Diagnostic Testing for Hepatitis C, Hepatitis B and HIV:
Information for Substance Misuse Services

2014 UPDATE

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To outline the background to, and requirements for, BBV testing for patients of substance misuse services in Wales.

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1 Purpose of this document

This document outlines the background to the optimum use of diagnostic services for blood borne virus (BBV) infection for patients of substance misuse services across Wales. It is intended as a resource to support substance misuse agencies across Wales to provide diagnostic testing for their patients and will explain the limitations and advantages of dried blood spot testing and venepuncture.

Background

The requirement for substance misuse services to provide both testing and referral for treatment for hepatitis B, hepatitis C and HIV and vaccination for hepatitis B is covered within the NICE QS23 Quality standard for drug use disorders, Quality statement 4: Blood-borne viruses.

The quality standard means that Service providers should ensure systems are in place for people accessing drug treatment services to be offered testing and referral for treatment for hepatitis B, hepatitis C and HIV, and vaccination for hepatitis B.

Diagnostic testing for blood borne viral hepatitis is comprehensively evaluated, and recommended in the NICE guidelines Hepatitis B and C - ways to promote and offer testing to people at increased risk of infection PH43. Within recommendation 6 (Testing for hepatitis B and C in drugs Services) the NICE guidance states the following:

- Drugs services should designate a hepatitis lead for the service. The lead should have the knowledge and skills to promote hepatitis B and C testing and treatment and hepatitis B vaccination. Consideration should be given to training peer mentors and health champions from the drugs service to support this work (for further information see NICE guidance on community engagement).
- Drugs services should:
  - offer hepatitis B vaccination to all service users in line with the Green book.
  - provide information to injecting drug users about the importance of hepatitis B vaccination for sexual partners and children (see the Green book).
  - ensure staff have the knowledge and skills to promote hepatitis B and C testing and treatment
  - offer and promote hepatitis B and C testing to all service users
  - have access to specialist phlebotomy services in order to encourage hepatitis C treatment in the community, particularly for people who inject drugs.
- have access to dried blood spot testing for hepatitis B and C for people for whom venous access is difficult
- ensure staff who undertake pre- and post-test discussions and dried blood spot testing are trained and competent to do so
- ensure people diagnosed with hepatitis B and C are referred for specialist care; for hepatitis C this may involve offering hepatitis C treatment in the community for people who are unwilling or unlikely to attend hospital appointments, and whose hepatitis C treatment could be integrated with ongoing drug treatment (such as opiate substitution treatment)
- offer annual testing for hepatitis C to people who test negative for hepatitis C but remain at risk of infection
- provide information to women with hepatitis C about the importance of testing in babies and children born after the woman acquired infection

2 Overview of venepuncture and DBS – summary of pros and cons

Venepuncture samples remain the sample of choice for the diagnosis of BBV infections. A venepuncture sample allows for:

- Better sensitivity and specificity than assays based on dried blood spots, therefore the test is better at detecting infection
- Confirmatory tests to be performed on the initial sample without in the first instance a further blood sample being required
- A more rapid turnaround time from the laboratory services

The only reason for not using venepuncture is the increased difficulty of obtaining a venepuncture sample from patients, due to compromised venous access.

Dried blood spot (DBS) tests are easier to obtain from patients, but do not offer the same versatility. They can currently only be used for Hepatitis B surface antigen (HBsAg), HIV combined antigen antibody test (HIV Ag/Ab test) and HCV antibody test. Also no further confirmatory tests can be carried out on these samples, a follow up venepuncture sample is required. The turnaround times are longer, due to the requirement for a dedicated testing protocols and a pre-processing step.
3 Blood borne virus infection in Wales

Surveillance data on the prevalence of blood borne viral hepatitis infection in Wales is publically available, and updated at:

Substance misuse services in Wales also contribute to the ongoing ‘Unlinked Anonymous Monitoring Survey of People Who Inject Drugs (PWID)’ co-ordinated by Public Health England, results are regularly updated.

Research from South Wales suggests that the majority of HCV positive drug injectors do not know they are infected,\(^1\) much HBV exposure is also likely to be undiagnosed. Recent research suggests that the incidence of HIV is increasing amongst IDUs in the UK.\(^2\)

Low rates of diagnosis will contribute to the future burden of liver disease in Wales through late identification of viral hepatitis infection manifesting as clinical disease. An opportunity to reduce the further transmission of infection is also missed.

Public Health Wales now provide a laboratory service testing for HIV, HCV antibody and HBsAg from a dried blood spot sample. This service is available in addition to testing based on venepuncture samples that is currently available from health board and Public Health Wales laboratories. The service offered aims:

- To improve uptake of testing for HCV, HBV and HIV in those where poor venous access precludes use of venepuncture
- To improve the current low rates of HCV and HBV diagnosis amongst current and past injecting drug users in Wales and those deemed at risk (i.e may include sharing crack pipes/unprotected sex etc.)
- To improve HIV diagnosis amongst injecting drug users in Wales
- To monitor the prevalence of infection amongst individuals coming forward for testing
4 Setting up diagnostic testing for blood borne viral infection within a substance misuse service

4.1 Requirements for services providing diagnostic testing for blood borne viral infection

The following services are eligible to offer diagnostic testing to their patients:

1. Statutory NHS services (community and prison based) providing clinical services to at risk individuals
2. Voluntary sector organisations working with individuals at high risk of infection (predominately current and ex injecting drug users)

Essential criteria to be met by services prior to provision of testing:

- Lead registered medical practitioner who can take overall responsibility for the diagnostic testing carried out within the service; this could be a Doctor who is responsible for opiate substitution therapy and/or senior nursing staff (nurse practitioner) responsible for clinical work with patients (e.g. facilitating of opiate substitution treatment, Hepatitis B vaccination, wound care)
- Evidence that the service has access to clinical staff who have the appropriate skills and training to carry out pre and post discussion with patients and to take the blood or dried blood spot sample safely
- Appropriate mechanisms in place to ensure the safe disposal of sharps and training to minimise the risk of needle stick injuries
- Existence and evidence of an agreed pathway of sample delivery and processing, including the feeding back of results to the test requestor from the NHS microbiology services. Agencies currently not customers of NHS microbiology services will need to make the appropriate arrangements with the laboratory prior to commencing testing
- Existence and evidence of an agreed pathway of referral for individuals reactive for blood borne viruses with local viral hepatitis treatment services and HIV treatment services
- An understanding of the **requirement to confirm reactive tests by venepuncture** and the capacity to carry this out, or an established mechanism for referral to an appropriate service
- Existence and evidence of an agreement for the registered medical practitioner responsible for the diagnostic service (lead clinician) to fulfil statutory requirements for notification of viral hepatitis
4.2 Overview of the DBS testing process

Dried blood spot testing is a simple procedure. If carried out correctly the process is both safe for the individual being tested and the individual taking the sample. DBS can be introduced within services already providing venepuncture with modest modification to existing protocols.

A summary of the steps involved in venepuncture and DBS testing of substance misuse service patients is outlined in the BBV testing algorithm in Figure 1. It will be the responsibility of each participating agency to draw up a locally relevant algorithm which should be agreed with the local microbiology laboratory. Local arrangements may influence the final algorithm for each area.

4.2.1 Who can take a dried blood spot sample?

DBS can be taken by any clinical key worker deemed by the service management to be competent to take responsibility for; a) pre and post test discussion on the implications of the test, b) taking the sample, c) arranging transport of the sample, and d) feeding back test results to the individual being tested.

The relevant competencies should be documented as part the training process.

4.3 Venepuncture or dried blood spot test?

Where possible patients should be tested by venepuncture; DBS is suitable for those who would not otherwise come forward for venepuncture based testing.

Individuals that test reactive by DBS will be asked to provide blood by venepuncture for confirmation; this needs to be explained as part of the informed consent process before testing. In line with General Medical Council guidelines for serious infectious diseases every individual with an initial reactive test result must have a confirmatory test.

There are a number of complex diagnostic algorithms of nationally agreed protocols that determine the investigations required to confirm the presence of BBVs. These apply to both samples testing reactive on DBS sample types and also venepuncture samples. Adherence to these protocols is essential if an accurate diagnosis of a BBV is to be achieved.

Your local microbiology laboratory will be able to provide you with information on samples required for confirmatory tests of reactive DBS tests.
Risk identification and pre-test discussion

Pre-test discussion with patient:
- Discussion of testing options (DBS or venepuncture)
- Ensure patient understands the meaning of the test and the implications of the results and that a venepuncture test is needed for confirmation

Venepuncture as preferred test, DBS if venous access is difficult

Request form completed and sample taken and sent to laboratory, if venepuncture this may require referral to phlebotomy or other specialist clinic. An enhanced surveillance form is started with patient’s consent

Post test discussion
If DBS antibody reactive for any test then follow up patient with confirmatory test; this requires a venepuncture sample and therefore may require referral to phlebotomy or specialist clinic (see section 4.14 acting on test results)
Complete enhanced surveillance form by entering the test results and send form to CDSC Public Health Wales
Give information on reducing future risk exposure

Post test discussion
If DBS antibody negative test; review risk history; if ongoing or recent risk reported repeat test within one year or if possible within 6 months
Complete enhanced surveillance form by entering the test results and send off form to CDSC Public Health Wales
Give information on reducing future risk exposure

Post test discussion
If venepuncture antibody reactive for any test then refer patient for follow up by specialist team (see section 4.14 acting on test results)
Complete enhanced surveillance form by entering the results and send off form to CDSC Public Health Wales
Notify Health Protection Team of venepuncture confirmed hepatitis infection
Give information on reducing future risk exposure

Post test discussion
If venepuncture antibody negative test; review risk history; if ongoing or recent risk reported repeat test within one year or if possible within 6 months
Complete enhanced surveillance form by entering the test results and send form to CDSC Public Health Wales
Give information on reducing future risk exposure

Figure 1. BBV testing Algorithm
4.4 Co-ordinating with your local microbiology laboratory

PRIOR TO FIRST STARTING TO CARRY OUT DBS IN THE ORGANISATION IT IS ESSENTIAL THAT THE CLINICIAN RESPONSIBLE FOR DIAGNOSTIC TESTING WITHIN YOUR SERVICE CARRIES OUT THE FOLLOWING:

- Liaises with the microbiology laboratory to which samples are to be sent (see appendix)
- Confirms address of the microbiology laboratory to which samples should be sent
- Confirms sample transport details
- Confirms the local pathway for test results to be sent from the microbiology laboratory to the service carrying out the testing
- Confirms financial arrangements are in place between health boards/voluntary sector organisation and the Microbiology services to fund all tests required

It will be of use to the laboratory if you can estimate likely work load and sample throughput

Appendix 1 outlines contact details for microbiology laboratories across Wales. The target turn around time for return of DBS results from the laboratory is two weeks.

4.5 In what environment can the sample be collected?

DBS can be taken in any setting deemed by service management to be safe for the patient and worker. Equipment for clearing up any blood spillages should be readily available. Samples can thus be taken in health service clinic settings or in a patient’s home. Venepuncture should be carried out only within clinical settings. Sharps bins must be available for safe disposal of sharps and clinical waste.

4.6 What equipment is needed and where can it be obtained?

Participating agencies should ensure sufficient supplies of the following are available to all key workers carrying out dried blood spot testing. Much of the equipment should be available through local NHS supplies.
All agencies will be provided with a start up kit containing:

- Virology BBV test request forms with attached specimen bag
- Disposable single use lancets
- Dried blood spot collection cards
- Enhanced Surveillance of BBV in Wales forms (please use these with venepuncture samples as well as DBS)

Each service will need to provide the following (these are available from local NHS supplies):

- Surgical gloves
- Alcohol swabs
- Cotton wool
- Plasters
- Spillage kits for cleaning up blood
- Sharps bin

Equipment purchase:

Further supplies of lancets and dried blood spot collection cards and padded transport envelopes can be purchased from suppliers listed in the appendix.

Virology BBV test request forms will be available from Cardiff Virology (address below).

4.7 Pre and post test discussion and informed consent

All patients being tested by either DBS or venepuncture should receive appropriate pre and post test discussion.

An example of a pre and post test discussion check list is provided in the appendix

Patients must give informed consent prior to being tested.

Patient consent should also be obtained for the completion of a surveillance form (see 4.8 part 3). The completion of this is voluntary.

Services will be expected to ensure that local Health Board consent policy is adhered to. It is anticipated that Health Boards will have pre and post test guidelines in place. Sources for information are listed below:

HIV: Guidelines on pre and post test discussion for HIV testing have been produced by the British Association for Sexual Health and HIV:

HBV: The Department of Health ‘green book’ (Immunisation against infectious diseases) is the essential resource for up to date guidance on hepatitis B vaccination and is available online via the DoH.

NICE (the National Institute for Health and Care Excellence) is a good source of information on current advice surrounding blood borne virus diagnosis and treatment. Guidelines are updated and can be obtained via the NICE website (www.nice.org.uk) using the search facility. Of particular relevance to substance misuse services are;

Public health guidance PH43 *Hepatitis B and C: ways to promote and offer testing to people at increased risk of infection*

NICE Quality Standards, QS23 on *drug use disorders* - Issued: November 2012

*Please note:*

The Royal College of General Practitioners offers a course on the Detection, Diagnosis and Management of Hepatitis B and C in Primary Care. For details see: [http://elearning.rcgp.org.uk/course/info.php?id=76](http://elearning.rcgp.org.uk/course/info.php?id=76)

This course can also be completed as a stand-alone activity for your self-directed learning. To obtain the full RCGP Part 1 Certificate you will need to first complete the online course and then attend one of the accredited face-to-face training days.

4.8  **Procedure for blood spot collection**

See below
Steps to successful dried blood spot collection

BEFORE TAKING A DRIED BLOOD SAMPLE PLEASE COMPLETE THE FOLLOWING PAPERWORK

IT IS ESSENTIAL THAT THE REQUEST FORM AND DRIED BLOOD SPOT COLLECTION CARDS ARE FILLED OUT CORRECTLY – IF THEY ARE NOT THE SAMPLE WILL NOT BE TESTED:

1) Write the patient’s name, date sample taken and date of birth on dried blood spot collection card

![Image of dried blood spot collection card]

2) Complete the Virology BBV request form (see image below).

Please ensure the following is clearly entered:

- Patient’s name
- Patient’s date of birth
- Patient’s address
- Requesting clinician’s name
- Requesting clinician’s office address (this is where the results will be sent)
- Tests required (i.e. HCV antibody, HBV surface antigen, HIV)
- Date sample taken
- Nature of specimen (dried blood spot)

![Image of Virology BBV request form]

3) TAKE DRIED BLOOD SPOT SAMPLE  (step by step guide follows below)
4) Complete the enhanced surveillance of BBV in Wales form (see image below). Consent must be given to collect requested information. You will be provided with pre-printed copies of this form. **NOTE:** form should be completed for each individual tested each time diagnostic testing for BBV is initiated whether DBS or venepuncture sampling is used.

Record the ID Number located on the top right of the form in the patient notes. WHERE THE NUMBER IS RECORDED IN NOTES SHOULD BE AGREED LOCALLY - THE NUMBER SHOULD BE EASILY RETRIEVABLE. if the patient is retested please enter this first unique number on the subsequent surveillance form. This form must NOT contain any patient identifiable data. Results should be added when received from the laboratory. **REMEMBER TO THEN SEND OFF FORM IN TIMELY FASHION.** Further details of this form are addressed below.

![Enhanced Surveillance of BBV in Wales Form](image-url)
TAKING THE DRIED BLOOD SPOT SAMPLE

1. BEFORE YOU BEGIN TAKING A DRIED BLOOD SPOT SAMPLE
   - Lay out the lancet, blood spot collection card, cotton wool and plaster.
   - Ensure you have a sharps bin
   - Put on a pair of latex or non-latex disposable surgical gloves.
   - Fill out name, date of birth and date on card BEFORE taking sample

   AT ALL TIMES ENSURE INFECTION CONTROL MEASURES ARE ADHERED TO – SURGICAL GLOVES TO BE USED, SURFACES CLEANED BEFORE AND AFTER, DISPOSE OF USED KIT APPROPRIATELY

2. CHOOSE FINGER
   - Ask the patient to wash their hands with warm water and soap and dry thoroughly. Or use an alcohol wipe to clean finger
   - To help increase blood flow, ask patient to rub their hands together for 10 seconds, then allow hand to hang at their side for 30 seconds.
   - Place the chosen hand with the palm side up on a flat surface or table.

3. REMOVE SAFETY CAP FROM LANCET
   - Gently unscrew safety cap from the lancet.

4. POSITION LANCET FIRMLY ON FINGER
   - Hold lancet steady on tip of finger.
   - Press trigger until it clicks. The blade will puncture the skin and automatically retract.
   - Discard the lancet into a sharps bin.
   - Observe the finger to see if blood is flowing from the incision site.
5. GENTLY MILK FINGER
   - Holding hand downward, gently milk finger from palm to fingertip to produce blood. DO NOT squeeze the finger as this blocks blood flow.

6. FILL AT LEAST THREE CIRCLES ON THE CARD –
   - Wait until the drop of blood is large and hanging. Allow blood to drop onto the dried blood spot collection card or carefully touch the filter paper with the drop. Use 1-2 drops of blood to fill each circle.
   - Ensure at least three circles are filled to their perimeter and the underside of the paper is also saturated. To do this check that the blood spot is as big on the underside of the paper as it is on top.
   - Once all circles are filled give patient cotton wool to hold to puncture site until bleeding stops and apply plaster.

7. LET SPOTS AIR DRY – IT IS VERY IMPORTANT TO LET THE SPOTS DRY COMPLETELY
   - THIS IS AN IDEAL TIME TO COMPLETE THE QUESTIONNAIRE
   - Leave collection card open to allow blood spots to dry for five minutes. Once dried and without touching the filter paper, close the Whatman filter card.

8. ENSURE INFORMATION IS CORRECTLY ENTERED ONTO THE Virology BBV request form and dried blood spot collection card

9. PLACE SAMPLE IN PLASTIC SPECIMEN BAG. ENSURE YOU ARE WEARING DISPOSABLE GLOVES WHEN HANDLING THE COMPLETED CARD
   - Please make sure the name on the dried blood spot collection card is easily visible without having to remove the sample; this will help the laboratory staff who need to check that names match

10. CLEAN WORK SURFACES WITH APPROPRIATE CLEANING MATERIALS

11. PLACE SPECIMEN BAG INTO A PADDED ENVELOPE

12. TRANSPORT PROMPTLY (the same day) TO YOUR LOCAL MICROBIOLOGY LABORATORY

   - WHEN RESULTS HAVE BEEN RETURNED FROM THE LABORATORY PASS THEM PROMPTLY TO THE PATIENT also ENTER THEM ONTO THE Enhanced Surveillance of BBV in Wales form. RETURN THE Enhanced Surveillance of BBV in Wales form BY POST USING THE STAMPED ADDRESSED ENVELOPE PROVIDED.
4.9 What tests are used?

The tests used on the dried blood spot sample will test for the presence of antibodies to HCV, and HIV and for HBV surface antigen. Confirmation of an infection with a BBV cannot be made from a DBS sample. Further venepuncture confirmatory tests are essential to confirm reactive DBS and patient identity. Patients will be offered tests to all three viruses. The laboratory will test for all three viruses unless it is clearly indicated on the Whatman filter card and on the request form that the patient wishes to opt out of any of the tests.

- A reactive HCV test will require further tests carried out on a venepuncture sample (using further serological tests to confirm the antibody test and PCR to determine the presence (or otherwise) of virus). A PCR reactive result indicates current infection.

- It is important to ensure that correct sample tubes are used for confirmatory samples. The laboratory currently require 3 x5mls of EDTA for a HCV genotype and viral load

- A reactive hepatitis B surface antigen will require confirmatory tests carried out on a venepuncture sample (1 x 5mls clotted sample)

- A reactive HIV test will need to be followed up with a venepuncture test to confirm the result and test for the presence of HIV 1 or HIV 2 (1 x 5mls clotted sample, and 2 x 5mls EDTA sample)

- It is important to state on the virology form that the blood test is A FOLLOW UP FROM A REACTIVE DBS. Specific sticky labels for this will be available from the Cardiff laboratory

**Confirmation of results where there is significant difficulty in obtaining a venepuncture sample:**

- Ensure all avenues for obtaining a blood sample have been explored such as Phlebotomy clinics, clinical services with expertise in obtaining blood samples.

- If it remains impossible to collect a blood sample a second DBS sample can be submitted for repeat DBS testing. It is impossible to complete all tests required to confirm the presence of infection on a DBS sample. At this time it would be appropriate to discuss with the laboratory if there are any other testing options that could support the confirmation of infection.

If it is not possible to collect blood because of poor venous access and all avenues have been explored to obtain blood (for example by referral to phlebotomy clinics or to other local clinical services with expertise in
obtaining blood) then please contact the consultant virologists in the virology unit in Cardiff to discuss options (contact details in appendix).

Actions that should follow the issuing of test results back to the requesting clinician are discussed in section 4.14 below.

4.10 Sample storage and transport

Samples should be dispatched promptly (same or next day) to the local microbiology service. Samples should be transported to the local microbiology department by the Health Board sample transport systems.

However if an NHS sample transport system is not available and DBS need to be sent by post then use registered post so there is a chain of evidence that the specimen has been sent and received.

In packing the DBS use a primary and a secondary container.

The primary container will be the specimen request bag that is attached to the specimen request form. A sealable plastic bag acts as the secondary container. Once used for sample collection the DBS card should be inserted into the cardboard envelope and the fold over flap folded to secure the contents. Further wrap the sample in absorbent material and place in the specimen request bag.

Place the specimen request bag in a sealable plastic bag. Up to 15 cards may be placed in each plastic bag. Avoid using plastic sealable bags that are too big as the cards will move around during transportation.

The inner plastic bags can then be inserted into a heavy duty plastic bag, jiffy bag or heavy duty envelope to protect specimen during transportation through Royal Mail to the testing laboratory.

Dried blood spot specimens are exempt from current regulations for the transport of Biological Substances.

4.11 Managing the test results

Test results will be fed back to the requesting clinician in the same manner as venepuncture test results are currently fed back. It is important to clarify this process with your local microbiology laboratory. The details of these arrangements will reflect local working practices.

Ensure that there is a mechanism in place so that the paper or electronic results will be promptly dealt with if the requesting clinician is on leave or out of office.
4.12 Recording test uptake

Public Health Wales will wish to access anonymous service-specific data to support both the ongoing monitoring of the effectiveness of diagnostic BBV testing in Wales and to support clinical management of blood borne virus infection. Therefore it is important that your agency keeps a record of who has been tested by DBS, what follow up venepuncture confirmatory tests have been carried out and which individuals have been referred for clinical management of infection. It is intended that this aspect will be audited.

4.13 The Enhanced Surveillance of BBV in Wales Form

The roll out of testing for BBV across Wales offers an opportunity to strengthen the surveillance of HCV, HBV and HIV infection amongst current and ex drug injectors. As all DBS samples will be tested by one central laboratory in Cardiff it will be possible to keep a record of the overall prevalence of blood borne viral infection amongst individuals tested by this method.

The Enhanced Surveillance of BBV in Wales form that you have been asked to complete for each patient tested is an important component of the dried blood spot roll-out and now seeks to include information on individuals tested by venepuncture as the first diagnostic test (please do not use the form for confirmatory venepuncture tests).

The information collected will be linked by the unique identifier to any further blood borne viral tests the individual has. The questions concerning patterns of drug use will help in monitoring where and how transmission is occurring.

Anyone considered to be at risk should be offered a BBV screen and asked to complete the surveillance form, not just those with an injecting history - although this is high risk group.

As we are asking for more information than is required for routine diagnostic testing it is essential that individuals who are tested realise that they are not obliged to provide any of this surveillance information. Their decision to provide or not provide, and any information they may give, will in no way influence decisions about their treatment.

It is important to emphasise that the clinical team responsible for the clinical care and treatment decisions surrounding an individual’s hepatitis B/C/HIV treatment will not have access to the surveillance form.

This form will be sent to the Communicable Disease Surveillance Centre (CDSC). Please use originals and not photocopies as this form needs to be electronically scanned. To order new forms, ring the surveillance team on 029 2040 2472.

Also ensure the patient is aware that a copy of the form may be kept in the patient notes held within the substance misuse service.

A step by step guide to completing this form follows:
Public Health Wales BBV Surveillance Form

WHAT TO DO

1. Each time an individual has a blood spot diagnostic sample or a venepuncture sample taken, please complete a Public Health Wales surveillance form (titled ‘Enhanced Surveillance of BBV in Wales’). This does NOT include venepuncture samples taken as confirmatory tests.

2. This form will be scanned, so please complete all questions by writing clearly in the boxes with a black pen.

3. Each form has a unique number so please use a differently numbered form for each person and do not photocopy the form.

4. Complete questions 1 to 12 when a sample is taken.

5. If this is the first time a form has been completed for an individual, please record the unique number on the top right of the form in the individual’s notes in a place where it can be easily accessed if patient is tested again.

6. If the patient has been previously tested at your agency, please record the previous unique number in the box provided on the form.

7. Please keep the form in the individual’s notes whilst awaiting test results.

8. When the test results are available, please update the last section of the form and send in the envelope provided to Daniel Thomas at Public Health Wales in Cardiff. Do not fold the form as this might affect scanning.

9. Keep a copy of the form in the individual’s notes for future reference. Ensure that patient is aware of this.

To speak to someone about this scheme contact us at: surveillance.requests@wales.nhs.uk or phone 02920 402472

Please note: Completion of the form is voluntary. Information provided will be used to assess trends in infection rates.

THANK YOU FOR HELPING US.
4.14 Acting on test results

**Please Note:** It is essential that the actions following a test result (either negative or reactive) are agreed at a local level with the appropriate partners (consultant microbiologists, gastroenterologists, hepatologists and genito-urinary medicine (GUM) specialists) AND with the clinical lead for the blood borne viral hepatitis action plan developments in your health board (see appendix for contact details). There may be differences in local protocols. **It must be clear how reactive results for HCV, HBV and HIV are followed up and by whom.**

Once HCV reactive results have been confirmed by venepuncture sample a PCR referral should be made to local health board services. This may be a specialist substance misuse service HCV clinic, or a consultant gastroenterologist or hepatologist, or to infectious disease specialist, depending on the arrangements in the area. Referral should be made to a consultant in genito-urinary medicine or an infectious disease specialist for anyone with a positive result for HIV.

**Notification of viral hepatitis:** There is a legal requirement for clinicians (in this case the clinician first receiving the test result indicating viral hepatitis), on the basis of a clinical diagnosis of viral hepatitis to notify the proper officer for the local authority (in the local Health Protection Team). This will ensure appropriate action is taken to minimise the risk of spread to others and appropriate care is provided to the infected individual.

See below for contact details:

**North Wales Health Protection Team:**
Preswylfa, Hendy Road, Mold, CH7 1PZ  
Tel: **01352 803234** Fax: 01352 700043.

**South East Wales Health Protection Team:**
Cardiff Office: Temple of Peace and Health, Cathays Park, Cardiff CF10 3NW  
Tel: **029 20402478** Fax: 029 20402503.  
Gwent Office: Mamhilad House, Mamhilad Park Estate, Pontypool, Torfaen, NP4 0YP  
Tel: **01495 332219** Fax: 01495 745860.

**Mid and West Wales Health Protection Team:**
Carmarthen Office: PO Box 108, St David's Park, Job's Well Road, Carmarthen, SA31 3WY  
Tel: **01267 225081** Fax: 01267 225220.  
Swansea Office: 36 Orchard Street, Swansea, SA1 5AQ  
Tel: **01792 607387** Fax: 01792 470743

For further information see:  
**Acting on a test result**

The following table summarises potential actions that may follow a reactive or negative test result. **Please emphasise to the patient that all reactive DBS results need confirmation by venepuncture.** Note – please remember when the results are available, and if patient has consented, to enter them onto the surveillance form.

<table>
<thead>
<tr>
<th>Test result</th>
<th>Action.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-HCV reactive DBS</td>
<td>Refer for follow up venepuncture test taken into 3 x 5mls of EDTA whole blood containers to determine if currently infected – this will be a repeat anti-HCV test and PCR test. (if any doubt speak to the local microbiology laboratory)</td>
</tr>
<tr>
<td>HB surface antigen (HBsAg) reactive</td>
<td>Refer for follow up venepuncture test for confirmation and assessment of stage of disease (1 x 5mls clotted sample)</td>
</tr>
<tr>
<td>Anti-HIV reactive DBS</td>
<td>Refer for follow up venepuncture (1 x 5mls Clotted blood and 2 x 5mls EDTA sample) to confirm the result and additional viral load and typing assays as required</td>
</tr>
<tr>
<td>Anti-HCV negative DBS or venepuncture based test</td>
<td>Retest within 12 months, if possible retest every six months. If continued risk of exposure then retest again after a further 6 months</td>
</tr>
<tr>
<td>Anti-HIV negative DBS or venepuncture based test</td>
<td>Retest within 12 months, if possible retest every six months. If continued risk of exposure then retest again after a further 6 months</td>
</tr>
</tbody>
</table>
| Anti-HCV reactive venepuncture based test | Refer for follow up venepuncture test to determine if currently infected – this will be by a PCR test  
**After PCR test**  
- If RNA reactive by PCR then patient should be referred for specialist follow up and notification of health protection team  
- If RNA negative by PCR retest by PCR after 6 months. If continued risk of exposure then Retest within 12 months, if possible retest every six months.  
- If reactive provide information to women with hepatitis C about the importance of testing in babies and children born after the woman acquired infection                                                                 |
| HBsAg reactive venepuncture based test | Refer for follow up. Notify Health Protection Team                                                                                                                                                                                                                                                                                        |
| Anti-HIV reactive venepuncture based test | Refer for follow up                                                                                                                                                                                                                                                                                                                         |

**Note:** If the DBS and venepuncture results are discordant (i.e. a negative venepuncture follow up after an initial reactive DBS) the venepuncture should be repeated.
4.15 **Hepatitis B vaccination summary**

1. Vaccinate if not fully vaccinated. If testing is required take blood sample prior to administration of vaccine

2. The dried blood spot tests used for Hepatitis B do not indicate a person's hepatitis B vaccination/immunity status

3. Vaccinate at the first opportunity. Do not routinely test for an antibody response to hepatitis B vaccine or for previous hepatitis B infection prior to commencing vaccination

4. If an individual is found to have had, or is currently infected with, HBV and a course of vaccination has been started it is not necessary to continue with subsequent doses of vaccine. Reassure the patient that the vaccine they have received will not have any adverse effects

5. If patient documentation reliably indicates the number of doses of hepatitis B vaccination received, complete the course of vaccinations as appropriate

**However:**

6. If there is any doubt as to the vaccination status of an individual start the course again

4.16 **Check list for your service before you start dried blood spot testing**

- Have you confirmed that your service fulfils the essential criteria outlined in section 4.1

- Do you have all the kit and all the paper work?

- Have you established a safe and secure means to transport samples from your service to the microbiology laboratory that will be booking in your samples?

- Are all staff clear about where samples are sent and where surveillance forms are sent?

- Have all staff who are going to take DBS tests been trained in pre and post test discussion?

- Have you in place a clear care pathway for individuals who receive reactive results?
• Have you in place a clear care pathway for individuals who receive negative results?

• Have you contacted your local microbiology laboratory and discussed with the laboratory manager:
  - the DBS testing process, and how and when samples will be delivered?
  - the anticipated workload?
  - how results are going to be fed back to your agency from the microbiology service?

Establishing a dialogue before starting DBS should greatly help the smooth running of the process.
5 Appendix 1

5.1 Contact Details for Microbiology Laboratories

Central testing laboratory will be:
Welsh Specialist Virology Centre, Public Health Wales Cardiff, University Hospital of Wales, Heath, Cardiff CF14 4XW
Tel/Ffon 029 2074 2178, Request to speak to Consultant virologist

Enhanced surveillance of BBV in Wales form should be returned to: CDSC, Temple of Peace and Health, Cardiff, CF10 3NW. Any queries, or to order new forms, ring the surveillance team on 029 2040 2472

Note: For clinical enquires regarding test results please ask to speak to the Consultant Microbiologist located within the relevant microbiology laboratory

<table>
<thead>
<tr>
<th>Area of Wales in which testing is occurring</th>
<th>Booking laboratory</th>
<th>Microbiology laboratory</th>
<th>Laboratory contact number (ask to speak to laboratory manger, or lead for serology)</th>
</tr>
</thead>
<tbody>
<tr>
<td>North West Wales</td>
<td>Ysbyty Gwynedd Bangor</td>
<td></td>
<td>01248 384367</td>
</tr>
<tr>
<td>Powys</td>
<td>Princess Royal Hospital Telford</td>
<td>Hereford Hospital</td>
<td>01952 641222 / 01432 355444 ext 5717</td>
</tr>
<tr>
<td>North East Wales</td>
<td>Wrexham Maelor Hospital</td>
<td>Glan Clwyd Hospital, Bodelwyddan</td>
<td>01978 725256 / 01745 583737</td>
</tr>
<tr>
<td>West Wales</td>
<td>West Wales General Hospital Carmarthen</td>
<td>Bronglais Hospital Aberystwyth</td>
<td>01267 237271/01267 236964 / 01970 635813</td>
</tr>
<tr>
<td></td>
<td>Bronglais Hospital Aberystwyth</td>
<td>Withybush Hospital Haverford West</td>
<td>01437 773238</td>
</tr>
<tr>
<td>Gwent</td>
<td>Royal Gwent Hospital, Newport</td>
<td></td>
<td>01633 234505</td>
</tr>
<tr>
<td>Cardiff and Vale</td>
<td>University Hospital of Wales, Heath Park, Cardiff</td>
<td></td>
<td>029 2074 3432 / 2094</td>
</tr>
<tr>
<td>Cwm Taf</td>
<td>Royal Glamorgan Hospital, Llantrisant</td>
<td>Prince Charles Hospital Merthyr Tydfil</td>
<td>01443 443557 / 01685 728274</td>
</tr>
<tr>
<td>Abertawe Bro Morgannwg</td>
<td>Singleton Hospital Swansea</td>
<td></td>
<td>01792 285055</td>
</tr>
<tr>
<td></td>
<td>Princess of Wales Hospital Bridgend</td>
<td></td>
<td>01656 752318</td>
</tr>
</tbody>
</table>
5.2 Contact Details and Addresses for HCV Clinical Leads

**Abertawe Bro Morgannwg University Health Board**
Dr Chinlye Ch'ng
Singleton Hospital
Sketty Lane
Sketty
Swansea
SA2 8QA
Chinlye.ch'ng@wales.nhs.uk

**Aneurin Bevan Health Board**
Dr Marek Czajkowski,
Royal Gwent Hospital,
Cardiff Road
Newport
NP20 2UB
Marek.Czajkowski@wales.nhs.uk

**Betsi Cadwaladr University Health Board**
Dr Thiriloganathan Mathialahan
Wrexham Maelor Hospital
roesnewydd Road
Wrexham
LL13 7TD
Thirologanathan.mathialahan@wales.nhs.uk

**Cardiff & Vale University Health Board**
Dr Brendan Healey
University Hospital of Wales
Heath Park
Cardiff
CF14 4XW
andrew.godkin@wales.nhs.uk

**Cwm Taf Health Board**
Dr Ruth Alcolado
Royal Glamorgan Hospital
Ynys Maerdy
Pontyclun,
Llantrisant
CF72 8XR
Ruth.alcolado@wales.nhs.uk

**Hywel Dda Health Board**
Dr Ian Rees
Consultant Gastroenterologist, Prince Phillip Hospital
Bryngwyn Mawr, Dafen, Llanelli, SA14 8QF
Tel: 01554 756567
Secretary’s contact details:
Telephone: 01554 756567 x3129
Ian.Rees@wales.nhs.uk
5.3 Purchasing further equipment

Further equipment can be obtained from the sources below.

**Blood collection cards**
Whatman 903 Protein Saver Cards (item no: 10531018)
These can be ordered in boxes of 100. Minimum order one box. From; Scientific Laboratory Supplies Lt, Wilford Industrial Estate, Ruddington lane, Wilford, Nottingham, NG11 7EP,
Tel : 0115 9821111
The Whatman cards have a two year shelf life

**Lancets**
**Unistik 3 Extra.**  21 gauge safety lancet
Code: AT1014
These can be ordered via normal NHS procurement routes in boxes of 200 or 100. Minimum order one box.

5.4 Glossary

DBS - Dried blood spot
HCV – Hepatitis C virus
HBV – Hepatitis B virus
Anti HBc – Anti Hepatitis B core antibody
HBsAg – Hepatitis B surface antigen
PCR – Polymerase Chain Reaction (tests for the presence of a virus)

5.5 References


## 5.6 Example Pre and Post Test Discussion Check List

### BBV Pre and Post Test Discussion

<table>
<thead>
<tr>
<th>Name:</th>
<th>ID Number</th>
<th>Date of Interview &amp; Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Knowledge and Awareness Checklist</th>
<th>Discussed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Yes</strong></td>
<td><strong>No</strong></td>
</tr>
</tbody>
</table>

**Modes of transmission**

**Differences between HIV, HCV and HBV**

**Patients perception of risk activities and last date of risk behaviour including:**

- Unsafe sex
- History of drug use and injecting
- Exposure to blood or blood products
- Tattooing
- Occupational risk
- Overseas travel / country of origin

**Previous HBV vaccination**

**Advantages/Disadvantages and implications of reactive or negative result for the individual**

**Requirement for notification of active infection**

**Hepatitis B (HBV)** – a reactive result for hepatitis B surface antigen must be reported to local Health Protection Team with name and contact details of individual

**Hepatitis C (HCV)** – as of 2010, a reactive PCR result for hepatitis C must be reported to local Health Protection Team with name and contact details of individual

**Testing and treatment**

What these initial tests can tell us – need for further testing to confirm diagnosis

Antibodies take 3 months (HIV) – 6 months (HCV) to develop – repeat test required?

Natural history and disease progression – impact of treatment

Referral and treatment

Life assurance and mortgage issues including confidentiality

Pregnancy issues

**Contact tracing**

**HBV** - Details of close household contacts and sexual partners may be established with tester following reactive result in order to provide prophylaxis or vaccination to at risk individuals

**HCV** - Details of close household contacts and current sexual partner may be established with tester following reactive result and discussion may take place regarding contact tracing and testing of those contacts
Support and Coping Considerations
Implications and support if results reactive...

<table>
<thead>
<tr>
<th>Taking the Tests</th>
<th>Discussed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advised to repeat any test</td>
<td>Yes</td>
</tr>
<tr>
<td>Appointment for results made: ……./…./………</td>
<td></td>
</tr>
</tbody>
</table>

Consent
1. I consent to have my blood taken for the following tests HIV, Hepatitis B, Hepatitis C (please delete as appropriate) and that in the case of a reactive result for hepatitis B and / or hepatitis C that my name and contact details must be reported to Health Protection, Public Health Wales as required by Health Protection Legislation (Wales) 2010
2. I consent to share the results of my tests with specialist clinicians responsible for continued patient care (as below)

<table>
<thead>
<tr>
<th>Name (please print)</th>
<th>Named others (please print)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BBV Post-Test Discussion
Date of Interview

<table>
<thead>
<tr>
<th>Future Prevention</th>
<th>Discussed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention of transmission (household and social contacts)</td>
<td>Yes</td>
</tr>
<tr>
<td>Harm reduction (including safer injecting)</td>
<td></td>
</tr>
<tr>
<td>Safer sex advice</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Onward Referral following confirmatory test</th>
<th>N/A</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialist clinicians responsible for continued patient care</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes