Public Health England

Protecting and improving the nation's health

Bloodborne virus-related infection control breaches:

A toolkit for risk assessment, investigation and incident management (interim guidance)

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Contents

Introduction

This toolkit has been created to provide support to teams within PHE investigating incidents where an infection control breach or failure has led to potential risk of bloodborne virus transmission.

Incidents should be investigated using standard procedures and any internal reporting or escalation of the incident should follow existing arrangements (for example, NIERP).

Audience

The audience is Protection and Field Service (FS) teams involved in leading or supporting the risk assessment of breaches of infection control that have led to possible exposure to bloodborne viruses (BBVs).

This includes incidents where PHE is required to:

- support or lead hospital-based incidents
- support or lead investigations in healthcare settings outside hospital
- support or lead local authorities in investigating incidents in non-health care settings (for example, tattoo parlours, beauty salons, other therapies)

Purpose

To provide:

- descriptions of infection control procedures and the risks posed by breaches or poor practice
- guidance on risk assessment – and possible outcomes
- checklist of information to guide risk assessment
- information about support and resources available

Support to investigating teams

A range of expert support is available through teams within National Infection Service (laboratory, epidemiology and FS) including:

- microbiological advice regarding decontamination of instruments and environments
- virological and epidemiological advice about risks of or factors affecting transmission of BBVs
- advice on investigation based on experience from a wide range of incidents
- links to expert advice in other organisations
- information on national databases of BBV cases and use of data in risk assessment and investigation

The expert advisers within NIS work as an advisory group which can be contacted by incident leads (please email: emily.phipps@phe.gov.uk, Head of Hepatitis C / BBV infections in Blood Safety, Hepatitis, STIs and HIV Department). Members of the group are available to join local incident control teams if required or requested, or can work with PHE colleagues to formulate advice which can then be used locally.

Using this toolkit

The toolkit provides information about infection control risks, settings which might be at higher risk for transmission, risk assessment and practical guidance on investigations. It is envisaged that a local investigating team would use the information in this toolkit to guide their investigation and then contact the national advisory team to discuss any concerns or seek further advice.

This toolkit does not cover incidents where there are concerns about non-BBV infection control risks, for example, CJD or other bacterial infections. However, incident management teams should consider these risks as part of their assessment.

For advice about investigation and management of these incidents, please contact the relevant expert teams.

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Background

This toolkit is designed to provide support to staff from health protection and other PHE teams who might be involved in the risk assessment and management of infection control breaches.

The guidance only addresses issues regarding the risk of bloodborne viruses (BBV) as this is the most common reason PHE advice is sought. Advice about other infections (for example, bacterial infections) should be sought from the relevant specialist epidemiology and/or microbiology colleagues as appropriate .

This guidance does not cover incidents where a healthcare worker has been found to be infected with a BBV. Guidance on the investigation of these incidents is available from the UK Advisory Panel (UKAP): https://www.gov.uk/government/collections/bloodborne-viruses-bbvs-in-healthcare-workers

The investigation of these incidents, which can occur in healthcare or non-healthcare settings, can be complex and there is often a lack of clarity about who should lead the investigation and coordinate the actions required.[1]

In healthcare settings, the role of the Health Protection Team (HPT) or Field Service (FS) team is usually to provide advice on risk assessment and the public health aspects of management, but HPTs can also provide useful advice about communications and links with the wider health or public health system as necessary.

Leadership of incident investigation and management

The lead or chair of an incident control team for an incident in a healthcare setting would usually be from the organisation (for example, hospital trust, Clinical Commissioning Group (CCG)). Exactly who leads the investigation will vary according to local arrangements but it may be the Director of Infection Prevention and Control, Medical Director, the Director of Nursing or a delegated deputy.

In non-hospital healthcare settings (for example, primary care or dental practice), there should be local discussion about which organisation or individual chairs the incident control team. Possibilities include NHS England, CCG, or Health Protection Team. If an incident occurs in a prison or custodial setting, there should be discussion between NHS England and the prison healthcare team regarding local leadership.

In community (non-health) settings, it will be more usual for the HPT to lead the investigation and chair the incident control team.

1. A PHE-wide guide to Management of an incident where patient recall or notification may be required is being developed

The Health and Safety Executive (HSE) website has details of enforcement responsibilities for different non-health settings.[2]

Types of incident

Numbers and types of exposure

A wide variety of types of incident are covered by this guidance, including:

- failure of decontamination[3] of instruments
- infected patient(s) receiving dialysis
- inappropriate use of instruments (for example, re-use of single use instruments)
- lapses in infection prevention and control
- BBV transmission which may have occurred in a health care setting

It is difficult to quantify the number of incidents that occur or the number that PHE teams are involved with due to the variety of ways in which they are managed and recorded. However, most HPTs deal with at least one incident of this nature per year and the national teams described above support between 5 to 10 incidents per year.

Healthcare and non-healthcare settings (lists are not exhaustive)

Incidents have occurred in a range of healthcare settings include general hospital ward settings, endoscopy and surgical services, dialysis units, dental surgeries and GP premises, and in non-healthcare settings such as beauty salons, tattooists and the use of equipment in a non-regulated setting (for example, in someone's home).

It is known that responses to these incidents vary and HPTs are not always involved in the risk assessment and/or management, or are invited in at a later stage in the incident investigation.

Risk assessment or quantification of the risk of transmission of BBVs in an incident is complex, but usually finds a very low (negligible) level of risk. However, there are other considerations that the organisation responsible may take into account when deciding on actions to take. This is particularly the case in healthcare settings where the 'Duty of Candour' requirements of organisations may over-ride the public health risk assessment.

This toolkit will not comment further on the issues regarding duty of candour. Further detail of organisations' responsibilities is available on the CQC website.[4]

2. http://www.hse.gov.uk/lau/lacs/23-15.htm
3. Decontamination is, in this context, defined as any combination of cleaning, disinfection and sterilisation that makes a reusable item safe for re-use
4. https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour#full-regulation

Overview of infection control risks

Infection control risks can range from a breakdown in very basic general hygiene measures to specific failings with specialised equipment. The risks can also relate to human behaviours as well as equipment, so all aspects of the process should be considered.

The sections below describe points where risks or failures may occur.

A: General healthcare settings: decontamination

Hands

It is unlikely that un-gloved hands would make contact with body fluids that could transmit BBVs and not subsequently be washed. Infection control risk is far more likely to involve a HCW not changing gloves contaminated with blood between sequential patient contacts, or making contact with a surface with dirty gloves that then comes into contact with clean gloves before contact with a susceptible site in another patient.

Environment

If a clean (decontaminated) instrument is put on a surface contaminated by an un-decontaminated instrument, there is a substantial risk of contaminating the clean instrument.

If surfaces are dirty but no decontaminated instruments are put on them, there is no risk.

If a surface that has had a dirty instrument on it is to be safe to put clean instruments on, it must be thoroughly decontaminated before the clean instrument makes contact with it. It will need cleaning and good disinfection between every dirty and clean contact – ‘regular’ cleaning is not enough.

It is better to have separate, distinct surfaces for dirty and clean. There should be a clear dirty-to-clean flow of items to be reprocessed. Environmental decontamination and any risks from it should be seen in this context.

If there is a dirty-to-clean cross-contamination risk, a surface should be disinfected (with pre-cleaning if there is visible organic matter). This needs to be a controlled process with good coverage and reasonable length of exposure. Disinfectant will only work while wet;. Alcohol wipes evaporate rapidly and a single wipe used on a large surface will get progressively drier (and therefore less effective) the more it is used.

B: Sterilisation: processes and points where failures could occur

Steam sterilisation

Steam sterilisation is a robust process with very high overkill, designed to eliminate heat-resistant microbes such as bacterial spores. BBVs are very susceptible to heat inactivation. Only the most catastrophic failures could start to be a BBV survival risk. If there are cleaning failures (for example, visible blood on steam sterilized instruments), this does not constitute a BBV risk.

Before steam sterilisation, surgical instruments are processed in washer-disinfectors with a thermal disinfection element. The microbial inactivation in this process is to make them safe to handle prior to subsequent sterilisation.

Whilst surgical instruments need to be cleaned effectively for a wide variety of reasons, BBVs are readily killed by heat even if in organic matter. Cleaning is far more relevant to decontamination processes that rely on chemical disinfection where organic matter can both inactivate the disinfectant and shield viruses within accumulations

The Department of Health's guidance on decontamination of surgical instruments (Health Technical Memorandum 01-01) can be found at: https://www.gov.uk/government/publications/management-and-decontamination-of-surgical-instruments-used-in-acute-care. These 5 volumes of guidance focus mainly on engineering parameters.

Each provider of acute care would usually retain the services of an external engineer, an Authorising Engineer (Decontamination), to assess validation and verification of engineering aspects of decontamination processes. That person could be useful in interpretation of engineering data in possible failures. Similar guidance for primary care dental practices is in Health Technical Memorandum 01-05, available at: https://www.gov.uk/government/publications/decontamination-in-primary-care-dental-practices

If there are failures in the thermal disinfection in surgical instrument washer-disinfectors, there is no patient risk from instruments if they have subsequently been steam sterilised.

Low temperature sterilisation

There is an increase in using alternative low temperature sterilisation technologies to reprocess delicate instruments that would be damaged by heat – these are mostly robotic surgery instruments. Sterilisation by these methods is a less robust process – usually hydrogen peroxide vapour. Failures of sterilisation here could be more of a risk, but there is no experience or body of knowledge here.

Bespoke sterilisation

There are also bespoke chemical or chemo-thermal sterilisation processes for specific products such as human cadaver bone for transplant. Failures here would need careful scrutiny against the process validation but again, there is no experience or body of evidence to act as a risk assessment guide.

C: Decontamination ('reprocessing') of endoscopes: processes and points where failure could occur

Flexible endoscopes

These are expensive, delicate, heat-sensitive, usually lumened (nasendoscopes are an exception) instruments. While they can be sterilised using low temperature processes, this is exceptional and tends to be used only for endoscopes used surgically. They are normally decontaminated by sequential cleaning and chemical disinfection, followed by controlled storage. Cleaning needs to be of good quality to ensure effective subsequent disinfection.

The Department of Health's guidance on cleaning and disinfection of endoscopes (Health Technical Memorandum 01-06), along with the associated quality assurance measures, can be found at: https://www.gov.uk/government/publications/management-and-decontamination-of-flexible-endoscopes

The guidance comprises 5 volumes and focuses on engineering parameters. Each healthcare organisation normally retains the services of an independent expert, an Authorising Engineer (Decontamination), who should be able to assist in interpretation of engineering-based failures. This person is normally contactable via a hospital's Estates and Facilities Department. (See Department of Health guidance on decontamination.[5])

The normal processes in decontamination are:

1. Bedside clean: Immediately after use, gross contamination is removed by wiping the outside and sucking water (with or without detergent) through the main ('suction or biopsy') channel. If this is not done, subsequent processes may not be effective.

2. Leak test**:** If the scope has developed holes, patient body fluid may ingress and escape removal and disinfection. The body fluid can be expelled into subsequent patient as the scope if mobilized during use. All flexible scopes must be leak tested following every use. Poor leak testing technique can fail to spot holes.

5. Department of Health, March 2016 Health Technical Memorandum 01-06: Decontamination of flexible endoscopes Part A: Policy and management https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/530418/HTM0106_PartA.pdf

3. Manual clean: the scope is wiped externally and the suction or biopsy lumen is brushed and irrigated and other smaller lumens are irrigated.

4. The scope is then put in a washer-disinfector that will automatically irrigate the outside and the lumens to sequentially wash, disinfect, rinse and partially dry the scope.

There are multiple types of failure that could be broadly classified into:

- manual clean process unsatisfactory
- total failure to decontaminate for example, a clean looking but un-decontaminated scope is used in error
- failure to irrigate channels: Can occur in multiple ways for example, wrong connectors used, lumens blocked, fluid pumps broken, washer-disinfector not programed for a specific scope, other problems in washer-disinfector programing
- irrigation does not use the correct chemical fluids (detergent and/or disinfectant): fluid reservoir empty, fluid pump not working, fluid reservoirs incorrect (for example, loaded with 2 canisters of detergent rather than one detergent and one disinfectant or, for disinfectants that mix 2 components to form an active, 2 lots of the same component put in the machine)
- leak testing not routinely performed, performed inadequately or results suggesting leaks not acted upon

Post-decontamination

The scope should either be used within 3 hours (never fully dried by the washer-disinfector; bacteria remaining in damp lumens can replicate) or stored for more extended periods in a drying cabinet where each lumen is irrigated with filtered air to forcibly dry them). Failures in this area are not a BBV risk and will not require a related lookback.

Nasendoscopes

These instruments do not have lumens so do not require the more rigorous decontamination of other endoscopes. They do require leak testing but can be decontaminated by manual cleaning and wiping with a disinfectant – this should be a controlled process by trained staff. Endoscope washer-disinfectors can also be used.

Intra-cavity probes: (mainly transvaginal, transrectal and transoesophageal)

These can be contaminated by both direct patient contact and, more widespread, by staff hands contaminated with patient body fluid. The whole instrument must be fully decontaminated (not just the parts that come into direct patient contact) after every use. The use of sheathes or barriers on probes does not reliably prevent contamination and does not remove the requirement for decontamination.

Re-use of single-use instruments

Re-use of single use instruments should not occur for a variety of reasons: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/403442/Single-use_medical_devices__implications_and_consequences_of_re-use.pdf. However, as long as they are decontaminated to the same standard as reusable instruments, there is no infection risk from reusing single-use instruments. If they are not decontaminated adequately, there are the same risks as for reusable instruments - see relevant section on failures of decontamination of reusable instruments for the risk assessment.

D: Safe injection practices

Injection Safety

Injection Safety comprises the measures taken to perform injections in a safe manner for patients and healthcare workers. Safe injection practices prevent harms such as needlestick injuries and prevent transmission of infectious disease from:

- patient to patient
- patient to healthcare worker
- healthcare worker to patient

Resources are available from a number of sources.[6]

Unsafe injection practices include, but are not limited to:

Syringe re-use

The re-use of syringes has been implicated in a number of bloodborne transmission events and patient notification exercises. Syringe re-use can be direct or indirect.

Direct syringe re-use (re-use of syringes to administer medication to multiple patients) involves using the same syringe from patient to patient (with or without the same needle).

Indirect syringe re-use (re-use of syringes to access shared medications) involves using the same syringe to access medications from vials that will be used on subsequent patients (with or without the same needle).

6. http://apps.who.int/iris/bitstream/handle/10665/44298/9789241599252_eng.pdf?sequence=1 http://www.who.int/infection-prevention/tools/injections/training-education/en/ https://www.nice.org.uk/guidance/cg139

Single-use medications re-use

This involves administration of medication from a single-dose or single-use vial to multiple patients. This can occur when vials containing quantities in excess of those needed for a single patient are purchased in the mistaken belief that they can be used in a multi-dose fashion or in a bid to reduce wastage and save money.

Inappropriate handling of multi-dose medications

Under ideal circumstances, multidose medications should be used for single patients only. However, this is not always practical and if multidose vials must be used for more than one person they should be stored and prepared in a dedicated medication preparation area. Bloodborne virus transmission can occur as a result of:

- using unsterile or re-using needles or cannula and syringes to access multi-dose vials
- keeping multidose vials in the immediate patient treatment area where they may come into contact with potentially contaminated patient equipment

Sharing intravenous solutions

This involves using bags or bottles of intravenous solution as a common source of supply for multiple patients. This also includes the use of vials of water for injection or saline flushes.

Use of non-aseptic technique

This involves failure to use aseptic technique when preparing and administering injections. Failure to maintain separation between clean and contaminated workspaces has been implicated in outbreaks of bloodborne viruses in hospital settings.

Needle or other sharps re-use

Reusing needles is a well-documented risk factor for the transmission of bloodborne viruses (hepatitis C transmission as a result of use of shared needles by people who inject drugs). Apart from the examples above, where needles may be re-used along with syringes, there are other examples where needles or other sharps or equipment used for injections may be inappropriately used and can give rise to potential disease transmission risks.
Another factor is that these specific types of risks may be associated with other settings apart from hospitals and clinics, such as GP surgeries, care homes, day centres, health fairs, custodial settings and schools. Examples include:

Inappropriate blood glucose monitoring

Monitoring of blood glucose levels is frequently performed to guide therapy for persons with diabetes. The process usually involves the use of fingerstick devices (also called lancing devices) that are used to prick the skin and obtain drops of blood for testing a testing strip where the blood is collected onto as well as a handheld blood glucose meter used to obtain a blood glucose level reading. Exposure to bloodborne viruses can occur as a result of:

- using fingerstick devices or lancets for more than one person
- using a blood glucose meter for more than one person without cleaning and disinfecting it in between uses
- failing to change gloves and perform hand hygiene between fingerstick procedures

Inappropriate insulin administration

Self or assisted insulin administration with insulin pens is common practice in diabetic patients. Insulin pens and other medication cartridges and syringes are for single-patient-use only. Exposure to bloodborne viruses can occur if insulin pens are used for more than one person. This also includes the re-use of insulin demonstration pens from one individual to another during training sessions.

Vacutainer barrel re-use

Observational studies have shown that blood is frequently detected visually or chemically on vacutainers after single and multiple use. The mechanism of contamination is likely by direct contact with blood at the venepuncture site or indirect contact via blood-stained gloves and other phlebotomy apparatus. Contamination of the vacutainer by blood escaping from the rubber-tipped needle to which it is connected is considered less likely as a source of contamination.

Vacutainer re-use has been implicated in the transmission of bloodborne viruses. The mechanism of transmission is thought to have been as a result of indirect contact transmission where the vacutainer might act as a fomite.

The HSE also provides guidance on the management of sharps.[7]

7. http://www.hse.gov.uk/healthservices/needlesticks/

E: Other risks

Human origin products

Less common contamination issues include injection of unregulated stem cells or blood products which are available in private practice or for purchase via online websites. In these circumstances the concerns may be about:

- adequacy of donor screening
- lack of traceability in the system (should a donor subsequently seroconvert)
- production not operating to good manufacturing practice (GMP)
- adequacy of sterility and virus screening and inactivation processes

Information on blood transfusion risks and investigation is available at NHS Blood and Transplant website.[8]

Drug Diversion

Drug diversion is the diversion of a drug intended for a patient to a healthcare worker. It can be defined as any criminal act or deviation that removes a prescription drug from its intended path from the manufacturer to the patient. Risk of infection with bloodborne viruses can occur if a healthcare worker tampers with injectable drugs meant for patients. This can lead to contaminated injection equipment and supplies being present in the patient care environment. Exposure of patents can occur from the use of contaminated drugs or equipment for patient injection or infusion.

8. http://hospital.blood.co.uk/diagnostic-services/reporting-adverse-events/investigation-of-possible-transmission-of-non-bacterial-transfusion-transmitted-infection/

Specific settings

A: Renal dialysis units

There is high risk of bloodborne virus transmission in renal dialysis units hence national guidelines[9] exist which form the cornerstone of prevention, and for which regular clinical audit is required. These guidelines should form an integral part of good practice and of a renal unit's contribution to local clinical governance.

Immunisation of patients

Immunisation against the hepatitis B virus (HBV) is recommended for patients on dialysis[10]. All patients should be immunised before undergoing dialysis. Patients with chronic renal failure should be immunised against hepatitis B as soon as it is anticipated that they may require dialysis or transplantation.

Management of BBV infected patients

Patients infected with HBV and the hepatitis C virus (HCV) should ideally be dialysed in separate isolation facilities. If not available, patients should be segregated in a separate area from other patients during dialysis. Segregation of HIV infected patients should be considered based on a local risk assessment. Because of the risk of cross infection, patients with different BBV infections should not be dialysed in a single segregated area at the same time. Staff caring for infected patients should adhere rigorously to infection control precautions. Guidance on infection control relating to health clearance and management of BBV infected staff can be found in BBVs in healthcare workers: health clearance and management - GOV.UK.

Use of dedicated dialysis machines

Separate machines should be used for patients infected with HBV. Dedicated machines are not required for patients with HCV or HIV provided that cleaning and disinfection processes are properly carried out between patients according to the manufacturers' instructions.

Equipment and prevention of BBV transmission

Dialysers should not be re-used unless specified by the dialyser manufacturer.

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9. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/382207/good_practice_guidelines_renal_dialysis_transplantation.pdf
10. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/503768/2905115_Green_Book_Chapter_18_v3_0W.PDF

If they are not single-use then they should be decontaminated and cleaned appropriately according to the manufacturer's guideline. Accessory equipment supplied for use with renal dialysis machines (for example, tubing) should be disposed of appropriately if designated as single use.

B: Dental practices

Dental practices have different set-ups to hospital and other primary care settings. There are ongoing challenges about who takes responsibility for infection control and, as most dentists are independent providers who may contract with the NHS, private contract or a combination of the 2. Therefore, identifying who supports the risk assessment when a problem is raised may be complicated.

Incidents involving dental practices or practitioners may come to light through a number of routes, including an acute BBV notified to health protection team and dental practice or procedure is the only identified risk factor.

In these situations, problems with infection control may arise from:

- failure to comply or not meet requirements for infection control standards for example, missing or poor infection control audit
- poor documentation of maintenance of washer disinfector or proper use of washer disinfector unclear
- failure of any part of the decontamination cycle
- staff not trained in infection control procedures
- failure to check BBV status of dentists when 'employed' – and for dentist to update practice if this changes.
- failure to use or change gloves
- not changing rinsing cup between patients
- dentist using their own equipment which have not been properly processed for example, ental burs (drill pieces)
- failure of patients to declare their status

As in any case of BBV diagnosis, it is important to recognise that infection may not be from clinical exposure but could be due to personal lifestyle or treatment abroad and it may be difficult to find primary source.

PHE Dental Public Health colleagues and NHSE Dental Advisors can support investigation in these settings and have useful links with the commissioning and contracting aspects of dental practice work, which can be invaluable in identifying patients or procedures undertaken.

C: General practice or primary care settings

A range of procedures are carried out in general practice or primary care settings including immunisation and minor surgical procedures. There may be specific risks relating to the layout and equipment available, including limited facilities for decontamination or more general issues including the re-use of single use equipment as described above (for example, re-use of cautery tips, re-use of syringes in multi-dose vial vaccinations).

D: Non-healthcare settings

There are a wide range of non-healthcare settings where a breach in infection control processes could lead to risk of exposure to BBVs. These include established or registered premises where tattooing and skin piercing, beauty treatments, acupuncture and other therapy are undertaken, but may also include mobile units or peripatetic practitioners who visit clients at home.

Local authority requirements for the special treatment licensing conditions or safety precautions vary between individual local authorities. The tattooing and body piercing toolkit (CIEH toolkit) has been developed to assist local authorities, practitioners and businesses in maintaining effective control of risk in these activities and to promote a consistent approach.

Where an issue has arisen within a non-healthcare type setting it is important to establish the precise details of procedures or treatments offered.

The table below summarises some treatments which could lead to exposure to BBVs. This list is not exhaustive but is included to give examples of procedures to consider.

Table 1: Some treatments which could lead to exposure to BBVs

Acupuncture type treatment	Tattooing type treatment	Cosmetic piercing type treatments	Other
• acupuncture • dry needling • Korean hand therapy • moxibustion	• micro-pigmentation (semi-permanent makeup) • tattooing • tattoo removal • temptooing (temporary tattoos)	• beading • bioskin jetting • body piercing • electrolysis • microdermal anchors	• botox • chiropody/podiatry • cosmetic fillers • wet cupping • dermabrasion • dermaroller • manicures • pedicures • scarification • tongue splitting

Common issues that arise in non-healthcare settings include:

Awareness of infection risks and infection control

- lack of awareness of infection control requirements
- lack of guidance about what basic training is recommended for providers
- lack of appropriate equipment to undertake decontamination
- premises whose design or layout or equipment make it difficult to implement standard infection control practices (lack of wipe-down surfaces, use of soft furnishings and so on)

Record keeping

- lack of ‘health’ type records – often limited information about customers, so undertaking risk assessment is more complicated
- no clear guidance or requirement about what patient information should be collected, where it should be stored or how long for
- no guidance about maintaining a record of supplies purchased nor what, where and for how long this information should be stored

Capacity to respond to incident

- single-handed operators without support for communications to customers or affected persons

Regulation and enforcement

- different levels of regulation or registration required to undertake practices and as a result, different approaches needed to mitigate risks

Materials to support risk assessment and local investigation

Describing and Assessing Risk

Terminology for describing risks

It is important that the terms used to describe risk in these incidents are used consistently. In an ideal situation, the actions recommended would also be consistent for a incidents of the same level of risk, however, as noted below there are often other factors (about the exposure, the population involved or the responsible organisation's wider remit) that may lead to different outcomes of the risk assessment.

The Calman Risk communication is a method of illustrating numerical risks (often involving large numbers) with real world examples. It is useful for providing context regarding terminology, but in BBV-infection control type incidents it should be considered as part of the discussion, with an awareness of the range of assumptions that any calculation is based on.

Term used	Risk range	Example	Risk estimate
High	>1:100	Transmission to susceptible household contacts of measles and chickenpox	1:1-1:2
		Gastrointestinal effects of antibiotics	1:10-1:20
Moderate	1:100-1:1000	Death from smoking 10 cigarettes perday	1:200
		Death all natural causes, age 40	1:850
Low	1:1000-1:10,000	Death from Influenza	1:5000
		Death accident on road	1:8000
Very low	1:10,000-1:100,000	Death from accident at work	1:43,000
		Homicide	1:100,000
Minimal	1:100,000-1:1,000,000	Death from train accident	1:500,000
		Vaccination associated polio	1:1,000,000
Negligible	<1:1,000,000	Hit by lightning	1:10,000,000

Calman K C (1996) Cancer: Science and Society and The Communication of Risk. BMJ: British Medical Journal, 313,7060, 799-802
http://www.bmj.com/content/315/7113/939.long

Most BBV infection control incidents would be considered very low or minimal risk, although calculating a numerical estimate of risk in these types of incidents is difficult (see below).

Assessing risk of transmission

The risk of transmission is often hard to define and depends on a number of factors listed below. There may be evidence in the literature about the transmission risk in similar past situations.

Main points to recognise are:

- risk assessment requires a combination of information on a number of different aspects of the incident
- there is no simple numerical cut-off for when further public health action is or is not indicated
- judgement about the actions required will be based on all factors in the incident, not just the public health risk assessment
- each incident will be different and the actions taken will be very dependent on the individual circumstances identified

See Appendix A for a review of the evidence of transmission from decontamination failures that was undertaken as part of a recent investigation.

Phases of risk assessment

The process of risk assessment can be divided into:

1. Initial information gathering and preliminary assessment of risk

Factors to consider at this stage include:

Prevalence of BBV in the source population

To be able to estimate the prevalence of BBVs in the source population, the demographic characteristics of this population need to be considered with respect to risk factors for BBV. This will help to ensure that the most comparable reference population BBV rates are used. Risk factor information to enquire about includes age, sex, ethnicity, sexual orientation, country of birth and geography of residence.

Discuss the various sources of information available on BBV prevalence rates in reference populations with your local FS team. For HIV, these include:

- diagnosed HIV prevalence in the adult population by LA (PHE fingertips)
- diagnosed HIV prevalence rates by ethnic group by PHE Centre
- estimates of total (undiagnosed and diagnosed) HIV prevalence in different risk groups in London and outside London
- antenatal screening data.

For HBV, these include antenatal screening data at a Trust level. For HCV, these include modelled estimates of HCV prevalence by LA. A range of rates can be used for example, low and high estimates to capture uncertainty.

It is also worth identifying whether there are any known BBV diagnoses among the source population and whether there is any assessment for BBV – for example, are patients asked about their BBV status or tested – and whether this is documented in the notes.
The results of any matching exercise of the source population to BBV databases may also alter the risk assessment.

Degree of contamination of device

An assessment needs to be made as to whether the device in question has been exposed to body fluids possibly containing a bloodborne virus and to what extent. The assessment should also refer to decontamination failure and the individual significance of that or those failure(s). (See Overview of infection control risks.)

Transmission risk of individual procedure

It is often very difficult to estimate the transmission risk of individual procedures. A literature review may identify evidence from past incidents. In addition, comparisons may be able to be made with routes of transmission where good evidence exists for example, BBV transmission after needlestick incidents[11]. In the absence of known BBV infection in the source population for example, a known HIV positive patient, the risk of hepatitis B transmission is typically much higher than hepatitis C, which in turn is much higher than HIV.

Any known transmission event will obviously impact on the risk assessment. In addition, the results of any matching exercise of the at risk population to BBV databases may also alter the risk assessment.

In the case of a device not being decontaminated appropriately it is important to consider a) the particular use of the device with consideration of potential routes of transmission of BBV for example, percutaneous use b) the likely partial effectiveness of any cleaning measures in reducing BBVs including consideration of the ability of the device to be decontaminated appropriately due to damage and c) the frequency of use of the device (and therefore the time period between use in sequential patients – relating to survival of BBVs).

It may be helpful to consider the number of times or length of time after a device has been used on an infected patient beyond which there is unlikely to be an increased risk of BBV transmission for example, due to partial effectiveness of cleaning employed or due the length of time reducing survival of BBVs.

Period of risk

It is important to try and define the period of increased risk over and above what may be expected in normal practice for example, is there a date when a) robust measures were last known to be in place b) a particular device was used c) a particular operator was working. It may help to get independent professional opinion as to expected normal and likely variation in practice.

Population at risk

The characteristics of the population at risk also need to be considered regarding their increased susceptibility to, or complications from, being infected with a BBV for example, underlying liver disease, immunocompromised status.

11. Beltrami EM, Williams E, Shapiro C, Chamberland ME. Risk and Management of Blood Borne Infections in Health Care Workers. Clinical Microbiology Reviews (2000) 13(3) 385-407

Quantifying risk

The presence of a BBV is one part of the chain of events required for BBV transmission and can be estimated through record linkage between the list of patients at risk and existing BBV (HIV, HBV and HCV) diagnosis databases. The estimated risk of transmission thereafter can be calculated by multiplying the independent probabilities of each step in the chain. It is important to note that there are no clearly defined numerical cut-off values for action or no action and the range of risk calculated is likely to be wide due to the inaccuracies in some of the data used and the number of assumptions that have to be made.

A number of risk calculators for use in this type of incidents are available[12,13,14,15] but the accuracy or utility of the calculation is very dependent on the estimates used to parameterise it. There are also differing views about whether it is appropriate to attempt to quantify the risk for every incident (for example, whether using population models to estimate risk from an individual index case or exposure), so appropriateness and applicability should be discussed as part of risk assessment.

In general, any quantified risk should be considered in conjunction with the qualitative assessment and should not be the deciding factor alone on subsequent actions.

If local investigators wish to formally calculate risk, there should be a discussion with the epidemiology teams from the National Infection Service. Risk calculators may have been developed for other scenarios which may be adapted.[16]

Outcome of initial risk assessment

Following the initial stage of risk assessment, it may be clear that there is no risk requiring further action at which point the investigation can be closed. A more likely

12. Saskatchewan Health: Population Health Branch (2009). Assessing Risk from Syringe Re-use in Saskatchewan: Report. Available at: http://www.health.gov.sk.ca/syringe-re-use-assessment
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16. A risk calculator generated by team within NIS (Dr Nick Andrews) has been used in recent incidents: contact NIS team for further information

situation is that there will be some uncertainty about the risk and further investigation is required.

2. Refining the risk assessment

Cross-matching a list of exposed patients (or members of the public) against databases or registers of known cases of BBV infections can provide further refinement of the risk assessment.

It is important to recognise the limitations of cross-matching, in particular the fact that not all people with a BBV infection have had it diagnosed, different levels of reporting to databases (local vs. national) and the likelihood of testing for BBVs in different demographic groups.

It is not always necessary to undertake a cross-matching exercise; the decision will be based on factors relating to the type of infection control breach and practical considerations regarding data available and possible wider concerns within the reporting organisation.

Appendix C describes the process including information required by local and national teams.

Examples of possible outcomes following risk assessment

There are a number of possible outcomes of the risk assessment. It should be noted that risk assessment is a dynamic process which can change as more information comes to light. As a result of this, recommended actions may also change.

If a transmission event is identified or suspected, further public health actions (identifying at risk population and consideration of patient notification) will almost always be indicated.

Outcomes can be summarised as:

No risk identified

- no action required

Risk considered extremely low or minimal and no further investigation required

- consider whether communication to exposed patients or customers is needed
- consider whether regulation or improvement or enforcement actions is required
- consider whether ‘near miss’ has occurred and needs to be flagged

Risk to patients identified

- this may be based on quantifiable risk or on the description of the failed process.
- in these circumstances, more detailed investigations may be indicated; standard approaches to reporting risk (including messages to public / media) should be followed

Patient notification exercise

Once the risk assessment has been completed, a Patient Notification Exercise (PNE) may be indicated.

There is a range of levels of notification that could be considered including:

- 'information only' providing information to patients about the risk or exposure but reassuring that, following expert risk assessment, no further action required
- offering test or screening – providing information about the exposure, reassuring that risk if very low but offering or test (as a reassurance) if requested; this may include suggesting that tests are undertaken by GPs – and will require close liaison with primary care or other services
- recommending test or screening – this would be the most 'proactive' approach to PNE and would be implemented when highest level of concern (for example, an identified transmission event); it may include arranging dedicated testing or screening clinics, helplines and proactive media messages to ensure that all those potentially exposed are made aware

Details of the practical steps involved in undertaking a PNE are available in guidance published by the UK Advisory Panel for Healthcare Workers Infected with Bloodborne Viruses (UKAP) BBVs in healthcare workers: health clearance and management - GOV.UK.

Appendix A: Review of transmission risk

Evidence from past incidents involving endoscope decontamination failure (prepared as part of incident response, 2016)

The risk of bloodborne virus transmission with an inadequately decontaminated endoscope during endoscopic investigation is likely to be low (1). Different mechanisms and extents of decontamination failure could also be associated with different levels of infection transmission risk. Based upon the lack of suitable and available documented evidence it is not possible to quantify what the associated levels of risk are. However, failure to decontaminate an endoscope adequately has been associated with the transmission of a number of bacterial infections from one patient to another (1). Implicated bacteria have included salmonella, pseudomonas and mycobacteria (2) (3). Transmission of BBVs has been associated with endoscopy but the associated lapses in infection control procedures are unclear. It has been speculated that transmission of a bloodborne virus infection may be more difficult to associate with the endoscopic procedure undertaken due to the longer incubation period of these diseases.

A previous systematic review identified literature on the risk of patient-to-patient transmission of bloodborne viruses at endoscopy associated with recognised lapses in endoscope decontamination (1). The results from the review suggested that the transmission risk of a bloodborne virus at endoscopy is low, even with inadequate decontamination procedures.

Considering hepatitis B, C and HIV, hepatitis B is known to be the most infectious. However, the results of this systematic review of transmission of hepatitis B following endoscopy did suggest that although transmission of hepatitis B may occur following failure to decontaminate the endoscope adequately, it is likely to be low.

In May 2004, the Northern Ireland Adverse Incidents Centre (NIAIC) informed the UK Medicines and Healthcare Products Regulatory Agency (MHRA) of an endoscope decontamination failure reported from a hospital (4). A medical advice alert was issued by the MHRA and an Endoscope Task Force was established. Its main objectives were; to review endoscope decontamination incidents and to ensure a co-ordinated approach in terms of risk communication, provision of advice on the management of incidents and further action required to protect public health.

A systematic review of the evidence on patient-to-patient transmission of bloodborne viruses following upper or lower gastrointestinal endoscopy was also undertaken, in order to help the Endoscope Task Force in its consideration of decontamination failures. The literature review, covering incidents in England from 2003 to 2004, indicated that endoscopy carried a very low risk of transmission of bloodborne viruses.

Following the review, the Endoscope Task Force issued a list of 10 recommendations which included the following 2 points which are pertinent to this current incident. These were that:

- all endoscope users must ensure that endoscopes are reprocessed and decontaminated according to the appropriate manufacturer's instructions
- there is a requirement to be able to trace endoscopes through the decontamination process, and be able to link the endoscope to the patients on whom they had been used. This information should be documented and subject to audit

Appendix B: Checklist for initial information gathering

General questions: all incidents

There are a number of settings where an incident could lead to exposure to bloodborne viruses and subsequent transmission beyond the setting identified. There are a number of key questions that should be considered to gather some basic information around the incident that will help guide the risk assessment.

General questions to consider include:

- **pathogen:** which BBV has been identified or indicated that person(s) or patient(s) have been exposed to (if known)?
- **source:** has the source been identified?
- **setting:** where did the incident or exposure(s) occur?
- **period:** what period is covered in relation to the incident or exposure, for example a single point in time or continuous exposure over a defined period? Dates and time of when incident or exposure occurred
- if the exact date of onset of failure of an automated decontamination process cannot be established, use routine test records to establish when a process was last verified as adequate (for example, endoscope washer-disinfector last tested on a particular date and working adequately)

Detail about the procedures and points of failure

Questions on clinical or surgical procedures include:

- what procedures has the person(s) or patient(s) been subjected to? For example, dentistry, endoscopicinvestigation, haemodialysis, cardiothoracic surgery, stem cell treatment, acupuncture, alternative medical therapies
- who did what and when?
  - staff explain how they undertook procedure
  - you may need to speak to colleagues – for example, dental assistants – to triangulate information and provide supporting evidence
  - were any incidents recorded or witnessed?
- what training did they have?
  - are they qualified or bogus?

Questions on infection control procedures include:

- who did what and when?
  - ask staff explain how they undertook procedure
  - may need to speak to colleagues for example, dental assistants to triangulate information and provide supporting evidence
  - any incidents recorded or witnessed
- what infection control training did they have?
  - are they suitably qualified?
- maintenance records of cleaning equipment or medical device
- documentary evidence of correct procedures
- expert examination of cleaning equipment to assess functionality
- expert examination of medical device to assess whether possible to clean robustly
- previous infection control or other audits?
- consider asking independent professional group expert for example, ENT surgeon – of normal expected practice
- try to identify time points when particular practice started or stopped.
- do procedures differ in different settings – for example, same surgeon, but instruments cleaned differently in different locations?

Questions related to exposed persons include:

- **index cases(s):** number of index cases, if any, that have been identified, that is person or persons identified as the initial case(s) reported in a chain of infection, or a single case with no known secondary cases
  - the index case(s) represent(s) the starting point for the process of contact tracing and may or may not have infected other persons (contacts)
- **source population:** for example, likelihood of BBV among source population – private patients or non-UK born or particular ethnicity or origin or BBV risk group – use local epidemiological information
  - any known to be BBV infected?
  - are people are asked about BBV status?
  - is this documented?
  - what is the infectious status of any known positives?
- **exposed population[17]:** who and how many persons/patients have been exposed to the pathogen?
  - can the exposed population be clearly defined?
  - is there any information on the exposure/procedures the person/patients have been subject to?
  - any private patients?
  - any known to be immunocompromised?
  - any known to have died?

17. Exposed and source population are often the same if infection control incident

- **patient records:** is there any available stored information on the persons/patients, for example, medical records (including record of any procedure, infection(ious) status, GP letters), theatre records, GP records, billing information?
  - is there information that enables a patient to be contacted, for example, address, telephone, email?
  - where are they?
  - who has access?
  - are they electronically held or paper copies?
  - see appendix for guidance on legal position re information sharing.
- **immunisation status:** is there evidence that the person/patients or HCW have had a response to the hepatitis B vaccine providing evidence of vaccine induced immunity?
- **contact of cases:** are there any potential contacts of the index cases that have been identified?
  - a 'contact' being defines as a person with relevant exposure to an infectious or potentially infectious index case
  - the relevancy of exposure is assessed and described by referring to event-specific factors such as pathogen, infectiousness of index case, infectious period, availability and validity of information on exposure, possible alternative exposures, risk factors for infection, immunisation status, and susceptibility of contacts

Information about actions taken so far should also be gathered, for example:

- **source:** if this is a medical instrument has use of the instrument ceased?
  - is the source a healthcare worker infected with a BBV? If so, has the HCW been stopped from practising?
- **instruments:** have implicated instruments/equipment been prevented from being used, isolated and stored for further investigation?
- **further control measures:** what control measures have already been put in place for example, cleaning, decontamination, isolation?
- **case finding:** have any known individuals positive for a BBV been identified when interrogating patient records?
- **visit to setting:** have the premises/site where the incident or exposures occurred been visited?

In relation to the index case (if known), consider the following:

- **post exposure prophylaxis:** has post exposure prophylaxis (PEP) been administered?
  - if PEP has been administered, is there exact information on how many of those exposed (and contact persons of cases) actually received PEP?
- **immunisation:** have Occupational Health records been checked to identify those successfully immunised against hepatitis B infection?
  - has hepatitis B immunisation history of HCW been checked and is there evidence of a recorded protective response to vaccine?

- **successfully traced contacts:** the term ‘successfully traced contacts’ is used for contacts with clear evidence of infection/non-infection, for example, laboratory evidence or clinical diagnosis
  - if laboratory tests were not available, the absence of symptoms after 2 incubation periods is considered as evidence of non-infection.

Specific questions for dialysis unit incidents include:

- numbers of patients being dialysed and whether or not they have been immunised against hepatitis B
- number of dialysis machines being used
- area where patients are dialysed and availability of segregated areas
- hepatitis B Immune status of patients (if known) (and staff if necessary)
- procedures for immunising new patients coming on to the dialysis unit
- decontamination methods for dialysis machines and itemisation of single-use machine accessories
- environmental practices in place for cleaning and decontamination of the renal unit areas where dialysis is carried out
- use of staff protective clothing (for example, appropriate changing of gloves)
- any lapses in infection control with respect to any equipment

Incident management arrangements should include:

- considering whether an ICT should be established. If yes, which organisation is leading? Which other organisations are involved?
- general principles of an ICT should be shared with all stakeholders
- agree questions to be asked / information to be gathered at ICT meeting
- agree who should liaise with clinician involved, preferably single person to promote trust and relationship building
- discuss how best to obtain written copies of evidence for example, signed copy of interview notes
- external organisations may need to be involved, for example UKAP, CIEH, MHRA, GMC/GDC and other regulatory bodies, CQC, NHS England, DPH, Medical Directors at affected healthcare settings

Appendix C: Policy and wider guidance

Comprehensive guidance on the decontamination (cleaning, disinfection and sterilisation) of medical devices can be found in the Department of Health's Health Technical Memorandum (HTM) 01 series, all of which are freely available on the government website www.gov.uk:

- HTM 01-01 covers the decontamination of reusable surgical instruments
- HTM 01-04 covers healthcare laundry
- HTM 01-05 covers decontamination in dentistry
- HTM 01-06 covers the decontamination of flexible endoscopes

These should be used as guidance but cannot be definitive in terms of assessing the possibility of BBV transmission. There may be decontamination non-compliances that still represent adequate prevention of BBV transmission.

It should be noted that compliance with guidelines does not exclude hazardous procedures not covered, for example placing a sterilized instrument on a contaminated surface

Appendix D: Cross-matching

Cross-matching is a process by which the patient details are compared against laboratory and surveillance databases for BBVs at local and national levels. This has 3 primary purposes:

- to ascertain possible unrecognised BBV transmission
- to ascertain BBV status of the source population
- a team should be nominated to manage the patient list and coordinate cross-matching

Process

The main components of cross-matching are to:

- generate a patient list
- cross-match against local laboratory BBV data
- cross-match against national BBV datasets

Information governance and data protection

The collection of clinical data for the cross-matching is required for health protection purposes as part of a public health investigation therefore ethical approval is not required.

All data held by the NHS is managed in accordance with the Data Protection Act and NHS Caldicott Guidelines. Any individual accessing patient information must comply with these and maintain confidentiality.

PHE staff process all information under medical supervision and are trained to treat any personal details in the strictest confidence, in compliance with the Data Protection Act and NHS Caldicott Guidelines. Any deliberate or negligent breaches of these may be disciplinary offences.

Patient list

A patient list of the source population and those potentially exposed will be required as guided by the IMT regarding the period of interest. This can be used as a basis to cross check against local laboratory information and national PHE NIS BBV datasets.

Personal identifiable information must be included in order to support the cross-match comparison with known BBV cases. The Patient Demographic Service should be used to enrich the patient list with missing patient information. This is particularly useful for instances where NHS number, first name, last name, date of birth or sex are missing.

Field list

Suggested fields for this dataset are:

- your ID number
- NHS number
- hospital Number
- hospital
- first name
- surname all (double barrel names included)
- surnames 1 (first of double barrel names separated)
- surname 2 (second of double barrel names separated)
- date of birth (dd/mm/yyyy)
- sex (M/F)
- postcode of residence
- local authority of residence
- lower Super Output Area (LSOA)
- first relevant date of interest for example, date of procedure
- second relevant date of interest for example, date of procedure
- third relevant date of interest, for example, date of procedure

Data cleaning prior to cross-match

The following steps should be followed when cleaning data prior to cross-match:

- ensure the variable holding the patient NHS number is of a numerical type and not string or free text
- generate separate variables for first name and last name (if the data is not already structured as such)
- amend the first name and surname variable types to free text, removing any capitalisations (in case the cross-matching software package used is case-sensitive) and removing hyphens
- identify and split multiple and hyphenated first names and last names, storing these as separate variables – surname 1 and surname 2 (code with sequential unique names) for example, ‘smith-davis’ becomes ‘smith and ‘davis’
- remove any extraneous spaces before or after each data item recorded in each variable for example, ‘smith’ becomes ‘smith’
- where there are multiple dates of interest for example, procedure dates, for the same patient, reshape the data to wide format such that each row represents a single patient (code additional procedures with sequential unique names) for example, date_1, date_2 and so on
- save the cleaned data with a unique filename

Cross-matching against local laboratory data

The cross-match process itself will include:

- local laboratory data serving the health care provider(s) should be checked in case BBV positive patients have not been reported to PHE, that is, they are on the laboratory information management system (LIMS) but have not been reported to PHE's Second Generation Surveillance System (SGSS)

- health care providers should generate a list of positive isolates for the BBV of interest from their local microbiology laboratory
  - it is recommended that LIMS are searched to provide the requested data
  - each laboratory should have technical staff skilled and trained to undertake such tasks
  - local health care providers need clear guidance from the incident lead regarding the specified dates they should use to generate the laboratory list

Local cross-match process

Once the cross-match data has been provided locally, the following actions are recommended:

- open the cleaned patient list data
- using a computer package such as STATA, merge this dataset with the cleaned laboratory data file, using combinations of NHS number, last name, first name and date of birth
  - where multiple or hyphenated first names and last names existed, cross-matching should also be performed on the sequentially named variables holding these data
- any identified positive matches should be reviewed to confirm the veracity of these (that is, number of matched identifiers, specific fields matched and so on)
  - the specimen date of each matched isolate should be reviewed with reference to the date of interest, noting if the specimen date preceded the date of interest or was less than the incubation period of the BBV
  - health care providers should record if any positive matches fall into the following groups: deceased (consider identifying the cause of death), stillbirths/neonatal deaths, terminally ill, patients suing the Health Care Provider
- following completion of each local cross-matching exercise, health care providers should record the outcome of:
  - a) the summary of the process – period of interest, number of positives checked, number of matches
  - b) details of individuals with a match and provide these to the designated coordinator in a secure manner

The above rigorous approach to matching on combinations of patient identifiers is suggested due to possible differences between datasets in how these variables may be coded or recorded. For instance, differences in spelling names and multiple NHS numbers relating to the same patient have been identified in cross-matching.

National cross-match process

Contact should be made with the PHE National Infection Service (NIS) HIV and Hepatitis teams regarding cross-matching against national datasets.

HIV

To arrange cross-matching for HIV, please contact the NIS HIV team: HARSQueries@phe.gov.uk

The HIV team will carry out the cross-matching within 10 working days.

The NIS HIV team holds a database of individuals ever diagnosed with HIV in the UK, and those accessing HIV care. These data are used to inform the public health response to HIV infection and for the planning of services. Due to the sensitive nature of these data, the HIV team does not directly collect full name and address, but use a 'surname soundex', and first initial. Together with date of birth and sex, this provides a reliable mechanism for surveillance purposes for de-duplicating patients diagnosed at more than one setting, and to follow up patients in care to assess their clinical outcomes. However, while this level of information is sufficient for surveillance purposes, at the individual level the HIV team cannot definitively use this information to confirm whether individuals have been diagnosed with HIV.

The following additional caveats apply regarding the national cross-matching process:

- there are a small number of people who use different personal identifiers when accessing HIV care. Therefore matching based on soundex, date of birth and sex may not have detected such individuals
- individuals with an undiagnosed infection will not be detected through this linkage as the databases contain only individuals who have been diagnosed with HIV infection

The HIV team need the following core information:

- first name
- surname (no hyphens)
- date of Birth (dd/mm/yyyy)
- sex (M/F)

The following fields will also help the cross-matching process so should be provided if available:

- your ID number
- hospital number
- hospital name
- postcode of residence
- local authority of residence
- LSOA

The HIV team will code the first name and surname into initial and soundex code respectively for matching and the first name and surname will then be deleted.

The patient list should be transferred via the HIV team's secure web portal. The HIV team can set you up a web portal account.

Hepatitis B and C

To arrange cross-matching for hepatitis B and C please contact the NIS hepatitis team: koye.balogun@phe.gov.uk

Depending on whether just hepatitis B or C is required or both, this cross-matching can take 2 to 3 weeks.

NIS hepatitis surveillance databases include laboratory reports of acute and chronic hepatitis B diagnoses and hepatitis C reported from England and Wales going back to the early 1990s and updated on a monthly basis from SGSS.

Data should be sent in a password-protected Excel spread sheet in the following format with the following core variables:

- your ID number
- first name
- surname
- date of Birth (dd/mm/yyyy)
- sex (M/F)

The following fields will also help the cross-matching process so should be provided if available:

- hospital number
- postcode of residence

Please ensure there are no commas, full stops, question marks, exclamation marks asterisks or any other characters in any of the data fields apart from the required text as set out below.

Your ID number	First name	Surname	DOB	Sex
1	George	Smith	22/11/1944	M
2	Sandra	Leah Carter	13/09/2011	F
3	Simone	De Souza	23/05/1979	F
4	William	O'Leary	12/11/1965	M
5	Katy Sarah	Jones	13/09/2001	F

Of note to include:

- first name (if there is a second and third name or more, please include in the same column as the first name, as in 5)
- apostrophes in forenames or surnames are acceptable (4)

The patient list will be matched against the national hepatitis surveillance database that is required. The highest level match will be those that match on first name, surname, date of birth (and sex). These highest level matches will be returned by password protected Excel spreadsheet to the local requesting team.

Appendix E: Guidance on information sharing in relation to public health incidents

This is covered by the The Health Service (Control of Patient Information) Regulations 2002

Guidance from the General Medical Council

In the public interest:
http://www.gmc-uk.org/guidance/ethical_guidance/confidentiality_36_39_the_public_interest.asp

To protect others:
http://www.gmc-uk.org/guidance/ethical_guidance/confidentiality_53_56_disclosures_to_protect_others.asp

About serious communicable diseases:
http://www.gmc-uk.org/guidance/ethical_guidance/30080.asp

Includes notifications:
http://www.gmc-uk.org/guidance/ethical_guidance/confidentiality_17_23_disclosures_required_by_law.asp

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