Report of the Refugee and Applicants Seeking Protection Blood Borne Virus/Tuberculosis Screening Implementation Advisory Group

HSE Social Inclusion

Final Report

Foreword

No one is safe until everyone is safe

Infectious diseases are not equally distributed in society here in Ireland nor across the globe. Poverty, lack of resources and poor living conditions often contribute to risks for infection with a range of diseases, increasing chances of exposure and decreasing access to preventive, diagnostic or therapeutic interventions. Among these infections stalking the poor and under-served populations of the world are blood-borne viruses (BBVs) (Hepatitis B, Hepatitis C and HIV) and tuberculosis (TB).

The global burden of TB and BBVs is considerable, with most parts of the world suffering much greater levels of infection than Ireland. Globally, about a quarter of the population is estimated to have been infected with TB at some stage. Every year, 10 million people fall ill with TB and 1.5 million people die. There are approximately 296 million people (4% of the global population) living with Hepatitis B virus (HBV), 1.5 million new infections and 820,000 deaths annually. There are approximately 58 million people (0.8% of the global population) living with Hepatitis C virus (HCV), about 1.5 million new infections and 290,000 deaths annually. And there are approximately 39 million people living with HIV (including 0.7% of adults aged 15–49 years globally), with 1.3 million acquiring HIV and 630,000 people dying of HIV-related illness annually. Tragically, some of these infections are preventable through vaccination (e.g. Hepatitis B vaccine), some are treatable to cure (e.g. Hepatitis C infection and drug-sensitive TB), and some are controllable with medication preventing harm to the infected individual and transmission to others (e.g. HIV/AIDS). But due to structural inequalities in economics, health services and opportunity, many people who could benefit from these interventions cannot avail of them in their home countries.

When people come to Ireland, whether seeking refuge from war, political oppression or the impact of climate change, or simply seeking a better life as economic migrants, we have a responsibility to diagnose and treat people with TB or BBV infections as soon as practicable not only to protect their health but also to protect the health of the wider population. Infectious diseases in any of the population pose a threat to the whole population - no one is safe until everyone is safe. Screening is an instrumental part of this when linked firmly with laboratory, treatment, contact tracing and vaccination services. This report provides a comprehensive approach to protecting health among new migrants to Ireland, and by extension, protecting the wider population.

I would like to extend my thanks to the Advisory Group for their efforts in completing this landmark report and strongly encourage all stakeholders and partners to implement its recommendations comprehensively and quickly. It is in everyone's interests to safeguard the health of some of our most vulnerable residents and thereby safeguard the health of all.

Dr Éamonn O'Moore,
Director, National Health Protection Service of Ireland
Stiúrthóir, An tSeirbhís Náisiúnta um Chosaint Sláinte na h-Éireann

Executive Summary

This Group was formed to:

- define detailed end-to-end protocols for Blood Borne Virus (BBV) screening of Refugees and Applicants Seeking Protection using a) Standard Laboratory Blood Testing (SLBT), or b) Capillary Blood Testing (CBT), or c) lateral flow Rapid Diagnostic Testing (RDT);
- appraise the three BBV screening options by test parameters such as sensitivity and specificity, feasibility and resources in relation to capacity and financial resources available.
- define end-to-end protocols for screening of active thoracic tuberculosis (TB);

The following are the recommendations of the Group:

1. Screening for BBVs:
    a. by lateral flow RDT, should be offered to all of the target population over the age of 16 years, and to children over 18 months of age who are not accompanied by a biological parent.
    b. for children under 18 months of age who are not accompanied by a biological parent, they should be offered SLBT by phlebotomy in their nearest paediatric clinic or the Children's Health Ireland Rainbow Clinic.
2. Link with the SH:24 programme to offer home-screening by CBT as an alternative to adult Refugees and Applicants Seeking Protection.
3. Active thoracic TB screening should continue using the current suite of TB questions relayed through a Health Status Questionnaire (HSQ), with any questions answered in the affirmative entailing an urgent Chest X-ray and follow-up as required.
4. A national Patient Information Management System is a requirement for the success of a programme like this, but the procurement of same should not delay implementation of the programme nationally.
5. The programme and Migrant Screening Teams should be coordinated and managed at a regional level by the Community Healthcare Organisation (CHO) Migrant Health Team. CHO Migrant Screening Teams should also be guided by a national programme coordination group, which could be chaired by National Community Operations in line with what is currently the case in relation to the Catch-up Vaccination Programme. The Screening Team clinical governance should be similar to that of the Catch-up Vaccination Programme, and could be registered Nurse-led. Primary Care follow-up of confirmed cases after linking with specialist ID Services should be undertaken by assigned GPs or CHO Sessional GP Clinics.
6. Each CHO Migrant BBV Screening Team should liaise with local/regional ID/hepatology services to agree a process of referral. This should include access to local service staff to coincide with RDT screening clinics for immediate referral to ID/hepatology services upon a reactive test result.
7. Safetynet will be asked to provide support and capacity building to Community Healthcare Organisation (CHO) BBV Screening Teams as required.
8. The Programme should be supported at national level by a Refugee and Applicants Seeking Protection (RASP) Blood Borne Virus/Tuberculosis (BBV/TB) Screening Implementation Oversight Group to continue the work of the Advisory Group and complete its fourth objective (Provide ongoing support to CHOs). The Oversight Group will support and provide strategic, operational and Public Health advice to the national programme coordination group (see Recommendation 5) CHOs and their Migrant Health Teams on the rollout of the Programme.
9. Next Steps
    - Engagement with procurement on suppliers for RDT test kits (including training).
    - Roll out of pilot. The learning from this will be used to develop Standard Operating Procedures (SOPs) for CHOs on RDTs.
    - Establish the national programme coordination group and the RASP BBV/TB Screening Implementation Oversight Group.

1

Background and Context

1.1. Background

Beneficiaries of Temporary Protection (BoTPs) and most International Protection Applicants (IPAs) arriving in the country come from nations with a higher burden of TB and BBVs than Ireland.

1.2. Task

The HSE Health Response for Refugees and Applicants Seeking Protection Primary Care Infectious Disease Testing Service Delivery Model Version 1.0 (Ratified 23/02/2023), recommended that a National Ukrainian and IPA Infectious Disease Testing Implementation Sub-Group be stood up with membership including Public Health, National Social Inclusion Office, National Laboratories, Health Protection Surveillance Centre, General Practitioners, Infectious Diseases, Integrated Operations Planning, Community Operations, and Safetynet.

The objectives of the Implementation Sub-Group would include:

1. To define detailed end-to-end protocols for each of three options currently under consideration.
2. To appraise the three current options.
3. The establishment of an evaluation panel if a formal tender is required.
4. On-going support to CHOs.

This Report covers the first three objectives.

1.3. Process

The first meeting of the Refugees and Applicants Seeking Protection Infectious Disease Screening Implementation Advisory Group was held on 16/2/2023, chaired by Dr Douglas Hamilton, Public Health lead for the HSE National Social Inclusion Office. Terms of Reference (see Appendix 1) were agreed during meetings held once every two weeks, until the last regular meeting of the full Group on 13/4/2023. A final meeting to discuss the first draft report was held on 09/06/2023.

The aim of the Group was to develop a programme to achieve maximum coverage of BBV/TB screening in the Refugee and Applicants Seeking Protection population, to commence in the second quarter of 2023. In order to achieve this, a number of key objectives were set:

- Urgently define detailed end to end protocols for BBV screening including informing of results, Public Health notification, household and sexual contact identification, screening of contacts and vaccination of cases and contacts, for each of three options currently under consideration (Standard Laboratory Blood Test (SLBT), Capillary Blood Testing (CBT), and Rapid Diagnostic Testing (RDT)).
- Define end to end protocols for screening of active thoracic TB
- Appraise the three current BBV screening options by test parameters such as sensitivity and specificity, feasibility and resources in relation to capacity and financial resources available.
- The establishment of an evaluation panel if a formal tender is required
- Support and provide strategic, operational and Public Health advice to CHOs and their Migrant Health Teams on issues relating to access to, and uptake of BBV/TB screening within the scope of this Programme. Provide guidance and direction to CHOs/Public Health Areas on dealing with challenges within the BBV/TB screening programme

Two working groups were created, the first to define end-to-end protocols, the second to draft a comparative appraisal between the three screening tests.

Additional asks from the National Director of Health Protection included:

- Consideration of multiplex testing e.g. using dried blood spot or other platform, to include not only BBVs but also Sexually Transmitted Infections (STIs) like syphilis.
- Consideration of BBV testing to ensure we have markers of active viral replication rather than antibody only.

2

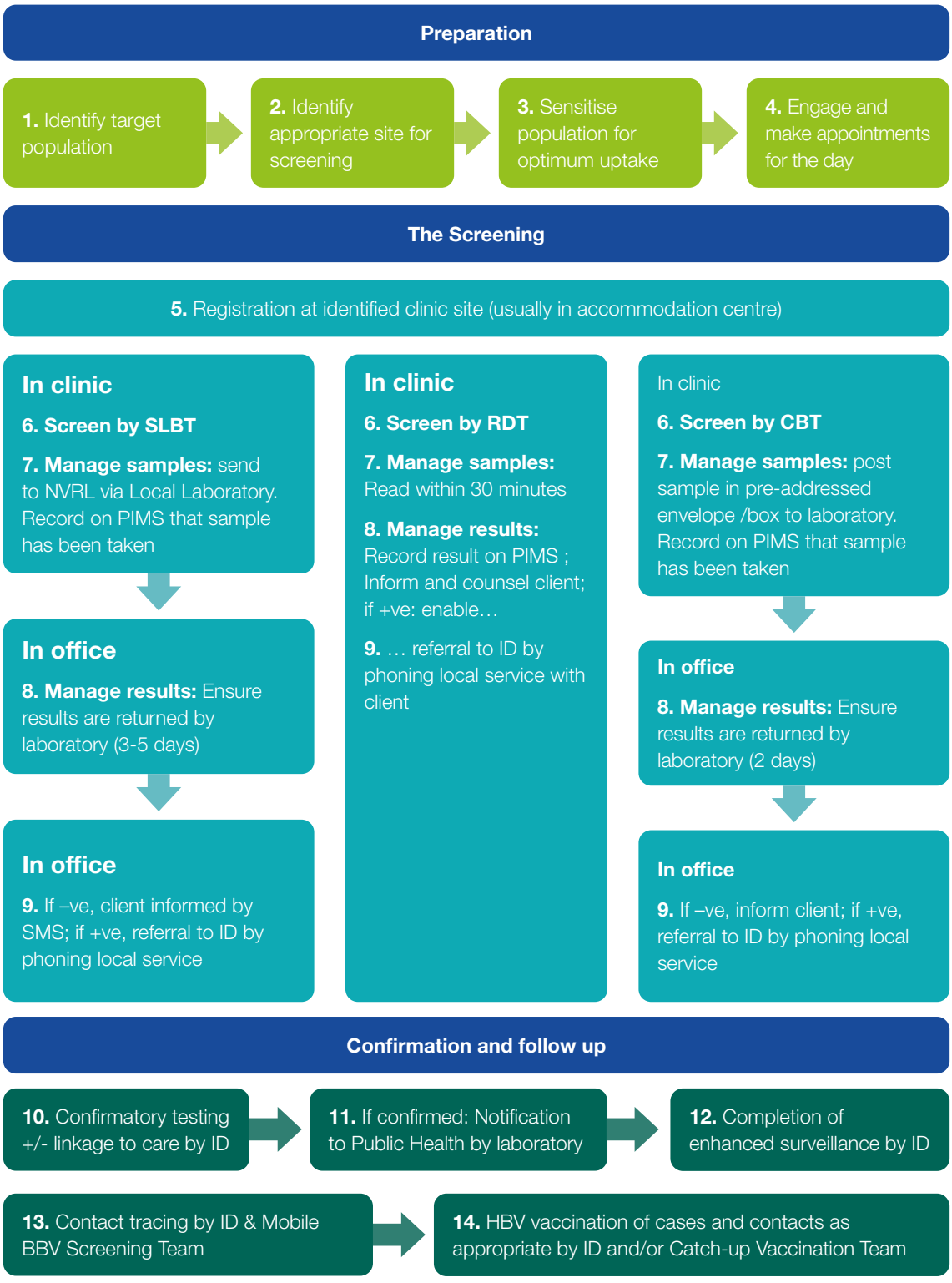
End to End Protocols

2.1. End to end protocols for BBV testing

Detailed description of each step of each option can be found in Appendix 2.

The steps in Diagram 1 were defined for each option – some are common for two or all three options.

Diagram 1: Flowchart of End-to-end Protocols



Number of contacts

- RDTs allow delivery of screening test results while the person is present at the screening clinic, reducing the risk of loss-to-follow-up (LTFU) if the client moves on over the next few days.
- RDTs require only one contact with the participant as opposed to two contacts for phlebotomy testing and CBT (the second being to inform regarding results +/- arranging for referral to ID).
- Multiple steps are completed within the same sitting in respect to RDTs, whereas the other two options require follow-up steps to be taken at another time – such as chasing results and informing clients about their results +/- arranging for referral to ID. Sometimes these steps may require multiple attempts before completion.

Human Resources

- RDTs and CBT only require a healthcare assistant, interpreter and administrator to be on site. SLBT testing also requires a phlebotomist to be on site.

Reading and sharing of results

- RDTs require manual reading of results and transcription of results into the participant's electronic healthcare record/Patient Information Management System (PIMS). This entails a risk of human error, however the risk of human error is not confined to RDTs as CBT and SLBT include a risk of mislabelling the sample. CBT and SLBT allow for results to automatically be sent via healthlink to the testing team and these results can then be uploaded into the patient's electronic healthcare record/PIMS.
- For CBT, non-reactive results are conveyed to the client after the screening clinic by an automated SMS system. For SLBT, negative results need to be identified and clients informed. For SLBT and CBT, reactive results are given, and ID clinic referrals made, by phoning the patient and the local ID/hepatology service without any face to face interaction. For the RDTs, results are given face to face during the screening clinic by a trained healthcare professional* and an interpreter, and further counselling and onwards referral to ID/ hepatology clinic by phoning the local service, also in the presence of the clinic healthcare professional / counsellor and interpreter.

2.2. Testing Protocol Appraisals

A number of issues of particular relevance to the current context and target populations were considered at the start of this process. They included:

- A substantial backlog: Approximately 65,000 IPAs and BoTPs recommended for BBV screening have not been offered screening – there is an urgent need for catch up screening.
- This is a very mobile population – with people being moved from CHO to CHO frequently and at short notice: this has risk implications for loss-to-follow-up (LTFU) if screened positive.
- Capacity constraints in many CHOs, especially in respect to health care workers.
- Financial: There is a limited budget approved for this programme.
- Take-up rates: There is evidence of a relatively high level of resistance to BBV screening, especially in the BoTP cohort, but also lately in the IPA cohort: this highlights the need for screening tests being as acceptable as possible for these populations. It also highlights the need for concerted, well-coordinated and effective BBV screening promotion campaigns prior to screening, that emphasize that results will not influence the decision on their application for International Protection, that there is treatment available and that testing results are strictly confidential. This may reduce any stigma that might be associated with screening.
- Need for a national repository of results. This is linked to the need for a patient information management system, and a Monitoring and Evaluation framework to accompany rollout.
- Need for validation of testing modality: The performance of the model chosen may need to be validated during roll-out: This is especially important in relation to minimising false negatives in screening tests.
- In 2020, the prevalence of hepatitis B surface antigen (HBsAg) was estimated at 1% in adults in Ukraine, and 3%[1,2] for hepatitis C (HCV-RNA positive). UNAIDS gives the estimate of HIV prevalence amongst adults in Ukraine as 1%[3].

* The healthcare professional could potentially be a healthcare assistant, if appropriately trained and supervised

Underlying assumptions to support comparative appraisal

There were approximately 75,000 BoTPs at the start of our work in February 2023 of whom 2/3 were adults. There were therefore in the region of 50,000 BoTPs eligible for screening. Take-up rate was estimated at 50% - therefore 25,000 screening tests would be required.

There were 20,000 IPAs (80% adults), therefore 16,000 IPAs eligible for screening – and 1,000 already done. This left 15,000. With an estimated take-up rate 80%, 12,000 screens would be required. Therefore a total of 37,000 screens would be required (the 50% and 80% estimates are based on best guess from catch-up vaccination uptake among BoTPs, and experience from the screening programme among IPAs in the National Reception Centre, Balseskin, respectively).

Pooling prevalence rates of BoTPs with IPAs (from screening in National Reception Centre in Balseskin and CHO4) gives rates of 1.71%, 1.80% and 2.21% for HIV, Hep B and Hep C respectively. See Table 1 below.

Table 1. BBV pooled prevalence IPA & BoTP in Ireland, 2022 (estimated)

										Demand (estimated)		
IPA	HIV	+ve	%	HBV	+ve	%	HCV	+ve	%	UKR	25000	50%
NRC	1585	50	3.15	1592	54	3.39	1592	9	0.57	IPA	12000	80%
CHO4	142	5	3.52	142	6	4.23	142	1	0.70	Total	37000	
Total	**1727**	**55**	**3.18**	**1734**	**60**	**3.46**	**1734**	**10**	**0.58**			
BoTP			1.00			1.00			3.00			
Pooled prevalence			**1.71**			**1.80**			**2.21**			

Detailed appraisal of each testing model is summarised in Table 2.

Formulas used for Table 2:

Negative Predictive Value (NPV) = (specificity x (1 – prevalence)) / [(specificity x (1 – prevalence)) + ((1 – sensitivity) x prevalence)]

Positive Predictive Value (PPV) = (sensitivity x prevalence) / [(sensitivity x prevalence) + ((1 – specificity) x (1 – prevalence))]

Table 2. Appraisal Framework

		RDTs			CBT			SLBT		
		HIV	HepB	HepC	HIV	HepB	HepC	HIV	HepB	HepC
Specs	Sensitivity	1.0000	0.9930	0.9930	1.0000	0.9930	0.9930	1.0000	1.0000	1.0000
	Specificity	0.9640	0.9810	0.9960	0.9640	0.9810	0.9960	0.9993	0.9996	0.9986
	NPV	1.000	1.000	1.000	1.000	1.000	1.000	0.999	1.000	0.999
	PPV	0.326	0.489	0.849	0.326	0.489	0.849	0.961	0.979	0.942
HR Needs	Dr	N	N	N	N	N	N	N	N	N
	Nurse	N	N	N	N	N	N	N	N	N
	Phlebotomy	N	N	N	N	N	N	Y	Y	Y
	HCA	Y	Y	Y	Y	Y	Y	N	N	N
	Interpreter	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Admin	Y	Y	Y	Y	Y	Y	Y	Y	Y
Contacts/patient		1	1	1	2	2	2	2	2	2
Turn-around time		30 mins	30 mins	30 mins	3-5 days	3-5 days	3-5 days	2 days	2 days	2 days
Tests	Screen	37,000	37,000	37,000	37,000	37,000	37,000	37,000	37,000	37,000
	Confirm	1,942	1,361	963	1,942	1,361	963	0	0	0
Cost/test (€)*	Incl VAT	8.11	9.15	8.17	19.72	14.74	19.81	8.60	9.32	11.44
Supplies								V,B	V,B	V,B
Transport								Y	Y	Y
Cost/patient		9.09	9.86	8.73	20.70	15.45	20.37	11.93	12.65	14.77
Cost for all	Per BBV	336,170	364,835	322,937	765,740	571,665	753,617	441,410	468,050	546,490
	For all 3 BBVs		1,023,932			2,091,022			1,455,950	
Facilities	Acc Centre	Y	Y	Y	Y	Y	Y	Y	Y	Y
Acceptability	Patient	Excellent	Excellent	Excellent	V. good	V. good	V. good	V. good	V. good	V. good
Impact of mobility		None	None	None	A risk	A risk	A risk	A risk	A risk	A risk
Service provider experience		Excellent		Excellent	Poor	Poor	Poor			
Feasibility		V. good	V. good	V. good	Good	Good	Good	Good	Good	Good
Information management	Recording results	Manual recording of RDT results			Automated recording by lab to national results repository			Automated recording by lab to national results repository		

*Estimates from Abbott (RDTs), Eurofins Biomnis (CBTs) and National Virus Reference Laboratory (SLBTs)

V= Vacutainer bottle; B= Bio-hazard bag; N= No; Y= Yes; VAT= Value Added Tax

The parameters tested for were:

- HBsAg (chosen over cAb as a measure of active infectivity from PH perspective)
- HCVAb
- HIVAb/Ag

Sensitivity and specificity specifications for RDTs (Abbott) are taken from the HSE Health Response for Refugees and Applicants Seeking Protection Primary Care Infectious Disease Testing Service Delivery Model Version 1.0, and verified with WHO pre-qualification data. These specifications were not available from Enfer or Eurofins Biomnis laboratories on the single test-assay platforms used for screening. These laboratories only had one set of specifications to provide based on testing in duplicate, which is not done on CBT samples due to volume constraints. The lack of testing in multiple entailed that similar values to the Abbott platform were assumed for both CBTs and RDTs (as similar single assay platforms are used for both CBTs and RDTs).

As can be seen in Table 2, the Group agreed that screening by RDT has advantages over CBT on 7 parameters, and CBT is superior on one parameter. However, CBT and SLBT also come with the additional quality assurance and accreditation standard of laboratory service providers. The methodology and quality assurance of process are the same. Both laboratory methods have full sample tracking once labelled, traceability of all reagents used, automatic result capture, identifiable authoriser, electronic transfer of results back to a clinic and retention of result in the lab indefinitely. An advantage of SLBT over CBT is that a reactive specimen can be retested without bringing the individual back for additional sampling.

The single contact process of sampling, testing, determining results, and post-test counselling and onwards referral to specialist ID/ hepatology services if result reactive at the same sitting has logistical and resource requirement advantages. Linked to this are significant time savings with a turn-around of 30 minutes compared to 3-5 days. This one-stop Point-of-Care (POC) process has also been shown to be more acceptable to clients4. It is likely that expressing one drop of blood as opposed to 16 drops will also be more acceptable. Increased acceptability normally leads to higher demand, key for a voluntary population screening service.

The service provider experience was superior for RDTs compared to CBTs.

The total cost for screening and confirmative testing of reactive results by phlebotomy is estimated to be €1,023,932, €2,091,022 and €1,455,950 by RDT, CBT and SLBT respectively. This entails that RDTs lead to a cost-saving of over €1,000,000 over CBTs, and over €400,000 over phlebotomy (plus the cost savings of transport of samples and a HCA as opposed to a phlebotomist for all screens).

Finally, in terms of the risks related to the high mobility of these cohorts, this is negligible for RDTs, whereas it may be an issue because of the turn-around time of CBTs. It has already been identified as an issue with phlebotomy.

CBT has the advantage of automated recording by the laboratory of results onto a national results repository, available through a password protected portal. SLBT results are available in the National Virus Reference Laboratory (NVRL) and can be available via Healthlink. This reduces the risk of human error in recording data, although human error is also a possibility when labelling the sample bottles for CBT and SLBT. Also, in the absence of a safe and secure PIMS, the storage of RDT results data in paper form or on Excel spreadsheets, even if saved on protected national shared HSE folders, will not be as safe for patients or as data secure as this CBT or SLBT national data repository. In saying that, the PIMS is needed for the whole programme, managing the end-to-end process of each service user, irrespective of the screening test used. Its absence would be a huge risk as the system would have to fall back on paper and Excel.

Representatives from this group had a meeting with SH:24 and Enfer laboratories on the 2nd May 2023 to further scope out the CBT screening option. Arising from this meeting was the suggestion that we should assess the preferences of service users and service providers. The NSIO decided to do this through a series of service provider interviews held in May 2023 and a multi-lingual survey of BoTP and IPA (refugees and applicants seeking protection) migrants which went live from the 17th – 23rd May 2023.

In terms of RDT, we undertook a consultation (by email) on the 9th May 2023 with a service provider where they have been using the Abbot Determine Combo HIV Ab/Ag RDT since 2018. They reported that this test is easy to use in the hands of an experienced Health Care Assistant. They get the result read by two health care workers. They have never gotten an indeterminate test or any false negatives (they take a serum sample at the same time as doing the RDT). They have had no sharps injuries as the lancet is very safe. If multiple tests are being performed, one would need a good system to make sure that that diskettes are labelled correctly.

We also had an interview on the 16th May 2023 regarding the Hepatitis C RDT service provider experience. They stated that the test is very easy to perform on the client and it is very easy to read. They have not had an indeterminate result thus far. They had no examples of false negatives retrospectively although this is not actively tested for. They reported that service providers are not worried about sharps injuries and there is very little blood.

We also had a discussion about the 2016 report ‘HIV Upsurge among People who Inject Drugs in Dublin’ with a service provider who reports that

using RDTs in a hostel situation was difficult and a recommendation arising from that report was that 'point of care blood testing was problematic'. The recommendation was for oral HIV swabs RDT (once validated) to be used instead in this setting. It should be noted that this cohort and setting are quite different to Refugees and Applicants Seeking Protection (RASP) and their accommodation settings.

In relation to CBT, we had a semi-structured interview on the 9th May 2023 with a service provider who piloted a CBT programme for HIV, Hepatitis B and Hepatitis C that was carried out across 4 sites in CHO 9. They tested 100 people and had 3 reactive tests for Hepatitis B and 1 reactive test for HIV. They reported that taking the test could be 'messy' which raises Infection Prevention Control (IPC) concerns and that the vast majority of people needed assistance in taking the test. They considered the two health care workers who they used to assist people in taking the test to be essential to the process. They said that even after watching the 'how to' video while waiting to take the test the vast majority of people needed assistance in collecting the sample properly to ensure enough blood was collected and to prevent haemolysis. In terms of the test being 'messy', IPC concerns were raised about the self-directed collection method (with many BoTPs and IPAs sharing accommodation).

In the BBV Screening Survey with service users, 51% of people said they would prefer CBT (assisted) as opposed to only 2% who said they would prefer CBT (self-testing). When asked to choose between assisted testing and self-testing the survey participants indicated their strong preference for assisted testing over self-testing (81% vs 4%). 91% agreed or strongly agreed with the statement that "In-person pre-test information/counselling provision is important, including why testing is being offered, how the tests will be taken and any follow up care if needed", while 64% agreed or strongly agreed with the statement "On-line pre-test information provision is adequate, including why testing is being offered, how the tests will be taken and any follow up care if needed." 77% agreed or strongly agreed that it was important that others do not know they are getting tested and only 2% disagreed with this statement.

We ran a focus group for BoTPs in CHO 7 on the 26th May 2023. There were 6 participants with one having to leave early. This group was selected by reaching out to a group of BoTPs with whom we had already formed a relationship during the catch-up vaccination programme. It is acknowledged that this is a small group and therefore results may be skewed. All participants had lived in Ireland for over one year. We went through the three different testing options (RDT, CBT (assisted) and CBT (self-testing)) giving the attendees the opportunity to ask questions about the tests between each test. There was good engagement of participants in the focus group.

- We then asked the participants to identify their preferred option for blood borne virus screening. 4 out of the 5 remaining participants stated their preference for RDTs. They cited that the test was easy to do and faster as the most common reasons for this. A few comments from the focus group in terms of RDT preference below:
  - » *"It is easy to take, not a lot of fuss, doctor comes to do the test. I would find it unusual to do the test myself, prefer someone else to do the test for me."*
  - » *"Agree with first participant, never do these tests by myself. The third option [CBT self-testing] is a no no for me. I prefer RDT because it is easy, with personal assistance."*
  - » *"It's fast, it's easy and if the accuracy is the same prefer this option."*
  - » *"I would be more comfortable to do it in here [at the hotel as opposed to at another location], but it would need to be at a time that suited people, as people have different things on."*
  - » *"It is convenient, it is easy and it not painful (not from the veins)."*

One participant favoured CBT (assisted). She stated *"My daughter in Ukraine couldn't get the right amount of blood for a test, and a positive result was received. However the second test was negative. CBT is better as more blood is taken and results will be more accurate" and "I think blood test should be taken in special locations, not in the hotel. I don't want to get a positive result there and then, not where you are living".*

When discussing the different elements of testing, all participants favoured in person pre-test counselling (as opposed to online) and all preferred assisted testing as opposed to self-testing. 4 out of 5 participants preferred to get the results within 30 minutes as opposed to at 3 days, especially if the accuracy was the same.

When discussing the role of the interpreter and whether the same interpreter was important to do the pre-test counselling and the post-test result giving or whether a different interpreter on the phone was ok when giving the results, one person stated that they would prefer to get a positive result by email rather than over the phone as this could be quite shocking and unexpected.

In response to the question 'Is other people not knowing that you are getting tested important?' one participant responded that it is "better that people don't know if the setting is in a place like this." Another participant stated "I would prefer to get an appointment to go somewhere else, not in the accommodation centre, [that it] is better to be in another setting." This participant had previously expressed this view in the focus group when she was discussing her preference for CBT (assisted).

2.3. End-to-end Protocol for Active Thoracic TB Screening

The protocol for active thoracic TB screening relies on a suite of TB questions relayed through a Health Status Questionnaire (HSQ) either in the National Transit Centre, National Reception Centre in Balseskin, or by migrant health in-reach teams at accommodation sites. These questions should also be asked to carers for all children in their care. The screening questions in the HSQ are as follows:

- Cough (for 3 weeks or longer)
- Unexplained weight loss
- Coughing up blood
- Drenching night sweats
- On-going Tuberculosis (TB)
- Close contact with TB in the last 6 months

If the person answers yes to any of the above questions they are referred for an urgent Chest X ray. If the Chest X ray is abnormal and suspicious of active thoracic TB, the person is referred urgently to a respiratory or ID physician based on local protocols. If symptomatic the person should be isolated while awaiting further investigations[5]. They ideally should also not be moved between accommodation sites while infectiousness is being determined or known to be infectious.

Referral pathways for children with a positive TB screen may be different. If a child is positive for symptoms such as unexplained weight loss, night sweats + known TB contact, a CXR may not be adequate screening for active TB, as extra-pulmonary TB is more common among children. If the question relating to close contact with TB in the last 6 months is positive for a child, the appropriate screening method (i.e. Mantoux versus Quantiferon) and the potential need for window prophylaxis and repeat screening should be considered and will vary by age. Positive TB screening cases in children can be discussed with the Regional Health Authority - Public Health TB teams, Paediatric ID service at Crumlin or Temple St, by phone in the first instance and advice will be given on appropriate screening.

2.4. Other considerations and evidence

National Patient Information Management System (PIMS)

A PIMS is essential for the whole screening programme, irrespective of testing option used, but especially vital for the RDT option because of the lack of a national results repository. RDT results are recorded locally manually, and then depend on a national PIMS network for national access.

Dried blood spot (DBS) testing

Clinical Diagnostic Laboratories are accredited to the ISO 15189 standard. The process of validation and verification of any new matrix for testing in an accredited environment is detailed and time consuming. This verification has not been done for DBS in Ireland, and until it is done, DBS cannot be considered.

Matrix refers to blood, urine, saliva etc., and within blood each of whole blood, serum, serum from a gel tube, heparinised plasma or EDTA plasma is a separate matrix. The validation step should be done by the manufacturer confirming that the assay configuration can use the matrix. It establishes reproducibility, sample stability, kit stability, sensitivity, specificity, lot-to-lot variation, upper and lower limits of detection and it usefulness in clinical discrimination between disease states. It must be compatible with the in-vitro medical devices regulations (IVDR). Once the manufacturer has done this, the laboratory must verify the assay works to specification in their hands. Again this involves confirming day to day reproducibility, Incoming Quality Control (IQC) limits and performance in External Quality Assessment (EQA) (with these 2 quality control checks using that matrix). Finally checks are undertaken to ensure that blood spot results are comparable with the standard matrix used, and Standard Operating Procedures (SOP), training records, etc., need to be produced.

It is not to be undertaken lightly, but might be considered if the recommended tests in this report perform poorly, including for particular sub-cohorts where DBS are likely to be particularly useful and feasible. In that case, the NVRL should be requested to undertake the above verification process.

Testing for Syphilis

- Although this is a complex issue, the ID specialists consulted recommended not screening all adult Refugees and Applicants Seeking Protection for syphilis in the current context, for the following reasons:
- The current test detects prior treated syphilis as well as untreated, and differentiation of this

requires specialist input and often further testing (patients will need to be referred to ID/STI services).

- At least in the western world the majority of cases are in gay/bisexual men who have sex with men (gbMSM). Women potentially at risk are screened during pregnancy and gbMSM should have comprehensive sexual health screening which would routinely include syphilis screening.
- The hierarchy of priorities – e.g., screening for latent TB amongst migrants from countries of high TB prevalence should take precedence.
- NICE guidelines reserves STI testing including syphilis for those with risk factors[6].

If we were to undertake syphilis screening as part of this Programme, ID services would need additional support to deliver a pathway.

However we must recognise that there may be risk factors for STIs including syphilis that are different in war-time settings. In this context it is advised that antenatal and Genitourinary Medicine (GUM) clinics identify vulnerable migrant groups and target them for syphilis testing. It is essential that all pregnant women are referred to Ante-Natal Clinics as soon as possible, where syphilis screening can be undertaken routinely. If there is likely to be a delay in this, syphilis screening through STI testing services should be arranged.

Consideration to include markers of active viral replication rather than antibody only

Currently there are no validated RD or CB tests for antigen/active viral replication for Hepatitis C. Markers of active viral replication are available for Hepatitis B and HIV using both the RDT and CBT platforms.

Validation and Quality Control of Testing

Two pathways for validation/quality control were suggested for identifying potential false negatives. First, all clients reporting a past history of BBV infection will be screened as normal, AND referred to the ID clinic for confirmatory testing. Both results will be recorded on the PIMS and compared. Secondly, one in ten clients in teams that do screening by phlebotomy will do CBT or RDT as well (depending on final option chosen) and both results will be recorded on the PIMS and compared.

Finally, validation of batches will be done upon arrival in the laboratory.

Other Evidence

(See Appendix 3)

We reviewed “The Pilot Online STI Testing Service in Ireland, 2021: Evaluation Report”[7] which evaluated the accessibility, feasibility, impact and acceptability of an online STI service in Ireland modelled on the SH:24 service in the UK. We also reviewed the WHO document “Updated recommendations on treatment of adolescents and children with chronic HCV infection, and HCV simplified service delivery and diagnostics[8].”

3

Discussion

The approved Primary Care Infectious Disease Testing Service Delivery Model document (23/02/2023) states that a pragmatic approach was applied for that work that acknowledges the limitations of the current delivery environment, future planning, and budgetary constraints. We have used the same approach in the work that underpins this report.

Comparative Appraisal Results

Our suite of criteria used for comparative appraisal of the three screening methods showed that RDTs outperformed or equaled CBTs in all but one criterion. The RDTs score better than CBTs for Contacts/patient, Turn-around time, Cost/patient, Acceptability, Impact of mobility, Service provider experience, and Feasibility.

In the remaining criterion, information management, the CBT process is superior, because Enfer has a system of automatic uploading and communication of results, and maintains a repository of these results for 10 years. However, whereas RDTs need to be read and interpreted by the service provider, the service providers interviewed unequivocally stated that this was easy and that they had never experienced a situation where the result was indeterminate. This is important, as indeterminate results are relatively common using the CBT modality. Moreover, having a repository for results only covers one component of information management system needs, with other critical parts still required (represented by only a few of the columns in the Individual Data Monitoring Template considered necessary from a Public health perspective, see Table 3).

Information management system needs

A Monitoring and Evaluation (M&E) framework to accompany rollout of RDT or CBT for BBV screening is essential. A PIMS is needed to support this. A national PIMS network, spanning across all CHOs, is considered critical for patient safety, data security and reporting capability. The merits of a national client server-based system like Socrates were discussed. The need to dovetail information management to a mainstream GP PIMS as patients transition out of the migrant health programme to mainstream services provides further rationale for a system like Socrates.

A national PIMS is critical for the success of the programme, but the procurement and implementation of same should not delay the implementation of the programme. A data monitoring template as below in Table 3 could be used. This would also be compatible with the Microsoft Health Status Questionnaire (HSQ) digital platform currently at an advanced stage of development. Table 3 shows the data fields to be used, which are to be recorded as in Table 3 in one long row, identical for each CHO.

Table 3 Data Monitoring Template

Name	DOB dd/mm/yyyy	Temp Protection or IPA No	CHO	BBV screen date dd/mm/yyyy	HIV Reactivity (+/-)	Referred to Clinic1	HIV Confirmed Positive (Y/N)	HIV Positive ESF done and sent to PH (Y)2	HCV Ab Reactivity (+/-)	Referred to Clinic1	HCV antigen or RNA result viraemic (+/-)	HCV viraemic case ESF done and sent to PH (Y)2	HBsAg Reactivity (+/-)	Referred to Clinic1	HBsAg confirmed Positive (Y/N)	HBeAg Positive (Y/N)	anti-HBc IgM Positive (Y/N)	HBsAg Positive case ESF done and sent to PH (Y)2	HBV Vaccinated (Y)2	Batch number	Sexual contacts identified, tested, and vaccinated as indicated (Y)2	Household contacts identified, tested, and vaccinated as indicated (Y)2
Name1																						
Name2																						
Name3																						
Name4																						
Name5																						

1. Could be drop down hospital or clinic
2. Just Y required, filled in when completed

The fields in each row are, in the following order: Name; DOB dd/mm/yyyy; Temp Protection or IPA No; CHO; BBV screen date dd/mm/yyyy; HIV Reactivity (+/-); Referred to Clinic[1]; HIV Confirmed Positive (Y/N); HIV Positive ESF done and sent to PH (Y)2; HCV Ab Reactivity (+/-); Referred to Clinic1; HCV antigen or RNA result viraemic (+/-); HCV viraemic case ESF done and sent to PH (Y)2; HBsAg Reactivity (+/-); Referred to Clinic1; HBsAg confirmed Positive (Y/N); HBeAg Positive (Y/N); anti-HBc IgM Positive (Y/N); HBsAg Positive case ESF done and sent to PH (Y)2; HBV Vaccinated (Y)2; Batch number; Sexual contacts identified, tested, and vaccinated as indicated (Y)2; Household contacts identified, tested, and vaccinated as indicated (Y)2.

There should be one file per site (or a small number of files per site if multiple staff are testing and recording results on a given day) with all details for each individual patient in one row. Multiple patients per worksheet make reporting data and finding data for each patient relatively easy. When it comes to national reporting, you should be able to combine a relatively small number of Excel files from each site to create the full dataset. A flat table, with a single row per patient also makes it easier to import existing data into the final database solution. Multiple files that look the same and are saved in one folder can be combined in Excel using the 'Get data' function and specifying the folder location.

Test Specificities and Sensitivities

The inability of the laboratories concerned (Enfer and Eurofins Biomnis) to provide accurate sensitivity and specificity data for the CBT screening option is a concern, as it not possible to estimate Negative (NPV) or Positive Predictive Values (PPV) for our prevalence estimates in their absence. Data from a SH:24 report showed a PPV of 17.2% with a prevalence rate of 0.4% for CBT for HIV. This clearly demonstrates that HIV CBT as used by SH:24 has significantly lower specificity +/- sensitivity than HIV SLBT. Positive Predictive Value data on Hepatitis B and Hepatitis C were not available at the time of writing this report. In the absence of this data, and as both use a one-stage testing platform for screening, we assume similar sensitivities and specificities for RDTs and CBTs.

Service provider experience

Service provider interviews (x2) showed strong support for RDT sampling, but a negative service provider experience (x2) in respect to CBT sampling.

Following our meeting with SH:24 we decided to explore self/home-testing using CBTs as an additional option for end-users.

End-user preference

Our limited end-user survey showed a better than expected demand for both RDT and CBT screening, albeit the people screened had a very high level of university educational attainment, not representative of overall IPA and BoTP populations. This high demand is promising.

The demand for home-testing appeared small, even with this relatively well-educated cohort. The possibility of making service users aware of the SH:24 service therefore remains an option without overwhelming the SH:24 programme – this is something that might be explored with that service.

There was a preference (non-statistically significant) for CBT testing in the survey. However, this result was inconsistent with 2 follow-up questions, suggesting there may have been some confusion with interpretation of the questions. The majority of respondents either agreed or strongly agreed 1) that it was important to get the test result back within 30 minutes (66%); and 2) with the statement that “In-person support by the health worker and interpreter in making the phone call for expert counselling and referral of a positive result is important” (87%), both of which can only be done through the RDT protocol.

This inconsistency was explained in the Focus Group session by a likely misunderstanding among respondents that CBTs have better sensitivity and specificity than RDTs. With the understanding that the specificities and sensitivities of the two screening tests are the same, the majority in the Focus Group stated a preference for RDTs. Another important point raised in the Focus Group session was the possibility of inconvenient timing for receiving the phone call with a positive CBT screening result – an issue that would not apply to RDTs as results are delivered at the same sitting as the sampling.

Oral Swab RDT BBV Screening

The recommendation from the report ‘HIV Upsurge among People who Inject Drugs in Dublin’ to move to oral HIV swabs RDT (once validated) could be considered for this programme once all BBVs have adequate quality and validated oral tests.

The expert opinion of the Clinical Lead for the Hepatitis C Programme (e-mail consultation) is that the oral HIV and HCV tests are good. However, blood RDT is superior to oral RDT- the drawback is reduced take up. The lack of an oral HBV test is a real problem.

The use of oral RD tests could be considered by the BBV screening programme once validated tests are available for all three BBVs.

Active Thoracic TB Screening

The protocol for active thoracic TB screening relies on a suite of TB questions relayed through a Health Status Questionnaire (HSQ) either in the National Transit Centre in Citywest, National Reception Centre in Balseskin, or by migrant health in-reach teams at accommodation sites. If the client answers yes to any of one of the suite of questions they must be referred for an urgent Chest X-ray. There is good availability of urgent x-rays by HSE radiology services across most parts of the country, the crucial element is the identification of the need at the HSQ stage and linking effectively with the Migrant Health Services in the CHOs to request the Chest X-ray.

It is important to highlight that this screening model is not suitable for extra-pulmonary TB, and the requirement for any such screening needs to be addressed separately.

Syphilis Screening

The Group, including ID colleagues, felt that syphilis screening would not be appropriate.

Dried blood spot (DBS) testing

Method verification to the Clinical Diagnostic Laboratory ISO 15189 standard has not been done for DBS in Ireland as yet, and until it is done, the Group advised that DBS should not be considered. Even if verified, it is doubtful that it would represent a significant advantage to RDTs for most cohort sub-groups.

Markers of active Hepatitis C viral replication

Currently there is no validated RD or CB tests for antigen/active viral replication for Hepatitis C. We feel that until validated, such tests cannot be considered currently.

Quality control pathways

Two pathways for validation/quality control were discussed:

- First, all clients reporting a past history of BBV infection will be screened as normal, AND referred to the ID clinic for confirmatory testing.
- Secondly, a proportion of clients in teams that can do phlebotomy will be offered testing by SLBT as well as RDT.

Core Screening Unit

The basic unit required for implementation is considered to be:

- Two Health Care Workers of at minimum Health Care Assistant (HCA) level, trained in basic pre-test counselling and in undertaking the RDT test.
- One Interpreter
- One Administrator

It would be important to ensure:

- That people with healthcare qualifications from overseas would be eligible to apply for the Health Care Worker Roles.
- That the two Health Care Workers are screened for BBVs prior to taking up employment and are offered vaccination for Hep B.
- That the core screening unit have access to immediate telephone interpreting for all languages.

Governance

Overall programmatic governance is most appropriate under the CHO Migrant Health Team or equivalent, as per the agreed Service Delivery Model. Specialist ID services should share patient information with the CHO Migrant Health Team (who in turn will present information to Sessional GP Clinics if applicable) AND patient's GPs if assigned, for follow-up of patients. The Screening Team clinical governance should be analogous to that of the Catch-up Vaccination Programme, and could be Nurse-led.

Standard Operating Procedure (SOP)

The logistics of clinics where large numbers of people are anticipated can be a significant challenge, including, for example ensuring the RDTs are linked to the correct individual. An SOP will therefore be required to guide in detail how this will be undertaken.

4

Conclusions

Screening by lateral flow Rapid Diagnostic Testing (RDT) assisted by Health Care Workers is the modality of choice for this programme. This can be undertaken in an appropriate location in the congregated accommodation setting or in a nearby clinic.

In keeping with previous advice (from the HSE Health Response for Refugees and Applicants seeking Protection, Primary Care Infectious Disease Testing Service Delivery Model, Date 23/02/2023, Version 1.0 Ratified), BBV screening via RDT should be offered to all Refugees and Applicants Seeking Protection over the age of 16 years, and to children over 18 months of age not accompanied by a biological parent. The rationale for the latter is that it is assumed that the vast majority of infections of children is by means of vertical transmission and therefore screening of the biological parent would suffice. In case of a parent being confirmed positive, screening would need to be undertaken for the child. Although flexibility is advised in implementation, more detail on the end-to-end protocol for RDT screening can be found in Appendix 2. Children under 18 months of age can be offered phlebotomy testing in their nearest paediatric clinic or the CHI Rainbow Clinic.

Home-screening by Capillary Blood Testing (CBT), linking with the SH:24 programme is an option, although it is unlikely to have a high demand, suggesting that numbers will be low. CBT is the modality of choice for self-testing.

Active thoracic TB screening is feasible and appropriate using a suite of TB questions relayed through a Health Status Questionnaire (HSQ) either in the National Transit Centre, National Reception Centre in Balseskin, or by migrant health in-reach teams at accommodation sites. If the client answers yes to any of one of the suite of questions they must be referred for an urgent Chest X-ray.

A national Patient Information Management System (PIMS) is essential for the safe, secure and efficient management of this programme.

5

Recommendations

The following are the recommendations of the Group:

1. Screening for BBVs:

a. by lateral flow RDT, should be offered to all of the target population over the age of 16 years, and to children over 18 months of age who are not accompanied by a biological parent.

b. for children under 18 months of age who are not accompanied by a biological parent, they should be offered SLBT by phlebotomy in their nearest paediatric clinic or the Children's Health Ireland Rainbow Clinic.

2. Link with the SH:24 programme to offer home-screening by CBT as an alternative to adult Refugees and Applicants Seeking Protection.

3. Active thoracic TB screening should continue using the current suite of TB questions relayed through a Health Status Questionnaire (HSQ), with any questions answered in the affirmative entailing an urgent Chest X-ray and follow-up as required.

4. A national Patient Information Management System is a requirement for the success of a programme like this, but the procurement of same should not delay implementation of the programme nationally.

5. The programme and Migrant Screening Teams should be coordinated and managed at a regional level by the Community Healthcare Organisation (CHO) Migrant Health Team. CHO Migrant Screening Teams should also be guided by a national programme coordination group, which could be chaired by National Community Operations in line with what is currently the case in relation to the Catch-up Vaccination Programme. The Screening Team clinical governance should be similar to that of the Catch-up Vaccination Programme, and could be registered Nurse-led. Primary Care follow-up of confirmed cases after linking with specialist ID Services should be undertaken by assigned GPs or CHO Sessional GP Clinics.

6. Each CHO Migrant BBV Screening Team should liaise with local/regional ID/hepatology services to agree a process of referral. This should include access to local service staff to coincide with RDT screening clinics for immediate referral to ID/ hepatology services upon a reactive test result.

7. Safetynet will be asked to provide support and capacity building to Community Healthcare Organisation (CHO) BBV Screening Teams as required.

8. The Programme should be supported at national level by a Refugee and Applicants Seeking Protection (RASP) Blood Borne Virus/Tuberculosis (BBV/TB) Screening Implementation Oversight Group to continue the work of the Advisory Group and complete its fourth objective (Provide ongoing support to CHOs). The Oversight Group will support and provide strategic, operational and Public Health advice to the national programme coordination group (see Recommendation 5) CHOs and their Migrant Health Teams on the rollout of the Programme.

9. Next Steps

- Engagement with procurement on suppliers for RDT test kits (including training).
- Roll out of pilot. The learning from this will be used to develop Standard Operating Procedures (SOPs) for CHOs on RDTs.
- Establish the national programme coordination group and the RASP BBV/TB Screening Implementation Oversight Group.

Membership of the Refugee and Applicants Seeking Protection Blood Borne Virus/Tuberculosis Screening Implementation Advisory Group

Name	Office/Organisation
Doug Hamilton	NSIO
Niamh Murphy*	HPSC/Surveillance
Sarah Jackson*	HPSC/Surveillance
Mark Campbell*	HPSC/Surveillance
Marie Culliton*	Pathology/Laboratory Representative
Pat Mulhare*	Pathology/Laboratory Representative
Kateryna Kachurets	GP Representative
Ksenia Davenport	ID Clinician
Siobhán O'Dea	cANP Sexual Health
Fiona O' Reilly*	Safetynet Representative
Angy Skuce*	Safetynet Representative/ GP
Fiona Cianci	Public Health
Aoibhinn Walsh*	Paediatrician
Bridget Freyne*	Paediatrician
James O'Connell	SpR in Public Health Medicine/TB
Camille Staunton	HSE – Integrated Operations/ Planning
Debbie Carroll	CHO Representative (CHO9)
Claire Dunne	NSIO
Emmanuel Bello	NSIO
Grainne Begley	NSIO

* Only one of these representatives required per meeting

Acknowledgements

The Implementation Advisory Group would like to thank the following individuals for their expert advice and guidance:

Dr Paula Baraitser, Medical Director, SH:24

Prof Colm Bergin, Consultant Physician in Infectious Diseases, St James's Hospital, Dublin

Suzie Coughlan, Scientific Director, Enfer Medical

Dr Grainne Courtney, Consultant in Genito-urinary and HIV & Specialist in sexual health and HIV at the GUIDe Clinic in St. James's Hospital and HSE The Gay Men's Health Service

Dr Gabriel Fitzpatrick, Consultant in Public Health Medicine, Department of Public Health, Area A

Dr Catherine Fleming, Consultant in Infectious Diseases and National Specialty Director of Infectious Diseases in RCPI

Caroline Hurley, Project Manager, Sexual Health & Crisis Pregnancy Programme

Prof Eamon Keenan, National Clinical Lead, Addiction Services, Assistant National Director Primary Care, HSE

Dr Fiona Lyons, Consultant Genitourinary/HIV medicine, St James's Hospital and National Clinical Lead for Sexual Health Services in the HSE

Prof Aiden McCormick, HSE Clinical Lead for the Hepatitis C Programme

Martina McKnight, Personal Support Worker, Gender Orientation Sexual Health HIV (GOSHH)

Sheila O'Toole, Clinical Nurse Specialist, National Hepatitis C Treatment Programme

Ann Piercy, Personal Support Worker, Gender Orientation Sexual Health HIV (GOSHH)

Adam Shanley, Programme Manager, MPOWER Programme at HIV Ireland

Appendix 1: Terms of Reference of Group

Terms of Reference

National Refugee and Applicants seeking Protection Blood Borne Virus/Tuberculosis Screening Implementation Advisory Group

V. 1.9

Draft Terms of Reference document	
Name of group:	National Refugee and Applicants seeking Protection Blood Borne Virus/TB Screening Implementation Advisory Group
Date approved:	30.03.23

Introduction

Ireland has welcomed thousands of people coming from other countries around the world seeking protection here. It is acknowledged that when a person comes to Ireland, access to healthcare is of high importance. It is therefore one of the main priorities for the HSE to ensure that those entering Ireland are offered screening and vaccination to protect them and the broader population against the harm of preventable diseases. In order to provide testing and appropriate treatment, the HSE is coordinating its services with other government agencies to provide voluntary health testing services upon arrival to Refugees and Applicants seeking Protecting, which includes Beneficiaries of Temporary Protection (BoTP) and International Protection Applicants (IPAs).

This Blood Borne Virus (BBV)/Tuberculosis (TB) Screening Implementation Advisory Group will focus on the introduction of an infectious disease testing programme designed for incoming BoTP and IPA migrants to Ireland. This programme focuses on infectious diseases that have significant consequences to the individual and the community if undiagnosed. In particular the group will focus on testing for Hepatitis B, Hepatitis C and HIV along with screening for TB. There will be several points in the health system where individuals will be in a position to access care.

Target Population

The following socially excluded groups are identified as the focus of the Blood Borne Virus/Tuberculosis Screening Implementation Advisory Group:

Applicants seeking Protection:

- **International Protection applicants (International Protection Accommodation Services (IPAs); those seeking 'asylum'):** On the 10th February 2023 there were approximately 19,741 people living in IPAS accommodation.
- **Beneficiaries of Temporary Protection (BoTP) under EU Temporary Protection Directive (2001/55 EC):** Ireland, as the rest of the EU, has committed to providing Temporary Protection (for 1 year; with same entitlements as Irish citizens) to people fleeing war in Ukraine (Ukraine nationals plus those ordinarily living in Ukraine). On the 10th February 2023 there were approximately 74,185 people fleeing the war in Ukraine already in the country.
- **Refugees under the Irish Refugee Protection Programme (IRPP).** Under this programme, the Government pledged in 2015 to accept a total of 4,000 persons under the Relocation and Resettlement Programmes into the State. Under IRPP 1 and 2, 3,804 people have arrived in Ireland, as well as 550 Afghans since 2021. 800 people are expected to arrive in 2023.

Aim

The overall aim of the group is to develop a programme to achieve maximum coverage of BBV/TB screening in the Refugee and Applicants for Seeking Protection population.

Key objectives

The following are key objectives of the Blood Borne Virus/Tuberculosis Screening Implementation Advisory Group. The group will:

- Urgently define detailed end-to-end protocols for BBV testing including informing of results, Public Health notification, household and sexual contact identification, screening of contacts and vaccination of cases and contacts, for each of three options currently under consideration (phlebotomy, capillary blood testing, and Rapid Diagnostic Testing).
- Define end-to-end protocols for active thoracic TB screening.

- Appraise the 3 current options by test parameters such as sensitivity and specificity, feasibility and resources in relation to capacity and financial resources available.
- The establishment of an evaluation panel if a formal tender is required
- Support and provide advice to CHOs/Public Health on strategic and operational issues relating to access to and uptake of Blood Borne Virus/TB screening within the scope of this programme. Provide guidance and direction to CHOs/Public Health Areas on dealing with challenges within the BBV/TB screening programme

Membership

Membership of the Blood Borne Virus/Tuberculosis Screening Implementation Advisory Group will include representatives from NIO, HPSC/Surveillance, Public Health, Labs, GP and ID clinicians

Name	Office/Organisation
Doug Hamilton	NSIO
Niamh Murphy*	HPSC/Surveillance
Sarah Jackson*	HPSC/Surveillance
Mark Campbell*	HPSC/Surveillance
Marie Culliton*	Pathology/Laboratory Representative
Pat Mulhare*	Pathology/Laboratory Representative
Kateryna Kachurets	GP Representative
Ksenia Davenport	ID Clinician
Siobhán O'Dea	cANP Sexual Health
Fiona O' Reilly*	Safetynet Representative
Angy Skuce*	Safetynet Representative/GP
Fiona Cianci	Public Health
Aoibhinn Walsh*	Paediatrician
Bridget Freyne*	Paediatrician
James O'Connell	SpR in Public Health Medicine/TB
Camille Staunton	HSE – Integrated Operations/ Planning
Debbie Carroll	CHO Representative (CHO9)
Claire Dunne	NSIO
Emmanuel Bello	NSIO
Grainne Begley	NSIO

*Only one these representatives required per meeting

Reporting

The Blood Borne Virus Implementation Group will be a sub-group of the Public Health advisory forum (or equivalent, currently also in the process of being established). The group will report to the National Director of Health Protection Dr Éamonn O'Moore.

Meeting arrangements

The group will meet fortnightly for an hour. Ad hoc meetings and webinars will be organised as required. The frequency of the meetings will be reviewed to respond to emerging needs.

A quorum for each meeting comprises representation from at least 50% plus one

The meeting is chaired by Dr Doug Hamilton, in circumstances where he is not available, a member of the group will be nominated to chair the group.

Members are expected to attend meetings; each member should forward apologies when not able to do so.

When a member is unable to attend, efforts should be made to nominate a substitute, where appropriate. Substitutes must be fully briefed, be capable of, and (ideally) have authority to make decisions on behalf of their nominating specialty area. In the event of a substitute being required for more than one meeting, for consistency the same person should act as substitute.

Proposed agenda items and associated documentation should be forwarded to the National Social Inclusion Office at least 2 days prior to the date of a next meeting.

Administration of the working group will be managed by the National Social Inclusion Office.

Appendix 2: Detailed description of each end-to-end protocol

END-TO-END PROTOCOL BBV SCREENING VIA RDT

1.	**IDENTIFY TARGET POPULATION**
	• Agree population for screening with Public Health, and appropriate site for screening
2.	**SENSITISE POPULATION FOR OPTIMUM UPTAKE**
a)	**LOCAL ADVERTISING** • Screening administrator to send posters translated to relevant languages to the accommodation centre manager. Ideally, send posters one week before the planned screening takes place so attendees have adequate notice to plan their attendance. • Screening administrator to ask accommodation management that posters are on display in areas where they will be seen and easily accessed
b)	**MATERIALS**
c)	**DETAILS OF SCREENING CLINIC** • Posters should explicitly state that screening is voluntary and free of charge. • Details of screening clinic times and dates to be included along with location of clinic within the accommodation centre. • Posters should include details of investigations offered at screening so that expectations are realistic.
3.	**MAKE APPOINTMENTS FOR THE DAY**
a)	**INFORMATION PROVIDED** • Posters available at time of sign up/ recruitment
b)	**QUEUING SYSTEM** • Appointment times and numbers given to participants so large crowds don't form
4.	**REGISTRATION**
a)	**CONSENTING** • Participant to sign consent form with screening administrator (ideally, consent form is available in the participants language). • Along with name (spelling to be taken directly from TRC card), DOB, country of origin, TRC number and details regarding need for interpreter
b)	**CONTACT DETAILS FOR RESULTS** • The participant must wait at the screening waiting area for 30 minutes to get their RDT test result in person. • If for some reason the patient cannot wait the participant needs to be contactable in case of positive result. Ask for mobile phone number and email address. Ideally, the participant will have an Irish phone number. If non-Irish number only, check that this number is contactable via WhatsApp to confirm the participant can be reached. If no Irish number then participant must have email address along with non-Irish number, which the participant should have regular access to

c)	**INFORMATION ON HOW TO GET RESULTS** • Healthcare assistant will give the participant a copy of screening letter, confirming investigations done. Explain that results will be available after 30 minutes and that the participant must wait to get a verbal and written report of their result after 30 minutes. If the participant does not wait 30 minutes they will be sent their results via email/SMS. • Healthcare assistant to assure participant that if any positive results are detected on BBV then they will be informed by phone and referred to relevant services.
d)	**REGISTERING ON PATIENT RECORD SYSTEM** • If participant ready to proceed with screening, screening administrator to add participant's details to electronic management system or equivalent recording method.
5.	**THE SCREEN**
	a. HIV b. Hep B c. Hep C
	• Healthcare assistant » Offers RDT screening to each adult and each child over 18 months of age not accompanied by a biological parent » Counsel that the results will take 30 minutes but need to be confirmed by a confirmatory test » RDTs can be used to screen unaccompanied minors and children over the age of 18 months not travelling with a biological parent. If a child screens positive they will need to be referred to the CHI Rainbow Clinic (by phone) for an early appointment to arrange confirmatory testing. » If HIV +Ve RDT: Phone central counselling team to refer to adult ID service if > 16 or if < 16 refer to CHI Rainbow clinic by phone where blood will be drawn for HIV Ab/AG test and viral load » If Hep C Ab +ve RDT: Phone central counselling team to refer to adult ID service if > 16 or if < 16 refer to CHI Rainbow clinic by phone where blood will be drawn for Hep C Antibody and Hep C RNA viral load » If Hep B Ab +ve RDT: Phone central counselling team to Enfer to adult ID service if > 16 or if < 16 refer to CHI Rainbow clinic by phone where blood will be drawn for confirmatory serology and Hep B viral load. » If known history of HIV, do RDT test. Assure the participant that they will be referred to specialist clinics irrespective of RDT result to get ARVs. Participant referred to ID clinic by phoning central counselling team. » If known history Hep C do RDT test. Participant referred to ID/hepatology clinic irrespective of RDT result by phoning central counselling team. » If known history Hep B do RDT test. Participant referred to ID clinic/hepatology clinic irrespective of RDT result by phoning central counselling team.
6.	**MANAGING SAMPLES**
	• RDTs to be stored and used according to manufacturer's instructions • RDTs to be appropriately labelled and the result read and noted at 15-30 minutes • Used RDTs to be handled and disposed according to Infection Prevention Control Guidelines

7.	**MANAGING RESULTS**
	• Results to be documented on a patient information management system. In the absence of a patient management system results to be documented on a secure Excel spreadsheet and uploaded to a secure shared folder. • For non-reactive results, the healthcare assistant will inform the patients in person and hand them a copy of their results. If the person does not wait for 30 minutes for the results, follow up of negative results will be managed by email with the healthcare assistant emailing the negative results.
8.	**ONWARD REFERRAL AND TREATMENT**
	For a reactive result, referral to ID/hepatology clinic is done at the time of consultation by phoning the referral service with client and interpreter present.
9.	**CONTACT TRACING**
	If adults – ID clinic/hepatology clinic will contact trace and screen sexual contacts, and the Mobile Screening Team will contact trace household contacts If children – refer to CHI for phlebotomy screening.
10.	**NOTIFICATION TO PUBLIC HEALTH**
	A confirmed positive test result is notified by NVRL to Public Health. The ID Clinic should inform the Mobile Screening Team/ the CHO Migrant Health Team of BBV phlebotomy test results
11.	**COMPLETION OF ENHANCED SURVEILLANCE FORM**
	Once the confirmatory test result is received ID clinic/hepatology clinic to fill the Enhanced Surveillance Form
12.	**VACCINATION OF CASE AND CONTACTS**
	ID clinic/hepatology clinic to arrange vaccination of Hepatitis C and HIV cases. Catch up vaccination team and/ or ID team to arrange vaccination of contacts of Hepatitis B cases.

END-TO-END PROTOCOL BBV SCREENING VIA CAPILLARY BLOOD TESTING

1.	**IDENTIFY TARGET POPULATION**
	• Agree population for screening with Public Health, and appropriate site for screening
2.	**SENSITISE POPULATION FOR OPTIMUM UPTAKE**
a)	**LOCAL ADVERTISING** • Screening administrator to send posters translated to relevant languages to the accommodation centre manager. Ideally, send posters one week before the planned screening takes place so attendees have adequate notice to plan their attendance. • Screening administrator to ask accommodation management that posters are on display in areas where they will be seen and easily accessed
b)	**MATERIALS**
c)	**DETAILS OF SCREENING CLINIC** • Posters should explicitly state that screening is voluntary and free of charge. • Details of screening clinic times and dates to be included along with location of clinic within the accommodation centre. • Posters should include details of investigations offered at screening so that expectations are realistic.

3.	**MAKE APPOINTMENTS FORTHE DAY**
a)	**INFORMATION PROVIDED** • Posters available at time of sign up/ recruitment
b)	**QUEUING SYSTEM** • Appointment times and numbers given to participants so large crowds don't form
4.	**REGISTRATION**
a)	**CONSENTING** • Participant to sign consent form with screening administrator (ideally, consent form is available in the participants language). • Along with name (spelling to be taken directly from TRC card), DOB, country of origin, TRC number and details regarding need for interpreter
b)	**CONTACT DETAILS FOR RESULTS** • Ask for mobile phone number and email address. Participant needs to be contactable in case of positive result. Ideally, the participant will have an Irish phone number. If non-Irish number only, check that this number is contactable via WhatsApp to confirm the participant can be reached. If no Irish number then participant must have email address along with non-Irish number, which the participant should have regular access to • If the patient has no contact details via phone number or email, the screening clinician to discuss with participant re obtaining local sim card and returning for screening. If clinician determines that participant is particularly vulnerable and that screening should not be delayed, clinician to offer screening at their own discretion.
c)	**INFORMATION ON HOW TO GET RESULTS** • Screening nurse will give the participant a copy of screening letter, confirming investigations done. Explain that results will be available after 5 days. Explain that they will receive non-reactive results via Email/SMS. • Screening nurse to assure participant that if any positive results are detected on BBV then they will be contacted by a counsellor through a central phone line and referred to relevant services. • If participant does not have access to email account, screening administrator will have added the participants name to a shared spreadsheet so that the screening team are aware that the participant will require a hard copy of results be sent to them. Hard copies will be sent via post or handed in person if screening team are regularly in that location.eg Citywest Transit Centre. • Explain we will phone participant to collect results or if he/she has moved to different accommodation centre, we can post.
d)	**REGISTERING ON PATIENT RECORD SYSTEM** • If participant ready to proceed with screening, screening administrator to add participant's details to electronic management system
5.	**THE SCREEN**
	a. HIV b. Hep B c. Hep C

	• Healthcare assistant » Offers capillary blood screening to each adult and each unaccompanied minor/child over the age of 12 not accompanied by a biological parent » Counsel that the results will take 5 days » Participants take the test themselves following watching an instructional video and with guidance from the healthcare assistant » Ensure that hands are warm/warmed before the test is taken » Capillary blood test (CBT) screening can be used to screen unaccompanied minors and children not travelling with a biological parent over the age of 12 years. If a child screens positive they will need to be referred to the CHI rainbow clinic (by phone) for an early appointment to arrange confirmatory testing. » If HIV +ve CBS: Central counselling service to refer to adult ID service if > 16 years of age, or if < 16 years of age, refer to CHI Rainbow clinic by phone where they will have blood drawn for confirmatory HIV Ab/ Ag test and viral load. » If Hep C Ab +ve CBS: Central counselling service to refer to adult ID service if > 16 years of age, or if < 16 years of age, refer to CHI Rainbow clinic by phone where they will have blood drawn for confirmatory Hep C Ab and HCV RNA Viral load. » If Hep B Ab +ve CBS: Central counselling service to refer to adult ID service if > 16 years of age, or if < 16 years of age, refer to CHI Rainbow clinic by phone where they will have blood drawn for confirmatory serology and HBV RNA Viral load. » If known history of HIV, do capillary blood test for HIV, Hepatitis B and C. Assure the participant that they will be referred to specialist clinics to get Anti-retroviral medication (ARVs) where they will also have bloods done to check for all other BBVs. Participant referred to ID clinic by central counselling service phone line. » If known history of Hep C do capillary blood test for Hepatitis C, Hepatitis B and HIV. Central counselling service phone line to refer patient to ID clinic/hepatology clinic for confirmatory serology and follow up. . Participant referred to ID clinic/hepatology clinic. » If known history of Hep B, do capillary blood test for Hepatitis B and C and HIV. Central counselling phone line service to refer participant to ID clinic/hepatology clinic for confirmatory serology and follow up.
6.	**MANAGING SAMPLES**
	• Capillary blood tests to be stored and used according to manufacturer's instructions • Capillary blood tests to be appropriately labelled and packaged for posting to the laboratory • Capillary blood tests to be handled according to Infection Prevention and Control Guidelines
7.	**MANAGING RESULTS**
	• Results to be documented on a patient information management system. In the absence of a patient information management system, results to be documented on a secure Excel spreadsheet and uploaded to a secure shared folder. • For non-reactive results, results will be managed by email, with the healthcare assistant emailing the participant with a copy of their results • If there is a reactive result, the participant should be phoned by a healthcare professional from the screening team whereby the patients will be counselled regarding the result and onwards referral to the local/regional ID/hepatology service.
8.	**ONWARD REFERRAL AND TREATMENT**
	On receipt of a reactive result a referral is made to the local ID/hepatology clinic via the liaison person through whom the referral can be facilitated. On receipt of confirmatory serology result the local ID/hepatology clinic to notify the disease to public health.

9.	**CONTACT TRACING**
	If adults – ID clinic/hepatology clinic will contact trace and screen sexual contacts and mobile screening team to contact trace and offer screening to household/other close contacts If children – refer to CHI for phlebotomy screening
10.	**NOTIFICATION TO PUBLIC HEALTH**
	A confirmed test result is notified by NVRL to Public Health. The ID Clinic should inform the Mobile Screening Team/ the CHO Migrant Health Team (or equivalent) of BBV phlebotomy test results.
11.	**COMPLETION OF ENHANCED SURVEILLANCE FORM**
	Once the confirmatory test result is received ID clinic/hepatology clinic to complete the enhanced surveillance form.
12.	**VACCINATION OF CASE AND CONTACTS**
	ID clinic/hepatology clinic to arrange vaccination of HIV and Hepatitis C cases. Catch up vaccination team and/or ID team to arrange vaccination of contacts of Hepatitis B cases.

END-TO-END PROTOCOL BBV SCREENING VIA PHLEBOTOMY (SLBT)

Contents:

1. IDENTIFY TARGET POPULATION
2. SENSITISE POPULATION FOR OPTIMUM UPTAKE
3. REGISTRATION
4. THE SCREEN
5. MANAGING SAMPLE
6. MANAGING RESULTS
7. ONWARD REFERRAL AND TREATMENT
8. CONTACT TRACING

1.	**IDENTIFY TARGET POPULATION**
	• Agree population for screening with Public Health, and appropriate site for screening
2.	**SENSITISE POPULATION FOR OPTIMUM UPTAKE / CLINIC PREPARATION**
a)	**LOCAL ADVERTISING** • Screening team to liaise with accommodation centre to agree suitable times/ date for screening in order to maximise uptake • Screening team to send posters translated to relevant languages to the accommodation centre manager. Ideally, send posters one week before the planned screening takes place so attendees have adequate notice to plan their attendance. • Request that posters are on display in areas where they will be seen and easily accessed

b)	**DETAILS OF SCREENING CLINIC** • Posters should explicitly state that screening is voluntary and free of charge. • Details of screening clinic times and dates to be included along with location of clinic (either within the accommodation centre or in static clinic). • Posters should include details of investigations offered at screening so that expectations are realistic.
c)	**SCREENING SET UP** • **Inreach:** If screening is to be done onsite at an accommodation centre, private rooms should be provided for each screening station to ensure privacy. Risk assessment to be done onsite before screening is started to ensure the set up is suitable. • **Outreach:** If screening is to be done in a static centre; a clinic room should be set up for each screening station.
d)	**MATERIALS** • Screening team to ensure all paperwork is available with correct details (consent forms, results letter template, headed paper). • Adequate supply of clinical equipment available and in date. Screening team must maintain adequate stock of all equipment.
3.	**RECRUITMENT ON THE DAY**
a)	**INFORMATION PROVIDED** • Posters available at time of sign up/ recruitment • Further queries from participants can be answered at time of sign up
b)	**SCREENING CLINIC SET UP** a. Onsite walk in screening (inreach) e.g. in Accommodation Centre For onsite screening; Walk-in in screening can be done without pre-booked appointments. Queue number 'cards' to be given for morning and afternoon of screening clinic to participants to avoid crowded area of those waiting and ensure privacy is maintained for those undergoing screening b. Screening in static clinic (outreach) e.g. Primary Health Care Centre Screening admin to book screening appointments for screenings that are done in static clinics. This can be done by coordinating with centre management if agreement in place for management to support with screening sign up. Centre management may support with organising transport, otherwise screening team to arrange transport if the static clinic is not within walking distance of the static health centre Ideally, members of the screening team will visit accommodation centre in advance of sign up if screening to take place in static centre. Screening team should visit the accommodation centre at busy time when common areas are likely to be well populated (e.g. during meal times). Screening team can sensitise the residents to encourage sign up for screening and importance to get the screening.

4.	REGISTRATION
a)	**CONSENTING** • Participant to sign consent form with screening administrator (ideally, consent form is available in the participants language). • Along with name (spelling to be taken directly from Temporary Residency Certificate for consistency and locating participant if needed as part of follow up), DOB, country of origin, TRC number, details regarding language(s) spoken and need for interpretation service.
	INTERPRETATION REQUIREMENT • Interpretation service must be available for screening. Professional interpretation services ideally to be used due to confidential nature of screening (avoid family members or friends acting as interpreter). • Chosen interpretation service e.g. Languageline should ideally provide interpreters on demand. • If no interpreter available at the time of screening via given Languageline, participant can be advised to return later that day or at an alternative scheduled time /date so that the screen can be done with aid of interpreter. • If screening is done via prebooked appointments, interpreter can be block booked and screenings booked in groups according to language spoken. • Screening clinician should be familiar with guidelines for using interpreting service (https:// www.hse.ie/eng/services/publications/socialinclusion/emaspeaking.pdf , https://emed.ie/_ docs/Guidance-Using-Interpretation-Services-20070912.pdf)
b)	**CONTACT DETAILS FOR RESULTS** • Participant should be contactable in case of positive result. Ideally, the participant will have an Irish phone number. If participant has non-Irish number only, check that this number is contactable via WhatsApp to confirm the participant is contactable. If no Irish number then participant should ideally provide email address (with regular access to their email account) along with non-Irish number. • If the patient has no contact details via phone number or email, the screening clinician to discuss with participant re obtaining local SIM card and returning for screening. If clinician determines that participant is particularly vulnerable and that screening should not be delayed, clinician to offer screening at their own discretion.
c)	**INFORMATION ON HOW TO GET RESULTS** • Screening nurse will give the participant a copy of screening letter template, confirming the investigations done. Explain that results will be available after stated period (timeframe agreed with lab) and that the participant will need to request their results via records email (advise participant to include name and DOB in their request email). • Screening nurse to assure participant that if any positive results are detected on BBV, then they will be contacted and referred to relevant services which will be free of charge. • If participant does not have access to an email account, screening administrator will have added the participants name to list of names including those who require a hard copy of result. Hard copies will be sent via post or handed in person if screening team are regularly returning to that location. Participant will be sent a text message to collect results; if he/she has moved to different accommodation centre, screening team can post the results.
d)	**REGISTERING ON PATIENT RECORD SYSTEM** • If participant is ready to proceed with screening, screening administrator to add participant's details to the chosen Electronic Health Record eg. Salesforce and Socrates.

5.	**THE SCREEN**
	BBV screening via phlebotomy offered to participant to check for a. HIV b. Hepatitis B c. Hepatitis C
	• Screening nurse will ask participant if they have ever had positive results on BBV screen in past i. If known history of HIV, no need to send a sample to confirm. The participant will be referred to local ID service to get ARVs. At local ID service they will also have bloods done to check for all other BBVs so no need for screening team to check for other BBVs (Doctor to complete referral if pathway not set up for nursing team to refer). ii. If known history Hepatitis B, include this information on request form that participant has known history Hepatitis B. Regardless if participant had previous Hepatitis B infection; all BBV screens will check for check for immunity to Hepatitis B, previous infection or active infection; HBsAg, Anti-HBc Total, Anti-HBs. iii. If known history of Hepatitis C send second serum sample and include on request form that participant has known history Hepatitis C. Request additional investigation for Hepatitis C RNA. • If no known history of any BBV, one serology sample in serum bottle to be obtained by phlebotomist or nurse as per local phlebotomy policy.
6.	**MANAGING SAMPLES**
a)	**STORAGE** • Screening nurse to ensure all samples are in specimen bags containing correct sample to match request forms with all necessary information. • Samples can be stored in fridge onsite or at base of screening team at +2-8 degrees if not sent via courier the same day.
b)	**TRANSPORT** • Couriers or screening team to transport samples from screening location/ clinic to the chosen lab e.g. NVRL
c)	**TIMINGS** • Routine BBV screen sample to be sent to NVRL lab within 72 hrs of obtaining the sample. • Note that if RNA samples sent for confirmation of Hepatitis C, this will need to go to the NVRL immediately / on the same day {timeframe tbc by NVRL}.
7.	**MANAGING RESULTS**
a)	**NOTIFICATION TO PARTICIPANT** Screening nurse to check results daily. Depending on set up, can export results from Healthlink to Electronic Health Record ie. Healthlink import to Socrates OR manually check each results on Healthlink and attach to patient file OR review results via post • For 'negative' results, the screening nurse will manage these via email and send copies on request. The results will be 'completed' and not require a Doctor to review. • If any positive results, the NVRL lab will phone the screening lead ahead of releasing unexpected/ new cases of Hepatitis B, C or HIV result. • The participant with positive result should then be invited to clinic to be told of results in person by Doctor. If the participant has been transferred, the Doctor can decide at their discretion if suitable to inform of diagnosis over the phone (eg. it may be suitable if participant speaks English, had known of infection). • Screening clinician will be informed via phone call from lab regarding unexpected positive results for HIV, Hepatitis B and Hepatitis C

	Hepatitis B • 'Negative" results of Hepatitis will include previous infection, non-immune and immune due to vaccination. These results will be available to participants when they request the result. The screening team will not contact the participant about these results. • Participants to be informed via phone call if previous Hepatitis B infection before the results are sent via email – to avoid alarming the participant when they see HBC Core positive result. • Participants who are non-immune to Hepatitis are advised in writing at time of sending result that they may request vaccination from their nominated GP once they have access to a GP or get a medical card • Participants who are HBsAg surface antigen positive will be informed by the Doctor and referred to nearest service
	Rubella • Screening nurse will check results for immunity to Rubella (for women of childbearing age only). • Screening nurse will inform women of their Rubella non-immune status via phone call. • Screening nurse will explain risks of Rubella during pregnancy and recommend MMR vaccine to prevent occurrence of risks. Screening nurse should offer referral for MMR vaccine via established pathway (local primary care centre, clinic attached to screening service etc). • Woman may want to consider the vaccine, screening nurse therefore to send result and information re Rubella to the woman's email. Ideally, information should be available in relevant language and links for video explanation should be available for women who do not have adequate literacy skills. • If women is hoping to become pregnant in near future, stress importance that participant gets vaccine before becoming pregnant. • If woman has moved to different CHO and plans to become pregnant soon, screening clinician to refer to nearest CHO Social inclusion team to provide appointment for woman to get vaccine. • If woman already has a medical card, advise her to ask own GP for vaccine and offer to send results to her own GP
b)	**NOTIFICATION TO PUBLIC HEALTH** • Screening clinician to ensure that the Enhanced notification form is sent via post or email to relevant Public Health Office for confirmed cases of a. HIV b. Hepatitis B c. Hepatitis C (see https://www.hpsc.ie/notifiablediseases/listofnotifiablediseases/)
c)	**INPUTTING RESULTS FOR REPORTING PURPOSES** • Screening team to ensure that results are inputted to Electronic Health Record system in order to maintain numbers for reporting purposes • Reports should be ran on monthly basis to ensure results are maintained and followed up in timely manner

8.	ONWARD REFERRAL AND TREATMENT
	• At time of consultation to inform participant of a positive result, the Doctor to send referral to local infectious diseases/ hepatology as appropriate. • Advise participant of timeframe expected for appointment. The Doctor should give the participant contact details of the screening team (phone and email) in case the participant does not get scheduled an appointment within certain timeframe or changes address and need referral to closer hospital.
9.	**CONTACT TRACING**
	• When participant has been made aware of positive result, clinician to ask participant if they have any close contacts (partner or children) travelling with them who would require contact tracing. • If adults – screening team to offer BBV screening appointment. • If BBV screen for adult partner is not possible to be done by the screening team e.g. if the partner lives in different CHO, BBV screening bloods to be requested either via Swiftqueue or partner to be referred to local CHO for BBV • If child contacts – refer to local children's hospital for phlebotomy. • If no close contacts are travelling with the participant; they should be advised to recommend testing to their contacts who are living outside of Ireland.

Appendix 3: Focus Group document

Notes from the Refugee and Applicants seeking Protection Focus Group

Date: Friday 26th May 2023

Time: 17.00 – 18.15

Facilitators: Dr Claire Dunne & Dr Emmanuel Bello

Translator: Dr Emmanuel Bello Note taker: Grainne Begley

Participants: 6 residents from a centre in CHO 7, who are Beneficiaries of Temporary Protection. All participants are living in Ireland for more than one year. One participant left early.

Pre-focus group information: Information sheet on Blood Borne Virus screening options and questions that would be asked during the focus group were circulated to participants prior to focus group.

Language: 5 of the 6 participants spoke very good English with one participant understanding English but responded in Ukrainian, which was translated.

Consent form: Participants were asked to read a consent form before the focus group started. All those present signed the consent form.

Welcome and introductions

The participants were welcomed, and the purpose of the focus group was reviewed based on the information sheet that was circulated prior to the focus group.

A contract with the following agreements was agreed to: Listen to others, respect for opinions, not important to agree and confidentiality, personal information is not shared outside of this room.

There was a round of introductions and some questions were asked from participants:

1. "Would we have to go to hospital for testing?" It was clarified that tests could be taken in a health centre nearby or in the hotel.
2. "Why are you doing this screening for us only?" It was clarified that this programme is for both Beneficiaries of Temporary Protection and International Protection Applicants.

Section 1

CD went through the three testing option, one by one asking for questions after each option.

3. Rapid Diagnostic Testing (RDT) Questions from participants

- "Would we have to go to the health centre/ hospital?"
- "After the 30 minutes do we wait or do we get the results by telephone or do we come back for the results?"

Statements from participants

- "I would be more comfortable to do it in the here (hotel), but it would need to be at a time that suited people, as people have different things on."
- "It is convenient, it is easy and it not painful (not from the veins)"

4. Capillary Blood Testing (Assisted) Questions from participants

- "Is the quality (of the tests) the same?"
- "Where do the tests get sent to?"
- "Should the blood be kept in a fridge?" Statements from participants
- "My daughter in Ukraine couldn't get the right amount of blood for a test, and a positive result was received. However the second test was negative. CBT is better as more blood is taken and results will be more accurate." CD noted that the accuracy was the same for both tests, and read out the sensitivity and specificity of the tests. CD noted that the process needs to ensure there are no false negatives.

5. Capillary Blood Test (Non-assisted) Questions from participants

- "Where should we keep the blood before posting?"
- "Is the blood ok when it's posted?" CD noted that the blood is ok to post, the test can be affected if the finger in banged against the microtainer while collecting the blood or if there is too little blood collected.

Participants were asked their preference

Participant 1: RDT: "It is easy to take, not a lot of fuss, doctor comes to do the test. I would find it unusual to do the do the test myself, prefer someone else to do the test for me."

Participant 2: RDT: "Agree with first participant, never do these tests by myself. The third option is a no no for me. I prefer RDT because it is easy, with personal assistance."

Participant 3: CBT assisted: "I don't agree easy is always the good option. Definitely not the third option. I think blood test should be taken in special locations, not in the hotel. I don't want to get a positive result there and then, not where you are living."

Participant 4: RDT: "Faster, confidential and if there is a false positive can get a second test straight away." CD/EB noted that the second test would be a venous test and would not happen that day. Participant noted that it won't be a problem that it would take longer.

Participant 5: RDT: "Its fast, its easy and if the accuracy is the same prefer this option."

Questions from participants

- How are Irish people screened? EB/CD outlined that the voluntary options for screening for people living in Ireland for example SH24, some services offer free testing for example Gay Men's Health Project.

Section 2

CD brought the participants through different elements of the testing.

Pre-test counselling – in-person or on-line

All preferred in person, one participant responded what's the use of having online information if the RDT is in person.

Testing – assisted v non assisted

All preferred assisted testing. One participant noted "I never did self-testing before and would find that difficult. Watching a video might be ok but prefer to have the test done in person."

Results – 30 minutes v 3 days

Four participants preferred the 30 minutes, if the accuracy was the same. One participant felt it was "better to wait and get results." One participant noted "that waiting can make you sick" and another participant noted "the earlier the better, 30 minutes is ok as long as accuracy is the same."

Interpreter – in person throughout the whole process v in person and then different interpreter on the phone

The role of the interpreter was discussed, RDT testing option has the same interpreter for the process, whereas CBT has a different interpreter, and participants were asked if this made a difference.

One participant asked "why can we couldn't get results by email, as this is how positive and negatives results are given in Ukraine. I would not like to talk to anyone if I had a positive result, I wouldn't expect to talk to anyone, as a call could be shocking. I could be at work or out with my children or driving. You could die getting the results, if driving. There could also be a problem with language and I don't understand the result."

Is other people not knowing you are getting tested important?

Question from participant

- "What do you mean by privacy, that your family and friends don't know?"

Statement for participant

- "Better that people don't know if the setting is in a place like this."
- "I would prefer to get an appointment to go somewhere else, not in the accommodation centre, that is was better to be in another setting."

Appendix 4: End-user Survey document

Blood Borne Virus Screening Survey – Refugees and Applicants Seeking Protection

Completed 23/05/2023

53 Responses in total

Country of birth and nationality

33 Responders identified their country of birth as Ukraine and 32 identified their nationality as Ukrainian. The rest of the respondents were international protection applicants from a diverse range of countries.

How long have you been living in Ireland?

36% had been living in Ireland less than 6 months. 47% had been living in Ireland 6 months to 1 year with only 17% living in Ireland for 1-2 years and no respondents living in Ireland for a longer period.

What age are you?

23% of respondents were aged 18-29. 43% were aged 30-39. 30% were aged 40-49. 4% were aged 50-59 with no respondents falling into an older age category.

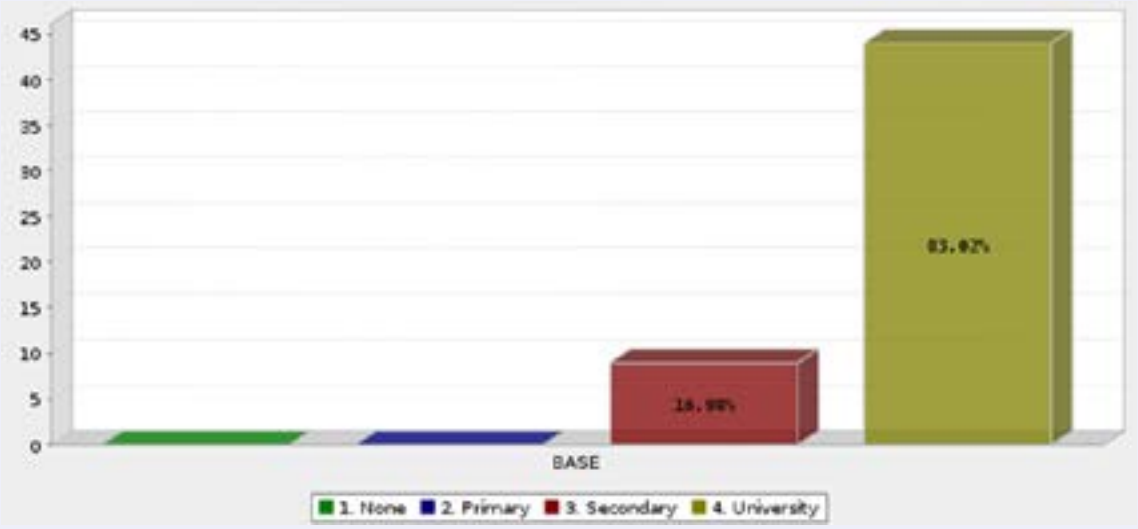
Sex

58% of those who responded to the survey were female and 42% were male.

What is your educational attainment?

83% of response had university level education with the remained having secondary school level education.

Graph 1: Educational attainment of respondents



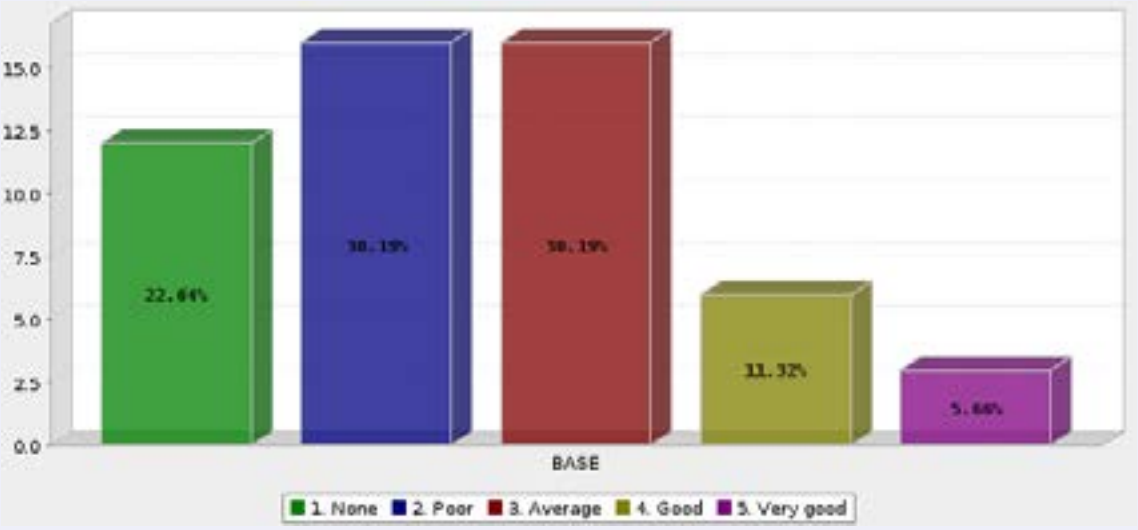
How would you rate your knowledge of health risks associated with the following blood borne viruses? (HIV, Hepatitis B and Hepatitis C)

34% rated their knowledge of HIV as good compared with 23% and 25% for Hepatitis B and Hepatitis C respectively.

How you rate your knowledge of the treatment available for the following blood borne viruses? (HIV, Hepatitis B and Hepatitis C)

The respondents who rated their knowledge of HIV treatment of good were 26% compared with 13% and 11% for Hepatitis B and C viruses respectively.

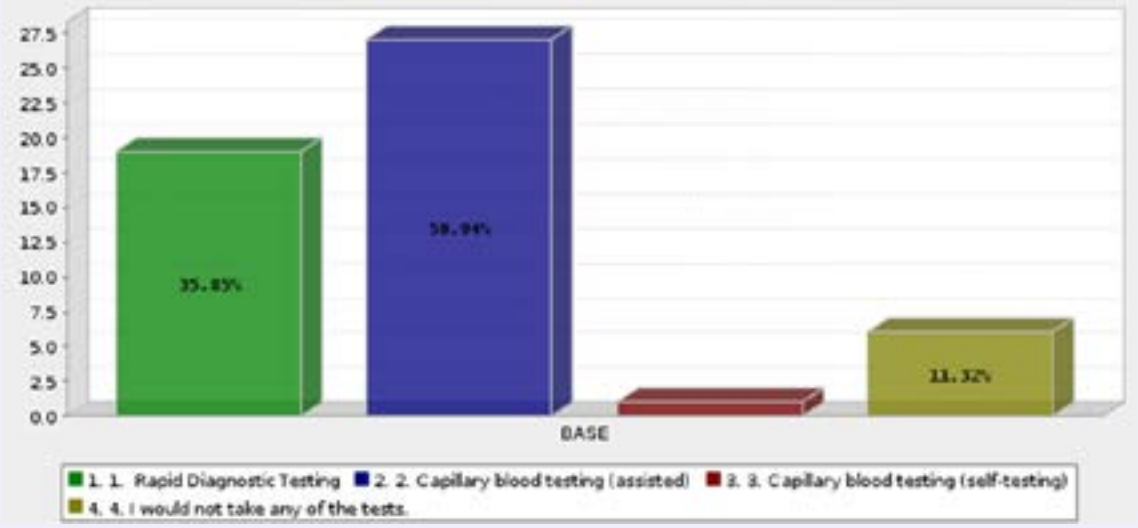
Graph 2: Knowledge of treatment available for Hepatitis C



Which one of the testing options would you prefer to use? (Rapid Diagnostic Test, Capillary Blood Test (assisted), Capillary Blood Test (self-testing)

36% picked RDT, and 51% picked Capillary Blood Test (assisted). This difference is not statistically significant (Odds Ratio 0.54, 95% Confidence Interval: 0.25-1.17). 2% picked Capillary Blood Test (self-testing). 11% said they would not take any of this tests.

Graph 3: Which testing option respondents would prefer to use



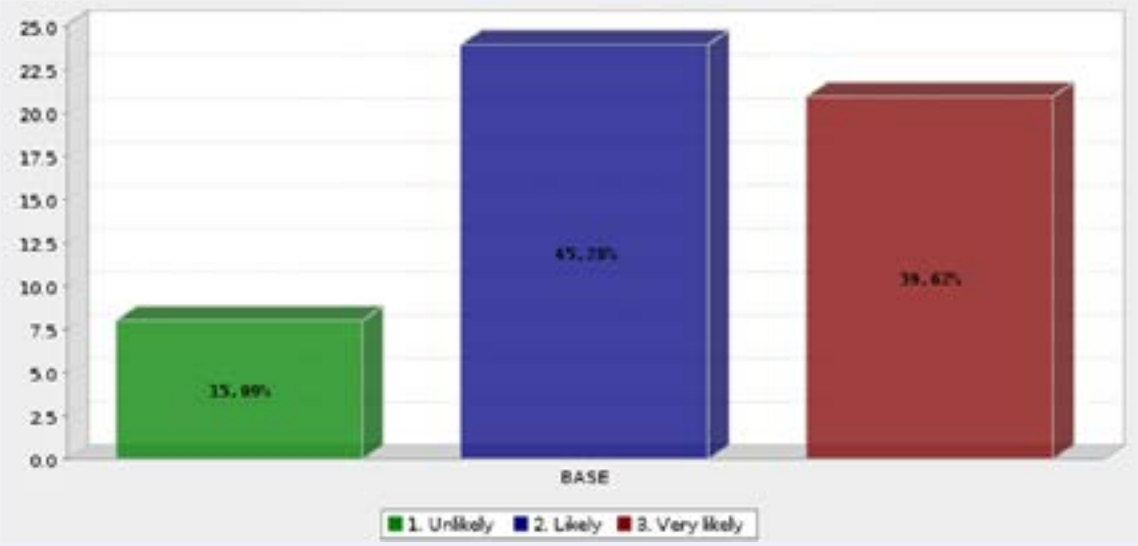
If you were offered Capillary Blood Testing would you prefer assisted testing where a health worker helps you take the test or self-testing where you take the test yourself?

81% said they would prefer assisted testing while only 4% said they would prefer to self-test. 15% said they would prefer neither.

If you were offered the following tests please comment on how likely you would be to take up the test?

85% said they were either likely or very likely to take up the Rapid Diagnostic Test with the remainder 15% picking unlikely.

Graph 4: How likely were respondents to take up Rapid Diagnostic Test

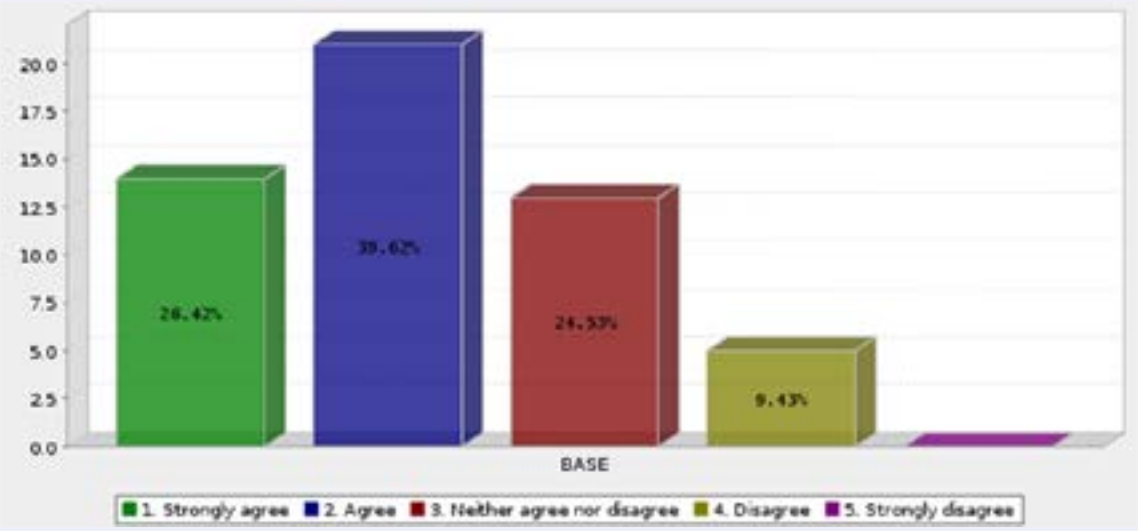


87% picked that they were either likely or very likely to take up the Capillary blood testing (assisted) with the remainder 13% stating that they were unlikely to take up this option. 51% stated that they were either likely or very likely to take up Capillary blood testing (self-test) with 49% choosing that they were unlikely to take up this option.

Please rate the following statements on how strongly you agree or disagree:

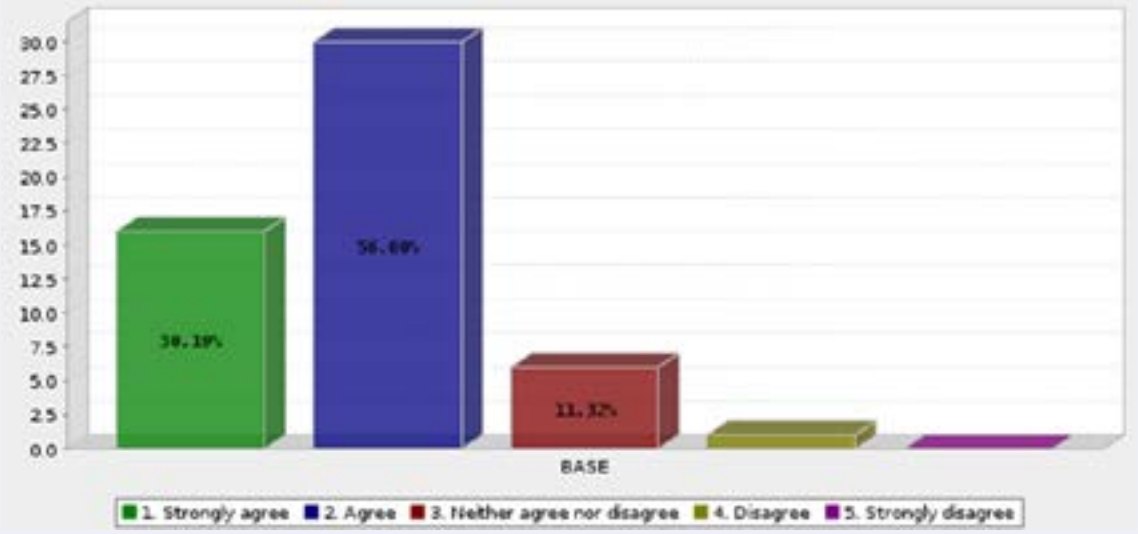
- In-person pre-test information/counselling provision is important, including why testing is being offered, how the tests will be taken and any follow up care if needed.
  91% either agreed or strongly agreed with this statement, with 4% either disagreeing or strongly disagreeing.
- On-line pre-test information provision is adequate, including why testing is being offered, how the tests will be taken and any follow up care if needed.
  64% either agreed or strongly agreed with this statement with 8% either disagreeing or strongly disagreeing and 28% neither agreeing nor disagreeing.
- It is important that others do not know that you are getting tested.
  77% either agreed or strongly agreed with this statement. 21% were neutral and 2% disagreed with this statement.
- In-person active assistance and support through the testing process is important.
  77% either agreed or strongly agreed with this statement. 19% neither agreed nor disagreed and 4% disagreed or strongly disagreed with the statement.
- Guidance through testing process by video is adequate.
  53% either agreed or strongly agreed with this statement. 34% were neutral and 31% either disagreed or strongly disagreed with the statement.
- In-person interpretation in your first language during the testing is important.
  70% agreed or strongly agreed with this statement. 26% neither agreed nor disagreed, and 4% disagreed.
- Translated on-line materials and videos are adequate to explain how the test is done.
  62% agreed or strongly agreed with this statement. 26% were neutral in their response to this statement and 11% disagreed.
- It is important to get the results back within 30 minutes of testing.
  66% agreed or strongly agreed with this statement. 25% neither agreed nor disagreed. 9% disagreed with this statement.

Graph 5: Importance of getting results back within 30 minutes of testing



- It is ok to get the results back within 3 days of testing.
  72% either agreed or strongly agreed with this statement. 25% neither agreed nor disagreed. 4% disagreed or strongly disagreed with this statement.
- In-person support by the health worker and interpreter in making the phone call for expert counselling and referral of a positive result is important.
  87% either agreed or strongly agreed with this statement. 11% neither agreed nor disagreed. 2% disagreed with this statement.

Graph 6: Importance of support from health worker and interpreter in making referral



- It is ok for the expert counsellor to call you with a positive result and make the referral directly with the assistance of a phone interpreter if needed.
  86.8% either agreed or strongly agreed with this statement. 9% neither agreed nor disagreed and 4% strongly disagreed with this statement.

Appendix 5: Other evidence reviewed

"The Pilot Online STI Testing Service in Ireland, 2021: Evaluation Report"

Accessibility:

An anonymous online questionnaire was completed by 398 individuals who identified themselves as being from the Republic of Ireland. The survey reached both new and regular users of STI testing services. Of the 305 people who responded to a question about where they would be most likely to access STI testing (and only being allowed to choose one option), responses suggested that users would prefer a range of testing options, and access to an online STI testing service would be a valuable additional testing option. Of the 363 people who responded to a question about where they would most likely go for an STI test, 97% of respondents said they would use a free online service for sexual health testing if it was available to them.

Feasibility:

The pilot had a target test kit return rate of higher than 75%. On completion, the return rate was 67% (9,181 test kits returned by the end of August). Clinician-confirmed user attendance at clinic upon receipt of a reactive result was high regardless of which STI reactive result a service user received, varying from 89% for service users with a hepatitis B reactive result up to 93% for service users with a chlamydia reactive result. Attendance may be underestimated, as there may have been cases where clinicians did not confirm attendance on the clinical record system. An overall reactive rate of 8% is consistent with other SH:24 services, which are provided across a mixture of urban and rural settings. Blood test outcomes: Of the returned test kits, 11.5% (931/8,064) had blood samples that were either haemolysed or insufficient, and 3.6% (294/8,064) were missing the blood component. The haemolysed/ insufficient /missing rate is consistent with those of the SH:24 UK service.

Impact:

Assuming that the same level of testing would have occurred in face-to-face services in 2021 had it not been for the impact of the COVID-19 pandemic, the online STI testing service added an estimated 33% to testing capacity in the pilot areas. SH:24 calculated the average cost to the health service of one individual using the online STI testing service from the pilot to be €55.61, which is predicted to decrease as the service matures.

Acceptability:

All 13,749 users of the pilot were sent a text message asking them to complete the user feedback form. Users were able to rate the service out of five stars and provide free text comments about the service. Of the 2,528 (18.4%) who responded, 94.7% (2,395 users) gave the service five stars out of five, 4.6% (117 users) gave it 4 stars, and 0.7% (16 users) gave it three stars or less. When asked about their experiences of using the service, respondents mentioned its ease and convenience, speed and efficiency, the support and logistics provided, as well as the privacy and discretion it afforded. SH:24 contacted 15 of the 16 respondents who rated the service three stars or less, and the only significant concern cited was difficulty using the blood test. SH:24 developed an anonymous online questionnaire to assess clinicians' (i.e. doctors' and nurses') experiences of and views on the online pilot. Seventeen people completed the questionnaire. The majority (16 of the 17 respondents) agreed that the pilot had improved their patients' care. All agreed or strongly agreed with the statement, "SH:24 has increased my patients' access to STI testing." Fifteen of the 17 respondents agreed or strongly agreed with the statement, "Patients with a positive result from SH:24 transition easily to clinics." All respondents agreed or strongly agreed with the statements, "Online testing increases patient autonomy," and "Online testing increases overall capacity for STI testing." Fifteen out of 17 respondents agreed that "Online testing frees clinic staff time for more complex care."

"Updated recommendations on treatment of adolescents and children with chronic HCV infection, and HCV simplified service delivery and diagnostics.

There were a number of points in this document relevant to our implementation group:

"We recommend reflex HCV RNA testing in those with a positive HCV antibody test result as an additional key strategy to promote linkage to care and treatment. This can be achieved either through laboratory-based reflex HCV RNA testing using a specimen already held in the laboratory or clinic based reflex testing in a health facility through immediate specimen collection following a positive HCV antibody RDT (conditional recommendation, low quality of evidence). Reflex testing is a linked HCV RNA (or HCVAg) test that is triggered among all people who have an initial positive HCV antibody screening test result. Reflex HCV RNA testing may be implemented in two ways: either laboratory-based reflex testing or clinic-based reflex testing."

"The use of DBS (Dried Blood Spot) specimens for HBsAg and HCV antibody serology testing may

be considered in settings where: … RDTs are not available or their use is not feasible".

"WHO already recommends that lay providers who are trained and supervised can independently perform HIV counselling and testing using RDTs".

"Clinic-based reflex sample collection for HCV RNA testing may be the preferred testing algorithm for populations such as key populations (such as people who inject drugs and men who have sex with men) and migrants and refugees who receive health care in community-based settings or in primary care and may have limited access to full-range phlebotomy and laboratory services … clinic-based reflex testing with initial HCV antibody RDTs followed by reflex sample collection for HCV RNA testing of those testing antibody-positive and then use of clinic-based POC HCV RNA testing may maximize linkage to care for such populations."

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