NHS National Services Scotland

Healthcare infection incidents and outbreaks literature review

Healthcare infection incidents and outbreaks in Scotland

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ARHAI Scotland

Antimicrobial Resistance and Healthcare Associated Infection

Key Information

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Document information	Description
Description	This literature review examines the available professional literature relating to the recognition, assessment, investigation and management of healthcare infection incidents and outbreaks in hospital/acute settings.
Purpose	To inform the Incidents and Outbreaks chapter of the National Infection Prevention and Control Manual in order to facilitate the prevention and control of healthcare associated infections in NHSScotland hospital/acute settings.
Target Audience	All staff involved in the prevention and control of infection in hospital/acute settings in NHSScotland.
Update/review schedule	Updated as new evidence emerges with changes made to recommendations as required. Review will be formally updated every 3 years with next review in 2024.
Cross reference	National Infection Prevention and Control Manual
Update level	Practice – No significant change Research – Further research required into the potential benefit of healthcare worker hand screening when specific 'hands on' procedures are implicated in outbreaks (such as drug preparation), healthcare staff who are carriers of pathogens, the management of 'near-miss' incidents and follow-up periods post-outbreak.

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Version history

This literature review will be updated in real time if any significant changes are found in the professional literature or from national guidance/policy.

Version	Date	Summary of changes
2.1	February 2024	The definition of an **exceptional infection episode** that was in version 2.0 of this literature review (defined as a single case of an infection that has severe outcomes for an individual patient OR has major infection control/public health implications e.g. infectious diseases of high consequence such as extensively drug resistant tuberculosis (XDR- TB), botulism, viral haemorrhagic fever, polio, rabies, diphtheria)), has been replaced with a new definition: An **exceptional infection episode**, defined as a single case of rare infection that has severe outcomes for an individual AND has major implications for others (patients, staff and/or visitors), the organisation or wider public health for example, high consequence infectious disease (HCID) OR other rare infections such as XDR-TB, botulism, polio, rabies or diphtheria. The 'single case of an infection that has severe outcomes for an individual patient' element within the exceptional infection episode definition of version 2.0 did not fully align with the evidence within the literature review, which refers to 'a single case of **rare** disease or serious illness'. Any infection may have severe outcomes for an individual patient, therefore the definition has been revised to include major implications for others ('AND' instead of 'OR'). The definition had examples of high consequence infectious diseases (HCID) that did not align with the UK 4 Nations Public Health agencies classification (XDR-TB, botulism, polio, rabies and diphtheria are not classified as HCIDs) and has been rephrased to account for this.

Version	Date	Summary of changes
2.0	June 2022	This review was updated using two-person methodology as outlined in NIPCM development process and methodology document. Peer-reviewed literature has been incorporated for the first-time in this literature review. The research question, 'How should potential healthcare infection incidents be assessed?' has been reworded to say; 'How should suspected healthcare infection incidents be assessed?' New research question added; How should a healthcare infection incident be 'closed', with lessons learned, recorded and disseminated nationally? A number of recommendations have been rephrased and new recommendations have been added. The grading of existing recommendations has also been changed to reflect the quality of the evidence-base used to inform them.
1.0	March 2017	New literature review

Approvals

Version	Date Approved	Name
2.0	May 2022	National Policies Guidance and Evidence Working Group

Contents

1. Objectives

The aim is to review the extant scientific literature relating to the recognition, assessment, investigation and management of healthcare infection incidents and outbreaks in hospital/acute settings to inform evidence-based recommendations for practice in Scotland. **For the purpose of this literature review, the terms 'incident' and 'outbreak' are used synonymously.**

The specific objectives of the review are to determine:

- What is the definition of a healthcare infection incident/outbreak?
- How can healthcare infection incidents/outbreaks be recognised/detected?
- How should suspected healthcare infection incidents/outbreaks be assessed?
- How should healthcare infection incidents/outbreaks be investigated and managed?
- When should staff screening be considered?
- Should deaths associated with healthcare infection incidents/outbreaks be reported?
- How should healthcare infection incidents/outbreaks be communicated?
- When would the National Support Framework 2017 be invoked in relation to a healthcare infection incident/outbreak?
- How should a healthcare infection incident/outbreak be 'closed', with lessons learned, recorded and disseminated nationally?

2. Methodology

This targeted literature review was produced using a defined two person systematic methodology as described in the National Infection Prevention and Control Manual: Development Process.

Following identification of a significant number of observational studies (outbreak reports) in relation to this topic and to balance breadth and depth of analysis, only literature from the previous 10 years was considered for this review. Outbreak reports were included if they made reference to any infection prevention or control measures including bundled measures. Reports were required to include confirmation of transmission via isolate matching through phenotyping/genotyping processes etc. This review did not include outbreak management in the neonatal setting or water-borne incidents/outbreaks as these are covered by separate literature reviews. The review also does not include reports of COVID-19 outbreaks or outbreaks in nursing homes/care homes.

3. Discussion

3.1 Implications for practice

What is the definition of a healthcare infection incident/outbreak?

Mandatory Scottish guidance and operational guidance from the UK Health Security Agency (UHKSA, previously Public Health England), both state that an outbreak or an incident should be considered:

1. if there are two or more people experiencing a similar illness which is temporally and spatially linked (time and place)

2. if there is a single case of a rare disease or a serious illness with major public health implications (e.g. botulism, viral haemorrhagic fever, extensively drug-resistant tuberculosis (XDR-TB), polio, diphtheria, rabies.

3. if there is a higher than expected rate of an infection which is over and above the usual background rate for the time and place where the outbreak occurred, or

4. if there is a high likelihood of exposure of a population to a hazard (e.g. a chemical, food, water or infectious agent) at levels sufficient to cause illness.[1, 2]

These guidelines are for public health incidents/outbreaks, however they are also applicable to healthcare associated incidents/outbreaks. There is lack of clarity in the guidance identified with regards to the interval between defined cases, however in practice that would most likely depend on the specific organism, setting, risk factors, local policy and findings from initial investigations.[3] It is unclear from the evidence base whether healthcare infection 'near miss' incidents (where persons could have been exposed to an infectious agent, but were not) fall under the definitional banner of a 'healthcare infection incident'.

Expert opinion from the Society for Healthcare Epidemiology of America (SHEA) states

that a single case may be considered as an incident/outbreak if previously there have been no cases in the facility (e.g. healthcare-associated legionella infection).[4] Another expert opinion from the National Institute for Health and Care Excellence (NICE) states that a single case of a disease can also be categorised as an incident if it has the potential to expose people to infection risk.[5] American expert opinion from the West Virginia Department of Health and Human Resources presented a healthcare associated infection (HAI) outbreak investigation/notification protocol whereby a single case of the following may constitute an outbreak; an infection with vancomycin-intermediate *Staphylococcus aureus* (VISA) or vancomycin-resistant *Staphylococcus aureus* (VRSA), an infection with a multidrug-resistant organism (MDRO) with an unusual resistance pattern, a single case of Legionellosis if the patient has been in the healthcare facility for the entire incubation period, acute hepatitis B or C in a patient with no known risk factors for hepatitis and who had an invasive procedure during the incubation period and finally, post-procedure infection with an unusual organism.[6] It is unclear what evidence has been used to produce this protocol, hence no conclusions can be drawn regarding its applicability in Scottish health and care settings.

There was a lack of consistency in outbreak reports regarding the criteria used for defining an outbreak/infection incident. Some reports cited a higher-than-expected rate of infection, for the given time and place, as the trigger for use of the 'outbreak' term descriptor. The majority of these incidents occurred in intensive care units (ICUs) and demonstrated data exceedance as per documented surveillance data.[7-11] Five studies identified two or more linked cases, associated with the same infectious agent, as the trigger for outbreak declaration, the majority of which involved MDROs such as multi drug resistant *Klebsiella pneumoniae*, Extended- spectrum beta-lactamase (ESBL) producers and Methicillin-sensitive *Staphylococcus aureus* (MSSA). [12-16] Outbreak reports that could not provide evidence of data exceedance, as per documented baseline rates, or a rationale for a trigger were excluded as evidence for this research question.

In relation to single cases triggering outbreak investigations, one report described a healthcare infection exposure event involving a single healthcare worker who was infected with *Mycobacterium tuberculosis.* Exposure to an infected patient as a result of premature de-escalation of airborne precautions led to a retrospective incident

investigation being triggered to identify further exposures.[17] A duodenoscope-related outbreak involving one case of Carbapenem-resistant *Klebsiella pneumoniae* triggered an outbreak investigation, the rationale being that the organism was listed as an 'urgent threat' in the US Centers for Disease Control and Prevention (CDC) Antibiotic Resistance Threats Report for 2019.[18] Other organisms listed as urgent threats in the CDC report were Carbapenem-resistant *Acinetobacte*r, *Candida auris*, drug-resistant *Neisseria gonorrhoeae* and drug-resistant *Clostridioides difficile*. The CDC report does not provide any details regarding outbreak or incident triggers and the threat classification is based on antibiotic resistance.[19]

Absence of an appropriate baseline rate may be a barrier to identification of a healthcare associated infection outbreak. The authors of one report that described an outbreak of *Clostridioides difficile* were unable to differentiate between community-acquired and hospital acquired cases.[20] It was unclear what definition was used to define the outbreak in a study with absence of a baseline rate, where an outbreak of *Mycobacterium abscessus* was declared after identification of the third case.[21]

How can healthcare infection incidents/outbreaks be recognised/detected?

The World Health Organization (WHO) states that an early and effective response to an actual or potential healthcare infection incident/outbreak is crucial.[22] Healthcare Improvement Scotland's Infection Prevention and Control (IPC) standards 2022 state that a healthcare organisation must implement local surveillance of infections and alert organisms. This system should make use of 'triggers' allowing prompt detection and response to any variance from normal limits, including those caused by possible outbreaks.[23, 24] The Infection Prevention & Control Team (IPCT)/Health Protection Team (HPT) should be aware of and refer to the national minimum list of alert organisms/conditions, which will aid in incident/outbreak recognition. Standard operating procedures should be in place for IPCTs to respond to these surveillance triggers. As per the Health Protection Scotland and Scottish Intensive Care Society Audit Group (HPS/SICSAG) protocol, all NHS Boards must continue to undertake surveillance of HAIs within ICUs. In wards or departments where high risk procedures

are undertaken, or where immunocompromised patients are cared for (such as haemato-oncology units, neonatal units, ICUs and hard organ transplant units), Boards should take special note of any fungal and Gram-negative infections.[25] A risk based approach should be applied for other vulnerable groups such as cystic fibrosis or oncology patients and those undergoing renal dialysis.[25]

English guidance from UKHSA (previously PHE) presents two methods of hospital surveillance; case-based surveillance which is based on statistical analysis of collated reports of individual cases, and event-based surveillance which is based on direct reporting of outbreaks or exceptional events, typically by clinical staff.[26] The latter is the more common mechanism of detection of locally confined, acute onset outbreaks, however, it must be noted that before declaration of an incident/outbreak, cases must be investigated locally as there may be other reasons for apparent clustering of cases, such as batching of reports to the surveillance system or changes in diagnostic protocols causing case over-ascertainment.[26]

Healthcare associated infection (HAI) surveillance systems can aid in incident/outbreak detection and investigation through retrospective detection of cases alongside prospective case finding. They can also facilitate the evaluation of trends against defined targets and allow comparisons to be made with local and national averages.[4] However, it must be noted that national averages may differ for different countries as well as between different settings, hence they must be interpreted accordingly. HAI surveillance systems were the main sources of detection of outbreaks of extended-spectrum beta-lactamase (ESBL) producers and MRSA in ICUs, norovirus in elderly care wards, *Acinetobacter spp.* in a neurological ICU, *Serratia marsecens* and Hepatitis C virus in hospital wards. [9, 10, 12, 13, 15, 27-29] A key observation was that many routine surveillance systems adopted in health and care settings usually address only specific wards (e.g. ICU) or a specific set of targeted organisms. This could potentially hinder outbreak detection out with this setting, although, it is worth noting, that these parameters may be adjusted by the user in line with extant policy for surveillance.

Two pathogen-specific guidelines presented unique criteria for outbreak identification or specific, defined, surveillance time periods. Steer et al. recommend a minimum time period of 6 months for retrospective surveillance of an HAI Group A Streptococcal

(GAS) infection and norovirus guidance from the CDC describe the Kaplan criteria for detection of an outbreak in absence of diagnostic certainty.[3, 30] The Kaplan criteria facilitates outbreak detection via clinical presentation of vomiting and epidemiological parameters such as mean incubation period and duration of illness.[30] UK expert opinion from the norovirus working party in 2012 on the other hand has rejected the use of the Kaplan criteria for defining a norovirus outbreak, based on the argument that norovirus outbreaks are predominantly diarrhoeal in nature and calculation of an incubation period would suggest that the criteria can only be used retrospectively. However, this working party document appears to be out of date with no scheduled update identified.[31]

This review identified eleven studies where incidents/outbreaks were detected through local reporting by a staff member/treating physician/IPCT.[7, 14, 21, 32-39] It must be noted that this method is highly subjective and dependent on individual assessment /interpretation by IPCT and adequacy of internal reporting systems. Outbreaks were also detected after alerts were raised by the microbiology laboratory with relation to MDRO cases with unusual resistance patterns detected within a short span of time in an ICU and following a bronchoscopy procedure.[40, 41]

In one report, an outbreak of vancomycin-resistant Enterococci was detected following an alert from a neighbouring hospital[42] and in another, a *Candida auris* international alert prompted a look-back exercise and subsequent detection of an outbreak of the same pathogen in a neurosciences ICU of a UK hospital.[11] Bacteraemia or unusual invasive infections with temporal linkage and severe implications for the patient were used as triggers for declaring outbreaks linked to *Bacillus cereus, Serratia marcescens, Burkholderia cepacia, Pseudomonas spp.*, multidrug-resistant *Acinetobacter baumannii* and Methicillin Sensitive *Staphylococcus Aureus*.[8, 16, 43-46] Discovery of a MDRO in a single patient with no known risk factors initiated further investigations and identification of two outbreaks.[47, 48] Routine screening of patients transferred from foreign hospitals where outbreak strains were endemic was helpful in identifying a point source for a multidrug-resistant *Acinetobacter baumannii* and a Carbapenemase-producing Enterobacterales outbreak in France. [49,50]

Two studies were identified where surgical site infection (SSI) surveillance was able to detect outbreaks involving *Serratia marcescens* in a neurosurgical site post

craniotomy[51] and a *Pseudomonas aeruginosa* infection following an arthroscopic surgery.[52] The Scottish SSI surveillance programme, established in 2002, currently monitors post procedural infection related to four surgeries; hip arthroplasty, caesarean section, planned large bowel surgery and planned major vascular surgery.[53]

Two outbreaks were detected as part of targeted patient notification and screening exercises, in the absence of SSI surveillance, both were Carbapenemase-producing Enterobacterales outbreaks following endoscopic procedures.[18, 54]

How should suspected healthcare infection incidents/outbreaks be assessed?

The Infection Prevention and Control (IPC) Standards 2022 state that where a potential/actual incident has been identified, an assessment should be undertaken by staff using an infection incident assessment tool.[24] Mandatory Scottish guidance states that on recognition of a healthcare infection incident, the IPCT/HPT within the affected NHS Board must undertake an assessment using the Healthcare Infection Incident Assessment Tool (HIIAT).[1, 23, 25, 55] The HIIAT should be used to assess every healthcare infection incident, this includes all outbreaks and incidents (including decontamination incidents or near misses). The 4 incident criteria assessed by the tool include severity of illness, impact on services, risk of transmission and public anxiety. Each aspect is assigned a descriptor of minor, moderate or major. Based on the collective evaluation of these descriptors, an incident is designated as 'Green', 'Amber' or 'Red'.[1]

The HIIAT was adapted from the Infection Control Outbreak/Episode Risk Matrix, developed as part of the Watt Report.[56] It is a tool for assessing and communicating healthcare infection incidents/outbreaks, both internally within an NHS Board/care organisation and externally to ARHAI Scotland and following this, the Scottish Government Health and Social Care Department (SGHSCD). It may or may not be necessary to formulate a Problem Assessment Group (PAG) prior to undertaking the HIIAT assessment. An individual member of the IPCT or HPT may undertake the initial assessment, and based on the HIIAT rating, it may then be deemed necessary to convene a PAG. More complex incidents/outbreaks may require rapid development of a

PAG to inform the initial HIIAT assessment.[1]

NHS Boards are required to report all HIIAT Green, Amber and Red assessments undertaken in acute settings (e.g. hospitals) to ARHAI Scotland.[1, 25, 55] The ongoing impact of an incident/outbreak should be monitored and escalated/de-escalated as appropriate using the HIIAT assessment. The HIIAT should remain Amber or Red only whilst there is ongoing risk of exposure, identification of new cases or until all exposed cases have been informed.[1]

Only one Scottish outbreak report mentioned the application of an HAI tool as part of a norovirus outbreak in a hospital for the elderly, although the authors did not provide the detailed findings of this assessment.[13]

Very limited evidence was identified with regards to assessment of incidents and outbreaks in the literature. Five reports documented the process of formation of a multi-disciplined outbreak control team to assess the incident/outbreak, however they failed to provide details on the outcomes of this process and did not report on key criteria such as severity, ongoing impact or public health implications of the incident.[8, 12, 17, 42, 45] In one outbreak report by Humphries et al, an assessment of a pathogen's antibiotic resistance was demonstrated to be the rationale behind declaring an outbreak.[18] The outbreak of carbapenem-resistant *Klebsiella pneumoniae* was assessed as an 'urgent threat' based on the CDC's assessment criteria of antibiotic resistance which categorises organisms as urgent, serious or concerning and assesses levels of threat based on factors such as clinical and economic impact, projection of incidence, transmissibility, availability of effective antibiotics and barriers to prevention.[19] Other methods of incident/outbreak assessment identified in literature included the use of a flagging system on patients' electronic records which assigned a level of risk to the patient based on proximity to the index case[14] and the use of an 'all hazards self-assessment' system, however, the latter pertained more to mass casualty events and hazard preparedness planning rather than HAIs.[4]

How should healthcare infection incidents/outbreaks be investigated and managed?

In response to a suspected incident/outbreak, it is the responsibility of the NHS Board (specifically the infection control doctor (ICD)/consultant microbiologist and/or consultant in public health medicine (CPHM)) to establish if an incident management team (IMT) is required. In the NHS hospital setting, the ICD will usually chair the IMT, as well as lead the investigation and management of healthcare infection incidents/outbreaks. Where there are significant implications for the wider community e.g. outbreaks of TB, measles, or rare events such as Variant Creutzfeldt-Jakob disease (vCJD) or a Hepatitis B virus/HIV look back, or where there is an actual or potential conflict of interest with the hospital service, the CPHM may chair the IMT.[1]

The membership of the IMT will vary depending on the nature of the incident, but will normally include an NHS Board Chair, HPT representatives, IPCT representatives, other relevant clinical staff, a communications officer and administrative support.[1]

According to mandatory Scottish guidance, the investigation will usually consist of the following elements; the epidemiological investigation, the microbiological investigation and a specific investigation into how cases were exposed to the infective agent and/or hazard (environmental investigation).[1] The IMT should also aim to identify any change(s) in the system e.g. staffing, procedures/processing, equipment, suppliers, which may have had a role to play in outbreak/incident causation. A step-by-step review of procedure(s) may be helpful.[1, 2]

EPIDEMIOLOGICAL INVESTIGATION

As part of the epidemiological investigation, a case definition(s) for the purpose of the incident should be agreed upon by the IMT at the outset. Case definitions should include the following: the individuals involved (e.g. patients, staff), the place (e.g. care area(s) involved) and an outbreak linked time frame, for identification of cases. The case definition(s) should be regularly reviewed and refined (if required) throughout the incident/outbreak investigation as more information becomes available.[1, 22] There was a lack of consistency in outbreak reports with regards to how cases were defined, with some reports failing to differentiate between colonised and infected cases and others failing to document a defined time period for case identification.[16, 33] As part of

the epidemiological investigation, a 'look back exercise' may be conducted for retrospective identification of cases alongside 'prospective surveillance' for active case finding. UK expert opinion on Group A streptococcal infections recommends retrospective analysis of GAS infections diagnosed in the past 6 months in hospital patients, although this represents pathogen-specific guidance with limited applicability to other outbreak scenarios.[3] Three outbreak reports involving *Pseudomonas aeruginosa* performed 'look-back exercises' spanning a period of 6 months-2 years and authors of one *S. aureus* outbreak report described a 3 month look back exercise.[16, 34, 41, 57]

The CDC outlines a range of data sources and methods that can be utilised in an epidemiological investigation to gather incident/outbreak information. These include occupational health records, case notes, billing records, infection control assessments, laboratory and radiology reports, interviews, contact tracing, pharmacy reports, log books, medical records, literature reviews and surveillance records.[58] Four outbreak reports documented the use of one or more of these resources as part of their investigation, often to identify common exposures and establish spatio-temporal links between cases.[16, 37, 59, 60] In two multidrug-resistant *Acinetobacter baumannii* outbreaks, contact tracing was useful in identifying case patients who had overlapping stays with an index case.[59, 60] In an outbreak of *Burkholderia cepacia* complex, a literature review helped identify chlorhexidine mouthwash as a potential pathogen source,[37] and a review of case notes identified a staff member as a potential source of *S. aureus* based on close contact with 15 patients.[16] Mandatory Scottish guidance and an expert opinion from USA both recommend implementation of 'line listing' and/or 'epidemic curves' for organisation of time, person and place data in an epidemiological investigation.[1, 58] A 'line list' typically involves a spreadsheet for analysis of data allowing rapid examination of exposures whereas an 'epi curve' is a visual illustration of the magnitude and time course of the outbreak which may aid in making inferences about the pattern of the incident/outbreak.[30, 58] It may be possible to form a working hypothesis regarding the transmission route and source of the exposure, based on initial investigation findings.[1] According to WHO expert opinion, the most common approach to hypothesis testing is a case-control study.[22] In two outbreaks, case-control analyses suggested that undergoing specific medical procedures was a strong risk factor for

infection/colonisation with the outbreak strains; *Acinetobacter baumanii* and Carbapenem-resistant *Klebsiella pneumoniae*, were both linked to ultrasound procedures[18, 33] whereas indwelling catheters and exposure to IV fluids were found to be associated with *Serratia marsescens* and carbapenem-resistant *Pseudomonas* outbreaks respectively.[43, 61] It should be noted that, in outbreak scenarios, case-control findings must be interpreted with caution as they are likely to have small sample sizes and ill-matched controls of convenience. Two tools were identified in the literature for investigation of hospital incidents/outbreaks, namely the ALARM tool which describes a formal, practical protocol for investigation and analysis of clinical incidents, and the Ishikawa's fishbone analysis, which is a visual tool utilising a people, process, equipment, material and management approach to create visual linkages.[35,- 62] No generalisations can be made regarding their applicability to Scottish health and care settings due to limited evidence.

MICROBIOLOGICAL INVESTIGATION

Scottish mandatory guidance states that, following an incident/outbreak, investigation into the nature and characteristics of the implicated hazard may be appropriate.[1] In healthcare infection incidents, this would be a microbiological investigation.[1] This typically involves obtaining relevant diagnostic specimens from suspected cases/environmental sources and/or a confirmation of the clinical diagnosis microbiologically.[22] Clinical sampling would be performed locally by the boards and be determined by the organism and/or clinical presentation and epidemiological requirements.

UK expert opinion on Group A streptococcal infections states that whenever a nosocomial outbreak is suspected, clinicians should immediately notify the reference laboratory and agree on a priority for typing of isolates.[3] Scottish expert opinion on *C. difficile* also states that molecular typing of isolates from cases should be discussed with the reference laboratory so that the epidemiology of *C. difficile* may be elucidated and isolates stored for future analysis.[23]

Molecular typing is aimed at establishing the relatedness of isolates which belong to the same species. Molecular investigations in an outbreak are often complicated by polyclonality which can create discrepancies between the molecular investigation

findings and those of the epidemiological investigation. In the majority of identified outbreak reports, clonal relatedness was proven through molecular typing [16, 43, 47] hence providing evidence for cross-transmission and epidemiological linkage. However, one outbreak of carbapenemase-producing Enterobacterales (CPE) was difficult to investigate as patient zero was colonized with four different CPEs.[48] In this outbreak, epidemiological investigation findings complemented and aided those of the molecular investigation, via identification of the index case who had a history of hospitalisation in a foreign hospital with proven direct contact with two further cases.

Outbreak reports identified a range of methods and numerous technologies for obtaining and processing specimens. Details regarding these methodologies is out-with the scope of this review.

ENVIRONMENTAL INVESTIGATION

According to mandatory Scottish guidance, a specific investigation into how cases were exposed to the hazard or the infectious agent must be conducted.[1] Therefore, if the findings of the epidemiological investigation suggest a common exposure to a potential environmental source, relevant environmental sampling should be undertaken with the sampling strategy influenced by the findings of the epidemiological investigation.[3, 58]

Joint Healthcare Infection Society (HIS) and Infection Prevention Society (IPS) guidelines on meticillin-resistant *Staphylococcus aureus* (MRSA) state that there is insufficient evidence to support the routine use of screening/sampling of equipment, however, it may be beneficial in specific circumstances, such as outbreaks.[63] Six outbreak reports were identified, which were associated with patient equipment; including bronchoscopes and uteroscopes colonised with *Pseudomonas aeruginosa* or multidrug-resistant *Acinetobacter baumannii* ,[41, 46, 57] duodenoscopes contaminated with carbapenem-resistant *enterobacteriaceae,* [54] re-usable shaving razors colonised with *Serratia marcescens* [51] and a urine collecting machine that was contaminated with carbapenem-resistant *Pseudomonas aeruginosa*.[61] Five outbreak reports were identified where the source of the outbreak was a pharmaceutical product, this included a disinfectant solution containing *Serratia marcescens,* [35] a central dispensing unit contaminated with *Acinetobacter baumannii,* [33] IV solutions

contaminated with *Pseudomonas aeruginosa* and *Serratia marcescens* [28, 45] and a chlorhexidine mouthwash contaminated with *Burkholderia cepacia*.[37] In three outbreak reports, findings from the environmental investigation identified an environmental reservoir, however, this being the original source of the pathogen could not be confirmed.[7, 21, 42] Two outbreak reports stated that an environmental investigation was conducted, although no positive isolates were found in the environment; the outbreaks involved *Streptococcus pyogenes* and CRE respectively. [47, 64] Environmental surveillance was omitted from one outbreak report because a healthcare worker was identified as the source of the outbreak of *S. aureus.*[16] In a food-borne outbreak involving Multidrug resistant *Klebsiella pneumoniae*, environmental sampling revealed contamination of hospital kitchen surfaces and a hand-made fruit puree, along with high faecal colonisation in cases. Further investigations identified carriers in the kitchen staff and food handlers.[15]

INFECTION PREVENTION AND CONTROL ASSESSMENT

Mandatory Scottish guidance states that, during an incident/outbreak, a review of current standards of practice must be undertaken to identify areas for immediate improvement.[1] This is a complex process which investigates whether standard IPC practices and control measures in line with the NIPCM are in place and compliance audited and reviewed. Two UK expert opinions, one on GAS infections and the other on *C. difficile*, both state that the frequency, standard and method of cleaning and decontamination of equipment and relevant ward areas should be reviewed.[3, 23] An online manual from CDC recommends that discrepancies in IPC practices can be identified through a combination of direct observations and a review of healthcare worker self-reported practices. The CDC manual further outlines the major IPC domains to consider while performing an IPC assessment. These include a review of the existing IPC program and IPC training; hand hygiene; use, availability and quality of personal protective equipment (PPE); prevention of HAI; injection safety; environmental cleaning; waste management; device reprocessing; and the surveillance of multidrug-resistant organisms.[58] The IPC assessment/review process was described in several outbreak reports. These included; lack of a clear definition of cleaning tasks in an outbreak of VRE,[42] sharing of dedicated healthcare workers between ICU and adjacent wards in a CPE outbreak, [48] use of multi-use vials of gel in an *A. baumanii*

outbreak, [33] administrative and technical problems in instrument reprocessing in an multidrug-resistant *A. baumanii* outbreak[46] and finally, a *Serratia marsecens* outbreak in which disinfectant solutions had been prepared in variable concentrations, dispensers were not authorised for hospital use and the canister used for preparation of disinfectant had never been reprocessed.[35] In a CPE outbreak investigation which identified a colonised duodenoscope, no breaches were identified in instrument reprocessing, however, following decommission of the scope, the outbreak was terminated.[54] For further details on CPE management, please refer to the Toolkit for the early detection, management and control of carbapenemase-producing Enterobacteriaceae in Scottish acute settings.

CONTROL MEASURES AND FOLLOW-UP

According to mandatory Scottish guidance, outbreak control measures should aim to reduce risk to public health. Measures should be directed at the source of the exposure and/or at affected persons in order to prevent secondary exposure to the infectious agent.[1] UKHSA guidance states that control measures should be initiated within 24 hours of receiving the initial report and should be implemented as per relevant guidance and investigation findings regarding the nature of the outbreak.[2] The WHO states that control measures should be determined by the results of the initial investigation after consultation with appropriate infection control professionals and a team of experts.[22]

In nine outbreak reports, no definitive source was identified and a bundled approach was applied for incident/outbreak management.[7, 21, 34, 42, 43, 46, 54, 59, 60] The most common control measures implemented were; isolation and cohorting of case patients [60 21] implementation of a screening protocol [7, 34, 42] contact precautions [43, 60] re-enforcement of hand hygiene [7, 46, 59] and introduction of enhanced cleaning strategies.[7, 34] It must be noted that, in outbreaks where a bundled approach is implemented in response to infection incidents/outbreaks, analysing the effectiveness of individual IPC measures in isolation is impossible. If outbreak reports could not demonstrate a post control measure implementation follow-up period with sustained reduction of/ no further cases, they were excluded from the evidence base, as no evaluation could be made regarding the efficacy of control measures implemented.

According to the CDC field epidemiology manual, control measures should be aimed at specific links in the infection transmission chain such as the agent, the source or the reservoir.[58] Expert opinion from the Society for Healthcare Epidemiology of America (SHEA) outlines a bundle of measures that may be used as a guide during incident management in acute settings.[4] These measures include; consideration of the hierarchy of controls, requirement for staff training, review of equipment use protocols, use of disposable items for infected patients (when appropriate and possible), use of dedicated patient care equipment on specific infected patients (for non-disposable items), limiting staff members caring for infected patients, exclusion from work of staff members who are ill, temporary closures of specific ward areas, electronic alerts/flagging for exposed patients, screening algorithms for triage purposes, surveillance and monitoring to detect an emerging outbreak, consideration of alternative ways to provide care (such as telemedicine), post-exposure prophylaxis, restriction of patient/visitor movement, PPE training and fit testing (where needed) and use of point of care testing (where possible).[4] This is not an exhaustive list and organism specific guidance should be referred to, when available.

A generic outbreak checklist can be found in the supporting materials section of Chapter 3 in the National Infection Prevention and Control Manual (NIPCM).

In six outbreaks where patient equipment was found to be the source or associated with the transmission chain, termination was achieved by removal or replacement of the implicated source/reservoir and/or complete re-engineering of reprocessing protocols coupled with enhanced screening.[41, 46, 51, 54, 57, 61] A *Serratia marcescens* outbreak related to a disinfection solution was managed by; procurement of a commercial, ready-to-use product, use of single-use bottles and implementation of a central disinfection preparation station.[35] An *Acinetobacter baumannii* outbreak associated with a central dispensing unit was managed by discontinuing use of the central dispenser, replacing multi-use vials with single-use vials and an education module.[33] Two outbreaks caused by contaminated IV solutions were managed by prompt removal of implicated products, re-enforcing IPC policies for drug preparation, sterility testing/quality control and altering IV regimens.[28, 45]
A *Burkholderia cepacia* outbreak associated with chlorhexidine mouthwashes was managed by prompt removal of the contaminated batch, the authors highlighted the

importance of traceability of non-sterile products like mouthwashes in an outbreak scenario, particularly when they are used on critically ill/vulnerable patients.[37]

Two outbreak reports that identified staff members as the source of the outbreak were both managed by referral of said staff member to occupational health for eradication therapy and/or redeployment to other wards.[16, 64] Expert opinion on GAS infections states that, if carriage has been linked to an incident/outbreak or confirmed transmission then an employee's fitness to return to work is at the discretion of the IPCT team in liaison with the occupational health practitioner and this must be discussed on a case-by-case basis after a risk assessment.[3]

CDC guidelines on norovirus recommend restriction of potentially infectious food handlers within healthcare facilities for a minimum of 48 hours after the resolution of symptoms or longer, although both these guidelines are pathogen specific and do not cover carriage with other organisms.[30] The food-borne outbreak associated with multidrug-resistant *Klebsiella pneumoniae* was managed by implementing structural and functional reforms in the kitchen, although no details of the reforms were provided.[15] In two outbreak reports, both caused by MDROs, there was evidence of cross-transmission between patients, either through direct contact (e.g. room sharing), via healthcare worker hands and/or through persistence of environmental reservoirs post discharge. Both of these were controlled through a multi-modal infection prevention and control strategy.[47, 49]

Follow-up periods identified in literature ranged from 28 days [47] to 9 years.[28] More clarity is required regarding optimal follow-up periods following an incident or an outbreak in health and care settings. The CDC field epidemiology manual states that surveillance should continue for a defined time-period after an outbreak to ensure that it has ended, control measures should be reviewed and a decision made regarding further enhancement or relaxation of the measures.[58] The literature identified in this review relates to multiple organisms from different settings, hence, it is not possible to make generalisations with regards to specific control measures and their post implementation surveillance periods. It must be emphasised that findings from outbreak reports must be interpreted with caution due to the inherent nature of the reports and their inability to prove causality, their small sample sizes, the rapid nature of the event, issues of validity and possible biases in case ascertainment.

When should staff screening be considered?

According to mandatory Scottish guidance, the IMT may decide that staff screening is necessary to identify carriage or infection among staff groups. The decision to screen should be based on the need for one or more of the following:

- To characterise the epidemiology of the outbreak in terms of time, place and person.
- To identify the likely source and index case, with a view to control the incident/outbreak.
- To assist with interrupting the chain of transmission of an outbreak.
- To confirm eradication of an outbreak.

Staff screening is undertaken by local occupational health (OH) Services and is a confidential process requiring staff consent. It involves collection of specimens from areas of the body where the particular type of organism(s) being looked for are most likely to be found. If an employee is found to be infected with the identified organism(s) they may be sent home (if appropriate) by OH (with the authority of the IMT). If necessary, appropriate treatment may be prescribed. Further advice regarding fitness to return to work will be provided by the OH services and supported by the IMT, where appropriate, in conjunction with health care providers.[65]

Joint Healthcare Infection Society (HIS) and Infection Prevention Society (IPS) guidelines on MRSA do not recommend routine screening of healthcare workers in an outbreak scenario, however, it may be implicated if there is continued transmission despite implementation of active control measures, unusual epidemiology or a reason to suspect staff as a source.[63] In regards to other pathogen-specific guidance, UK expert opinion on GAS infection states that staff screening should be performed if the healthcare worker has had direct contact with an infected patient and had symptoms during the week prior to the index patient's onset of infection, although under certain circumstances an asymptomatic healthcare worker may also be screened, such as following a case of postoperative necrotizing fasciitis.[3]

Staff screening was conducted in one exposure event involving *Mycobacterium tuberculosis* in a UK hospital, the authors reported use of 'a concentric circles

approach' to broaden the investigation if any staff member tested positive.[17] Criteria used by the outbreak control team to screen staff was: exposure of a staff member to an aerosol generating procedure (AGP) conducted on the undiagnosed infected case in absence of airborne precautions or continuous contact of > 4 hours with the patient. It should be noted that in this investigation, staff screening was initiated after diagnosis of active TB in a healthcare worker with the same strain as the index case, approximately one year after the exposure event and the rationale was to explore other possible transmission events of both patients and HCWs. Staff screening revealed 7 further HCWs who had evidence of direct contact with the index patient and were positive on Interferon gamma release assay (IGRA), but none had abnormalities detected on a chest x-ray and were considered to have latent TB infection (LTBI). It is unclear what the definitive source of infection was in these HCWs, as no strain typing results were available.[17]

In another outbreak report from Sweden, epidemiological investigation pointed towards a HCW as the carrier of a *Streptococcus pyogenes* outbreak strain, due to a strong epidemiological link with a majority of the cases.[64] Clonal relatedness was also proven when a fourth pharyngeal swab was positive for the implicated strain. The HCW was given eradication therapy and no more cases were reported on the ward. The possibility that the staff member was initially colonised via contact with an infected patient could not be excluded due to the asymptomatic nature of their illness.[64] An outbreak report from a thoracic surgical unit in the UK identified a HCW with psoriasis as a possible source of a methicillin-sensitive *Staphylococcus aureus* (MSSA) outbreak involving fifteen cases.[16] This was based on the findings from a case-control study which showed a strong association between the HCW's shifts and case patients as well as case notes which detailed direct contact between patients and the staff member. These findings were used as a rationale for screening. Clonal relation was proven through typing analysis. The HCW was referred to OH and dermatology and subsequently did not return to work in a surgical area. Termination of the outbreak was achieved, although the exact mode of transmission was not elucidated. The authors of the report highlight that there was no specific guidance for routine microbiological screening of HCWs with dermatitis at the time of this outbreak.[16]

Five outbreak reports, all from the ICU and all involving MDROs stated that a HCW

screening process was conducted as part of their investigation, although no rationale was provided and no guidance or protocols were cited to support their decision.[14, 38, 40, 46, 66] None identified HCWs as the source of the outbreak. Very limited evidence was identified on staff screening during incidents and outbreaks in health and care settings, it may be necessary to refer to organism specific guidance when available, which is out with the scope of this review.

Two outbreak reports involving *Serratia marcescens*, one in a paediatric ICU and the other involving a pharmacy unit, screened hands of HCWs. The investigators hypothesised that contamination of intravenous fluids may have occurred during drug preparation although in both scenarios, none of the HCWs tested positive.[28, 43] Similar to other reports, these articles outline that HCW screening was done but cannot provide evidence for its necessity or efficacy in outbreak investigation/control. In both investigations, HCW hands were identified as potential contamination sources which likely explains why HCW hand swabbing was conducted. Further research/data is needed on the benefits of HCW hand screening when specific 'hands on' procedures are implicated such as drug preparation, peripheral venous catheter (PVC) insertion etc.

Should deaths associated with healthcare infection incidents/outbreaks be reported?

The SGHSCD has outlined a process for the reporting of deaths associated with HAI incidents.[1] Specifically, deaths associated with HAI should be recorded on the medical certificate of the cause of death (MCCD) and reported to the Infection Control Manager (ICM). If an HAI was part of the sequence that directly led to the patient's death, then this should be noted in part I of the certificate. If an HAI contributed towards death but was not part of the direct sequence of events that led to death, then this should be included in part II. Death certificates should be completed after discussion with a consultant.[67] Only HAI deaths which pose an acute and serious public health risk must be reported to the Procurator Fiscal.[68]

Only one outbreak report from Northern Ireland outlined the procedural details for documenting HAI deaths, authors stated that registered medical practitioners who have treated the deceased patient in the 28 days before their death should fill the

MCCD, this was part of a lessons learned activity to improve recording of data and reinforce guidance on completion of MCCD.20

Organisations must consider activation of duty of candour procedures as per the duty of candour legislation which came into effect on 1 April 2018 if an unexpected or unintended event has led to death or harm.[69] From 1 January 2020, all significant adverse event reviews commissioned by NHS Boards for a category 1 adverse event (events that may have contributed to or resulted in permanent harm, for example unexpected death) should be reported to Healthcare Improvement Scotland (HIS) in alignment with the new national notification system.[70] For further information please see 'A national framework for Scotland'.[70]

How should healthcare infection incidents/outbreaks be communicated?

NHS Boards should have a communications plan which encompasses the Healthcare Infection Incident Assessment Tool (HIIAT) and electronic Outbreak Reporting Tool (ORT) and indicates how information about the incident/outbreak and its control will be provided. The following groups should be included within relevant communications: individuals/agencies involved in managing the incident/outbreak, professionals involved in treatment/diagnosis of cases, the general public, ARHAI Scotland and the SGHSCD.[1]

Following PAG/IMT, the NHS Board is required to communicate all HIIAT Green, Amber and Red assessments with ARHAI Scotland, by completing the electronic Outbreak Reporting Tool (ORT) within 24 hours of HIIAT assessment.[1] Incidents assessed as RED, AMBER and where ARHAI support is required GREEN will be reviewed for onward communication to SGHSCD. Reporting protocols are under review at the time of writing and will be updated once finalised.

UKHSA guidance states that where a HAI infection incident/outbreak may have an impact on the wider community, Health Protection Units (HPU) should routinely inform local commissioners (performance managers and regulators) and other health economy stakeholders.[26]

Regarding pathogen-specific guidance, expert opinion from the norovirus working party and CDC on norovirus, emphasised the importance of having a local communication plan and written policies in place with intensification of communication during increased norovirus activity.[30, 31]

The WHO states that during an outbreak, timely, up to-date information must be provided to hospital personnel, public health authorities, and, in some cases, to the public.[22] Regarding public and patient communication, if an unexpected event has led to death or harm, duty of candour procedures must be activated as per The Duty of Candour Procedure (Scotland) Regulations 2018.[69] A detailed explanation of duty of candour is out-with the scope of this review.

Multiple reports presented their hospital outbreak/incident communication protocols. The majority referred to a local reporting system/local intranet in place for incident notification which was facilitated by regular communications between the infection control teams, healthcare personnel and microbiology laboratories.[13, 14, 45, 48, 59] The frequency of communication, however, was not routinely documented in these reports. Two outbreak reports and one Norwegian government document referred to a notification process involving a public health authority or national infection control organisation. This was to facilitate alerts or early warnings for neighbouring hospitals or care homes in the event of a communicable disease outbreak or outbreak involving MDROs.[42, 50, 71]

Defective medical equipment/pharmaceutical products were also associated with a few HAI incidents and outbreaks. All reports stated that these product issues should be notified to regulatory organisations, manufacturers and surveillance agencies to facilitate investigation and an appropriate response.[8, 12, 37, 40, 44] In Scotland, any adverse event related to equipment or medication should be reported as soon as possible (within one working day) to the Incident Reporting and Investigation Centre (IRIC) and the escalation/de-escalation flowchart followed.[70]

Two reports referred to information sharing during an incident, particularly in reference to transfer of patients, involved in outbreaks/incidents, to neighbouring trusts/other hospitals.[14, 47] This should be performed in line with local policy and guidance.

When would the National Support Framework 2017 be invoked in relation to a healthcare infection incident/outbreak?

The 'National Support Framework 2017' sets out the roles and responsibilities of national agencies, including ARHAI Scotland and Health Facilities Scotland (HFS) to optimise patient safety during HAI incidents/outbreaks or when surveillance data suggests an NHS Board may need support to reduce HAI risks.

The National Support Framework may be invoked by the Scottish Government HAI /AMR Policy Unit or by an NHS Board during or following any healthcare infection incident/outbreak(s)/data exceedance or Healthcare Environment Inspectorate (HEI) visit/report.[72]

How should a healthcare infection incident/outbreak be 'closed', with lessons learned, recorded and disseminated nationally?

In addition to electronic reporting, Scottish guidance states that once the incident/outbreak is considered over, the IMT/NHS Board should evaluate and report on the effectiveness and efficiency of incident management (debrief).[1] This information should be shared so that the whole service can learn from the experience of others. The IMT Chair, in discussion with IMT members, should determine the most appropriate format for reporting the incident i.e. full IMT report, Situation, Background, Assessment, Recommendations (SBAR) format, or hot debrief paper. A full IMT report should be considered in the following situations: if significant lessons have been identified that should be shared locally or nationally; to address issues that require actions by other agencies; novel infections; incidents involving high morbidity or mortality; guidance change; or issues of significant public or political interest. The final report should be submitted to the NHS Board and relevant organisations with responsibility for taking forward report recommendations. Reports should also be sent to the Scottish Health Protection Network (SHPN), local authorities and the SGHSCD or other SG Directorate.[1]

As per adverse events management policy, all adverse events/near misses are subject to review. The category of the event will largely determine the level of review required, i.e. category I adverse events resulting in death, permanent harm or national adverse publicity will require a more extensive review compared to category II events.[73] Decisions about the level of review required may be assisted by a risk assessment process using locally approved risk management tools.[73] The review process may identify good practice and learning points for onward sharing and facilitation of further service improvements. In response to the findings and recommendations of Category 1 and Category 2 adverse event reviews, an improvement plan must be developed.[70, 73]

The authors of a Scottish norovirus outbreak report, involving nightingale-style wards, described the use of a debrief report at the end of the outbreak and a lessons learned activity. The action plan which was developed included an upgrade of the ward facilities, creation of 4-bedded bays, campaign roll-outs, situational posters and formation of a staff toolkit.[13] In four outbreak reports, system changes were made in response to the lessons learned from the incident/outbreak.[17, 18, 41, 52] This included a *Mycobacterium tuberculosis* exposure incident, following which, rapid testing was rolled out for early identification of future cases, a staff education and awareness program was initiated, thorough review of TB patients was recommended before halting respiratory precautions and a monthly multi-disciplinary meeting was instigated.[17] Secondly, in a CPE outbreak associated with an endoscopic procedure, the authors described an adverse event surveillance program for endoscope-related procedures as well as improvements made in reprocessing protocols and decontamination practices.[18] Finally, in two outbreak reports involving *Pseudomonas aeruginosa*, one associated with arthroscopic hand-pieces and the other with bronchoscopes, authors reported the introduction of specific instrument/patient tracking systems. Improvements were made in instrument reprocessing and an alert was raised with the regulatory authority in regards to an issue of retained biomaterial in arthroscopic shaver hand pieces.[41, 52] Following two CPE outbreaks, changes were made to screening policies, to ensure future early identification of high-risk groups.[14, 47] The lessons learned from one *S. aureus* outbreak led to a consultation process to facilitate creation of a national guideline for occupational dermatitis.[16] Lastly, in an outbreak that was associated with a *Burkholderia cepacia* contaminated

pharmaceutical product, an adverse event report was submitted to the regional drug regulatory authority, a product recall was performed and an investigation was launched into the manufacturer.[8] There was a lack of evidence in outbreak reports with regards to procedures in place for national dissemination of information, although publication in of itself can be considered a form of information dissemination.

3.2 Implications for research

There was limited robust literature available to inform this review. A substantial volume of literature identified was in the form of expert opinion, which is prone to reporting and publication bias, and consequently, when assessed, yields a low level of evidence and graded recommendation. It was also notable that the majority of outbreak reports identified in this review, combined multiple infection control interventions, hence it was impossible to assess the efficacy of any one control measure in isolation. Further research is required to validate the use of specific control measures. There was also significant variability in the way reports defined an incident/outbreak with some declaring an HAI incident/outbreak following one case whereas others specified involvement of two or more linked cases.

This review identified some areas for further research which included; the potential benefit of HCW hand screening when specific 'hands on' procedures are implicated in incidents/outbreaks (such as drug preparation); further guidance on health and care staff who are pathogen carriers, the management of 'near-miss' incidents and further evidence regarding follow-up periods post- outbreak. This review was only able to provide general recommendations for incident/ outbreak prevention and management as certain pathogens may require specific IPC measures/actions which are out with the scope of this review.

4. Recommendations

This review makes the following recommendations based on an assessment of the extant scientific literature on the recognition, assessment, investigation and management of healthcare infection incidents/outbreaks in the hospital/acute setting.

What is the definition of a healthcare infection incident/outbreak?

A **healthcare infection incident/outbreak** may be:

An **exceptional infection episode**, defined as a single case of rare infection that has severe outcomes for an individual AND has major implications for others (patients, staff and/or visitors), the organisation or wider public health for example, high consequence infectious disease (HCID) OR other rare infections such as XDR-TB, botulism, polio, rabies, or diphtheria.

A **healthcare infection exposure incident**, defined as an exposure of patients, staff or the public to a possible infectious agent e.g. via ventilation systems, water systems or decontamination failure.

A **healthcare associated infection outbreak**, defined as two or more linked cases associated with the same infectious agent, within the same healthcare setting, over a specified time period; or a higher-than-expected number of cases in a given healthcare area over a specified time period.

(Mandatory)

A **healthcare infection data exceedance**, defined as a greater than expected rate of infection compared with the usual background rate for the place and time where the incident has occurred.

(Mandatory)

A **healthcare infection near miss incident**, which had the potential to expose patients to an infectious agent but did not e.g. decontamination failure.

(Category C recommendation)

A healthcare infection incident should be suspected if there is:

A **single case** of an infection for which there have previously been no cases in the facility (e.g. infection with a multidrug-resistant organism (MDRO) with unusual resistance patterns or a post-procedure infection with an unusual organism).

(Category C recommendation)

How can healthcare infection incidents/outbreaks be recognised/detected?

An early and effective response to an actual or potential healthcare infection incident/outbreak is crucial. The Infection Prevention & Control Team (IPCT)/Health Protection Team (HPT) should be aware of and refer to the national minimum list of alert organisms/conditions, which will aid in incident/outbreak recognition.

(Mandatory)

Healthcare associated infection (HAI) Surveillance systems should be used to aid incident/outbreak detection using a combination of retrospective detection of cases alongside prospective enhanced surveillance in high risk settings (ICU/PICU/NICU, oncology/haematology). A risk based approach should be applied for other vulnerable groups e.g. cystic fibrosis, oncology and those undergoing renal dialysis.

(Mandatory)

Local surveillance/reporting systems should be used for recognition and detection of potential healthcare infection incidents /outbreaks within NHS Boards. Systems should make use of ‘triggers’ to allow prompt detection of any variance from normal limits.

(Mandatory)

The Infection Prevention & Control Team (IPCT)/Health Protection Team (HPT) should utilise surgical site infection (SSI) surveillance systems to identify specific post-surgical healthcare infection incidents/outbreaks (in line with national SSI surveillance program as a minimum).

(Category B recommendation)

How should suspected healthcare infection incidents/outbreaks be assessed?

On recognition of a potential healthcare infection incident/outbreak, an initial assessment using the Healthcare Infection Incident Assessment Tool (HIIAT) should be conducted by the Infection Prevention and Control Team (IPCT)/Health Protection Team (HPT) within the NHS Board.

(Mandatory)

Problem Assessment Group (PAG)/Incident Management Team (IMT) meeting must be considered, depending on the assessment of the incident or status of the HIIAT.

(Mandatory)

NHS Boards are required to report all HIIAT assessed Green, Amber and Red reports to ARHAI Scotland.

(Mandatory)

NHS Boards should monitor the ongoing impact of the incident by escalating and deescalating as appropriate, using the HIIAT assessment tool. The HIIAT assessment should remain Amber or Red whilst there is ongoing risk of exposure, identification of new cases and/or until all exposed cases have been informed.

(Mandatory)

How should healthcare infection incidents be investigated and managed?

It is the responsibility of the NHS Board to establish whether an IMT is necessary to further investigate a healthcare infection incident.

(Mandatory)

A healthcare infection incident investigation will usually consist of the following elements; an epidemiological investigation, a microbiological investigation and a specific investigation to identify how cases were exposed to the infectious agent (environmental investigation).

(Mandatory)

EPIDEMIOLOGICAL INVESTIGATION

As part of the epidemiological investigation, a case definition(s) must be established by the IMT.

Case definition(s) must be regularly reviewed and refined (if required) throughout the incident investigation as more information becomes available.

A working hypothesis regarding the transmission route and source of the exposure must be formed based on initial investigation findings.

(Mandatory)

MICROBIOLOGICAL INVESTIGATION

A microbiological investigation into the nature and characteristics of the implicated hazard/infective agent must be conducted.

(Mandatory)

ENVIRONMENTAL INVESTIGATION

An environmental investigation must be conducted if the findings of the epidemiological investigation suggest a common exposure to a potential

environmental source/environmental reservoir.

(Category B recommendation)

INFECTION PREVENTION AND CONTROL ASSESSMENT

An infection prevention and control assessment to review the existing IPC practices must be conducted, so that areas for immediate improvement can be identified.

(Mandatory)

CONTROL MEASURES AND FOLLOW-UP

Control measures must be directed at the source of the exposure and/or at affected persons in order to prevent secondary/further exposure to the agent.

(Mandatory)

Control measures must be initiated within 24 hours of receiving the initial report and should be implemented based on relevant guidance (e.g. pathogen specific) and investigation findings of the nature of the outbreak.

(Mandatory)

A follow-up period may be defined after an infection incident/ outbreak has ended to ensure its termination, including assessment of any ongoing control measures, and would be determined by the PAG/IMT.

(Category C recommendation)

When should staff screening be considered?

The IMT may decide that staff screening is necessary to identify carriage or infection among staff groups. The decision to screen should be based on the need for one or more of the following:

- To characterise the epidemiology of the outbreak in terms of time, place and person;
- To identify the likely source and index case, with a view to control;
- To assist with interrupting the chain of transmission of an outbreak;
- To confirm eradication of an outbreak.

Staff screening is undertaken by local Occupational Health Services in line with HR Policy (DL (2020)1).[65]

(Mandatory)

Should deaths associated with healthcare infection incidents/outbreaks be reported?

Deaths associated with HAI should be recorded on the Medical Certificate of the Cause of Death (MCCD) and reported to the Infection Control Manager (ICM). As per SGHD/CMO(2018)11, a death which is considered to pose an acute and serious public health risk should be reported to the Procurator Fiscal.

(Mandatory)

Duty of Candour procedures must be implemented as per the Duty of Candour legislation if an unexpected or unintended event has led to death or harm that is not related to the course of the condition for which the person is receiving care.

(Mandatory)

All significant adverse event reviews involving a category 1 adverse event (events that may have contributed to or resulted in permanent harm, for example unexpected death) should be reported to Healthcare Improvement Scotland (HIS) via the national

notification system.

(Mandatory)

How should healthcare infection incidents/outbreaks be communicated?

NHS Boards must have a communications plan which encompasses the HIIAT and ORT and indicates how information will be provided about the incident/outbreak and its control.

(Mandatory)

NHS Boards must brief ARHAI Scotland, local health and care staff, and partners in local and national agencies, in relation to incidents/outbreaks (where appropriate).

(Mandatory)

Following PAG/IMT, the NHS Board is required to communicate all HIIAT Green, Amber and Red assessments with ARHAI Scotland, by completing the electronic Outbreak Reporting Tool (ORT) within 24 hours of HIIAT assessment. Incidents assessed as RED, AMBER and where ARHAI support is required GREEN will be reviewed for onward communication to SGHSCD.

(Mandatory)

Reporting protocols are under review at the time of writing and will be updated once finalised.

(Mandatory)

Any adverse event related to equipment or medication must be reported as soon as possible (within one working day) to the Incident Reporting and Investigation Centre (IRIC) and the escalation/de-escalation flowchart followed.

(Mandatory)

When would the National Support Framework 2017 be invoked in relation to a healthcare infection incident/outbreak?

The National Support Framework 2017 may be invoked by the Scottish Government HAI /AMR Policy Unit or by an NHS Board to optimise patient safety during or following: any HAI incident/ outbreak(s)/data exceedance or HEI inspectorate visit/report.

(Mandatory)

How should a healthcare infection incident/outbreak be 'closed', with lessons learned, recorded and disseminated nationally?

In addition to mandatory electronic reporting, the IMT should decide on the most appropriate format for a report, to communicate incident management/lessons learned (IMT report /SBAR/ hot debrief paper). The final report should be submitted to the NHS Board and relevant organisations with responsibility for taking forward report recommendations. Reports should also be sent to the Scottish Health Protection Network (SHPN), local authorities and the SGHSCD or other SG Directorate.

(Mandatory)

A full IMT report must be considered in the following situations: if significant lessons have been identified that should be shared locally or nationally; to address issues that require actions by other agencies; novel infections; incidents involving high morbidity or mortality; guidance change; or issues of significant public or political interest.

(Mandatory)

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Appendices

Appendix 1: Grades of recommendation

Grade	Descriptor	Levels of evidence
Mandatory	'Recommendations' that are directives from government policy, regulations or legislation	N/A
Category A	Based on high to moderate quality evidence	SIGN level 1++, 1+, 2++, 2+, AGREE strongly recommend
Category B	Based on low to moderate quality of evidence which suggest net clinical benefits over harm	SIGN level 2+, 3, 4, AGREE recommend
Category C	Expert opinion, these may be formed by the NIPC groups when there is no robust professional or scientific literature available to inform guidance.	SIGN level 4, or opinion of NIPC group
No recommendation	Insufficient evidence to recommend one way or another.	N/A

Appendix 2: PRISMA Flow Diagram