford, Brighton, Blackpool).

Phase 2: To examine the facilitators and barriers to embedding implementation ED opt-out BBV testing we will conduct focus group discussions and in-depth interviews with ED staff, target patient populations and stakeholders.

Timeline

We will describe the different strategies and approaches of sites to implement BBV testing in EDs within 4 months and complete the evaluation within 12 months. Aimed start November 2022.

Funding required: £129,766.32 1 full time qualitative researcher and research team over 12 months

For more information contact: [redacted]

(2) Monitoring and evaluation (public health)

Justification

For any new intervention or programme it is important to build in an evaluation with defined measurable outcomes and a systematic method to study the intervention, to understand how well it achieves its goals. Evaluations help determine what works well and paves the way for improvements, noting that one size does not always fit all.

For the ED programme, opt out testing will be additional vials and tests for those already having blood tests. The demographic characteristics may vary between tested and non-tested patients and may have implications for yield of BBV. Therefore, we recommend within the programme sites where opt-out testing has already been introduced, there is at least one pilot site of adding on opt-out testing to every attendee (regardless of whether blood tests are being taken) during the course of the programme.

Available demographic data on age, sex, ethnicity and deprivation (based on IMD of home address) will be used to investigate differences in testing and diagnosis to explore

inequalities related to testing and accessing of treatment. This analysis will support sites in targeting interventions (e.g. assertive outreach and increased use of peer support) at populations who are less likely to engage and maintain contact with treatment services.

Proposed approach

Public health impact evaluation

(Further detail is contained within the attached proposed protocol)

Aim: evaluate the ED opt-out testing programme, comparing different models of delivery using mainly quantitative data (and mixed methods)

Method: This uses the input/ process /output and outcomes evaluation framework, which includes stakeholder consultation /survey and systems review, but focusing on standardised quantitative data collected at the level of the trust / ED and at patient level. The attached protocol includes proposed monitoring and evaluation datasets at the level of individual patients and at the level of trust, which will need to be agreed based on what data are available and feasible to be shared/ sourced by UKHSA and NHSE on a routine versus one-off basis). Existing routine data linkage and proposed additional data linkage for this evaluation will enable the follow up of patients from attendance at A&E to testing, results and treatment. Collaboration with ICS leads will enable comparison of data captured at sites with data reported in routine UKHSA surveillance datasets.

Where possible comparison between sites will support understanding of the effectiveness of the intervention depending on community prevalence of undiagnosed infections, however, this will depend on the availability of prevalence estimates (both undiagnosed and diagnosed) for each BBV at a small enough geographical level to compare between trust/ ICS areas.

In addition to performance metrics on outputs and outcomes e.g. test uptake, positivity, patients contacted, and linkage to care, time spent and costs incurred for specific “process” activities will be estimated for the economic evaluation component.

Deliverable: routine monitoring and enhanced evaluation of opt-out testing models in ED against defined output and outcome measures (including uptake of testing; proportion linked to care; proportion started on antivirals; number needed to test to diagnose one person) as defined in attached draft monitoring and evaluation protocol.

Monitoring

In addition to the formal evaluation, “real-time” monitoring of the programme through collection, synthesis, validation of data from UKHSA hepatitis and HIV surveillance systems will be carried out and routine reports produced. This “macro” level monitoring will cover all three BBVs from all ED testing sites will be carried out over the duration of the programme and complement (and be triangulated with) the “micro” level monitoring carried out by sites and ICS. This monitoring allows for issues and glitches in the programme delivery to be detected, analysed and acted upon, and tracks progress against programme metrics including linkage and engagement with effective treatment.

Timeline

Standardised data collection and monitoring throughout the programme (3years); interim analysis 12-18 months; final evaluation 30-36 months to inform any commissioning decisions regarding continued delivery of service beyond 3 years.

Funding required: approx. £155,000 including overheads to cover evaluation and monitoring aspects: for 1.0 WTE junior epi scientist /data analyst, 0.5 WTE mid-grade scientist for 2 years starting April 2023

Epi consultants, G6 and G7 (senior scientists) and kick-starting monitoring in year 1 costs will be absorbed by UKHSA.

For more information contact: [redacted]

(3) Economic evaluation (cost effectiveness analysis)

Justification

While the economic case has been made for HIV opt-out testing there are uncertainties around the cost effectiveness of testing for HBV and HCV. There is some evidence that testing could be cost-effective at a relatively low prevalence if linkage to care was sufficient; the opting out approach, ordering blood tests and following up patients may all influence cost-effectiveness. It is important to ensure that the most efficient model of service delivery is made to ensure value for money.

Proposed approach

Aim: to undertake cost effectiveness analysis of hepatitis and HIV testing in EDs comparing different models of opt-out, contacting patients and linkage to care

Method: Data from the ED testing programme will be used in existing cost-effectiveness models (Markov models) of ED testing to parameterize testing prevalence or yield, test costs, costs for following up new diagnoses and linking to care, and intervention effects (contact rates, linkage to care and subsequent treatment rate) in the different settings. The Markov models track the liver disease progression of people with HCV and HBV (including health care related costs for these people) and the effect of HCV or HBV treatment on reducing or ceasing liver disease progression. Similar models can be used for HIV with different health related outcomes and costs. The models will be used to estimate the quality-adjusted life-years (QALY) and health care related costs saved resulting from treating newly diagnosed individuals over the evaluation period (averting HCV or HBV related liver disease, and preventing AIDS) compared to what would occur through existing testing strategies (in ED and other settings where testing could occur). This will be done for a selection of sites to capture the main differences in epidemiology, outcomes and costs. Health related benefits (QALYs) and costs will be tracked over 30 or 50 years with both being discounted at 3% per year. The cost-effectiveness for each site will be evaluated in terms of the incremental cost-effectiveness ratio (ICER, incremental cost per QALY saved) and compared to a willingness to pay threshold of £20,000 per QALY saved. Probabilistic sensitivity analyses will be undertaken to assess the uncertainty in the impact

projections and around the ICER, accounting for uncertainty in the intervention outcomes as well as cost, behavioural and epidemiological inputs. The probability that each intervention is cost-effective will be estimated for different willingness-to-pay thresholds and cost-effectiveness acceptability curves constructed. Univariate sensitivity analyses for key parameters will be undertaken considering such things as changes in the: time horizon; discount rates; changes to the intervention costs and outcomes; and yield of the testing. We will also estimate the minimum prevalence of HIV, HCV (RNA-positive) and HBV (HBsAg) and levels of linkage to care required to make ED testing cost-effective at a willingness to pay threshold of £20,000 per QALY saved, and how that varies by changes in specific factors.

Outcome: Cost per QALY of different opt-out testing approaches in different settings; minimum prevalence required for cost-effectiveness to inform wider policy and testing guidelines.

Findings from the economic evaluation may inform grant proposals for a more comprehensive cost-effectiveness model to compare the relative value of different case finding initiatives for BBV, e.g. primary care testing versus ED. This is already being done for HCV and couple be adapted for HIV and HBV.

Timeline

Standardised data collection (similar data items as for monitoring metrics and public health intervention evaluation) throughout the programme, with actual analyses carried out 12-18 months into programme so findings can be shared and contribute to optimisation of programme.

Funding required: approx. £115,675 including overheads for 1.2FTE health economist over 24 months in years 1 and 2 and 0.125FTE of a mid-grade health economist over the same time period ([redacted]).

For more information contact: [redacted]

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23/9/2022