Guidelines for the public health management of tetanus, botulism or anthrax among people who use drugs.

NHS National Services Scotland

Scottish Health Protection Network

Scottish Guidance No 11.

Health Protection Scotland

Document Amendment Log

Version No.	Date	Page No.	Amendment Summary

The Scottish Health Protection Network (SHPN) is an obligate (jointly owned) network of existing professionals, organisations and groups in the health protection community across Scotland. The aims of the network are:

- To ensure Scotland has a Health Protection service of the highest quality and effectiveness that is able to respond to short term pressures and to long term challenges.
- To oversee the co-ordination of Scotland's health protection services under a network that promotes joint ownership and equitable access to a sustainable and consistent service.
- To minimise the risk and impact of communicable diseases and other (non-communicable) hazards on the population of Scotland and to derive long term public health benefits (outcomes) through the concerted efforts of health protection practitioners across Scotland.

In line with the above, SHPN supports a systematic approach to the development, appraisal and adaptation of health protection guidance, seeking excellence in health protection practice.

Health Protection Scotland
Health Protection Scotland (HPS) is a non-profit, public sector organisation which is part of the Scottish National Health Service. It is dedicated to the protection of the public's health.

Health Protection Scotland is part of NHS National Services Scotland.

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Professionals involved in the implementation of recommendations proposed in this document are expected to take them fully into account when exercising their professional judgment. The document does not, however, override the individual responsibility of professionals to make decisions appropriate to the circumstances of the individual cases, in consultation with partner agencies and stakeholders. Professionals are also reminded that it is their responsibility to interpret and implement these recommendations in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this document should be interpreted in a way which would be inconsistent with compliance with those duties.

Designed and typeset by:
Graphics Team, Health Protection Scotland

Table of Contents

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Comments on the published guidance

Comments on this guidance should be sent to the SHPN Guidance Group by emailing NSS.SHPN@nhs.net.

Acronyms and glossary

A&E	Accident and emergency department
ADP	Alcohol and Drug Partnership
AIGIV	Anthrax Immunoglobulin Intravenous
BBV	Blood-borne virus
CMO	Chief Medical Officer
COPFS	Crown Office Procurator Fiscal Service
CPHM	Consultant in Public Health Medicine
DPA	Data Protection Act 1998
ECDC	European Centre for Prevention and Disease Control
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
GBRU	Gastrointestinal Bacteria Reference Laboratory
GDG	Guidance Development Group
GMC	General Medical Council
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HNIG	Human Normal Immunoglobulin
SHPN	Scottish Health Protection Network
HPS	Health Protection Scotland
HPT	Health Protection Team
IEP	Injecting equipment provider/provision
IHR	International Health Regulations
IMT	Incident management team
ITU	Intensive treatment unit
LA	Local Authority
NHS	National Health Service
NSS	National Services Scotland
OST	Opioid substitution therapy
PAG	Problem Assessment Group
PHE	Public Health England
PHW	Public Health Wales
PII	Personal identifiable information
PWID	People who inject drugs
PWUD	People who use drugs
RIPL	Rare and Imported Pathogens Laboratory
SDF	Scottish Drugs Forum
SFB	Spore-forming bacteria
SMI	Standards for Microbiological Investigations
SSTI	Serious soft tissue infection
TIG	Tetanus Immunoglobulin
UK	United Kingdom

1. Introduction

1.1 Background

The association between injecting drug use and serious infections has long been recognised, with the earliest published incident a case of tetanus after the subcutaneous injection of morphine [1]. Infections, associated with drug use, caused by a wide range of bacterial, viral, fungal and protozoal pathogens have now been reported in the scientific literature [2].

Spores from clostridium and bacillus bacterial species are widely found in the environment; these spores are highly resistant to hostile conditions and can survive for long periods of time. Illness occurs when – following intravenous, intramuscular or subcutaneous injection – the spores germinate and produce potent toxins. These organisms often initially cause localised infections with the potent toxins they produce, resulting in severe systemic illnesses that can result in death [3]. The most likely source of spores is considered to be drugs, which may have become contaminated during processing, transport or storage [4]. Other sources of possible contamination are drug adulterants or cutting agents, that are used to increase the bulk of illegal drugs, or spores on the soiled hands of users and dirty injecting equipment [4; 5].

Since 2000, the UK has seen the emergence of illness among people who inject drugs (PWID) caused by toxins produced by spore-forming bacteria (SFB). Prior to this point, illness caused by SFB was more common in the United States and was associated with the use of black tar heroin from Mexico [6-8]. Few cases had been observed in Europe, where brown heroin originating from Afghanistan and Pakistan dominates the market. The majority of cases in Scotland have been observed during four major clusters:

- in 2000 and 2001, an outbreak of *Clostridium novyi* affected PWID across the UK and Ireland [9; 10];
- an outbreak of injecting-related tetanus cases was observed from 2003 to 2005, with “skin popping” the main route of exposure [11];
- the emergence of anthrax among drug users was first recorded in an outbreak during 2009 and 2010 [12; 13];
- the largest cluster of botulism cases among drug users seen so far in Europe, occurred over the first six months of 2015 [14].

Outwith these clusters, sporadic cases of tetanus and botulism have continued to be recorded among PWID in the UK [14]. Aside from the presumed point source outbreak mentioned above, *Clostridium novyi* has remained an uncommon isolate in injecting-related necrotising soft tissue infection [5].

While cases of illness caused by SFB have also been reported in two other north-western European countries that neighbour the UK (Norway and Ireland), few have been reported elsewhere in Europe [4]. Furthermore, there is marked regional variation within the UK, with higher rates of infections by SFB having been observed among people who use drugs in Scotland (especially in Glasgow), as compared with England [5]. The reasons for this marked regional variation remain unclear but might reflect drug trafficking routes, the type of drugs injected locally and/or differences in local injecting practices. For example, there is potentially a greater opportunity for the contamination of drugs to occur en route, given that Scotland lies at the end of many drug trafficking routes. Practices such as injecting into the skin or muscle, which tend to be more common among older injecting populations (due to vein damage caused by long periods of injecting drug use) may also increase the risk of infection [4; 5].

In the UK, microbiological testing has usually been unable to confirm the presence of bacterial species in surrendered or seized heroin linked to a clinical case [15], although *Clostridium botulinum* was isolated from a sample of heroin seized in Scotland in 2009 (K. Grant, personal communication).

This document provides guidance on the public health management of illnesses caused by SFB among PWID. The guidance focuses on the three infections that are considered to be a continuing, significant risk to public health and that are commonly encountered in an outbreak context, namely tetanus, botulism and anthrax (hereafter referred to as SFB). The principles of the approach can, however, also be applied to incidents of severe illness among PWID caused by other pathogenic SFB which may have a significant health impact (e.g. *Clostridium histolyticum*, *Clostridium perfringens*, *Clostridium sordellii* and *Clostridium novyi*).

The guidance aims to eliminate or minimise the risk of, and consequences from, infection and seeks to clarify the roles and responsibilities of the different organisations involved in the public health response. The guidance does not deal with the clinical management of the specific illnesses other than that required for the prevention of illness, e.g. post-exposure prophylaxis where appropriate. Guidelines on the clinical management are available from professional sources elsewhere though, in general, supportive care and sedation is accompanied by administration of antitoxin or immunoglobulin to inactivate unbound toxin, local wound drainage, debridement and antibiotics to halt further toxin production.

1.2 A note about the target population of these recommendations

Although the section above has alluded to injecting drug use as the main risk factor for acquisition of the infections of interest, it should be noted that, in the case of anthrax, the possibility that infection was acquired via the inhalation of drugs cannot be excluded [12; 16; 17]. Therefore, although the Guidance Development Group (GDG) acknowledges that the majority of SFB infections are likely associated with injecting drug use, this guidance will refer to the at-risk population as people who use drugs (PWUD), rather than PWID.

1.3 Rationale for the guidance

Due to the widespread occurrence of these spores, contamination is considered to be ongoing and it is clear that there is the potential for further outbreaks of SFB among PWUD. From previous outbreaks in Scotland, much experiential learning has been gained in a number of health boards across the years on the effective public health management of such outbreaks with all their complexities. For the first time, the experience of many of these individuals and the lessons learned from previous outbreaks has been considered and gathered into a single document, alongside expert knowledge and published evidence where available.

1.4 Intended users of this guidance

This guidance is intended for all those likely to be involved in the management of such incidents in Scotland, including:

- public health professionals, who may be required to carry out public health actions associated with a case of tetanus, botulism or anthrax;
- frontline staff, including those in drug/addiction and injecting equipment provision services, who play an important role in communicating harm reduction messages;
- police officers, who may carry out actions associated with identifying sources of contaminated heroin supplies, investigating distribution networks and potentially confiscating supplies where possible.

1.5 Development of this guidance

Details on the guideline development process, and membership of the Guidance Development Group, are provided in Appendix A.

2. Initial response

2.1 Statutory notification and reporting of spore-forming bacteria

The primary purpose of statutory notification is to give early warning of potential threats to human health caused by infectious disease, contamination and other hazards in order to assess if appropriate health protection action might be required (if any), to minimize the spread of such disease and the subsequent risk to human health. Notification is based on reasonable clinical suspicion and should not await laboratory confirmation. If the diagnosis later proves incorrect, the notification can be changed or denotified.

The rapid detection of future outbreaks is dependent on prompt recognition of possible cases. Anthrax, botulism and tetanus (and their causative agents) are all statutorily notifiable by a registered medical practitioner and diagnostic laboratories under the Public Health Act (Scotland) 2008 [18]. Suspected cases (clinically diagnosed but awaiting laboratory confirmation) and laboratory confirmed cases should all be notified to the appropriate health board Health Protection Team (HPT) urgently. In turn, health board HPTs should inform Health Protection Scotland (HPS) following receipt of such a notification.

2.2 Actions in the event of notification of a suspected case

At the time of report, a case of infection caused by SFB in PWUD may or may not be confirmed by the reference laboratory. Case definitions are detailed in section 3.1; laboratory diagnosis is detailed in section 4.

It is important that the diagnosis of botulism and tetanus is made promptly on the basis of clinical presentation, and that treatment is not delayed whilst waiting for laboratory confirmation. However, if such a diagnosis is made clinically then duty doctors should work with their local microbiologists to ensure appropriate samples are taken for testing before antitoxin and antibiotics are administered (see section 4).

Responsibility for leading and managing incidents of SFB associated with PWUD rests with a Consultant in Public Health Medicine (CPHM) or registered Specialist in Public Health, on behalf of the health board. Thresholds for the type of investigation and who should lead this investigation are detailed in Table 1 and will depend on other relevant cases described locally, nationally or in neighbouring countries. The scale of the response will be determined by the nature of the incident, which will also dictate the resources required, responsibility for the management of the incident and the communications pathways. For most incidents, it is unlikely that there will be significant risk to public health beyond the population directly exposed to the contaminated drug: there is negligible risk of SFB infection to frontline workers (e.g. police or environmental health

officers) or the public from drugs, drug litter or environmental contamination. However, the impact may extend beyond a single health board area. These actions are in line with those described in the Health Protection Network (HPN) guidance on the management of public health incidents [19], but with the added complexity that these are serious and unusual infections with a high mortality rate in a vulnerable group of people.

A single case of SFB infection in PWUD should be investigated promptly and trigger appropriate public health action. Local HPTs should ensure:

- that appropriate specimens are obtained for specialist testing and/or confirmation;
- the prompt completion, and return to HPS, of the relevant enhanced surveillance form (see section 3.2);
- local awareness-raising with both clinicians and frontline workers on the signs and symptoms of infection to ensure prompt diagnosis of further cases should they occur.

Table 1: Response required for one or more reports of spore-forming bacterial infections associated with people who use or inject drugs.

Organism	Management	Resources	Briefing
Sporadic case (a single case which is more than six weeks since the last case in the same geographical area and no increase in cases or cluster in neighbouring countries)			
Tetanus or Botulism	Health board led PAG Investigation managed locally	Local HPT	HPS
Anthrax	Health board led PAG Investigation managed locally	Local HPT	HPS (re Scottish alert) DPH in health board SGHD according to protocol PHE (re UK and Euro alert) IHR (re international alert) as appropriate
Two sporadic cases (two cases in more than one health board area which occur within six weeks of each other)			
Tetanus, Botulism or Anthrax	NHS led IMT with links to other health boards as required Investigation managed locally	Local HPT Support from HPS and other agencies as required	HPS (re Scottish alert) DPH in health board SGHD according to protocol Consider briefing Police Service of Scotland PHE (re UK and Euro alert) IHR (re international alert) as appropriate
Cluster of two cases (in one health board) or three or more cases (in more than one health board area) which occur within six weeks of each other			
Tetanus, Botulism, Anthrax*	NHS led IMT with links to other health boards as required (if across several boards, agree IMT lead - HPS or health board) Investigation of cases managed locally	Local HPT Support from HPS and other agencies as required	HPS (re Scottish alert) DPH in health board SGHD according to protocol Consider briefing Police Service of Scotland PHE (re UK and Euro alert) IHR (re international alert) as appropriate

* The principles of this approach may be used to manage three of more cases of severe illness associated with other spore-forming bacteria such as *C. sordellii*, *C. sporogenes*, *C. novyi* etc.

2.3 Activating an Incident Management Team

The CPHM responsible for initial action may opt to convene a Problem Assessment Group (PAG) in response to a single case of tetanus, botulism or anthrax being reported. The decision to establish an Incident Management Team (IMT) following initial assessment will be made on a case-by-case basis.

Investigation of two or more cases requires a multi-disciplinary team and is best managed by activating an IMT [19]. The membership of the IMT will vary depending on the nature of the incident, but would normally include:

- the Chair – usually the health board CPHM (for local investigations). Investigations involving several health boards may be HPS led[i];
- leads from other health boards (if required);
- health board Addiction service leads or ADP representative;
- communications lead (health board and/or HPS);
- local microbiology lead;
- HPS lead and epidemiologist;
- representatives from Scottish Drugs Forum and Police Scotland.

The Chair may also invite representatives from other relevant specialities and organisations e.g. Pharmacy, Crown Office Procurator Fiscal Service, Reference Laboratories, etc[ii], whose input may be essential to manage the incident.

The IMT will review the situation and agree appropriate management of the incident. A sample agenda for IMT meetings is given in Appendix B. Key investigation milestones for clusters will include the following:

- confirm laboratory results and agree case definitions specific to the incident;
- establish whether the cases are linked and this is a cluster;
- ensure arrangements for the care of patients (both clinical and addiction needs), are in hand;
- confirm that antitoxin supplies, where relevant, are sufficient and, if not, ensure supply;
- establish details of the cases through a line listing;

i Where more than one health board is involved in an incident, HPS will discuss with health board leads who is best placed to lead the investigation and where indicated HPS will take this lead

ii Anaerobic Reference Laboratory, Foodborne and Gastrointestinal Bacterial Reference Unit or the Rare and Imported Pathogens Laboratory

- establish risks associated with the reported cases by obtaining and using information from appropriate enhanced surveillance forms and local intelligence from health board HPTs and Alcohol and Drugs Teams;
- agree harm reduction interventions to raise awareness of the health risks associated with the incident and how to minimise these risks;
- agree materials to be sent out to alert drug users, frontline staff in injecting equipment provision and addiction services, microbiology services, GPs, clinical staff in relevant services (accident and emergency, infectious diseases etc), Directors of Public Health and health boards, as and when appropriate;
- agree communications to relevant agencies nationally and internationally if required;
- agree communication strategy for the media and/or the wider public if required (see section 6);
- agree frequency of meetings;
- agree criteria for standing the IMT down and declaring the end of the incident.

2.4 Agency roles and key objectives

2.4.1 Health Board Health Protection Team

Objectives

- Prevent people being put at risk from further exposure by rapid investigation of cases and implementation of an appropriate risk management strategy;
- reduce complications, disabilities and mortality in those affected;
- ensure appropriate clinical management of cases;
- communicate with the public and other relevant agencies.

Legislative framework

The relevant legislation is the Public Health etc. (Scotland) Act 2008 [18].

Under Part 1 Public Health Responsibilities, Section 2 of the Act places a duty on health boards to ensure provision is made within their area for the purposes of protecting public health. Section 3 of the Act also requires health boards to designate sufficient persons on behalf of the board for the purpose of protecting public health; this person is known by the term “Health Board Competent Person”.

Under Part 3 Public Health Investigations of the Act, sections 20 and 21 require health boards to investigate public health incidents and carry out public health investigations.

Actions

Through management of the IMT, the health board HPT will ensure that all key agencies clearly understand their respective roles and carry out their investigative and management tasks promptly and effectively in co-operation with each other as required.

Where the investigation is national and is co-ordinated by HPS, the health board HPT will co-ordinate activities in their own health board area and report to the national IMT. The health board HPT will develop local communications as required, consistent with national communications. The health board HPT will write up the incident (or contribute to a write up if co-ordinated by HPS) in an appropriate form which can be shared.

2.4.2 Health Protection Scotland (HPS)

Objectives

- National surveillance of cases of tetanus, botulism or anthrax associated with PWUD, including liaison with reference laboratories, to allow rapid identification of incidents and outbreaks;
- support to incident/outbreak investigations with specialist, timely and appropriate advice;
- development of national guidance and best practice for use in incidents/outbreaks of SFB associated with PWUD.

Legislative framework

The relevant legislation is the Public Health etc. (Scotland) Act 2008 [18].

Actions

HPS is responsible for the national surveillance of communicable diseases and environmental health hazards and the provision of expert operational support on infection and environmental health to health boards and local authorities (LAs) in Scotland. HPS will contribute to the health board led IMT by providing knowledge and expertise on the infections, and relevant surveillance intelligence, which may include advice on identified and suspected cases across geographical and organisational boundaries within Scotland, the UK and, where applicable, Europe. Further expert advice on analytical and epidemiological studies will be provided if required.

HPS works with appropriate organisations to ensure relevant guidance of value for the public health management of incidents involving SFB is available (e.g. case definitions, educational material, surveillance/investigational questionnaires, contacts details for accessing antitoxin, tetanus immunoglobulin, etc). Where gaps in knowledge are identified during the course of an investigation, HPS can support the rapid development of new protocols or guidance. HPS is also responsible for ensuring there are appropriate reference laboratory facilities available for ongoing surveillance and that these can accommodate demand during an outbreak; this is done by commissioning reference laboratory services in collaboration with NSS National Services Division.

For clusters affecting more than one health board area and where the public health management is HPS led, responsibility for coordinating the tactical health protection response by the health boards (e.g. surveillance, investigation, risk assessment, management and communication) will rest with HPS. Responsibility for the operational health protection response, including investigation of cases managed locally, will remain with the local health board with support from HPS if required.

2.4.3 Microbiologists

Objectives

- Identify the causative organism in human cases of tetanus, botulism and anthrax;
- liaise with reference laboratories to ensure appropriate specimens are collected from patients and transported to the reference laboratory for further specialist testing and/or confirmation.

Legislative framework

Local microbiology laboratories provide support to guide the clinical management of individual patients as determined by their commissioning body. Specialist testing and/or confirmation of *Bacillus anthracis*, *Clostridium botulinum* and *Clostridium tetani* (including the detection of their neurotoxins) is provided by Public Health England (PHE), who are commissioned by HPS on behalf of NHS Scotland to provide this service. Additional work related to an incident will be as directed by the IMT.

Actions

NHS diagnostic laboratory microbiologists will:

- report clinically suspected cases to the local HPT;
- provide advice on microbiological investigation and clinical management of suspected and confirmed cases as required;
- provide provisional laboratory diagnosis of clinically suspected cases;
- liaise with reference laboratory staff to ensure appropriate samples are obtained and transported for confirmation;
- communicate with clinical colleagues as required;
- notify clinicians and the local HPT of the results of specialist testing for *Clostridium botulinum*, *Clostridium tetani* (and their toxins) and *Bacillus anthracis*;
- attend IMT meetings if required.

Reference laboratory microbiologists will:

- ensure provision of advice and appropriate specialist and/or confirmation laboratory tests;
- report results to the local diagnostic laboratory microbiologists, HPS and local HPTs as appropriate;
- attend IMT meetings if required.

2.4.4 Scottish Drugs Forum

Objectives

- Improve the quality, range and effectiveness of service and policy responses to problematic drug use in Scotland;
- reduce future and recurring problematic drug use;
- promote and sustain recovery from drug problems.

Legislative Framework

The Scottish Drugs Forum (SDF) is a membership-based drugs policy and information organisation and is a national resource of expertise on drug issues.

Actions

The SDF will contribute to the IMT by providing expertise on drugs and patterns of drug use and will work collaboratively with NHS partners to:

- represent service users at IMTs to support a realistic response to an outbreak of SFB;
- utilise wide communication networks to disseminate public health alerts in relation to an outbreak of SFB in PWUD (e.g. via the use of social media, family support, homelessness and mental health services);
- develop training and resources to ensure front line staff are equipped with the knowledge to identify, inform and support those at risk;
- develop information and awareness-raising resources for those individuals at risk of infection due to their injecting or use of drugs, with the aim of reducing the number of individuals affected by, and the complications of, infection;
- engage and inform (using established peer networks) those individuals who are not in contact with health and harm reduction services.

2.4.5 Police Scotland

Objectives

In Scotland, the Lord Advocate through the COPFS is responsible for investigating where there is suspicion that a serious offence may have caused the death or injury of an individual and is the sole prosecuting body. Within the context of an outbreak of SFB associated with PWUD, Police Scotland will assume primacy for the investigation (under the direction of COPFS).

In this respect, the objectives of the criminal investigation are to:

- maximise the safety of all individuals involved in the outbreak and the wider public;
- minimise the risk to police and other emergency services / responders involved in the investigation;
- engage with partners, develop and implement a communications strategy to support the enquiry and public reassurance message;
- establish a full victim profile and determine the source of suspected contaminated controlled drugs with a view to removing, or reducing the amount of contaminated drugs in circulation;
- gather all available evidence and conduct a thorough and professional investigation, at all stages, utilising all necessary resources of Police Scotland.

Legislative framework

It is an offence, for someone to i) possess a controlled drug (in contravention of the 1971 Drug Misuse Act [20]) and ii) willfully and recklessly administer a dangerous substance such as a controlled drug, to another causing injury of death [21]. Additionally, the risks associated with abuse of Class A controlled drugs are so notorious that assisting another to abuse the drug may readily be seen as culpable and reckless conduct [22].

Furthermore, Part 1, Chapter 2, section 20 of the Police and Fire Reform (Scotland) Act 2012 [23] states that "it is the duty of a constable —

a) to prevent and detect crime,

b) to maintain order,

c) to protect life and property,

d) to take such lawful measures, and make such reports to the appropriate prosecutor, as may be needed to bring offenders with all due speed to justice."

Further common law or statutory legislation which assists Police Scotland in the investigation may be used as and when required.

Actions

Police Scotland will contribute to the IMT by providing knowledge and intelligence in relation to the parallel criminal investigation (in so far as possible[iii]) relevant to the public health management of the outbreak and will work collaboratively with NHS partners to ensure:

- that all key agencies clearly understand the Police objectives;
- clear links and demarcations between the police and public health investigation.

COPFS will:

- liaise closely with Police Scotland on its investigation into the deaths to establish if there is evidence of serious criminal offences and work in partnership with other enforcing authorities;
- work with the IMT to balance the risk of withholding IMT investigation findings and the effect on public health, with potential prejudice to the criminal investigation from releasing investigation findings.

2.4.6 Injecting Equipment Providers

Objectives

The main aim of injecting equipment providers (IEPs) is to reduce the transmission of blood-borne viruses and other infections caused by sharing injecting equipment. In turn, this will reduce the prevalence of blood-borne viruses and bacterial infections, so benefiting the individual, communities and wider society. IEPs also aim to reduce the other harms associated with drug use by providing:

- advice on reducing the harms caused by injecting drugs;
- information on less harmful methods of administration of drugs;
- referral to other supporting agencies, such as community addiction teams, health and welfare services.

iii from the time a person is arrested, a warrant for their arrest has been issued, a summons has been issued or someone has been charged with an offence, details of a case cannot be disclosed under the sub-judice rule.

Legislative framework

Under Section 9A of the Misuse of Drugs Act 1971 (1971 Act) [20], it is a criminal offence to supply or offer to supply articles for administering or preparing controlled drugs. The Act says an offence will be committed if the following circumstances exist:

- an article is supplied or offered to be supplied;
- the article may be used or adapted to be used (whether by itself or in combination with another article or articles) in the administration of a controlled drug;
- the person supplying or offering to supply the article did so in the belief that the article would be so used by any person, whether to administer the drug to themselves or another, in circumstances where that administration would be unlawful.

Section 9A exempts hypodermic syringes. In addition, the following articles are exempt if they are dispensed by a doctor, a pharmacist or someone working lawfully within drug treatment services: swabs, utensils for the preparation of a controlled drug, citric acid, filters, ascorbic acid, water ampoules of up to 2ml and foil.

Actions

IEP Co-ordinators will contribute to the IMT to ensure a mechanism is in place to facilitate a timely response to any emerging outbreak of bacterial infections. Working collaboratively with NHS partners, IEP Co-ordinators will:

- ensure information is cascaded to frontline staff, thus raising the awareness of any outbreak and developing an appropriate response;
- raise the awareness of any outbreak by dissemination of materials and facilitation of discussions with people using IEP outlets;
- create direct referral pathways between IEPs and hospitals or supporting agencies;
- ensure all IEPs stock a full range of injecting equipment and paraphernalia, such as water for injection and foil;
- help to identify innovative ways of delivering the service to meet the needs of those at immediate risk.

3. Epidemiological Investigation

Epidemiological investigation of cases of illness caused by SFB, and associated with drug use, is essential to establish the source of infection and so to assess if others are at risk. Due to the severity of these infections, public health interventions are indicated with a small number of cases in order to prevent vulnerable populations being affected.

3.1 Case detection and case definitions

Whilst cases of SFB may be suspected clinically, confirmation of a case requires the appropriate biological sample to be taken and the appropriate tests performed. Specialist and/or confirmation tests for botulism, tetanus or anthrax are undertaken in the appropriate UK reference laboratory and local microbiological services should obtain and forward appropriate samples to them without delay. This is discussed further in section 4.

Use of a common case definition allows for standardisation of the case of interest both within an ongoing outbreak and possibly between outbreaks that differ over time or geographical location. Within the context of a given outbreak, the case definition should include criteria for person, place, time and clinical features. The case definitions for botulism, tetanus and anthrax are given below. These have been adapted from the sources indicated, to be specific for PWUD. Case definitions can be further categorised by the degree of certainty regarding the diagnosis as “probable” or “confirmed”. It should be noted that a “possible” case classification is usually used, when appropriate, during the process of investigating suspect illnesses. This is not part of the formal case definition but, rather, is for use when dealing with reports of suspected illness while they are still being investigated – i.e. the suspected case may initially be classed as “possible” whilst corroboration is sought and thereafter formally classified when the information becomes available to do so. In occasional circumstances, corroboration is never achieved and the case remains “possible”.

3.1.1 Anthrax (*Bacillus anthracis)*

Table 2: Adapted from ECDC case definitions [24].

Criteria	Probable case	Confirmed case
Clinical Evidence of serious soft tissue infection (SSTI) or other clinical evidence compatible with anthrax infection*	Y	Y
Epidemiological Use of illicit drugs by any route within the 2 weeks prior to onset of symptoms	Y	Y
Microbiological Detection of B. anthracis (evidence of organisms or nucleic acid) or anthrax toxins or specific antitoxin to the organism consistent with recent infection		Y

* Where there is a history of recent injection use of heroin the following should be considered as possible presentations. Any PWUD who presents with: i) severe soft tissue infection, including necrotizing fasciitis and cellulitis/abscess particularly if associated with oedema (often marked); ii) signs of severe sepsis even without evidence of soft tissue infection; or iii) meningitis (especially haemorrhagic meningitis). Also be suspicious of users of heroin who present clinically and/or with CT scan evidence suggestive of a subarachnoid haemorrhage/intracranial bleed.

In addition, a "possible case" category for anthrax was developed and used during the 2009/2010 outbreak in Scotland [16] and may be useful in outbreak situations where microbiological evidence falls short of that required for a confirmed or probable case.

3.1.2 Botulism (*Clostridium botulinum*)

Table 3: Adapted from ECDC case definitions [24].

Criteria	Probable case	Confirmed case
Clinical Any person with at least one of bilateral cranial nerve impairment (e.g. diplopia, blurred vision, dysphagia, bulbar weakness) or peripheral symmetric paralysis	Y*	Y
Epidemiological Use of illicit drugs by any route within the 2 weeks prior to onset of symptoms	Y	Y
Microbiological Isolation of toxigenic *Clostridium botulinum* from infected wound and/or detection of botulinum toxin in a clinical specimen		Y

* high clinical suspicion of botulism

3.1.3 Tetanus (*Clostridium tetani*)

Table 4: Adapted from ECDC case definitions [24].

Criteria	Probable case	Confirmed case
Clinical Any person with at least two of the following three: painful muscular contractions primarily of the masseter and neck muscles leading to facial spasms known as trismus and 'risus sardonicus'; painful muscular contractions of trunk muscles; generalised spasms, frequently position of opisthotonus	Y	Y
Epidemiological Use of illicit drugs by any route within the 2 weeks prior to onset of symptoms	Y	Y
Microbiological Isolation of toxigenic *Clostridium tetani* from an infection site and/or detection of tetanus toxin in a serum sample		Y

3.2 Investigation of cases

Cases should be investigated as indicated in section 2.2.

The epidemiological tool for investigation is a questionnaire, which contains a range of questions aimed to identify risk factors for infection. There are established enhanced surveillance questionnaires, which should be used in the first instance for investigating these illnesses; see section 3.3. It is possible that incident/outbreak investigations will develop specific 'hypothesis-generating' or 'trawling' questionnaires to establish further incident/outbreak specific details. Usually the 'hypothesis generating' questionnaire will be used in addition to the enhanced surveillance questionnaire or in some outbreak investigations, may replace it; see section 3.3.

There are a number of challenges encountered when trying to complete surveillance forms with this population group. Initially, cases may be too ill and/or ventilated to be interviewed. Delaying contact until the case clinically improves, however, runs the risk of the case self-discharging before interview. To ensure the collection of high quality information about drug use and injecting behaviour, experience from previous outbreaks has shown that cases should be interviewed and the questionnaire completed by individuals who are best placed to understand drug taking behaviour and practices, such as frontline staff in drug and addiction services. Support with data collection in large scale outbreaks can also be obtained from HPS and/or the SDF.

3.3 Enhanced surveillance questionnaires

Botulism and tetanus surveillance is managed for the UK as a whole and PHE have designed and hold the national enhanced surveillance forms. The investigation of all cases of tetanus and botulism in PWUD should use these enhanced surveillance questionnaires in the first instance. Copies of the completed forms should be forwarded to HPS who will liaise with colleagues in PHE to ensure the information is collated at the UK level.

The enhanced surveillance form for 'wound botulism' form is available at: https://www.gov.uk/government/publications/botulism-reporting-questionnaires.

The national enhanced surveillance form for tetanus is available at: https://www.gov.uk/government/publications/tetanus-enhanced-surveillance-questionnaire.

There is no surveillance form that is used routinely for investigating cases of anthrax associated with drug use. As an alternative, health boards investigating an incident/outbreak of anthrax should use the trawling questionnaire developed during the previous outbreak of anthrax in Scotland during 2009/10: http://www.documents.hps.scot.nhs.uk/giz/anthrax-outbreak/anthrax-questionnaire.pdf.

3.4 Hypothesis-generating or trawling questionnaire

These may be developed by the investigation team during a incident/outbreak investigation. They are likely to be based on the enhanced surveillance questionnaire but have additional questions to identify incident/outbreak-specific risks, reflecting specific details of the situation under investigation. HPS will work with the IMT to develop a relevant questionnaire should this be indicated.

3.5 Analytical studies

For an incident or outbreak, at a minimum, a line listing of cases with other relevant data should be maintained electronically. In a large outbreak, a database will most likely be developed containing the information from the surveillance and/or hypothesis-generating questionnaire. The surveillance database will increase the ease of analysis of case data. HPS can support the development and completion of an outbreak database for health boards for local outbreaks, should this be necessary.

In some outbreaks further detailed epidemiological investigations may be indicated to further understand and identify the causes and risks associated with the infections. The decision to undertake an analytical study is taken by the IMT with advice from HPS. Such studies can be resource intensive and may require additional funding to support dedicated staff for the period of the study fieldwork and analysis. Epidemiological studies undertaken as part of outbreak investigation are not required to seek ethical approval from a national board, however they must follow approvals processes as detailed by the health board who is leading the IMT.

HPS can work with the IMT to summarise and interpret all the information that has been collected in order to inform IMT led public health interventions. HPS can also provide additional expertise to develop a study protocol and study tools (such as questionnaires) for further epidemiological investigations, if required.

4. Microbiological Investigation

It is essential to undertake microbiological investigation to establish a diagnosis. Further specialist molecular investigations of laboratory confirmed cases may also be undertaken to establish if cases are linked. This chapter provides a summary of existing guidance that should be used if SFB infection is suspected.

It is essential that appropriate samples for microbiological investigation are taken before treatment begins. The collection of an appropriate sample should not, however, result in a delay in treatment. The local Consultant Microbiologist should be contacted to ensure the correct specimens are obtained.

4.1 UK standards for microbiology investigations

Standards for Microbiology Investigations (SMIs) in the UK have been developed by PHE in partnership with the NHS, Public Health Wales and with relevant professional organisations. SMIs are algorithms and procedures for clinical microbiology, developed, reviewed and revised by various working groups that are overseen by a steering committee [25].

The following SMIs are relevant for the microbiological investigation of suspected cases of botulism, tetanus or anthrax (for latest versions see the SMI website [25]):

1. SMI B11 Investigation of Skin, Superficial and Non-Surgical Wound Swabs;
2. SMI B14 Investigation of Abscesses and Deep-Seated Wound Infections;
3. SMI B17 Investigation of Tissues and Biopsies;
4. SMI B26 Investigation for Fluids from Normally Sterile Sites;
5. SMI B37 Investigation of Blood Cultures (for Organisms other than Mycobacterium species).

4.2 *Bacillus anthracis* (Anthrax)

General information regarding anthrax associated with drug use, developed during the previous outbreak of anthrax in Scotland during 2009/10, can be found on the HPS website [26]. This includes guidance on the clinical diagnosis and management of infection and laboratory investigations.

4.2.1 Clinical diagnosis and management

Use the collated resources on the HPS anthrax webpage, which includes a clinical algorithm and clinical guidance [26]:

http://www.documents.hps.scot.nhs.uk/giz/anthrax-outbreak/clinical-algorithm-drug-users-possible-anthrax-v2.1.pdf;

http://www.documents.hps.scot.nhs.uk/giz/anthrax-outbreak/clinical-guidance-for-use-of-anthrax-immune-globulin-v12-2-2013-03-13.pdf.

4.2.2 Laboratory diagnosis

Use the collated resources on the HPS anthrax webpage including laboratory guidance [26] and SMI ID9 Identification of Bacillus species guidance [25];

http://www.documents.hps.scot.nhs.uk/giz/anthrax-outbreak/lab-guidance-investigation-anthrax-drug-users-v1-2010-01-18.pdf;

https://www.gov.uk/government/collections/standards-for-microbiology-investigations-smi.

4.2.3 Reference laboratory to approach for assistance and confirmatory testing

All positive isolates and cultures should be sent to the Rare and Imported Pathogens Laboratory (RIPL) at PHE Porton Down [27] for confirmation. In addition, samples may be sent there directly if local laboratories lack the facilities for dealing with them (i.e. Class 1 protective cabinet within a containment level 3 facility). Further information and sample submission form can be found at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/419656/RIPL_user_manual.pdf;

https://www.gov.uk/government/publications/rare-and-imported-pathogens-testing-form-to-submit-sample.

All samples and cultures must be packaged appropriately. The reference laboratory should be telephoned prior to sending to expect the sample (tel: 01980 612348). To arrange urgent testing outside normal working hours, the case should be discussed with the RIPL on-call medical consultant available via PHE Porton Down reception (tel: 01980 612100).

4.3 *Clostridium botulinum* (Botulism)

Details on the clinical presentation, diagnosis and laboratory tests for wound botulism cases associated with injecting drug use are available on the PHE website: https://www.gov.uk/government/publications/botulism-clinical-and-public-health-management/botulism-clinical-and-public-health-management#wound-botulism-cases-associated-with-injecting-drug-use.

4.3.1 Clinical diagnosis and management

The main clinical syndrome produced by botulinum toxin is an afebrile, descending, flaccid paralysis. Patients with botulism typically present with difficulty speaking, seeing and/or swallowing. They may have double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing and muscle weakness. If untreated, paralysis may progress to the arms, legs, trunk and respiratory muscles.

There is usually no fever, no loss of sensation and no loss of awareness. There may also be autonomic signs with a dry mouth, fixed or dilated pupils, and cardiovascular, gastrointestinal and urinary autonomic dysfunction.

Guidelines on the clinical management of botulism are available from professional sources elsewhere though, in general, supportive care is accompanied by administration of antitoxin to inactivate unbound toxin, and local wound drainage, debridement and antibiotics to halt further toxin production.

In Scotland, information on botulinum antitoxin holdings can be found on the Rarely Used Urgent Medicines List; a current copy is hosted on TOXBASE (www.toxbase.org). In the event that a supply of botulinum antitoxin is required for patient treatment, pharmacy colleagues in each health board can arrange to obtain a supply from one of the designated holding centres.

4.3.2 Laboratory diagnosis

Microbiological confirmation of botulism requires the timely collection of appropriate biological samples before antitoxin administration; the early collection of samples following onset of symptoms maximises the opportunity for diagnosis. Routine laboratory tests are not helpful and specimens should therefore be sent immediately to the reference laboratory. Use SMI ID8 Identification of Clostridium species guidance [25], which is available at: https://www.gov.uk/government/collections/standards-for-microbiology-investigations-smi.

4.3.3 Reference laboratory to approach for assistance and confirmatory testing

Suspected cases of botulism should be discussed with the Gastrointestinal Bacteria Reference Unit (GBRU) at PHE Colindale [28], prior to the sending of clinical specimens or samples. This is to ensure that the most appropriate samples are taken and sent under optimal conditions. During working hours, cases can be discussed with the Medical Microbiologist (tel: 020 8327 7142 or email: colindalemedmicro@phe.gov.uk) for advice on diagnosis, clinical interpretation of results and management of infections. Outside normal working hours, contact the Microbiology Services Division, Colindale, Duty Doctor (tel: 020 8200 4400). Further information is available at: https://www.gov.uk/guidance/gbru-reference-and-diagnostic-services.

4.4 *Clostridium tetani* (Tetanus)

Details on clinical presentation, diagnosis and laboratory tests for tetanus cases associated with injecting drug use are available on the PHE website: https://www.gov.uk/government/collections/tetanus-guidance-data-and-analysis.

4.4.1 Clinical diagnosis and management

Tetanus is a clinical diagnosis, defined as trismus with one or more of the following: spasticity, dysphagia, respiratory embarrassment, spasms or autonomic dysfunction. Patients may present with localised tetanus or with symptoms of generalised tetanus ranging from mild trismus ('lockjaw'), neck stiffness and/or abdominal rigidity to full blown tetanus, including general spasticity, severe dysphagia, respiratory difficulties, severe and painful spasms, opisthotonus and autonomic dysfunction. Generalised tetanus is the most frequently recognised form.

Guidelines on the clinical management of tetanus are available from professional sources elsewhere though, in general, supportive care is accompanied by administration of immunoglobulin to inactivate unbound toxin, and local wound drainage, debridement and antibiotics to halt further toxin production.

In January 2013, PHE convened an expert working group to review the published evidence on the use of Tetanus Immunoglobulin (TIG) for the treatment of clinically suspected tetanus. Whilst this review is being completed, the working group recommends the use of intravenous products only for the treatment of clinically suspected tetanus and whilst supplies of TIG remain limited, as an interim measure, intravenous human normal immunoglobulin (HNIG, trade-name Vigam) is advised based on weight. For tetanus-prone wounds requiring TIG, human normal immunoglobulin for subcutaneous use (trade-name Subgam) may be given intramuscularly as an alternative if stocks of TIG are not available. Further information can be found on the PHE website: https://www.gov.uk/government/collections/tetanus-guidance-data-and-analysis.

In Scotland, information on TIG can be found on the Rarely Used Urgent Medicines List; a current copy is hosted on TOXBASE (www.toxbase.org). Human normal immunoglobulin can be obtained from local pharmacy departments if required.

4.4.2 Laboratory diagnosis

Laboratory tests are available to support or confirm the clinical diagnosis of tetanus. Microbiological confirmation of tetanus requires the timely collection of appropriate biological samples before antitoxin administration; the early collection of samples following onset of symptoms maximises the opportunity for diagnosis. Although a serum sample should be taken before administering immunoglobulin, treatment of tetanus should never be delayed to wait for the laboratory result. Use SMI ID8 Identifcation of Clostridium species guidance [25], which is available at: https://www.gov.uk/government/collections/standards-for-microbiology-investigations-smi.

4.4.3 Reference laboratory to approach for assistance and confirmatory testing

Suspected cases of tetanus should be discussed with the GBRU at PHE Colindale [28], prior to the sending of clinical specimens or samples. This is to ensure that the most appropriate samples are taken and sent under optimal conditions. During working hours, cases can be discussed with the Medical Microbiologist (tel: 020 8327 7142 or email: colindalemedmicro@phe.gov.uk) for advice on diagnosis, clinical interpretation of results and management of infections. Outside normal working hours, contact the Microbiology Services Division, Colindale, Duty Doctor (tel: 020 8200 4400). Further information is available at: https://www.gov.uk/guidance/gbru-reference-and-diagnostic-services.

5. Public health interventions to prevent infection and illness associated with spore-forming bacteria among people who use drugs

5.1 General – prevention context

There are significant challenges associated with preventing cases of illness such as botulism, tetanus and anthrax in an incident/outbreak when the source of infection may be contaminated illegal drugs or cutting agents. Given that it is generally not feasible to remove the contaminated drugs or cutting agents from the market, the overall goal of a public health intervention during an incident/outbreak becomes the prevention of further harm.

This section comprises a summary of the key public health interventions that are recommended by the GDG to prevent infection and illness associated with SFB among PWUD. The detail of the evidence base and considered judgment for the recommended interventions is provided in Appendix C.

In reviewing the available evidence on public health interventions to prevent SFB among PWUD, the GDG found that: (i) there was a general lack of evidence on preventive interventions in relation to SFB and (ii) evidence was not, for the most part, specific to incident or outbreak situations. Thus, in relation to (i), it should be noted that the recommendations made by the GDG are largely based on expert opinion, best practice and experience of managing previous outbreaks. Where there was evidence to underpin a recommendation, it has been referenced. To address issue (ii), the GDG took a broad approach to gathering and considering evidence, by considering existing harm reduction interventions that might have an impact on SFB infections, and not solely interventions that could be deployed in an incident/outbreak situation. Accordingly, it is important to emphasise that some of the interventions recommended here are considered by the GDG to be standard practice in harm reduction services, whereas other interventions should augment existing services in the case of an incident/outbreak. To distinguish between the former and the latter, the recommendations have been categorised as either “routine” or “enhanced”, respectively.

The GDG also wishes to note that comprehensive, evidence-based guidelines for harm reduction interventions have been produced previously [29; 30]. The GDG endorses these as standards for routine harm reduction service provision, and they are referred to throughout this section, where relevant.

5.2 Recommended public health interventions

The recommended public health interventions for incidents/outbreaks of SFB among PWUD can be grouped as follows:

1. Encouraging PWUD to reduce or eliminate drug use;
2. Encouraging PWUD to switch to a safer route of drug use where appropriate;
3. Reducing the harm among those who continue to inject drugs
    a) Pre-exposure prophylaxis (tetanus only)
    b) Post-exposure prophylaxis (tetanus only)
    c) Provision of injecting equipment
    d) Advice on safer injecting behaviour;
4. Education and awareness-raising of the signs and symptoms of illness.

The interventions above are organised in a hierarchy of increasing risk, with emphasis placed on those interventions that aim to prevent exposure to, and where this has been unsuccessful, reduce the consequences of infection. This hierarchy recognises that there is no safe route of drug consumption and that the only way to eliminate risk of infection is to stop using drugs. It also, however, recognises that the nature of problem drug use is such that some individuals will continue to use drugs despite explicit warnings of the potential harms. Interventions within the context of an incident/outbreak should, therefore, also address how to reduce risk, in so far as possible, for those who continue to use drugs. Finally, among those who have already become infected, the goal is to reduce the risk of progression to serious illness through early recognition of the signs and symptoms, enabling prompt treatment.

A quick reference guide to the recommended interventions is given in Appendix D.This table also indicates whether the recommendation is considered routine (i.e. should be the standard of practice in existing harm reduction services) or enhanced (i.e. could be deployed in an incident/outbreak situation to augment exisiting services). As stated above, the full evidence base and considered judgment underpinning the recommendations is provided in Appendix C.

5.2.1 Encourage PWUD to reduce or eliminate drug use

The only way to eliminate the risk of infection is to stop using drugs. The aim of drug dependence treatment is to help individuals with a drug problem stop compulsive drug seeking and use. The GDG therefore endorses the recommendation of ECDC/EMCDDA [29] that:

1. **Drug dependence treatment should be available and easily accessible, in particular opioid substitution treatment (OST) for opioid users.**

The GDG consider that the provision of appropriately dosed OST (including a wide-range of OST options), in combination with other harm reduction interventions such as IEP services should be the norm. Thus, within the context of an incident/outbreak, the GDG also recommends that:

2. **Services providing OST should be reviewed and enhanced (where necessary) in order to maximise coverage.**

This might be achieved by reducing or removing waiting lists and reviewing eligibility criteria for commencing/continuing to receive OST, with a view to ensuring that there is no restriction on dosage and duration during the incident/outbreak period. The focus should be on reducing infection-related harm rather than abstinence

On recognition that many individuals continue to inject while receiving treatment for their drug problem, the GDG supports the recommendations that [31; 32]:

3. **IEP services should not discourage PWUD from accessing sterile needles and other injecting equipment on the basis of receiving treatment for their drug problem.**

4. **Services offering OST should also make needles and syringes available to their service users.**

5.2.2 Encourage PWUD to switch to a safer method of drug use

There was a consensus among the GDG that, with regard to botulism and tetanus, smoking poses a lower risk of infection than injecting. The GDG therefore recommends that:

5. **Advice and information encouraging people to switch to a non-injecting route of drug consumption should be considered, where there is no intelligence to suggest that drugs are co-contaminated with anthrax spores.**

The GDG does not, however, recommend that this intervention be employed as part of the public health management of an outbreak of anthrax, and endorses the message that heroin use by any route will carry a risk of infection if the heroin is contaminated with anthrax spores.

5.2.3 Reduce harm among those who continue to inject drugs

5.2.3.1 Pre-exposure prophylaxis (tetanus only)

The tetanus vaccine has been part of the routine childhood immunisation schedule in the UK for more than 30 years, with multiple doses, and two boosters, considered necessary to give good long-term protection [33]. It is likely that PWUD at risk of tetanus in Scotland will have some, albeit perhaps not complete, immunity, depending on how many doses/boosters were received.

The GDG therefore endorses the ECDC/EMCDDA [29] and Scottish Government [30] recommendations which state that:

6. **Tetanus vaccination status should be checked among PWUD, and a booster vaccine should be offered if vaccination status is uncertain, particularly for those users who have injection site infections.**

7. **Wherever possible, all IEP services should make available vaccinations (including tetanus) on-site and where IEP services do not offer on-site vaccination facilities, they should offer referrals.**

The GDG acknowledge the challenges of ascertaining vaccination status and that, for those with no previous immunisation history, the provision of the vaccine through a five dose schedule will not achieve effective immunity during the timeframe of the outbreak. Nonetheless, taking a pragmatic approach, the GDG recommends that:

8. **Within the context of an outbreak of tetanus, low-threshold services should be enhanced and every opportunity should be taken to ensure that those with no or incomplete immunisation status are identified and vaccinated.**

5.2.3.2 Post-exposure prophylaxis (tetanus only)

Tetanus can be prevented by the appropriate management of a tetanus-prone wound. One of the goals of post-exposure prophylaxis with regard to tetanus is to provide or induce high circulating concentrations of tetanus antibody, which inactivate tetanus toxin. Effective neutralizing antibody concentrations at the time of the injury can only be achieved by: (i) prior completion of the tetanus vaccine (see section 5.2.3.1) or (ii) immediate administration of tetanus immune globulin (TIG). Provision of the vaccine and/or TIG is dependent on immunisation status, any underlying potential immunosuppressive condition and to what degree the wound is tetanus-prone (see Table AC-1 in Appendix C). Although vaccination of an individual with a tetanus-prone wound will not prevent tetanus, a booster dose should be offered (to all those with a history of unknown or incomplete vaccination) opportunistically to prevent future infection.

Within the UK, intravenous preparations of TIG are in limited supply. If stocks of TIG are not available, the GDG endorses the PHE recommendation of subcutaneous HNIG (trade-name Subgam) for the management of tetanus-prone wounds (see section 4.4).

The GDG endorses the Green Book [33] recommendations:

9. **For the management of a tetanus-prone wound, a tetanus vaccine booster dose should be offered to all those whose vaccination status is unknown or incomplete.**

10. **For the management of a tetanus-prone wound, TIG or HNIG should be administered to those whose vaccination status is unknown or incomplete.**

5.2.3.3 Provision of injecting equipment

While recognising there is no evidence that the provision of sterile injecting equipment reduces the risk of infection with SFB, there is evidence that it can attract clients to, and retain them in, services [29]. In the context of an incident or outbreak, such contact may provide an opportunity to deliver enhanced harm reduction interventions. Furthermore, the GDG considers that the provision of sufficient sterile equipment (together with education on the correct single person use of each item) should provide some benefit in preventing SFB infections, with regard to reducing the risk of tissue damage that would facilitate infection with anaerobic spore formers.

The GDG therefore supports the principles of IEP as a harm reduction intervention and endorses the Scottish Government [30] and ECDC/EMCDDA [29] guidance recommendations that:

11. Services should aim at all times to ensure that all clients have a sterile needle and syringe for every injection.

12. Other non-needle drug injecting equipment should be supplied in sufficient quantities to enable the use of one item each per injection.

13. Provision of clean drug injection equipment should be part of a combined multi-component approach implemented through harm reduction, counselling and treatment programmes.

5.2.3.4 Advice on safer injecting behaviour

There is a lack of evidence that advice and education on safer injecting practices reduces the risk of SFB infection; nevertheless, the GDG considers that safer injecting behaviour is an important communication message to promote to PWUD in general. The GDG therefore endorses the ECDC/EMCDDA [29] and Scottish Government [30] guidance that recommends:

14. Health promotion messages should be tailored to the needs of the user and provided at every possible opportunity

15. IEP service staff should receive appropriate training prior to providing a service in relation to (amongst others) injecting risk behaviour and the correct, single person use of injecting equipment.

Specifically, the GDG endorses the following specific recommendations in relation to vein maintenance and safer injecting techniques:

16. PWUD should be encouraged to minimise the use of acidifier for mixing with drugs.

17. PWUD should be encouraged to wash their hands and the injecting site before injecting drugs.

18. PWUD should be discouraged from injecting intramuscularly or subcutaneously.

During an incident/outbreak, services should be proactive in using every contact with a person who is currently injecting as an opportunity to promote safer drug behaviour and increase PWUD understanding about the relevant infections, and infection prevention, with the aim of reducing the risk of contracting infection.

5.2.4 Education and awareness-raising of the signs and symptoms of illness

5.2.4.1 Among PWUD

There is no evidence that promoting recognition of the signs and symptoms of SFB infections among PWUD during an incident/outbreak does or does not have an impact on either healthcare seeking behaviour, improving diagnosis, improving outcomes or reducing the risk of death associated with infection. Nonetheless, the GDG believes that users should be informed of the nature of the hazard they face and encouraged to have a lower threshold for seeking medical care for any injection site infection during times of heightened awareness associated with an incident/outbreak. Consequently, the GDG recommends that:

19. Information on the signs and symptoms of illness (resulting from botulism, tetanus or anthrax infection), and guidance on when and where to seek medical care, should be communicated to users.

The GDG recommends that educational interventions utilised in an incident/outbreak should be tailored to the target population. The GDG does not explicitly recommend the use of posters or leaflets, as there is evidence suggesting these may not the most effective method of communicating with PWUD as a result of literacy problems [34]. However, where used, they should require minimal literacy and be backed up with verbal explanation of the written material delivered by people with credibility. The information provided should be consistent across generic (for example, leaflets) and face-to-face communication. Consideration should also be given to consistency with messages disseminated across the UK and Europe, if part of a wider outbreak.

Multiple sites should be considered for the dissemination of information during an incident/outbreak: IEP and addiction services are familiar with disseminating information on risks and are ideally placed to take a proactive approach during an incident/outbreak. Other locations that might be accessed by drug users include primary care, A&E, and hostels and housing departments.

Awareness-raising tends to be targeted at users of the services described above; however; the needs of PWUD admitted to hospital also need to be addressed. Prior to any discharge taking place (planned or self-discharge) interventions should include information on the signs/symptoms of illness associated with an incident/outbreak; however, priority should be given to providing overdose awareness information and supplying naloxone.

Alternative modes of delivering the information, such as peer-to-peer education, should be considered. The GDG acknowledges that establishing and training peer educators within the context of an incident/outbreak may be unachievable. If, however, trained peers are available, consideration should be given to utilising this approach.

5.2.4.2 Among healthcare professionals and staff in frontline drug and alcohol services

There is no evidence that raising awareness of the signs and symptoms of illness among frontline workers in IEP or addictions services shortens the period between symptom onset and access to medical care among infected PWUD. Nonetheless, the GDG considers frontline workers in IEP and addictions services to have a key role in identifying infected individuals and should actively assist individuals with suspected infection to the appropriate medical services for prompt treatment and care. In order that staff can recognise infected individuals, the GDG recommends that:

20. IEP and addictions staff should receive training on the usual clinical presentations of botulism, tetanus and anthrax.

Since practical experience of managing individuals with these infections is limited, and because early diagnosis and treatment improves outcomes, the GDG recommends that:

21. During an incident/outbreak, interventions to heighten and maintain awareness of the clinical presentation of illness should be undertaken with IEP and addictions staff.

Periodic reminders should be circulated throughout the duration of the outbreak and updated if a particular clinical presentation is associated with an ongoing incident. Guidelines to support the early recognition and management of tetanus (see section 4.4) and botulism (see section 4.3) are available and have been developed for anthrax during the previous outbreak in 2009/10 (see section 4.2).

With regard to clinical staff, knowledge of presenting symptoms and how/when to obtain the appropriate sample can improve the chances of a microbiological diagnosis confirming infection. Colleagues in Microbiology have a key role to play in ensuring that their clinical colleagues are familiar with the correct protocols (see section 4).

22. Healthcare professionals should be made aware of presenting symptoms and the appropriate diagnostic procedures, including the samples to be obtained prior to treatment commencing (although treatment should never be delayed).

6. Communication

6.1 Information Governance

Early collaboration and sharing information with addiction and IEP services and police, where appropriate, through a planned and established communication protocol is integral to effective outbreak management.

HPS and health boards are all bound by the undernoted legal, statutory and guidance documents when processing information for public health purposes.

6.1.1 Information Governance Principles

- The Data Protection Act 1998 [35] relates to the processing of personal and sensitive personal information of living individuals.
- The Human Rights Act 1998 [36] covers the fundamental rights and freedoms of individuals in the UK.
- The Common Law Duty of Confidentiality [37] provides information on circumstances where it is expected that a duty of confidence applies, i.e. information cannot normally be disclosed without the information provider's consent.
- The Information Governance Review (Caldicott 2) [38] ensures that there is an appropriate balance between the protection of patient information and the use and sharing of information to improve patient care.

6.1.2 Statutory and Clinical Guidance relating to public health

- The Public Health etc (Scotland) Act 2008 [18] provides a legal framework for public health investigation, which can require the sharing of patient identifiable information in the event of a public health situation of "significant risk".
- The Management of Public Health Incidents - Guidance on the Roles and Responsibilities of NHS led Incident Management Teams [19] provides guidance for the NHS in preparing for, and managing public health incidents in collaboration with partners, especially the Local Authorities.
- The International Health Regulations (2005) [39] aims to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade (Art. 2, IHR 2005).
- The Regulation (EC) No 851/2004 [40] establishes a European centre for disease prevention and control.

Aspects of a number of the aforementioned, other professional and specific guidance relating to sharing information between NHS and other non health organisations (i.e. Police Scotland) are expanded further below.

6.2 Data Protection and Confidentiality

6.2.1 Data Protection Act 1998

An individual's data is regulated under the Data Protection Act (DPA) and regulation is in place which covers the obtaining, holding, use or disclosure of such information. The principle purpose of the DPA is to prevent misuse of personal information. The DPA aims to strike a balance between the competing interests of the rights of individuals and the legitimate processing of personal data.

There are a number of exemptions under Part IV of the DPA, the most significant section for the purposes of public health incident investigation are under section 29, where there is an exemption of personal data from the non-disclosure provisions in any case for the prevention or detection of crime, or the apprehension or prosecution of offenders, or where the application of non-disclosure provisions would be likely to prejudice any of these matters.

6.2.2 Public Health etc. (Scotland) Act 2008

The relevant section for the purposes of public health incident investigation is 's.117 disclosure of information'. This section provides for the circumstances in which a relevant authority (which includes a health board) may disclose information held by it.

Subsection (1) allows disclosure to another relevant authority where this is required to facilitate either authority's functions under this or any other Act for protection of public health (the various references under relevant authority are those with a statutory duty under Part I of the Act).

Subsection (2) allows disclosure to any other person if the authority considers this to be necessary for the protection of public health.

Although information may be disclosed under these provisions, despite any prohibition or restriction on such disclosure imposed by or under any enactment or rule of law, the terms of the Data Protection Act 1998 must still be met, and this includes the exemptions as indicated above. A person who discloses information under this section will not be subject to any civil or criminal liability due to the disclosure.

6.2.3 Human Rights Act 1988

The Human Rights Act 1998 does not prevent the collection or sharing of personal information. The Act provides lawful restrictions on human rights in relation to the use of information by public authorities in certain circumstances; such as reasons of public safety, the protection of health and the prevention of disorder. Public Authorities can therefore share personal data if it is in pursuit of these lawful aims, of which sharing of data for the purposes of public health incident investigation is likely to be legitimate.

6.2.4 The General Medical Council

The General Medical Council (GMC) guidance "Confidentiality: disclosing information about serious communicable diseases" (September 2009) provides guidance to doctors responding to public health incidents. Important elements of the guidance include:

> "Personal information may, therefore, be disclosed in the public interest, without the patients' consent, and in exceptional cases where patients have withheld consent, if the benefits to an individual or to society as a whole outweigh both the public and patient's interest in keeping the information confidential".
>
> "Disclosure of personal information about a patient without consent may be justified in the public interest if failure to disclose may expose others to risk of death or serious harm".

6.2.5 Other guidance

For public health incident investigation, specific guidance on information sharing between NHS Scotland and the Police can be found in "Information sharing between NHS Scotland and the Police" (prepared by the Scottish Government's Healthcare Policy and Strategy Directorate and the Association of Chief Police Officers Scotland) [41]. The guidance explicitly addresses public health issues and patient confidentiality and states:

> "Information held in confidence can still be disclosed without the individual's consent, where it can be demonstrated that:
>
> - it needs to be shared by law;
> - it is needed to prevent, detect or prosecute crime;
> - there is a public health interest;
> - there is a risk of death or harm;
> - it is in the interests of the persons' health;
> - it is in the interest of the person concerned".

6.3 Information disclosure and dissemination

In order to ensure that health boards and/or HPS can effectively manage incidents relating to spore-forming bacteria associated with drug use, information about exposures, case status, relationships and other personal information relating to individuals is critical to proper investigation. Whilst the legislation discussed in the previous section highlights the legal position for information sharing, this may not fully address concerns health boards have regarding sharing PII with non-NHS agencies.

Information sharing with other non-health organisations, for example Police Scotland, may be considered on a case by case basis via IMTs and decisions will be the responsibility of multi-agency IMTs in accordance with the 'Management of Public Health Incidents' national guidance [19]. Consideration to share information should take into account the information governance knowledge and training of the receiving organisation and take advice from relevant Caldicott Guardians as required.

6.4 Public communication

Communications is a required IMT meeting agenda item (see Appendix B) and the chair should make sure to invite communications staff to assist the IMT (see section 2.3). Where a potential public interest in the incident/outbreak has been identified, the IMT should decide whether to take a proactive approach, such as releasing a media statement, or take a reactive approach by preparing lines in the event of media interest. The communications staff on the IMT has the responsibility for writing the media statement, which must be approved by the IMT chair, or delegated officer, and subsequently distributed for comment to all IMT members. Ultimate responsibility for authorization of any statement or release rests with the IMT chair or delegated officer. As a point of good practice all press releases should be shared with SGHSCD.

7. Reporting

Incident and outbreak control management plans and procedures need to be documented and reported by the IMT. The IMT should produce a final report detailing the investigation, outcomes and lessons learned, for dissemination to:

- members of the team;
- the Chief Medical Officer (CMO);
- the Chief Executive of the health board(s) where the outbreak took place;
- any other relevant stakeholders and participating agencies;
- the public - where appropriate.

Report template and guidance on content are detailed in the national guidance on 'Management of Public Health Incidents' [19].

If the Procurator Fiscal is involved in the investigation, before the report is finalised it should be reviewed by the Procurator Fiscal to ensure it will not prejudice any criminal investigation.

Appendix A: Guideline development process and group membership

Guidance Development Group

The guidelines were developed by a team of health professionals and technical experts following the method outlined by the Scottish Health Protection Network (SHPN). The membership of the Guidance Development Group is detailed below.

Membership of the Guidance Development Group

Name	Job title	Organisation
John Budd	GP	NHS Lothian
Amanda Burridge	Project Support Officer	Programme Management Services (PgMS)
John Campbell	Improvement and Development Manager	NHS Greater Glasgow & Clyde
Karen Dunleavy	Research Fellow	Health Protection Scotland (HPS)/ University of the West of Scotland (UWS)
Caroline Kelleher	Administrative Assistant	HPS
John Hood	Consultant Clinical Microbiologist	NHS Greater Glasgow & Clyde
Viv Hope	Senior Scientist	Public Health England
Carole Hunter	Lead Pharmacist	Addiction Services. NHS Greater Glasgow & Clyde
Dave Liddell	Chief Executive	Scottish Drugs Forum
Norah Palmateer	Epidemiologist	Glasgow Caledonian University/HPS
Josephine Pravinkumar	Consultant in Public Health Medicine	NHS Lanarkshire
Nicola Rowan	Programme Manager	HPS
Kirsty Roy (Chair)	Senior Epidemiologist	HPS
Stefano Rinaldi	Senior Solicitor	National Services Scotland
Kenny Simpson	Statement of Opinion (STOP) Manager	Scottish Crime and Drug Enforcement Agency
Avril Taylor	Professor/Chair in Public Health	UWS
Anne Weir	Administrative Assistant	HPS

The guidelines were prepared and written on behalf of the GDG by Alison Potts, Kirsty Roy and Norah Palmateer.

Appendix B: Sample IMT meeting agenda

Health Board

Agenda – Incident Management Team
Topic /Issue
Venue
Time

1. Welcome, Introduction & Apologies
2. Declaration of Interests and Confidentiality
3. Note of meeting (if applicable)
4. Matters arising (if applicable)
5. Situation Update
   a) Clinical
   b) Microbiology and other Laboratory Results
   c) Police
   d) Other
6. Risk Assessment
   a) Epidemiology
   b) Microbiology
   c) Police
   d) Other
   e) Summary of Risk Assessment
7. Risk Management
   a) Case Finding
   b) Contact Tracing
   c) Other
8. Further investigations - add laboratory, criminal, etc
9. Communications - add list of all those to be communicated with as below
   a) Communication with cases / contacts
   b) Alcohol and Drug Partnership
   c) SG, HPS, GPs, A&Es, OOH, Public
   d) Press Statement
   e) Information Sharing / Issues
10. Summary of actions
11. AOB
12. Date and Time of Next Meeting

Appendix C: Evidence base/considered judgement for recommendations

The evidence base underpinning the recommendations in section 5 was generated in order to answer the key questions:

- what public health interventions can be taken to reduce the harms associated with using potentially contaminated illegal drugs during an actual or potential incident?
- what advice and guidance can be given to PWUD in the event of an actual or potential incident of SFB to reduce the harms associated with using contaminated illegal drugs?
- what are the appropriate methods of communicating advice and guidance to PWUD in the event of a future incident of SFB to reduce the harms associated with using contaminated illegal drugs?

A literature search identified relevant studies to answer these questions, the studies were appraised, and evidence statements were derived from the study findings. The sections below are a reflection of the discussion and consensus of the GDG in its consideration of the evidence in order to formulate recommendations (Stage 4 of the SHPN guidelines development process, see Appendix A). The evidence that the GDG drew upon comprised the evidence statements and expert opinion of GDG members.

Encourage PWUD to reduce or eliminate drug use

Drug dependence treatment is intended to help individuals with a drug problem stop compulsive drug seeking and use. It is also recognised as being an important component of a comprehensive response to preventing infections associated with drug use [29; 30; 32]. Effective treatment typically incorporates a range of medical, psychological, social and behavioural strategies to stop or reduce drug use and injecting, which can be delivered in outpatient or in residential settings.

There is a high level of evidence that opiate substitution therapy (OST) is associated with reduced frequency of injection and, when combined with other harm reduction measures, the prevention of other (blood-borne) infections, e.g. HIV and HCV [29; 42; 43]. There is no evidence, however, that increasing availability and/or dose of OST, in order to reduce number of injecting events, is effective at preventing SFB infections (either alone or in combination with other treatment approaches). Nonetheless, the GDG acknowledges that reducing injection frequency not only limits exposure to contaminated heroin but also reduces the potential for skin and soft tissue damage and, consequently, the appropriate environment for the germination of the spores from the anaerobic pathogens such as *Clostridium tetani* and *Clostridium botulinum*. The GDG therefore endorses the recommendations of ECDC/EMCDDA [29] that drug dependence treatment should be available and easily accessible, in particular OST for opioid users.

The GDG considers that the provision of appropriately dosed OST (including a wide-range of OST options), in combination with other harm reduction interventions such as IEP services, should be the norm. However, there was consensus among the GDG that there may be potential issues in existing OST service provision that could limit its effectiveness in the event of a SFB outbreak including: i) PWUD not in contact with OST services (and it is this group who may be the most vulnerable to SFB infection); ii) the sometimes punitive approach with respect to missed OST scripts; iii) waiting times for commencing treatment, and iv) inconsistent OST provision across the country. Thus, within the context of an incident/outbreak, services providing OST should be reviewed and enhanced (where necessary), with a focus on reducing infection-related harm rather than abstinence. Approaches to reduce and, where possible, remove waiting lists should be considered, alongside a review of eligibility criteria to commence and continue to receive OST to ensure that there is no restriction on dosage and duration during the outbreak period. Specifically, and in recognition that many individuals continue to inject while receiving treatment, the GDG support the recommendations that IEP services should not discourage injectors from accessing sterile needles and other injecting equipment on the basis of receiving treatment for problem drug use [32] and services offering opioid substitution therapy should also make needles and syringes available to their service users [31].

Encourage PWUD to switch to a safer method of drug use

The GDG acknowledges that there is no safe route of drug consumption and that the only way to eliminate risk of infection is to stop using heroin. They also, however, recognise that problem drug use is characterised by intense and, at times, uncontrollable drug craving and that some individuals will continue to use drugs despite explicit warnings of the potential harms that they face. Interventions within the context of an incident/outbreak should, therefore, also address how to reduce risk, in so far as possible, for those who continue to use drugs.

There is insufficient evidence to support smoking, or other non-injecting routes of consumption, as an effective harm reduction intervention to prevent infection with tetanus, botulism or anthrax. There was, however, consensus among the GDG that in general, smoking poses a lower risk of infection than injecting (albeit the relative risk of infection associated with the different routes of drug consumption remain unknown) because:

1. intravenous injection introduces infectious agents directly into the blood stream, bypassing the body's natural defences;
2. skin and soft tissue damage as a consequence of injection provides an appropriate environment for the germination of the spores from the anaerobic pathogens.

There was also recognition that, while the risk of exposure to anthrax spores via inhalation or ingestion was considered to be lower, the consequences for those infected by these routes were significant with a more rapidly progressive and serious infection, in general, compared to those infected following injection of heroin [16; 17].

Therefore, within the context of an outbreak of botulism or tetanus, and if there is no intelligence to suggest that drugs are co-contaminated with anthrax spores, the GDG recommends that advice and information encouraging people to switch to a non-injecting route of drug consumption should be considered as part of a pragmatic harm reduction approach to reduce exposure. The GDG does not recommend that this intervention be employed as part of the public health management of an outbreak of anthrax, and endorses the message that heroin use by any route will carry a risk of infection if the heroin is contaminated with anthrax spores.

Reduce harm among those who continue to inject drugs

Pre-exposure prophylaxis (tetanus only)

Tetanus is completely preventable through adequate immunisation and good wound management. The tetanus vaccine has been part of the routine childhood immunisation schedule in the UK for more than 30 years. Five doses (given at 2, 3 and 4 months, three and a half years (pre-school booster) and 13-14 years (teenage booster)) are considered necessary to give good long-term protection [33]. Since its introduction, the uptake of tetanus in the primary schedule has been very good (currently running at >95% in Scotland). The uptake for the booster dose in the teenage years is variable.

There is insufficient evidence to conclude that vaccine coverage rates for tetanus are low among PWUD, and that targeted immunisation strategies and novel approaches to immunisation delivery are needed for this group [44]. However, the evidence focuses on herd immunity and consequently the generalisability of the findings as a public health intervention in response to an incident or outbreak of SFB is uncertain.

While it is not known how many Scottish PWUD have been vaccinated or have immunity against tetanus, it is likely they will have some cover - albeit that they may have missed the booster dose in the teenage years. Historically, outbreaks of tetanus have been documented among PWUD who report a history of no or partial immunisation [4].

Despite the lack of evidence from the literature, there was consensus among the GDG that PWUD should be offered tetanus vaccinations and boosters as routine prevention practice, as outlined in the Green Book and existing guidelines. The GDG therefore endorses the ECDC/EMCDDA [29] and Scottish Government [30] recommendations which state that: tetanus vaccination status should be checked among PWUD, and a booster vaccine should be offered if vaccination status is uncertain, particularly for those users who have injection site infections [29] and; wherever possible, all IEP services should make available vaccinations (including tetanus) on-site and, where IEP services do not offer on-site vaccination facilities, they should offer referrals [30].

Within the context of an outbreak of tetanus, low-threshold services should be enhanced and every opportunity should be taken to ensure that those with no or incomplete immunisation status are identified and vaccinated. The GDG acknowledge the challenges

of ascertaining vaccination status and that, for those with no previous immunisation history, the provision of the vaccine through a five dose schedule will not achieve effective immunity during the timeframe of the outbreak. Nonetheless, the pragmatic approach should be to offer a booster dose to all those whose vaccination status is unknown and/or those who do not have a history of receiving vaccine (in the last 12 months) for the management of a tetanus-prone wound.

The GDG also considered vaccines for the prevention of botulism and anthrax infection. There is, however, no vaccine to prevent infection with *Clostridium botulinum*. A vaccine for the prevention of anthrax is available in the UK but is only indicated for those working with infected animals or processing material from infected animals [33]. Although there have been no recorded cases of anthrax infection in vaccinated individuals, there have been no formal efficacy trials of the vaccine. There is consequently insufficient evidence for the efficacy of using anthrax vaccination as pre-exposure prophylaxis to prevent infection among PWUD during an outbreak.

Post-exposure prophylaxis (tetanus only)

Tetanus can be prevented by the appropriate management of a tetanus-prone wound. The goals of post-exposure prophylaxis following tetanus exposure are twofold. First, to remove the source of toxin production and secondly, to neutralize any toxin which may have been released. The first goal is best achieved by timely, thorough wound cleaning and surgical debridement (if required, see section 4.4 for links to current guidance on the clinical management of tetanus). The second goal is achieved by providing or inducing high circulating concentrations of tetanus antibody, which inactivate the toxin. Effective neutralizing antibody concentrations at the time of the injury can only be achieved by prior completion of the tetanus vaccine or immediate administration of tetanus immune globulin (TIG). Provision of the vaccine and/or TIG is dependent on immunisation status, any underlying potential immunosuppressive condition and to what degree the wound is tetanus-prone. The UK recommendations for active immunisation for clean or tetanus-prone wounds according to immunisation history are reproduced in Table AC-1. Within the UK, intravenous preparations of TIG are in limited supply. As an alternative, the GDG endorses the PHE recommendation of HNIG for subcutaneous use (trade-name Subgam) for the management of tetanus-prone wounds (see section 4.4).

The anthrax vaccine is currently not licensed for post-exposure prophylaxis nor is there evidence that anthrax vaccine administered post-exposure would be effective at preventing anthrax. Post-exposure vaccination, by itself, is unlikely to provide protection because the disease has a short incubation period and a rapid course. While there is Anthrax immune globulin intravenous (AIGIV), this is neither licensed in the UK nor is there any evidence that – administered alone or in combination with vaccine and/or antibiotics – it is effective at preventing illness among those exposed.

In terms of post-exposure prophylaxis, there is insufficient evidence for the feasibility and efficacy of using appropriate antibiotics to prevent SFB infection among PWUD. Of note, at the point of use by the individual, it is unknown whether the heroin is contaminated with any spores. Therefore, prophylaxis cover would need to be available to all individuals at risk of exposure (at which point it would become a pre-exposure intervention) and

would need to continue for a significant period given the uncertainties regarding how many weeks or months spores may remain in the drug supply. The logistics and issues around compliance and potentially unnecessary and inappropriate use of antibiotics render this control measure impractical and undesirable.

Table AC-1: Immunisation recommendations for clean and tetanus-prone wounds.*

Immunisation status	Clean wound: vaccine	Tetanus-prone wound: vaccine	Tetanus-prone wound: human tetanus immunoglobulin
Fully immunised, i.e. has received a total of five doses of vaccine at appropriate intervals	None required	None required	Only if high risk (i.e. heavy contamination with material likely to contain tetanus spores and/or extensive devitalised tissue)
Primary immunisation complete, boosters incomplete but up to date	None required (unless next dose due soon and convenient to give now)	None required (unless next dose due soon and convenient to give now)	Only if high risk, as above
Primary immunisation incomplete or boosters not up to date	A reinforcing dose of vaccine and further doses as required to complete the recommended schedule (to ensure future immunity)	A reinforcing dose of vaccine and further doses as required to complete the recommended schedule (to ensure future immunity)	Yes: one dose of human tetanus immunoglobulin in a different site
Not immunised or immunisation status not known or uncertain	An immediate dose of vaccine followed, if records confirm the need, by completion of a full five-dose course to ensure future immunity	An immediate dose of vaccine followed, if records confirm the need, by completion of a full five-dose course to ensure future immunity	Yes: one dose of human tetanus immunoglobulin in a different site

* Adapted from the Green Book [45]

Provision of injecting equipment

The GDG acknowledges that, since the source of these specific infections is most likely heroin contaminated with bacterial spores, the provision of sterile injecting equipment will not prevent exposure to spores, if they are present. It is not surprising, therefore, that there is no evidence that the distribution of sterile injecting equipment reduces the risk of infection with spore-forming bacteria. However, there is evidence that the distribution of such equipment acts as an incentive to attract and retain clients to services [29] and, in the context of an incident/outbreak, such contact gives the opportunity to provide appropriate harm reduction interventions and signpost to treatment services if required. The GDG also considers that the provision of sufficient sterile equipment, together with education on the correct single person use of each item, should provide some harm reduction benefit for SFB infections with regard to reducing the risk of tissue damage that would facilitate infection with anaerobic SFB.

The GDG therefore supports the principles of IEP as a harm reduction intervention and endorses the Scottish IEP [30] and ECDC/EMCDDA [29] guidance that recommends services should: (i) aim at all times to ensure that all clients have a sterile needle for every injection; (ii) [other non-needle drug injecting equipment] should be supplied in sufficient quantities to enable the use of one item each per injection and; (iii) provision of, and legal access to, clean drug injection equipment, including sufficient supply of sterile needles and syringes free of charge, as part of a combined multi-component approach implemented through harm reduction, counselling and treatment programmes.

Advice on safer injecting behaviour

The GDG recognises that there is no "safe" method of preparing drugs for injection that will remove or destroy spores and eliminate the risk for those individuals who chose to continue to take drugs during an incident/outbreak of spore-forming bacteria.

Five potential public health interventions were considered in this regard: the quantity of acid used (for dissolving drugs); the heating of drugs (during preparation for injection); the filtration of drugs; injecting hygiene; and injecting into the skin/muscle.

There is insufficient evidence to support the use of small quantities of acid dissolvers as an effective harm reduction intervention for SFB [4]. It is, however, recognised that too much acidifier can devitalise tissue around the injecting site, increasing the risk of infection with the anaerobic spore formers [3]. Thus minimising excess acidity should, logically, be encouraged.

The process of heating heroin, typically 65-70°C for up to 20 seconds, likely destroys non-spore-forming bacteria, but will not kill the spores of Clostridium and Bacillus species. The spores are highly resistant to heat, and their destruction requires temperatures that would be neither achievable at the point of heroin preparation, nor desirable as the heroin would evaporate [46]. Therefore, the GDG does not make any recommendations with regard to heating drugs.

While there is some evidence that filters with pore widths of 0.22μm are significantly better than cigarette filters in rendering syringes bacteria-free [47], there is neither the evidence to support the use of filtration nor a commercially available filter that would provide sufficient filtration to remove spores from prepared heroin.

There is limited evidence that interventions to improve injecting hygiene may reduce the risk of infection from the user's skin or the environment [48]. Furthermore, cleaning hands and the injection site will not eliminate the potential for exposure to spores contaminating the drugs. Nonetheless, good injecting hygiene may help to minimise the level of the more common staphylococcal skin and soft tissue infections among PWUD, which may confuse the early diagnosis of atypical and/or mild presentation of illness caused by spore-forming bacteria. The GDG also considers that hygienic injecting is a good message to promote to PWUD in general. The GDG therefore recommend that PWUD should be encouraged to wash their hands and the injecting site before injecting drugs.

Drug practices such as intramuscular and subcutaneous injection (intentionally or accidentally) appear to be a risk factor for infection with Clostridium species [3; 9; 11; 49]. These routes of injection cause significant local muscle inflammation and tissue damage and can result in the creation of anaerobic conditions that promote spore germination, vegetative cell growth and toxin production. The GDG therefore takes the view that avoiding the routes of injection associated with tissue damage will reduce the risk of infection, and that PWUD should therefore be discouraged from injecting into the skin or muscle. This advice, however, will not reduce the risk of infection with the non-aerobic *Bacillus anthracis*.

Despite the lack of evidence that advice and education on safer injecting practices reduces exposure to SFB infections, the GDG considers that safer injecting behaviour is an important communication message to promote to PWUD in general. The GDG therefore endorses the ECDC/EMCDDA [29] and Scottish IEP [30] guidance that recommend:

1. health promotion messages should be tailored to the needs of the user and provided at every possible opportunity;
2. IEP service staff should receive appropriate training prior to providing a service in relation to (amongst others) injecting risk behaviour and the correct, single person use of injecting equipment, and that messages should be given repeatedly and consistently to users.

With a background level of knowledge and awareness around safer injecting practices considered the norm, the provision of additional information within the context of an incident/outbreak, should require minimum training of frontline workers, and users should have some familiarity with infectious diseases, infection transmission and infection prevention.

During an incident/outbreak, services should be proactive in using every contact with a person who is currently injecting as an opportunity to promote safer drug behaviour and to increase PWUD understanding about the relevant infections, and infection prevention, with the aim of reducing the risk of contracting infection.

Education and awareness-raising of the signs and symptoms of illness

Among PWUD

There is no evidence that promoting recognition of the signs and symptoms of SFB infections among PWUD during an incident/outbreak does or does not have an impact on either healthcare seeking behaviour, improving diagnosis, improving outcomes or reducing the risk of death associated with infection. Nonetheless, the GDG believes that users should be informed of the nature of the hazard they face and encouraged to have a lower threshold for seeking medical care for any injection site infection during times of heightened awareness associated with an incident/outbreak.

The GDG acknowledges that this may be straightforward for tetanus and botulism, where infection is dominated by neurological symptoms that can be clearly defined. With anthrax, however, the spectrum of symptoms and the difficulties differentiating these symptoms from more routine skin and soft tissue infection, make this more difficult to articulate. Nonetheless, prompt treatment, particularly for tetanus and botulism, where immunoglobulin and antitoxin is the only specific therapy, greatly improves outcome.

There are many different approaches that can be used to communicate information to users [50]. The GDG recommend that educational interventions utilised in an incident/outbreak should be tailored to local drug use settings. The use of leaflets and posters has historically been common in previous outbreaks. However, there is evidence suggesting this is not the most effective method of communicating important messages to injecting drug users since some have literacy problems [34]. Where used, they should:

- use visual methods of communicating;
- limit the amount of written text;
- use appropriate language;
- require minimal literacy;
- be backed up with verbal explanation of the written material delivered by people with credibility.

In addition, there was consensus among the GDG members that:

- the advice provided should be consistent across generic and tailored face-to-face messages to avoid mixed messaging and confusion, and to ensure credibility; and
- any advice should be consistent with messages disseminated across the UK and Europe (if part of a wider incident/outbreak).

In recognition that IEP and addiction services are familiar with disseminating information on risks, the GDG believe that these services are ideally placed to take a more proactive approach during an incident/outbreak with every contact being an opportunity to raise awareness and signpost individuals to appropriate services if required. Other locations that might be accessed by drug users, such as primary care and A&E, could also be utilised to disseminate information. Consideration should also be given to augmenting the more established routes of health messaging dissemination to optimise engagement with, and to ensure that the message is passed to, marginalised and vulnerable groups who are not in contact with services, for example distribution of information through locations such as hostels and housing departments.

Awareness-raising tends to be targeted at users of the services described above; however, the needs of PWUD admitted to hospital (whether as part of an incident/outbreak or for another reason) also need to be addressed. The GDG feels that there is an important window of opportunity to intervene before discharge. If it is identified that the patient is a PWUD, then a member of the local addiction team should make an initial visit as soon as is possible to address the individual's drugs problem. It is important to discourage early self-discharge; for this reason, an appropriate care plan should be in place in relation to pain management. The GDG recommends that for PWUD admitted to hospital (whether as part of an incident/outbreak or not), prior to any discharge taking place (planned or self-discharge), interventions should seek to provide information on the signs and symptoms of illness and address an individual's drug problem, which should include addressing pain management, providing overdose awareness information and supplying naloxone.

While there is some evidence which suggests that peer-to-peer interventions delivered in a variety of models are effective at communicating increased risk to users [34; 50], there is no evidence of the effectiveness of peer educators delivering harm reduction messages in an incident/outbreak situation. Nonetheless, the GDG endorses the Scottish IEP [30] and ECDC/EMCDDA [29] guidelines that suggest:

- outreach or peer-led services may be suitable for providing education to those injectors who may prefer not to attend fixed site services to obtain their injecting equipment;
- peer-delivered services can provide much easier access to the most at-risk population; messages delivered by peers can [thus] have a greater impact (and lead to better intervention uptake) than those delivered by health workers.

The GDG acknowledges that establishing and training peer educators within the context of an incident/outbreak may be unachievable. If, however, trained peers are available, consideration should be given to utilising this approach.

Among healthcare professionals and staff in frontline drug and alcohol services

Individuals who continue to inject drugs, may come into contact with various professional and occupational groups who may be key to recognising individuals at risk. There is, however, no evidence that raising awareness of the signs and symptoms of illness among frontline works in IEP or addictions services shortens the period between symptom onset and access to medical care among infected PWUD. Nonetheless, the GDG considers frontline workers in IEP and addictions services to have a key role in identifying infected individuals and should actively assist individuals with suspected infection to the appropriate medical services for prompt treatment and care. It is, therefore, essential that this group of staff receive training on the clinical presentation of the illness under investigation and are familiar with where users can receive medical help, if required.

Diagnosis of illness such as tetanus, botulism and anthrax among users is not difficult when it is strongly suspected, for example when there is a recognised outbreak. However, where cases occur singularly, or with early cases of an outbreak, diagnosis may be delayed, or even missed. This may be especially true for anthrax as the clinical presentation may be varied and atypical. As practical experience of managing individuals infected with these infections is limited, and because early diagnosis and treatment improves outcome and risk of death (especially when administration of immunoglobulin or antitoxin is required), the GDG recommends that interventions to heighten and maintain awareness of the clinical presentation of illness should be undertaken with appropriate frontline staff. Periodic reminders should be circulated throughout the duration of the outbreak and updated if a particular clinical presentation is associated with an ongoing incident. Guidelines to support the early recognition and management of tetanus (see section 4.4) and botulism (see section 4.3) are available and have been developed for anthrax during the previous outbreak in 2009/10 (see section 4.2).

In addition, healthcare professions should be made aware of presenting symptoms and the appropriate diagnostic procedures, including the samples to be obtained prior to treatment commencing (treatment should never be delayed). The appropriate sample, collected at the correct time, and/or transported correctly to the laboratory (local or reference laboratory) can improve the chances of a microbiological diagnosis confirming infection. Colleagues in Microbiology have a key role to play in ensuring that their clinical colleagues are aware of and are familiar with the correct protocols (see section 4).

Appendix D: Summary of recommended public health interventions for the management of incidents/outbreaks of infection with spore-forming bacteria among people who use drugs

Table AD-1: Encourage PWUD to reduce or eliminate drug use.

Recommended intervention	Evidence for recommendation	Routine or enhanced	Rationale
1. Drug dependence treatment should be available and easily accessible, in particular OST for opioid users	Existing guideline [29]	Routine	Drug dependence treatment can help to achieve a reduction/ cessation of drug use in order to reduce/eliminate exposure to SFB
2. Services providing OST should be reviewed and enhanced where necessary in order to maximise coverage	GDG expert opinion	Enhanced	It may be possible to reduce /remove waiting lists and/or review eligibility criteria for receiving or remaining on OST to ensure that OST is maximised during an incident/outbreak period
3. IEP services should not discourage PWID from accessing sterile needles and other injecting equipment on the basis of receiving treatment for their drug problem	Existing guideline [32]	Routine	In recognition that many individuals continue to inject while receiving drug dependence treatment, the GDG supports these existing recommendations
4. Services offering OST should also make needles and syringes available to their service users	Existing guideline [31]	Routine	In recognition that many individuals continue to inject while receiving drug dependence treatment, the GDG supports these existing recommendations

Table AD-2: Encourage PWUD to switch to a safer route of drug use.

Recommended intervention	Evidence for recommendation	Routine or enhanced	Rationale
5. Advice and information encouraging people to switch to a non-injecting route of drug consumption should be considered where there is no intelligence to suggest that drugs are co-contaminated with anthrax spores	GDG expert opinion	Enhanced	Smoking (or other non-injecting routes of consumption) poses a lower risk of infection (except in the case of anthrax) than injecting, since injecting: (i) introduces infectious agents directly into the bloodstream, and (ii) skin/soft tissue damage as a consequence of injecting provides an appropriate environment for the germination of anaerobic SFB

Table AD-3: Reduce harm among those who continue to inject drugs.

Intervention category	Recommended intervention	Evidence for recommendation	Routine or enhanced	Rationale
Pre-exposure prophylaxis (tetanus only)	6. Tetanus vaccination status should be checked among PWUD, and a booster vaccine should be offered if vaccination status is uncertain, particularly for those users who have injection site infections	Existing guideline [29]	Routine	The GDG endorses these existing recommendations, which may help to prevent future incidents or outbreaks associated with tetanus.
Pre-exposure prophylaxis (tetanus only)	7. Wherever possible, all IEP services should make available vaccinations (including tetanus) on-site and where IEP services do not offer on-site vaccination facilities, they should offer referrals	Existing guideline [30]	Routine	The GDG endorses these existing recommendations, which may help to prevent future incidents or outbreaks associated with tetanus.
Pre-exposure prophylaxis (tetanus only)	8. Within the context of an outbreak of tetanus, low-threshold services should be enhanced and every opportunity should be taken to ensure that those with no or incomplete immunisation status are identified and vaccinated	GDG expert opinion	Enhanced	Acknowledging that the provision of the vaccine through a five dose schedule will not achieve effective immunity during the timeframe of an outbreak, a pragmatic approach is nevertheless to offer a booster dose to all those whose vaccination status is unknown or incomplete
Post-exposure prophylaxis (tetanus only)	9. For the management of a tetanus-prone wound, a tetanus vaccine booster dose should be offered to all those whose vaccination status is unknown or incomplete 10. For the management of a tetanus-prone wound, TIG or HNIG should be administered to those who vaccination status is unknown or incomplete	Existing guideline [33]	Routine	Tetanus can be prevented by the appropriate management of tetanus-prone wounds; the GDG endorses these existing UK recommendations for the management of tetanus-prone wounds

Table AD-3: Reduce harm among those who continue to inject drugs (cont).

Intervention category	Recommended intervention	Evidence for recommendation	Routine or enhanced	Rationale
Provision of injecting equipment	11. Services should aim at all times to ensure that all clients have a sterile needle for every injection 12. Other non-needle drug injecting equipment should be supplied in sufficient quantities to enable the use of one item each per injection 13. Provision of clean drug injection equipment should be part of a combined multi-component approach implemented through harm reduction, counselling and treatment programmes	Existing guidelines [29; 30], GDG expert opinion	Routine	The GDG considers that the the provision of sterile injecting equipment may provide a benefit with respect to SFB infections because: (i) there is evidence that such provision attracts/retains clients to/in services, which may provide an opportunity to intervene in an incident/outbreak situation and (ii) such equipment may improve injecting hygiene and reduce the risk of tissue damage that could facilitate infection with anaerobic SFB
Advice on safer injecting behaviour	14. Health promotion messages should be tailored to the needs of the user and provided at every possible opportunity 15. IEP service staff should receive appropriate training prior to providing a service in relation to (amongst others) injecting risk behaviour and the correct, single person use of injecting equipment	Existing guidelines [29; 30]	Routine	The GDG considers that safer injecting behaviour is an important communication message to promote in general, and therefore endorses these existing recommendations
Advice on safer injecting behaviour	16. PWUD should be encouraged to minimise the use of acidifier for mixing with drugs	Existing guideline [30]	Routine	Excess acidity can devitalise tissue around the injecting site, increasing the risk of infection with anaerobic SFB

Table AD-3: Reduce harm among those who continue to inject drugs (cont).

Intervention category	Recommended intervention	Evidence for recommendation	Routine or enhanced	Rationale
Advice on safer injecting behaviour	17. PWUD should be encouraged to wash their hands before preparing drugs	Existing guideline [30]	Routine	Good injecting hygiene may help to minimise the level of the more common staphylococcal skin and soft tissue infections that may confuse the early diagnosis of illness caused by SFB
Advice on safer injecting behaviour	18. PWUD should be discouraged from injecting intramuscularly or subcutaneously	Existing guideline [29]	Routine	These routes of injection can cause local tissue damage, which can result in the creation of anaerobic conditions that promote spore germination, vegetative cell growth and toxin production

Table AD-4: Education and awareness-raising of the signs and symptoms of illness.

Target group	Recommended intervention	Evidence for recommendation	Routine or enhanced	Rationale
Among PWUD	19. Information on the signs and symptoms of illness (resulting from botulism, tetanus or anthrax infection), and guidance on when and where to seek medical care, should be communicated to users	GDG expert opinion	Enhanced	Users should be informed of the nature of the hazard they face; prompt treatment may improve outcomes
Among healthcare professionals and staff in frontline drug and alcohol services	20. IEP and addictions staff should receive training on the clinical presentation of botulism, tetanus and anthrax	GDG expert opinion	Routine	PWUD may regularly come into contact with IEP and addictions frontline workers, who may be key to recognising infected individuals and facilitating medical care
Among healthcare professionals and staff in frontline drug and alcohol services	21. During an incident/outbreak, interventions to heighten and maintain awareness of the clinical presentation of botulism, tetanus and anthrax should be undertaken with IEP and addictions staff	GDG expert opinion	Enhanced	Practical experience of infected individuals is limited due to these infections being rare, thus it is important to refresh training during incidents/outbreaks
Among healthcare professionals and staff in frontline drug and alcohol services	22. Healthcare professionals should be made aware of presenting symptoms and the appropriate diagnostic procedures, including the samples to be obtained prior to treatment commencing (although treatment should never be delayed)	GDG expert opinion	Routine	The appropriate sample, collected at the correct time, and/or transported correctly to the laboratory (local or reference laboratory) can improve the chances of a microbiological diagnosis confirming infection

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