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Dried blood spot testing for hepatitis C, hepatitis B and HIV: Information for substance misuse services

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Purpose and Summary of Document:

To outline the background to and requirements for successful implementation of dried blood spot testing for hepatitis C, hepatitis B and HIV amongst clients of substance misuse services in Wales

Publication/Distribution:

- Substance misuse and other specialist services in Wales offering testing for blood borne viruses

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1 Purpose of this document

This document outlines the background to, and action required for, the implementation of dried blood spot (DBS) testing of substance misuse service clients across Wales for evidence of exposure to hepatitis C virus (HCV), hepatitis B virus (HBV) and HIV. It is intended as resource to support substance misuse agencies across Wales to provide DBS for their clients.

2 Background to dried blood spot testing

Approximately one quarter of drug injectors in Wales are infected with HCV.^{1,2} 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.³

Low rates of diagnosis will contribute to the future burden of liver disease in Wales through late identification viral hepatitis infection manifesting as clinical disease and HIV infection diagnosed at late stages of disease. An opportunity to reduce the further transmission of infection is also missed. There is thus a clinical risk with failing to improve the currently poor rates of diagnosis.

Existing diagnostic testing protocols require the taking of blood samples by venepuncture; this can be problematic amongst drug injectors who often have very poor venous access. A much simpler dried blood spot approach, testing for antibodies to HCV, HBV and HIV, which requires only a very small amount of blood to be taken, has been piloted by the North West Wales Substance Misuse Service amongst individuals who do not wish to undergo venepuncture. Positive DBS test results require confirmation with venepuncture tests. Data from the North Wales pilot suggest that the dried blood spot testing protocol is both feasible and likely to increase the numbers of individuals coming forward for testing.

Public Health Wales will, over 2010, roll out DBS testing across Wales. Sample collection will be carried out within specialist drug treatment services across Wales and samples will be tested by the Wales Specialist Virology Centre. The process of requesting tests and feeding back of results to drug services will be through existing microbiology service channels in the same manner as venepuncture based testing is currently processed.

The DBS roll out will not replace venepuncture based testing; rather it is intended as a pre-test aimed at individuals with compromised venous access for whom venepuncture testing may be problematic.

Aim of service development

1. To improve the current low rates of HCV and HBV diagnosis amongst injecting drug users in Wales
2. To improve HIV diagnosis amongst injecting drug users in Wales
3. To monitor the prevalence of infection amongst individuals coming forward for testing

3 Setting up dried blood spot testing within a substance misuse service

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

Services potentially eligible to offer diagnostic testing to their clients:

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 clients (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 clients and to take the dried blood spot sample safely
- 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 positive for blood borne viruses with local viral hepatitis treatment services and HIV treatment services
- Existence and evidence of an agreement for the registered medical practitioner responsible for the diagnostic service (lead clinician) to full fill statutory requirements for notification of viral hepatitis
- Existence and evidence of an agreement to collaborate with Local Public Health teams in actions following the identification of viral hepatitis

3.2 Overview of the testing process

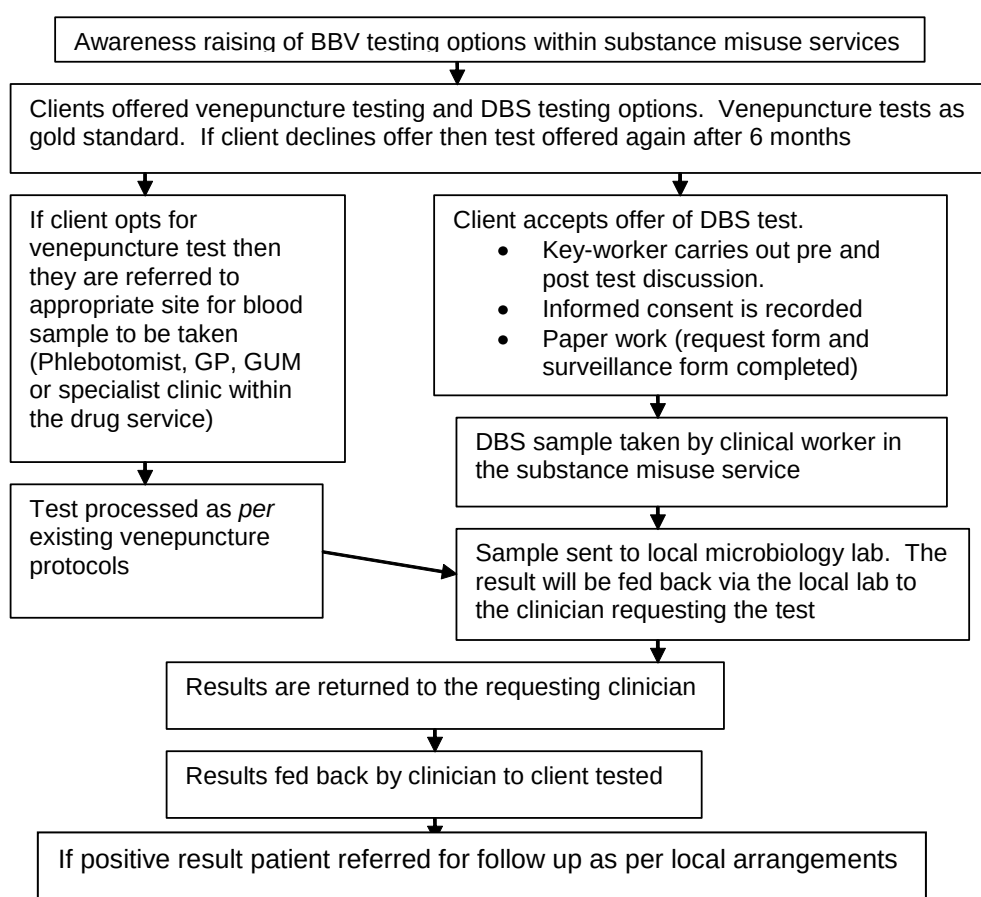
Dried blood spot testing is a simple procedure. If carried out correctly the process is both safe for the individual being tested and the individual taking the sample. DBS can be introduced within services already providing venepuncture with modest modification to existing protocols.

A summary of the steps involved in DBS testing of substance misuse service clients is outlined in the flow diagram below. 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.

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 of the sample, c) arranging transport of the sample, and d) feeding back of test results to the individual being tested.

The testing process



3.3 Venepuncture or dried blood spot test?

DBS is most suitable for those who would not otherwise come forward for venepuncture based testing. Individuals that test positive 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 positive individual should have a confirmatory test.

3.4 Co-ordinating with your local microbiology laboratory

The pilot project in North West Wales has shown the importance of close communication between the substance misuse service and the local microbiology laboratory. It is thus essential to discuss, prior to testing, the logistics of sample transport, sample processing and feeding back of results with your local microbiology laboratory. Normally this will best be achieved by talking to the lead consultant microbiologist and microbiology laboratory manager at your local microbiology service. It will be of use to the laboratory if you can estimate likely work load and sample throughput.

The details of these arrangements will reflect local working practices. A small amount of time spent ensuring local details are clarified will greatly help the smooth running of the diagnostic service. Appendix 1 outlines contact details for microbiology laboratories across Wales. **The target turn around time for return of the results from the laboratory is two weeks**

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:

- Rings the senior biomedical scientist or laboratory manager in the local microbiology laboratory to which you will be sending your samples (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

3.5 In what environment can the sample be collected?

DBS can be taken in any setting deemed by service management to be safe for the client and worker. Facilities for clearing up any blood spillages should be present. Samples can thus be taken in health service clinic settings or in a client's home.

3.6 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
- Padded transport envelopes

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

- Latex and non-latex surgical gloves
- Alcohol swabs
- Cotton wool
- Plasters
- Spillage kits for cleaning up blood
- Sharps bin

Equipment purchase list for participating agencies:

When further supplies of lancets and dried blood spot collection cards and padded transport envelopes are required services will need to purchase further supplies. Details of suppliers are shown in the appendix. The costs associated with these purchases are modest. Virology BBV test request forms will be available from Cardiff Virology (address below).

3.7 Pre and post test discussion and informed consent

All clients being tested by either DBS or venepuncture should receive appropriate pre and post test discussion, have given informed consent to be tested and, if they are willing to provide the information, consent to provide information on the surveillance form (see 3.8 part 3). 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 however sources for up to date guidelines are indicated below.

HIV: Guidelines on pre and post test discussion for HIV testing have been produced by the British Association for Sexual Health and HIV:
http://www.bashh.org/guidelines/2006/hiv_testing_june06.pdf

HCV: The department of health provide guidance for health care professionals in Hepatitis C - Essential information for professionals and guidance on testing:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4097933

HBV: The 'green book' (Immunisation against infectious diseases) is the essential resource for up to date guidance on hepatitis B vaccination:
<http://www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/index.htm>

3.8 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 client's name, date sample taken and date of birth on dried blood spot collection card



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

Please ensure the following is clearly entered:

- Client's name
- Client's date of birth
- Client'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 antibody, HIV)
- Date sample taken
- Nature of specimen (dried blood spot)

SURNAME / Clinic No.		FORENAME		RETURN ADDRESS		LABORATORY SPECIMEN No.
HOME ADDRESS or Area / Residence				HOSPITAL / SURGERY		DATE RECEIVED
				WARD OR DEPARTMENT		
				CONSULTANT		
POSTCODE		D.O.B.		TO ENSURE URGENT TESTS, TELEPHONE LAB BEFORE SENDING		NPHS MICROBIOLOGY 1st Floor 'C' Block University Hospital of Wales Health Park, Cardiff CF14 4XW
SEX:	Previous Test YES / NO	Date:	Lab. Number:	General Enquiries: *029 2074 2094 Medical Advice via: *029 2074 2178		
CLINICAL AND EPIDEMIOLOGICAL INFORMATION (INCLUDING DATES WHERE RELEVANT)				NATURE OF SPECIMEN: (Information for Phlebotomist - PTO)		
Signature				Date (& time) of Collection:		
				TEST(S) REQUESTED		
FOR LAB USE ONLY				VIROLOGY Blood Borne Virus		
PLEASE REFER TO NOTES ON BACK OF 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.

Record the ID Number in the patient notes. WHERE THERE 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. Further details of this form are addressed in section 3.13 below.

 Enhanced Surveillance of BBV in Wales		ID Number: 000601																									
Providing this information is voluntary and confidential Any information you provide will be used to assess trends of blood borne virus infection in Wales																											
This form should be completed every time an individual is tested for a blood borne virus infection																											
PLEASE WRITE CLEARLY INSIDE BOXES (USING CAPITAL LETTERS) AND BLACK INK OR PLACE A ☒ IN THE BOXES TO INDICATE A RESPONSE																											
PLEASE DO NOT PHOTOCOPY (AS EACH FORM HAS A UNIQUE NUMBER)																											
1. Today's date <table border="1"><tr><td>d</td><td>d</td><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>		d	d	m	m	y	y	y	y									10. Were you born in the UK? yes ☐ no ☐ If no, in which country were you born? <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>									
d	d	m	m	y	y	y	y																				
2. Agency/GP Surgery <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>										11. Have you ever been in prison? yes ☐ no ☐ If yes, when were you last released? <table border="1"><tr><td>m</td><td>m</td><td>y</td><td>y</td><td>y</td><td>y</td></tr><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>		m	m	y	y	y	y										
m	m	y	y	y	y																						
3. Location (eg Llanelli) <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>										What was the last prison you were in? <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>																	
4. Demographics Male ☐ Female ☐ Age <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>								12. Have you previously been tested for the following? Hep C ☐ HIV ☐ If yes, what was the result and year of test: <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>																			
5. Have you been homeless in the last 12 months? (hostel/street/no fixed abode) yes ☐ no ☐ If yes, how many months have you been homeless in the last 12 months? <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>								Hep C ☐ +ve ☐ -ve ☐ HIV ☐ +ve ☐ -ve ☐																			
6. In the last 12 months have you been prescribed opiate substitute treatment? yes ☐ no ☐ If yes, how many months in the last 12 months have you been prescribed? <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>								Health care worker: If this is the first time you have completed this form for this patient please record the unique number (see top of page) in the patient's notes. If you are retesting a patient previously tested please check patient's notes and re-enter previous unique number below: <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>																			
7. How many years ago did you first start injecting? (please select one option) <1yr ☐ 1-2yrs ☐ 3-4yrs ☐ 5-10yrs ☐ >10yrs ☐ never ☐		Please update when you receive the Antibody Test Results: <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>																									
8. Have you injected any of the following in the last 12 months? yes ☐ no ☐ Heroin ☐ Crack cocaine ☐ Crack & heroin together ☐ Steroids, performance/image enhancing drugs ☐ Amphetamine ☐		Hep B ☐ +ve ☐ -ve ☐ equivocal ☐ not tested ☐ Hep C ☐ +ve ☐ -ve ☐ equivocal ☐ not tested ☐ HIV ☐ +ve ☐ -ve ☐ equivocal ☐ not tested ☐																									
9. How often do you drink EIGHT or more (if male) or SIX or more (if female) units of alcohol on one occasion? (please see advice sheet on alcohol units) daily ☐ weekly ☐ monthly ☐ never ☐		When form is completed with antibody test results send to: Dr Daniel Thomas, Public Health Wales, CDSC, Temple of Peace and Health, Cathays Park, Cardiff, CF10 3NW Thank you for providing this information																									

TAKING THE DRIED BLOOD SPOT SAMPLE

1. BEFORE YOU BEGIN TAKING A DRIED BLOOD SPOT SAMPLE

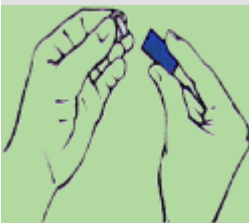
- Lay out the lancet, blood spot collection card, cotton wool and plaster.
- Ensure you have a sharps bin
- Put on a pair of latex or non-latex disposable surgical gloves.
- Fill out name, date of birth and date on card BEFORE taking sample

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 client 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 client 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 gray 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.

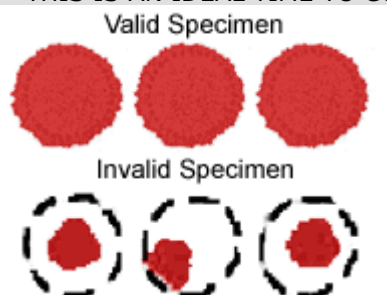
6. **FILL AT LEAST THREE CIRCLES –**



- 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 client 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

CLEAN WORK SURFACES WITH APPROPRIATE CLEANING MATERIALS

10. **PLACE SPECIMEN BAG INTO A PADDED ENVELOPE**

11. **TRANSPORT PROMPTLY TO YOUR LOCAL MICROBIOLOGY LABORATORY**

12. **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.**

3.9 What tests are used?

The tests used on the dried blood spot sample will test for the presence of antibodies to HCV, HBV and HIV. Further confirmatory tests will be required to demonstrate current infection. The laboratory will also test for Hepatitis B surface antigen. Patients will be offered tests to all three viruses. If a patient wishes to opt out of one of the tests then this must be clearly indicated on the Whatman filter card and on the request form.

- 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 positive result indicates current infection
- A reactive HBV test (in this case showing evidence of anti hepatitis B core antibody and/or hepatitis B surface antigen) will require confirmatory tests carried out on a venepuncture 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.

Actions that should follow the issuing of test results back to the requesting clinician are discussed in section **3.13** below.

3.10 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.

3.11 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. As above the details of these arrangements will reflect local working practices.

Ensure that the paper or electronic results will be promptly dealt with if requesting clinician is on leave or out of office.

3.12 Recording test uptake

Public Health Wales will wish to access anonymous service-specific data to support both the ongoing monitoring of the effectiveness of DBS 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.

3.13 The Enhanced Surveillance of BBV in Wales form

The roll out of DBS 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.

The Enhanced Surveillance of BBV in Wales form that you have been asked to complete for each client tested is an important component of the dried blood spot roll-out. The information collected will be linked by the unique identifier to any further blood borne viral tests the individual has. This will allow the prevalence of infection to be determined for IDUs who have been injecting for different lengths of time; knowing the prevalence amongst recent onset injectors gives a picture of current rates of transmission that looking at overall prevalence rates does not. Similarly, the questions concerning patterns of drug use will help in monitoring where and how transmission is occurring.

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 C treatment will not have access to the information collected on the surveillance form. This form will be sent separately 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.

Please see next page for a step by step guide to completing this form:

Public Health Wales BBV surveillance form (green)

WHAT TO DO

1. Each time an individual has a blood spot sample taken, please complete a green Public Health Wales surveillance form (titled 'Surveillance of BBV in Wales').
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.
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.
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. No postage is required as this will be paid for by Public Health Wales.
10. Keep a copy of the form in the individual's notes for future reference.

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

3.14 Acting on test results

Please Note: It is essential that the actions following a test result (either negative or positive) are ratified 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 positive results for HCV, HBV and HIV are acted on.**

Referral for positive results should be into local trust services. For viral hepatitis referral should be to a specialist substance misuse service HCV clinic, or a consultant gastroenterologist or hepatologist, or to infectious disease specialist (arrangements may vary by area), and for HIV to a consultant in genito-urinary medicine or an infectious disease specialist.

Notification of viral hepatitis: There is a legal requirement for clinicians, on the basis of a clinical diagnosis of infectious hepatitis (acute) to notify the proper officer for the local authority (in the local Health Protection Team). This will ensure appropriate action is taken and outbreaks identified/prevented. As well as notifying acute infections please notify the appropriate health protection team when chronic carriage is identified i.e. HBsAg positive or HCV PCR positive. This will ensure risk of spread to others is minimised 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: <http://howis.wales.nhs.uk/sites3/page.cfm?orgid=457&pid=37230>

Acting on a test result

The following table summarises potential actions that may follow a positive or negative test result. Please emphasise to the client that all positive DBS results need confirmation by venepuncture. Note – please remember when the results are available to enter them onto the surveillance form.

Test result	Action.
Anti-HCV positive DBS	Refer for follow up venepuncture test taken into 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 lab)
HB surface antigen (HBsAg) positive	Refer for follow up venepuncture test for confirmation and assessment of stage of disease
Anti-HBc positive DBS	Refer for follow up venepuncture test to determine if currently infected
Anti-HIV positive DBS	Refer for follow up venepuncture test to confirm result and if confirmed to determine if HIV 1 or HIV 2 infection.
Anti-HCV negative DBS or venepuncture based test	Retest after 6 months. If continued risk of exposure then retest again after a further 6 months.
Anti-HBc negative DBS or venepuncture based test	Retest after 6 months. If continued risk of exposure then retest again after a further 6 months. Check vaccination status and vaccinate if needed.
Anti-HIV negative DBS or venepuncture based test	Retest after 6 months. If continued risk of exposure then retest again after a further 6 months.
Anti-HCV positive venepuncture based test	Refer for follow up venepuncture test to determine if currently infected – this will be by a PCR test. <u>After PCR test</u> • If RNA positive by PCR then patient should be referred for specialist follow up. • If RNA negative by PCR retest after 6 months. If continued risk of exposure then retest again after a further 6 months
HBsAg positive venepuncture based test	Refer for follow up. Notify Health Protection Team
Anti-HIV positive venepuncture based test	Refer for follow up

Note: Should there be divergent DBS results (i.e. a negative venepuncture follow up after an initial positive DBS) the venepuncture should be repeated.

3.15 Hepatitis B vaccination summary

1. Vaccinate prior to testing if not fully vaccinated
2. The dried blood spot tests used for Hepatitis B do not indicate a person's hepatitis B vaccination 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 it is not necessary to continue with subsequent doses of vaccine if a course of vaccination has been started. It is important to reassure the patient that the vaccine they receive 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

3.16 Evaluation of PCR on dried blood spots (note this component is time limited)

The sensitivity of the PCR test to detect HCV RNA on DBS is unknown; currently all PCR testing (detecting HCV RNA i.e. directly detecting presence of the virus) is carried out on samples collected by venepuncture. The roll out of DBS testing for HCV across Wales provides an opportunity to evaluate the sensitivity of PCR testing on DBS. The Welsh Specialist Virology Centre in Cardiff wishes to evaluate this process by comparing the PCR carried out on the venepuncture sample with the PCR carried out on the DBS.

All individuals identified by DBS testing as anti-HCV positive should be asked by their key worker or clinician to provide a venepuncture blood sample for a confirmatory antibody test and for PCR testing. This follow up test provides an opportunity to compare the sensitivity of the PCR test as carried out on a DBS sample to that carried out on a venepuncture sample.

- Agencies who arrange the collection of venepuncture themselves within their own clinics are asked to collect, at the same time as taking the venepuncture sample, a second DBS test.

Process for validation work:

When collecting the venepuncture sample and the second DBS please complete a test request form for the venepuncture sample using the specimen request form/bag normally used for venepuncture PCR tests by your service

- The repeat DBS card should be sealed in a specimen bag – please then discard the paper part of the bag and put the now securely sealed DBS sample in the SAME SPECIMEN BAG as the venepuncture (this latter sample should still have a completed request form attached).
- The words 'DBS validation sample enclosed' should be clearly written on the request form.

The sample you send to the microbiology laboratory should now consist of a completed test request form requesting a PCR test and any other tests required with the attached bag containing:

1. The venepuncture blood samples
 2. The dried blood spot sample INSIDE a further clear plastic specimen bag without the attached paperwork (please tear this off and discard)
- All individuals providing a sample should sign the informed consent form and be provided with the patient information form (these will be provided)

Please submit the two samples as per normal venepuncture protocols to your local microbiology laboratory.

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

- Have you confirmed that your service full fills the essential criteria outlined in section 3.1
- 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 positive 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.

Appendix: Important contacts

Central testing laboratory will be:

Welsh Specialist Virology Centre, NPHS Cardiff, Heath Hospital, CF14 4XW

Tel/Ffon 029 2074 2178, Lead Consultant virologist: Dr Elizabeth McCruden

Enhanced surveillance of BBV in Wales form should be returned to: Dr Daniel

Thomas, 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

Area of Wales in which testing is occurring	Booking Microbiology laboratory	Laboratory contact
North West Wales	Ysbyty Gwynedd Bangor	Kim Bowden 01248 384367
Powys	Princes Royal Hospital Telford	Karen Howells 01952 641222
	Hereford Hospital	Lorraine Wadley 01432 355444 ext 5717
North East Wales	Wrexham Maelor Hospital	David Williams 01978 725256.
	Glan Clywd Hospital, Bodelwyddan	Malcolm Gallagher 01745 583737
West Wales	West Wales General Hospital Carmarthen	Andrew Keen 01267 237271/01267 236964
	Bronglais Hospital Aberystwyth	Caroline Longman 01970 635813
	Withybush Hospital Haverford West	Mike Williams 01437 773238
Gwent	Royal Gwent Hospital, Newport	Jane Phillips / Steve Curnow 01633 234505
Cardiff and Vale	University Hospital, Heath Park, Cardiff	Ian Phillips / Jonathan Evans 029 2074 3432 / 2094
Cwm Taf	Royal Glamorgan Hospital, Llantrisant	Jennifer Hancock 01443 443557
	Prince Charles Hospital Merthyr Tydfil	Jennifer Hancock 01685 728274
Abertawe Bro Morgannwg	Singleton Hospital Swansea	Ian Thomas 01792 285055
	Princess of Wales Hospital Bridgend	Lesley Olson 01656 752318

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 Peter Neville,
Neville Hall Hospital,
Brecon Road,
Abergavenny,
Gwent.
NP7 7EG
Phillip.Neville@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 Andrew Godkin
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
Withybush Hospital
Fishguard Road
Haverfordwest
Pembs
SA61 2PZ
Ian.Rees@wales.nhs.uk

Purchasing further equipment

Further equipment can be obtained from the sources below.

Blood collection cards

Whatman 903 Protein Saver Cards (item no: 10531018)
<http://www.whatman.com/903ProteinSaverCards.aspx>

These can be ordered in boxes of 100. Minimum order one box. From;
Scientific Laboratory Supplies Ltd, Wilford Industrial Estate, Ruddington
lane, Wilford, Nottingham, NG11 7EP,
Tel : 0115 9821111 (approx cost £75.24 per box of 100).
The Whatman cards have a two year shelf life

Lancets

Unistik 3 Extra. 21 gauge safety lancet

Code: AT1014

<http://www.owenmumford.com/en/range/14/unistik-3.html>

These can be ordered via normal NHS procurement routes in boxes of 200
or 100. Minimum order one box.

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)

References

1. NPHS Incidence of HCV in South Wales; <http://nwww.nphs.wales.nhs.uk/> (2006)
(part of BBV reports 2006)
2. Craine N A, Walker M, Williamson S, Brown A, Hope V D. Hepatitis C and hepatitis B sero-prevalence and risk behaviour among community recruited injectors in North West Wales. *Communicable Disease and Public Health* 2004; 7(3): 216-9
3. Hope VD, Judd A, Hickman M, Sutton A, Stimson GV Parry JV and Gill ON. HIV prevalence among injecting drug users in England and Wales 1990 to 2003: evidence for increased transmission in recent years *AIDS* 2005; 19 (11) 1207-1244