NHS National Services Scotland

Management of non-invasive, reusable, shared Care Equipment

Considered Judgement Forms

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Antimicrobial Resistance & Healthcare Associated Infection (ARHAI) Scotland
An NHS Scotland Assure Service

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
1.0	March 2026	New document

Approvals

Version	Date Approved	Group/Individual
1.0	March 2026	National Policy, Guidance and Evidence (NPGE) Working Group
		Care Home Infection Prevention and Control (CHIPC) Oversight and Advisory Group

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Research Question 1: What legislative requirements or standards should be adhered to when decontaminating non-invasive, reusable, shared care equipment?

A Quality of Evidence

1.1 How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is no available evidence to answer the key question, go to section B.

Comments	Evidence level
In total, 25 pieces of evidence were included for this research question. • Six regulations or legislative documents were graded as SIGN 50 mandatory.[1-6] • Sixteen standards were graded SIGN 50 Level 4, expert opinion.[7-22] • Two HSE guidance documents [23, 24] and one Scottish technical guidance [25] were graded as SIGN 50 Level 4, expert opinion, due to a lack of evidence of a rigorous scientific development process. Evidence graded as SIGN 50 Level 4 is subject to methodological and reporting limitations and is considered low quality evidence. However, many of these documents were BS EN standards which are required for use in Scottish and UK settings. These documents detail the minimum standards that should be achieved and evidenced by the manufacturer to be considered. Overall, this evidence was considered a sufficient volume and quality, as the question did not require primary	6 x SIGN 50 Mandatory 19 x SIGN 50 Level 4

Comments	Evidence level
studies, only relevant legislation, policies, and standard documents were included.	

1.2 Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the judgement was formed as to the overall direction of the evidence.

Comments
Legislation It was not possible to determine consistency with regards to the legislation. This is due to the fact that each legislation is different in terms of topic. • There are two legislations relevant to medical devices published by the UK Government [2] and the European Parliament.[5] • Four remaining legislations are related to Health and Safety at Work,[6] the Control of Substances Hazardous to Health (COSHH),[3] and Biocide use,[1] and the Public Health etc. (Scotland) Act 2008, which ”makes provisions for the protection of public health in Scotland”, including the prevention and control of infectious diseases.[4] • Two guidance documents, graded SIGN 50 level 4, were published by the UK Health and Safety Executive (HSE) to support implementation and adherence to legislation, including the COSHH [23] and the biocidal regulations.[24] • The Scottish Health Technical Note 00-04, published by NHSScotland Assure, provides a summary of relevant guidance, legislation, standards, and policy in Scotland relating to all medical devices and equipment.[25] **British Standards** There is a lack of consistency across the 16 included British Standards (graded as SIGN 50 Level 4) because they are related to different specific elements, such as the fungicidal activity versus virucidal activity of a chemical.[7-22] Due to their differences each standard will need to be individually considered where it is relevant.

Comments

- Fourteen of the included standards were applicable to chemical disinfectants and antiseptics intended to be used within medical settings. These standards pertain to bactericidal, sporicidal, and virucidal activity claimed against relevant microorganisms.[7-17, 20-22]
- BS EN 14885 provides an overview of the standards required for chemical disinfectants and antiseptics. This document lists key standards for different antimicrobial activity claims and their corresponding test methods for substantiating product claims. Generally, scientific evidence must be provided to substantiate each activity claim a product makes against bacteria (including mycobacteria and spore-forming bacteria), fungi and viruses.[22]
- British Standard BS EN 17664-1:2021 outlines details that are required to be provided by manufacturers of medical devices that will be cleaned, disinfected, or sterilised in health and care settings.[19]
- British Standard PD CEN ISO/TR 24971:2020 provides guidance on the development, implementation and maintenance of a risk management system for managing medical devices.[18]

Although there was no consistency in the evidence base, legislation is mandatory and therefore must be adhered to in full where applicable.

1.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments

The country or countries in which the guidance applies are as follows:

- United Kingdom (UK) (n=23)[1-4, 6-25]
- Europe (n=1)[5]

Five of the included legislation documents are directly applicable to Scottish health and care settings [1-4, 6] while one applies to Europe.

The 16 British Standards [7-22] and three guidance documents [23-25] included are directly applicable to Scottish health and care settings. It is noteworthy that

Comments
standards only provide laboratory-based tests to justify product activity claim, but not its real-world effectiveness on different non-invasive, reusable, shared care equipment care equipment that might be encountered in Scottish health and care settings. However, UK legislation and British standards have a wide coverage, therefore, must be read in full then interpreted and implemented accordingly.

1.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
There were no primary studies found in relation to this research question, therefore, issues such as sample size and methods of sample selection are not applicable.

1.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
Not applicable.

B: Evidence to Decision

1.6 Recommendations

What Recommendations or Good Practice Points are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach

Recommendation	Grading
R1.1. The following legislation must be adhered to when decontaminating non-invasive, reusable, shared care equipment in Scottish health and care settings: • The Biocidal Products Regulations 2001 • The Medical Device Regulations 2002 • Medical Device Regulation (EU) 2017/745 • The Control of Substances Hazardous to Health Regulations (COSHH) 2002 • The Health and Safety at Work etc Act 1974 • Public Health etc. (Scotland) Act 2008.	Recommendation
GPP1.1 Chemical disinfectants intended for decontaminating non-invasive, reusable, shared care equipment in Scottish health and care settings should have broad-spectrum antimicrobial activity and meet the relevant standards for any claimed antimicrobial effects (for example bactericidal, virucidal, yeasticidal, fungicidal and sporicidal). Appendix 4 of the literature	Good Practice Point

Recommendation	Grading
review provides a non-exhaustive list of relevant standards.	

1.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about benefits.

Benefits
R1.1 Adhering to relevant legislation and regulations will support compliance with associated corporate and social governance responsibilities, including the legal requirements of the applicable health and safety management policy. GPP1.1 Procurement of products that have broad-spectrum antimicrobial activity and meet relevant industry standards support compliance with regulations such as COSHH, provides assurance of efficacy against representative infectious agents, promotes standardisation, and may result in increased user confidence.

Risks and harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about risks and harms.

Risks and harms
R1.1 and GPP1.1 No risks or harms anticipated.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the:

- individual service user, staff or visitor perspective
- the societal perspective
- or both of the above

Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events or vice versa.

Benefit-Harm assessment
R1.1 and GPP1.1 Only benefits identified.

1.8 Feasibility

Is the Recommendation or Good Practice Point implementable in the Scottish context?

Describe (if applicable):

- financial implications
- opportunity costs
- material or human resource requirements
- facility needs
- sustainability issues
- human factors

or any other issues that may be associated with following a Recommendation or Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
R1.1 There will be ongoing human resources needs to maintain training and keep up to date with legislative and standards changes. GPP1.1 There may be financial implications and human resource requirements associated with procuring suitable and compliant products, as well as the need to consider their suitability for specific non-invasive, reusable, shared care equipment. GPP1.1 Users of the products, including the local authority, IPC Teams, senior staff or a named individual may need to assess the suitability of products for specific situations or settings and take these considerations into account when developing local policies and standard operating procedures (SOP).

1.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
R1.1. Only mandatory legislation [1-6] was used to underpin this recommendation. There is no additional expert opinion to note. GPP1.1. Although this good practice point was informed by British, European, and international standards, with limited details on methodology, laboratory-based test and all graded SIGN 50 level 4,[7-25] they are considered best practice in UK industry settings. Therefore, it is the expert opinion of ARHAI Scotland and its stakeholders that chemical disinfectant products used in health and care settings should have broad-spectrum antimicrobial activity and meet the relevant standards to ensure consistency and reliability.

1.10 Value judgements

Summarise value judgements used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
R1.1 and GPP1.1 No value judgements to note.

1.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation or Good Practice Point. If none was intended, state “none”. Recommendations or Good Practice Points should be clear and specific, but if there is a decision to be vague, acknowledging the reasoning clearly promotes transparency. Reasons for vagueness may include:

- inadequate evidence
- inability to achieve consensus regarding evidence quality
- anticipated benefits or harms, or interpretation of evidence
- legal considerations
- economic reasons
- ethical or religious reasons

Intentional vagueness
R1.1 and GPP1.1 No intentional vagueness to note.

1.12 Exceptions

List situations or circumstances in which the Recommendation or Good Practice Point should not be applied.

Exceptions
R1.1 and GPP1.1 No exceptions to note.

1.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
Published research investigating product efficacy against specific pathogens using BS EN standards methodology would support transparency and comparison of findings relating to active ingredients in disinfectants. Furthermore, BS EN standards methodologies which investigate real-world product efficacy on different non-invasive, reusable, shared care equipment that might be encountered in Scottish health and care settings may strengthen the evidence base for effectiveness in health and care environments, and therefore support assessment of applicability to Scottish health and care settings.

Research Question 2: How should care equipment be categorised?

A Quality of Evidence

2.1 How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is no available evidence to answer the key question, go to section B.

Comments	Evidence level
In total, 16 pieces of evidence were included for this research question.[2, 5, 25-37] • Two regulations or legislative documents were graded as SIGN 50 mandatory.[2, 5] • Fourteen guidance documents were graded SIGN 50 Level 4, expert opinion.[25-38] Level 4 guidance is subject to methodological and reporting limitations, thus is considered low quality evidence.	2 x SIGN 50 Mandatory 14 x SIGN 50 level 4

2.2 Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the judgement was formed as to the overall direction of the evidence.

Comments
There was no clear definition of care equipment identified in the included evidence sources. However, there are legislative requirements for care equipment, to be considered as a medical device where it meets the definitions provided in legislation.[2, 5, 26] At the time of writing, the UK Medical Device legislation states that “devices are classified as belonging to Class I, IIa, IIb or III in accordance with the

Comments

classification criteria set out in Annex IX of Directive 93/42".[2] The EU directive which replaces 93/42/EEC (2017/745) defines a medical device in detail.[5]

- The Scottish Health Technical Note 00-04,[25] graded SIGN 50 level 4, propose that there is no clear definition for the term 'medical equipment', with both medical equipment and medical device considered subcategories of health technology.
- There is consistency within four SIGN 50 level 4 guidance document that there are three broad categories of medical equipment (including medical devices).[25, 30, 35, 36] This includes:
    - Single use – Care equipment that is intended to be used once for one patient or service user and then discarded.[25, 30, 35, 36]
    - Single patient use – Care equipment that is intended to have designated use for one single patient or service user, it may be used multiple times for that individual, as appropriate. [25, 30, 35, 36]
    - Reusable – Care equipment that is intended to be multi-use, across different patients or service users.[25, 30] This was further broken down into:
        I. Invasive – described in SIGN 50 level 4 guidance as care equipment that in whole or partially penetrates inside the body of a patient or service user for example through a body orifice or through the surface of the body.[35]
        II. Non-invasive – described in SIGN 50 European parliament legislation as care equipment that is in contact with intact skin and does not penetrate (partially or fully) into the body and is in contact with intact skin only.[5]

Reusable care equipment

There was a lack of consistency within the evidence base regarding the name and scope for classifications of reusable care equipment.

- Eleven of the included guidance documents (SIGN 50 level 4) refer to three variable categories of care equipment based on the function and risk associated with the equipment.[25, 27-34, 36, 37] The Spaulding classification was referred to within eight of these documents.[25, 27-29, 31-34] The variable categories include:

Comments

- Critical – equipment that enters sterile tissue, cavity or blood stream and are generally considered as high risk when contaminated.[25, 27-29, 31, 32, 34, 37]
- Semi-critical – described as care equipment that has contact with non-intact skin and (or) mucous membranes,[25, 29, 31-34, 37] or equipment that has contact with another device which has contact with non-intact skin or mucous membranes.[32]
- Non-critical – care equipment that has contact with intact skin but not with mucous membranes.[25, 27-29, 31-34, 37] There is an overlap between this term and the term 'non-invasive' as described by the European parliament legislation.[5]

- The American Institute of Ultrasound Medicine (AIUM) appear to align with the above classifications but were termed most critical (critical), less critical (semi critical) and noncritical (non-critical).[38]
- Two UK guidance documents, published by the Department of Health and Social Care (DHSC) and Royal College of Nursing (RCN) propose that reusable care equipment may be classified based on categories of risk as low (intact skin), medium or intermediate (mucous membrane and contaminated items), and high risk (close contact with non-intact skin or mucous membrane and devices that enter the body).[30, 36]

An exhaustive list of examples of equipment for each classification was not provided in the included evidence.

There are inconsistencies regarding how equipment that has contact with blood and body fluids (BBF) should be classified:

- A SIGN 50 level 4 guidance document that specifically mentions commodes, bedpans or similar places them in the category of 'non-critical' equipment.[31]
- However, three SIGN 50 level 4 guidance documents by the WHO, UK DHSC and the RCN lists commodes, urinals, or bedpans as 'semi-critical' equipment.[30, 34, 36] The DHSC also lists toilets as 'low risk' despite the fact they would have contact with body fluids and would usually be considered as part of the care environment.[36]

A further inconsistency in the evidence (SIGN 50 level 4) was related to the classification of ultrasound equipment.

Comments
• A SIGN 50 level 4 guidance document by the European Society of Radiology Ultrasound Working Group reports that ultrasounds may be considered as non-critical (intact skin only) or critical but not as semi-critical (mucous membrane and body fluids).[28] Whereas, the society of diagnostic medical sonographers defines some ultrasound transducers as semi-critical.[32]

2.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The country or countries in which the guidance applies are as follows: • UK (n=6)[2, 25, 26, 30, 35, 36] • Europe (n=2)[5, 28] • Australasia (n=1)[33] • International (n=1)[34] • USA (n=4)[31, 32, 37, 38] • Canada (n=1)[29] • Australia (n=1)[27] The guidance documents published within the UK are directly applicable to Scottish health and care settings. Non-UK country specific guidance may have lower applicability but are considered adaptable to a Scottish health and care settings because they are from internationally recognised organisations and the terms or categories described are applicable.

2.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
There were no primary studies found in relation to this research question, therefore issues such as sample size and methods of sample selection are not applicable.

2.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
Not applicable.

B: Evidence to Decision

2.6 Recommendations

What Recommendations or Good Practice Points are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach

Recommendation	Grading
This research question reports on how care equipment is categorised in the literature, therefore there are no associated recommendations or good practice points. Care equipment is classified in the literature as single-use, single-patient use and reusable. Reusable care equipment is further classified as invasive and non-invasive, or according to infection risk (that is, low or non-critical, medium, intermediate or semi-critical and high).	Not applicable

2.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or Good Practice Point on service users, visitors, and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about benefits.

Benefits
Not applicable.

Risks and harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about risks and harms.

Risks and harms
Not applicable.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the:

- individual service user, staff or visitor perspective
- the societal perspective
- or both of the above

Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events or vice versa.

Benefit-Harm assessment
Not applicable.

2.8 Feasibility

Is the Recommendation or Good Practice Point implementable in the Scottish context?

Describe (if applicable):

- financial implications
- opportunity costs
- material or human resource requirements
- facility needs
- sustainability issues
- human factors

or any other issues that may be associated with following a Recommendation or Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
Not applicable.

2.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
Not applicable.

2.10 Value judgements

Summarise value judgements used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
Not applicable.

2.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation or Good Practice Point. If none was intended, state “none”. Recommendations or Good Practice Points should be clear and specific, but if there is a decision to be vague, acknowledging the reasoning clearly promotes transparency. Reasons for vagueness may include:

- inadequate evidence
- inability to achieve consensus regarding evidence quality
- anticipated benefits or harms, or interpretation of evidence
- legal considerations
- economic reasons
- ethical or religious reasons

Intentional vagueness
Not applicable.

2.12 Exceptions

List situations or circumstances in which the Recommendation or Good Practice Point should not be applied.

Exceptions
Not applicable.

2.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
Not applicable.

Research Question 3: What is the risk of healthcare associated infection (HAI) from non-invasive, reusable, shared care equipment?

A Quality of Evidence

3.1 How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is no available evidence to answer the key question, go to section B.

Comments	Evidence level
There were four studies included for this research question. • All four studies were graded SIGN 50 Level 3 as they are descriptive outbreak reports or investigations.[39-42] These studies provide evidence of real-world situations where infection transmission was linked to non-invasive, reusable, shared care equipment. However, they are considered as SIGN 50 Level 3, low quality evidence, due to the retrospective nature, methodological limitations, failure to provide strong evidence on direction of infection transmission and use of IPC measures that were implemented in bundles. Therefore, although genomic link was established between equipment and patient isolates, it is not possible to confirm direction of infection transmission. The included studies were conducted over 10 years ago, two were conducted before 2003 [39, 42] and two before 2014,[40, 41] therefore, they may not be reflective of current IPC practices in Scottish health and care settings.	4 x SIGN 50 Level 3

3.2 Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the judgement was formed as to the overall direction of the evidence.

Comments
It was not possible to assess consistency within the included evidence due to heterogeneity between the outbreak studies, including the settings, patients, and organisms involved.[39-42] • The included studies reported on four types of non-invasive, reusable, shared care equipment, including EKG (ECG) leads,[42] breast milk pumps,[41] breast milk thawing or warming devices,[39] and blood pressure cuffs,[40] that were considered as a vector in the transmission of vancomycin-resistant *enterococci* (VRE), *Acinetobacter baumannii, Pseudomonas aeruginosa,* and Carbapenem-resistant *Acinetobacter baumannii* (CRAB) respectively in the described outbreaks. • Pulse field gel electrophoresis (PFGE) was used to confirm that the outbreak strains, isolated from cases, matched isolates from the respective devices.[39-42]

3.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
None of the included studies were conducted in the UK. The country or countries in which the included outbreak studies were conducted are as follows: • France (n=2)[39, 40] • Turkey (n=1)[41] • USA (n=1)[42]

Comments
The included studies are considered applicable to Scottish health and care settings due to the nature of the research question, which aims to identify evidence of transmission events via non-invasive, reusable, shared care equipment to demonstrate HAI risk. However, IPC and healthcare practices in non-UK settings, particularly over ten years ago, may not be common to Scottish health and care settings.

3.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
The included studies lack generalisability. The nature of the outbreak reports means that 'samples' were not prospectively selected, as they are retrospective and are largely descriptive. The outbreaks occurred within specific care areas or units of hospitals, including two reports in neonatal patients or settings which may not generalise to other populations,[39, 41] one on patients within a burn intensive care unit,[42] and one on general intensive care patients.[40]

3.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
A formal assessment of publication bias was not conducted. The studies included are outbreak investigations and so there is a likelihood of publication bias as not all outbreaks or infection incidents are published in scientific journals.

B: Evidence to Decision

3.6 Recommendations

What Recommendations or Good Practice Points are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach

Recommendation	Grading
GPP 3.1. Although evidence of transmission of infection from non-invasive, reusable, shared care equipment is limited, risk is present where there is contamination with viable infectious agents. Therefore, non-invasive, reusable, shared care equipment should be considered a potential source or vector for transmission of healthcare-associated infections.	Good practice point

3.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about benefits.

Benefits
GPP3.1. This will highlight the potential risk of healthcare associated infection (HAI) from non-invasive, reusable, shared care equipment if effective decontamination has not been carried out, as appropriate. GPP3.1. This will also support investigation and management of incidents and outbreaks in health and care settings.

Risks and harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about risks and harms.

Risks and harms
GPP3.1 No risks or harms anticipated.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the:

- individual service user, staff or visitor perspective
- the societal perspective
- or both of the above

Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events or vice versa.

Benefit-Harm assessment
GPP3.1 Only benefits identified.

3.8 Feasibility

Is the Recommendation or Good Practice Point implementable in the Scottish context?

Describe (if applicable):

- financial implications
- opportunity costs
- material or human resource requirements
- facility needs
- sustainability issues
- human factors

or any other issues that may be associated with following a Recommendation or Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
GPP3.1 Human resource will be required to ensure the risk associated with non-invasive, reusable, shared care equipment is considered, including auditing of equipment cleanliness and decontamination schedules. This may also include staff education and training.

3.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP3.1 The evidence regarding the risk of HAI from non-invasive, reusable, shared care equipment was insufficient in terms of demonstrating clear transmission events. However, the expert opinion of ARHAI Scotland and its stakeholders is that other factors support there being a risk. In particular, it is well established that equipment surfaces can become contaminated with infectious agents, some of which may remain viable for extended periods, thus may pose an onward transmission risk.

3.10 Value judgements

Summarise value judgements used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
Not applicable.

3.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation or Good Practice Point. If none was intended, state “none”. Recommendations or Good Practice Points should be clear and specific, but if there is a decision to be vague, acknowledging the reasoning clearly promotes transparency. Reasons for vagueness may include:

- inadequate evidence
- inability to achieve consensus regarding evidence quality
- anticipated benefits or harms, or interpretation of evidence
- legal considerations
- economic reasons
- ethical or religious reasons

Intentional vagueness
Not applicable.

3.12 Exceptions

List situations or circumstances in which the Recommendation or Good Practice Point should not be applied.

Exceptions
Not applicable.

3.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
The evidence regarding risk of healthcare associated infection from non-invasive, reusable, shared care equipment is limited and inconsistent. More rigorous primary studies demonstrating the risk of HAI from non-invasive, reusable, shared care equipment would be a beneficial addition to the evidence base. However, it is acknowledged that this type of research might be difficult to obtain due to ethical issues and other difficulties associated with conducting and reporting epidemiological studies in health and care settings.

Research Question 4: What is the definition of decontamination for non-invasive, reusable, shared care equipment?

A Quality of Evidence

4.1 How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is no available evidence to answer the key question, go to section B.

Comments	Evidence level
Ten guidance documents were included to answer this research question.[25, 27-31, 34-36, 43] • All ten guidance documents were graded SIGN 50 Level 4, expert opinion.[25, 27-31, 34-36, 43] Level 4 guidance is subject to methodological and reporting limitations, and has not included sufficient systematic methods, thus, it is considered low quality.	10 x SIGN 50 Level 4

4.2 Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the judgement was formed as to the overall direction of the evidence.

Comments
There is consistency within nine of the included guidance documents (SIGN 50 level 4) that decontamination is an umbrella or over-arching term which is used to describe the different elements of the removal, destruction, or inactivation of micro-organisms, that may be used in combination.[25, 27-31, 34-36]

Comments
• Six SIGN 50 level 4 guidance documents, published in the UK, propose that decontamination involves cleaning, disinfection, and sterilisation.[25, 28, 30, 35, 36, 43] • NHS England national cleaning standard states that decontamination of non-critical care equipment should involve disinfection and cleaning only.[43]

4.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The country or countries in which the included guidance applies are as follows: • UK (n=5)[25, 30, 35, 36, 43] • International (n=1)[34] • Europe (n=1)[28] • USA (n=1)[31] • Canada (n=1)[29] • Australia (n=1)[27] The included guidance are considered applicable to Scottish health and care settings due to the nature of the research question, which is focused on general definition of decontamination of non-invasive, reusable, shared care equipment.

4.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
There were no primary studies found in relation to this research question therefore issues such as sample size and methods of sample selection are not applicable.

4.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
Not applicable.

B: Evidence to Decision

4.6 Recommendations

What Recommendations or Good Practice Points are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach

Recommendation	Grading
This research question aimed to outline how decontamination of non-invasive, reusable, shared care equipment is defined in the literature, therefore, has no associated recommendations or good practice points. Decontamination of non-invasive, reusable, shared care equipment is described in the literature as a process of removal, destruction, or inactivation of microorganisms, through any or a combination of cleaning, disinfection, and sterilisation.	Not applicable

4.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about benefits.

Benefits
Not applicable.

Risks and harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about risks and harms.

Risks and harms
Not applicable.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the:

- individual service user, staff or visitor perspective
- the societal perspective
- or both of the above

Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events or vice versa.

Benefit-Harm assessment
Not applicable.

4.8 Feasibility

Is the Recommendation or Good Practice Point implementable in the Scottish context?

Describe (if applicable):

- financial implications
- opportunity costs
- material or human resource requirements
- facility needs
- sustainability issues
- human factors

or any other issues that may be associated with following a Recommendation or Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
Not applicable.

4.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
Not applicable.

4.10 Value judgements

Summarise value judgements used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
Not applicable.

4.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation or Good Practice Point. If none was intended, state “none”. Recommendations or Good Practice Points should be clear and specific, but if there is a decision to be vague, acknowledging the reasoning clearly promotes transparency. Reasons for vagueness may include:

- inadequate evidence
- inability to achieve consensus regarding evidence quality
- anticipated benefits or harms, or interpretation of evidence
- legal considerations
- economic reasons
- ethical or religious reasons

Intentional vagueness
Not applicable.

4.12 Exceptions

List situations or circumstances in which the Recommendation or Good Practice Point should not be applied.

Exceptions
Not applicable.

4.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
Not applicable.

Research Question 5: How should decontamination methods be categorised?

A Quality of Evidence

5.1 How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is no available evidence to answer the key question, go to.

Comments	Evidence level
Seventeen guidance documents were included to answer this research question. • All included guidance documents were graded SIGN 50 Level 4 expert opinion.[27-34, 36, 37, 43-49] Level 4 guidance is subject to methodological and reporting limitations, and has not included sufficient systematic methods, thus, it is considered as expert opinion.	17 x SIGN 50 Level 4, expert opinion

5.2 Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the judgement was formed as to the overall direction of the evidence.

Comments
The included guidance documents categorised decontamination methods into cleaning, disinfection, and sterilisation.[27-34, 36, 37, 43-49]

Comments

Cleaning

- There is consistency across nine SIGN 50 Level 4 guidance documents that cleaning involves the physical removal of contamination which may not destroy pathogens.[27-30, 34, 36, 43, 44, 49]
- Cleaning is described as the first step of decontamination which removes contamination to the extent required for further processing (disinfection or sterilisation, as required),[27, 28, 30, 33, 34, 37, 43, 45, 49] or further use.[33, 34, 43, 45, 49]
- There is consistency across eleven guidance documents, graded SIGN 50 Level 4, that cleaning involves physical (friction or use of water) or mechanical action to remove contamination.[27, 29, 30, 34, 36, 43-45, 47-49]
- There is consistency across eleven guidance documents, graded SIGN 50 Level 4, that cleaning may involve the use of detergents, as appropriate.[27-30, 34, 37, 43, 45-47, 49]
- Two Scottish guidance documents, graded SIGN 50 level 4, highlight that an automated washer-disinfector may be used to clean equipment, where appropriate.[47, 48]
- Two SIGN 50 Level 4 guidance documents, published by the WHO and the American College of Emergency Physicians (ACEP), outline that an enzymatic (proteolytic) cleaner may be considered following physically cleaning an item, as appropriate.[34, 45]

Disinfection

- Nine guidance documents (SIGN 50 Level 4) consistently describe disinfection as the destruction or reduction of viable microorganisms, using thermal or chemical methods.[27, 30, 33, 36, 37, 43-45, 47]
- Nine guidance documents (SIGN 50 Level 4) consistently advise that disinfection may not result in the inactivation of all pathogens, especially some viruses and bacterial spores.[27, 30-32, 34, 36, 37, 43, 45]

There were some inconsistencies in the included literature regarding the levels of disinfection.

- Two guidance documents (SIGN 50 Level 4) separate disinfection methods into two categories, low- and high-level disinfection.[29, 32]
- Seven guidance documents (SIGN 50 Level 4) describe three categories of disinfection: high, low, and intermediate levels.[27, 28, 31, 33, 34, 37, 45]

Comments

- High level disinfection is generally described within the included evidence (n=4, SIGN 50 Level 4) as destroying or removing most pathogenic material, other than large numbers of endospores.[27-29, 32]
- Intermediate level disinfection is described within expert opinion guidance (n=3, SIGN 50 Level 4) as a middle level destroying most microorganisms including mycobacteria, most spores, virus, and fungi.[28, 31, 33]
- Low level disinfection is generally described within the included evidence (n=5, SIGN 50 Level 4) as the inactivation of vegetative bacteria, enveloped and some non-enveloped viruses and most fungi.[27-29, 31, 32] Two of these guidance documents suggest that low level disinfection may often be achieved in 10 minutes or less.[31, 32]

- Two SIGN 50 level 4 guidance documents indicated that disinfection may be carried out using an automated process such as a washer-disinfector.[46-48]

Sterilisation

- There was consistency across ten guidance documents (SIGN 50 Level 4) that sterilisation is the process by which microorganisms are rendered fully destroyed or inactivated, making equipment free of virus, fungi, and bacteria, including spores.[27-29, 33-35, 37, 43, 44, 46]
- Various methods of sterilisation are described in the included literature, including automated sterilisers,[28, 34, 43, 46, 48] steam or dry heat,[28, 34, 37, 46] or chemicals in the form of gas or liquids.[28, 32, 34, 37, 46].
- The standards required for sterilisation are specified in BS EN ISO 14937:2009.[50]

5.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The countries for which the included guidance was published for are as follows: • UK (n=6)[30, 36, 43, 46-48] • USA (n=6)[31, 32, 37, 44, 45, 49] • Australia (n=1)[27] • Canada (n=1)[29] • International (n=1)[34] • Australasia (n-1)[33] • Europe (n=1)[28] The included studies are considered applicable to Scottish health and care settings due to the nature of the research question, which is focused on categorisation of decontamination methods.

5.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
There were no primary studies found in relation to this research question therefore issues such as sample size and methods of sample selection are not applicable.

5.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
Not applicable.

B: Evidence to Decision

5.6 Recommendations

What Recommendations or Good Practice Points are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach

Recommendation	Grading
This research question aimed to outline how decontamination methods is categorised in the literature, therefore, has no associated recommendations or good practice points. Decontamination methods can be categorised into: • Cleaning • Disinfection which can be further divided into high, intermediate, and low-level disinfection. • Sterilisation.	Not applicable

5.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about benefits.

Benefits
Not applicable.

Risks and harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about risks and harms.

Risks and harms
Not applicable.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the:

- individual service user, staff or visitor perspective
- the societal perspective
- or both of the above

Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events or vice versa.

Benefit-Harm assessment
Not applicable.

5.8 Feasibility

Is the Recommendation or Good Practice Point implementable in the Scottish context?

Describe (if applicable):

- financial implications
- opportunity costs
- material or human resource requirements
- facility needs
- sustainability issues
- human factors

or any other issues that may be associated with following a Recommendation or Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
Not applicable.

5.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
Not applicable.

5.10 Value judgements

Summarise value judgements used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
Not applicable.

5.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation or Good Practice Point. If none was intended, state “none”. Recommendations or Good Practice Points should be clear and specific, but if there is a decision to be vague, acknowledging the reasoning clearly promotes transparency. Reasons for vagueness may include:

- inadequate evidence
- inability to achieve consensus regarding evidence quality
- anticipated benefits or harms, or interpretation of evidence
- legal considerations
- economic reasons
- ethical or religious reasons

Intentional vagueness
Not applicable.

5.12 Exceptions

List situations or circumstances in which the Recommendation or Good Practice Point should not be applied.

Exceptions
Not applicable.

5.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
Not applicable.

Research Question 6: When and how should detergents be used to decontaminate non-invasive, reusable, shared care equipment?

A Quality of Evidence

6.1 How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is no available evidence to answer the key question, go to section B.

Comments	Evidence level
Sixteen pieces of evidence were included to answer this research question.[27-34, 37, 38, 43, 46, 47, 51-53] • One guideline document was graded AGREE II: 'Recommend with modifications'.[51] This guideline used low-quality primary studies, including studies with a bundled IPC approach to inform recommendations. There is also a lack of clarity regarding the process of review by external stakeholders, as well as the expertise of those stakeholders and limited detail was provided about patient representative(s).[51] Therefore, recommendations in this guideline that are relevant to this research question are considered as expert opinion despite the document being graded as AGREE: 'Recommend with modifications'. • Fifteen guidance documents were graded as SIGN 50 Level 4, expert opinion.[27-34, 37, 38, 43, 46, 47, 52, 53] Level 4 guidance is subject to methodological and reporting limitations, and has not included sufficient systematic methods, thus, it is considered low quality.	1 x AGREE II: 'Recommend with modifications' 15 x SIGN 50 Level 4

Comments	Evidence level
There was no primary evidence of sufficient quality identified as relevant for this research question.	

6.2 Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the judgement was formed as to the overall direction of the evidence.

Comments
Considerations for when to use a detergent • There is consistency across eleven expert opinion guidance documents, graded SIGN 50 Level 4, and a guideline document, graded AGREE II: 'recommend with modifications', that a detergent should be used as part of the 'cleaning' phase of decontamination.[27-34, 38, 51, 52] • Two evidence sources (a guidance document, graded SIGN 50 Level 4, and a guideline document, graded AGREE II: 'recommend with modification') advise that local policy should inform when only detergent should be used or where other decontamination methods may be required.[43, 51] • Although it was difficult to find consistency due to heterogeneity, the use of a detergent was outlined as part of the decontamination process for various types of care equipment including: non-invasive ultrasound transducers,[32, 33, 38] other ultrasound equipment,[28, 33] bed and bed rails,[27, 29] blood pressure cuffs,[27, 29, 37, 52] stethoscopes,[37, 52] stands and brackets (for example, for holding catheters or to facilitate administration of intravenous drug therapy),[27] pulse oximeter probes and cables,[29, 52] electrocardiographic cables,[52] hoists,[27] mattresses,[27] commodes or bedpans,[27, 29] and toys or games in direct contact with patients or their environment.[29] Considerations for selecting a detergent • There is consistency within seven expert opinion guidance documents, graded SIGN 50 Level 4, that detergents should be selected based on their compatibility with the equipment being decontaminated, as stated by the equipment manufacturer's instructions.[27, 29, 31-34, 47]

Comments

- Three SIGN 50 Level 4 guidance documents propose that factors to consider when selecting detergents should include:
    - type of contamination or soiling (such as with blood)[34, 46]
    - efficacy, cost, time, complexity, and designated location for reprocessing[32]
    - water quality, temperature of water, and availability of cleaning products.[34]

Considerations for how to use a detergent

- Two guidance documents, Australian IPC guidelines [27] and WHO guidance on decontamination and reprocessing of medical devices,[34] recommend that detergents should be prepared (for example, dilution with water) and used according to the manufacturer's instructions.

There was a lack of clarity regarding how detergents may be used, general principles of cleaning suggested in the literature include:

- Manual cleaning, such as using friction, where indicated.[31, 34]
- Submersion where compatible with equipment and appropriate.[34]
- The use of brushes, damp soft, non-linting cloths or gauze pads, where appropriate.[34, 38]
- Disassembling equipment prior to decontamination, where appropriate.[34]
- changing water for each cleaning 'session' or when visibly soiled.[34] Although it is not specified what is encompassed in a cleaning 'session'.
- Mechanical cleaning, such as using a washer-disinfector, ultrasonic equipment or similar, where appropriate.[31]
- Rinsing of equipment after 'cleaning' with a detergent,[27, 31, 34, 53] followed by drying of equipment.[28, 34, 53]

The NHS England National standards of healthcare cleanliness [43] outlined the following general cleaning practices:

- Cleaning from top to bottom,
- Cleaning from clean to dirty,
- Dusting techniques should not disperse dust (use of damp cloth or dusting device),
- Starting at the furthest point,

Comments
• High horizontal surfaces should be cleaned first, • Larger surfaces should be cleaned in an S shape motion (slightly overlapping but not going over the same area twice). • Care should be taken as transference of microorganisms is possible between surfaces on cleaning cloths, wipes, and hands.

6.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The countries for which the included evidence was designed for are as follows: • UK (n=5)[30, 43, 46, 47, 52] • International or multi-country (n=1)[34] • Australasia (n=1)[33] • Europe (n =2)[28, 51] • Australia (n=2)[27, 53] • USA (n=4)[31, 32, 37, 38] • Canada (n=1)[29] The expert opinion guidance document published within the UK is directly applicable to Scottish health and care settings.[30, 43, 46, 47, 52] The applicability of non-UK guidance documents may be limited where facilities, resources or local policy differ to current Scottish health and care settings. However, these guidance documents were from internationally recognised organisations, and practices in these countries are not anticipated to significantly differ from the UK. Moreover, the included studies are considered applicable to Scottish health and care settings due to the nature of the research question, which is focused on general decontamination practices using detergents.

6.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
There were no primary studies found in relation to this research question therefore issues such as sample size and methods of sample selection are not applicable.

6.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
Not applicable.

B: Evidence to Decision

6.6 Recommendations

What Recommendations or Good Practice Points are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach

Recommendation	Grading
GPP6.1 Detergents should be used as part of the 'cleaning' phase of decontaminating non-invasive, reusable, shared care equipment.	Good practice point
GPP6.2 Local policy should inform which detergent should be used for decontamination of specific non-invasive, reusable, shared care equipment, based on surface compatibility and manufacturer's instructions.	Good practice point
GPP6.3 Detergent products should be prepared according to the manufacturer's instructions and used to clean equipment following the equipment manufacturer's instructions.	Good practice point
GPP6.4 The process of cleaning non-invasive, reusable, shared care equipment should be carried out from the cleanest or least soiled area to the dirtiest or most soiled area.	Good practice point

6.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about benefits.

Benefits
GPP6.1, GPP6.2 and GPP6.3 Adherence to these good practice points when cleaning non-invasive, reusable, shared care equipment can support workforce efficiency, enable the standardisation of practice across health and care settings and promote the safety of staff, patients, and service users. It may also improve staff, patients and service users' confidence in the organisation's arrangements for maintaining the cleanliness of care equipment. GPP6.1, GPP6.2 and GPP6.3 Using appropriate products when cleaning non-invasive, reusable, shared care equipment and following manufacturer's instructions for use can help to prevent damage to the equipment and support compliance with regulations such as COSHH. GPP6.3 Adherence with manufacturers' instructions ensures that the product is used as intended, for example, at the correct concentration and may reduce the risk of HAI from non-invasive, reusable, shared care equipment. GPP6.4 Following this general principle when cleaning non-invasive, reusable, shared care equipment will minimise the risk of spreading infectious agents and support effectiveness of the cleaning process.

Risks and harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about risks and harms.

Risks and harms
GPP6.1, GPP6.2 and GPP6.3 Only benefits anticipated.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the:

- individual service user, staff or visitor perspective
- the societal perspective
- or both of the above

Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events or vice versa.

Benefit-Harm assessment
GPP6.1, GPP6.2, GPP6.3 and GPP6.4. Only benefits identified.

6.8 Feasibility

Is the Recommendation or Good Practice Point implementable in the Scottish context?

Describe (if applicable):

- financial implications
- opportunity costs
- material or human resource requirements
- facility needs
- sustainability issues
- human factors

or any other issues that may be associated with following a Recommendation or Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
GPP6.1, GPP6.2 GPP6.3, and GPP6.4 Human resources would be required to develop and support local policy provision, staff education and training, and compliance monitoring (for example, auditing). Although it is assumed that for most settings these practices are already established, ongoing monitoring is needed to ensure that resource requirements continue to be met.

6.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP6.1 This good practice point is informed by eleven SIGN 50 Level 4 guidance and one guideline document, graded AGREE II: ‘recommend with modifications’, that consistently advise that detergents should be used as part of the ‘cleaning’ phase of decontamination.[27-34, 38, 51, 52] No additional expert opinion to note. GPP6.2 ARHAI Scotland and its stakeholders support the two evidence sources (a SIGN 50 Level 4 guidance document and a guideline document, graded AGREE II: ‘recommend with modification’) advising that local policy should inform which detergent should be used to decontaminate non-invasive, reusable, shared care equipment based on surface compatibility and manufacturer’s instructions.[43, 51] GPP6.3 ARHAI Scotland and its stakeholders support the two SIGN 50 Level 4 guidance documents, which recommend that detergents should be prepared according to the manufacturer’s instructions.[27, 34] Additionally, It is ARHAI Scotland and its stakeholders expert opinion that consideration should be given to equipment’s manufacturer’s instructions, including compatibility and cleaning methods, when using detergent to clean equipment. GPP6.4 This good practice point is informed by ARHAI Scotland and its stakeholders expert opinion that cleaning non-invasive, reusable, shared care equipment should be carried out from the cleanest or least soiled area to the dirtiest or most soiled area.

6.10 Value judgements

Summarise value judgements used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
GPP6.1, GPP6.2, GPP6.3 and GPP6.4. No value judgements to note.

6.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation or Good Practice Point. If none was intended, state “none”. Recommendations or Good Practice Points should be clear and specific, but if there is a decision to be vague, acknowledging the reasoning clearly promotes transparency. Reasons for vagueness may include:

- inadequate evidence
- inability to achieve consensus regarding evidence quality
- anticipated benefits or harms, or interpretation of evidence
- legal considerations
- economic reasons
- ethical or religious reasons

Intentional vagueness
GPP6.1, GPP6.2, GPP6.3 and GPP6.4. No intentional vagueness to note.

6.12 Exceptions

List situations or circumstances in which the Recommendation or Good Practice Point should not be applied.

Exceptions
GPP6.1, GPP6.2, GPP6.3 and GPP6.4. No exceptions to note.

6.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None.

Research Question 7: When and how should disinfectant be used to decontaminate non-invasive, reusable, shared care equipment?

A Quality of Evidence

7.1 How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is no available evidence to answer the key question, go to section B.

Comments	Evidence level
Twenty-six sources of evidence were included to answer this research question.[25, 27-38, 43-47, 49, 51, 53-58] • Two guidelines were graded as AGREE II: Recommend with modifications.[51, 54] There were several limitations identified with these publications. Tacconelli et al. used low-quality primary studies, including studies with a bundled IPC approach to inform recommendations. There is also a lack of clarity regarding the process of review by external stakeholders, as well as the expertise of those stakeholders, and limited detail was provided about patient representative(s).[51] Loveday et al. also had several limitations, including being 10 years since the last update, limited rigour of development, and there were no references in the section related to equipment decontamination.[54] Therefore, recommendations relevant to this research question from both guidelines are considered as expert opinion despite the documents being graded as AGREE: 'Recommend with modifications'.	2 x AGREE II: 'Recommend with modifications' 24 x SIGN 50 Level 4

Comments	Evidence level
• Twenty-four guidance documents were graded SIGN 50 level 4, expert opinion.[25, 27-38, 43-47, 49, 53, 55-58] Level 4 evidence is subject to methodological and reporting limitations as it has not included sufficient systematic methods, thus, is considered low quality evidence.	

7.2 Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the judgement was formed as to the overall direction of the evidence.

Comments
Considerations for when to use a disinfectant The included guidance highlighted many considerations for when to use a disinfectant product for the decontamination of non-invasive, shared, and reusable patient care equipment. This includes: Local decision or policy • Two UK guidance documents, graded SIGN 50 level 4,[35, 43] and a European guidance document, graded AGREE II: 'recommend with modifications' (though the details related to decontamination were considered as primarily expert opinion),[51] state that the use and selection of a disinfectant should be based on local decision or policy. Routine use There was a lack of consistency regarding if disinfectant use is required each time non-invasive, shared, reusable care equipment is decontaminated. • Twelve guidance documents, graded SIGN 50 level 4, suggest that disinfection of equipment may be conducted as part of routine decontamination processes.[28, 29, 31-33, 38, 44, 45, 49, 53, 56, 58] • A CDC guidance document, graded SIGN 50 level 4, advocate the routine use of disinfectants for decontaminating care equipment arguing that medical equipment surfaces (for example, blood pressure cuffs,

Comments

stethoscopes) can become contaminated with infectious agents and contribute to the spread of healthcare associated infections.[49]

- Four guidance documents, graded SIGN 50 level 4, suggested that decontamination may involve disinfection 'if indicated'.[25, 27, 30, 36]
- A guidance document from the Australasian Society for Ultrasound in Medicine, graded SIGN 50 level 4, propose that a detergent should be used to clean non-critical equipment and that this "may" be followed with a low-level disinfectant.[33]

Low level disinfection

- Eight SIGN 50 level 4 guidance documents propose that low-level disinfection should be conducted as standard for 'non-critical' or non-invasive, shared, reusable patient care equipment, per the Spaulding or similar equipment risk classification system.[28, 29, 31-34, 38, 45]
- A policy statement from the American Academy of Pediatrics, graded SIGN 50 level 4, propose that low-level disinfection may include use of low-level disinfectants such as phenolic compounds, quaternary ammonium compounds or dilution of 1:500 sodium hypochlorite.[37]

Enhanced disinfection

Seven guidance documents, graded SIGN 50 level 4, propose more regular use of disinfectants [27, 45] or a higher level of disinfection for certain circumstances, based on the perceived risk.[30, 33, 35, 38, 53] This includes:

- where a patient has a suspected or confirmed infection,[27, 36, 53] including when undergoing contact precautions,[27] when patient has a multidrug resistant infection,[27, 55] and during outbreaks.[27, 30]
- If equipment will be used for immunocompromised patients,[36]
- where a procedure is considered as high risk for aerosolization of infective agents,[38, 45]
- the level of contamination, where items have contact or likely contact with blood or body fluids,[30, 36, 45]
- where it is recommended that products with efficacy against mycobacteria and bloodborne pathogens [38, 45] or that a suitable high-level disinfectant be used.[33]

Considerations for selecting a specific disinfectant

Comments

- There is consistency across eleven SIGN 50 level 4 guidance documents and one guideline, graded AGREE II: Recommend with modifications, that disinfectant products should be selected based on compatibility with the equipment being decontaminated, as stated in manufacturer's instructions or guidelines.[27-29, 33, 34, 47, 49, 53, 54, 56-58]
- A CDC guidance document, graded SIGN 50 level 4, advises that high level disinfectants should not be used on non-critical equipment where it does not align with manufacturer's instructions.[49]
- CDC guidance highlight the importance of considering the level of contamination, microorganisms present and any resistance, concentration of disinfectant, contact time and temperature, when selecting a disinfectant.[49]
- A WHO guidance document, graded SIGN 50 level 4,[34] propose that other aspects that should be considered when selecting a disinfectant are:
    - the purpose of the device,
    - disinfectant chemical stability, cost effectiveness, effectiveness in the presence of organic compounds,
    - ability to rapidly destroy microorganisms including spores,
    - compatibility with surfaces, and the ability to penetrate crevasses.
- Five guidance documents (SIGN 50 Level 4) provide recommendations for specific types of disinfectant.[27, 31, 34, 43, 49] Generally, there was no consistency on which type of products should be used for non-critical, shared, reusable equipment decontamination.
- Three guidance documents, graded SIGN 50 level 4, recommended the use of chlorine-releasing agents during outbreaks in haemodialysis units,[27] when there is visible contamination with blood,[27, 31] and for decontamination of mattresses, where a concentration of 1:500 sodium hypochlorite was suggested.[43]
- Four guidance documents (SIGN 50 level 4) recommend that products previously considered a sterilant, such as formaldehyde-alcohol,[31] formaldehyde,[34] and glutaraldehyde[34, 43] should not be used as disinfectants, because they are not sporicidal, can damage some equipment (shellac, rubber and plastics), and may not be effective over larger surfaces.[31, 34, 49]

Considerations for how to use a disinfectant

Comments

- There was consistency across six guidance documents, graded SIGN 50 Level 4, that manufacturer instructions or guidance should be followed when using a disinfectant.[29, 31, 38, 44, 49, 58]
- Australian National Health and Medical Research Council (NHMRC) guidance suggest that 2-in-1 (detergent and disinfectant) products may be considered but provide no recommendation stating any preference compared to using a detergent product followed by a disinfectant.[27]
- Considerations for use described within SIGN 50 level 4 evidence include:
    - Submersion or immersion of some equipment, where this aligns with the manufacturer's instructions or guidelines.[38]
    - Using 'correct' concentration of a chemical disinfectant, per manufacturer instructions.[31, 33, 49]
    - Fresh solution be made for each decontamination.[33, 34]
    - Contact time (exposure time), which may differ per product.[31]
- Six SIGN 50 level 4 guidance documents consistently recommend rinsing of equipment after decontamination with a disinfectant to remove residues from disinfectant agents.[33, 38, 43, 49, 53, 56]
- Two SIGN 50 level 4 guidance documents consistently recommend that equipment should be dried following decontamination,[33, 53] using a single-use, dry, clean, non-linting cloth,[33, 53] or by air drying.[53]

7.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments

The country or countries in which the guidance applies are as follows:

- UK (n=8)[25, 30, 35, 36, 43, 46, 47, 54]
- USA (n=11)[31, 32, 37, 38, 44, 45, 49, 55-58]
- Australia (n=2)[27, 53]

Comments
• Canada (n=1)[29] • Europe (n=2)[28, 51] • Australasia (n=1)[33] • International (n=1)[34] The expert opinion guidance document published within the UK is directly applicable to Scottish health and care settings. [25, 30, 35, 36, 43, 46, 47, 54, 59] The applicability of non-UK guidance documents may be limited where facilities, resources or local policy differ to current Scottish health and care settings. However, these guidance documents were from internationally recognised organisations, and practices in these countries are not anticipated to significantly differ from the UK. Moreover, the included studies are considered applicable to Scottish health and care settings due to the nature of the research question, which is focused on general decontamination practices using disinfectant.

7.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
There were no primary studies included for this research question, therefore, issues such as sample size and methods of sample selection are not relevant.

7.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
Not applicable.

B: Evidence to Decision

7.6 Recommendations

What Recommendations or Good Practice Points are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach

Recommendation	Grading
GPP7.1 Disinfectant products should be used to decontaminate non-invasive, reusable, shared care equipment when it has been contaminated with blood or body fluids, or when it has been used for an individual with a suspected or confirmed transmissible infection.	Good practice point
GPP7.2 Disinfectant products should be selected based on compatibility with the equipment being decontaminated, as stated in manufacturer's instructions.	Good practice point
GPP7.3 Disinfectant products should be prepared and used according to manufacturer instructions including chemical concentration, application style and contact time, whilst taking into account the specific equipment manufacturers instructions.	Good practice point
GPP7.4 Non-invasive, reusable, shared care equipment should be cleaned prior to disinfection. Cleaning should involve the use of detergent (unless a combined	Good practice point

Recommendation	Grading
detergent and disinfectant product is used), as part of the decontamination process.	
GPP7.5 Local policy should inform when and how disinfectants should be used for decontamination of specific non-invasive, reusable, shared care equipment based on surface compatibility and the manufacturer's instructions.	Good practice point
GPP7.6 When disinfecting non-invasive, reusable, shared care equipment, the process should be carried out from the cleanest or least soiled area to the dirtiest or most soiled area.	Good practice point
GPP7.7 Appropriate steps, including rinsing and drying, should be taken to remove residues of disinfectant agents from non-invasive, reusable, shared care equipment after decontamination.	Good practice point

7.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about benefits.

Benefits
GPP7.1, GPP7.2, GPP7.3, GPP7.6 and GPP7.7. Adherence to these good practice points when disinfecting non-invasive, reusable, shared care equipment will support workforce efficiency, enable the standardisation of practice across health and care settings, prevents misuse of disinfectants, and promote the safety of patients and service users. GPP7.1, GPP7.2 and GPP7.3. Adherence to these good practice points when disinfecting non-invasive, reusable, shared care equipment supports increased

Benefits
staff and service user confidence in the organisation's arrangements for maintaining care equipment cleanliness. GPP7.1, GPP7.2 and GPP7.3. Following manufacturer's instructions and using appropriate products when disinfecting non-invasive, reusable, shared care equipment may help to prevent damage to the care equipment and supports compliance with regulations such as COSHH. GPP7.4 and GPP7.5. Adherence to these good practice points when disinfecting non-invasive, reusable, shared care equipment will support the effectiveness of the equipment decontamination process. GPP7.6. Following this general principle when cleaning non-invasive, reusable, shared care equipment will minimise the risk of spreading infectious agents and support effectiveness of the cleaning process.

Risks and harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about risks and harms.

Risks and harms
GPP7.1, GPP7.2, GPP7.3, GPP7.4, GPP7.5, and GPP7.6. Frequent use of disinfectants may result in damage to equipment, including corrosion or discoloration of vital parts of non-invasive, reusable, shared care equipment. GPP7.1, GPP7.2, GPP7.3, GPP7.4, and GPP7.5. Use of disinfectants in health and care settings may contribute to antimicrobial resistance. However, this is an unknown risk, which cannot be quantified based on the evidence from the current literature review. GPP7.7. No harms anticipated.

Benefit-Harm assessment

Classify as "benefit outweighs harm" (or vice versa) or a "balance of benefit and harm." Description of this balance can be from the:

- individual service user, staff or visitor perspective
- the societal perspective
- or both of the above

Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events or vice versa.

Benefit-Harm assessment
GPP7.1, GPP7.2, GPP7.3, GPP7.4, GPP7.5, and GPP7.6. The benefit of adhering to manufacturer's instruction when using disinfectants, including standardisation of decontamination process, patient safety, and compliance with COSHH regulations outweighs the potential risk of equipment damage from frequent use. GPP7.1, GPP7.2, GPP7.3, GPP7.4, and GPP7.5. It is anticipated that the IPC benefits of using chemical disinfectant for decontamination, including prevention of onward transmission of infectious agents, will outweigh the potential risk of contribution to antimicrobial resistance. GPP7.7. Only benefits identified.

7.8 Feasibility

Is the Recommendation or Good Practice Point implementable in the Scottish context?

Describe (if applicable):

- financial implications
- opportunity costs
- material or human resource requirements
- facility needs
- sustainability issues
- human factors

or any other issues that may be associated with following a Recommendation or Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
GPP7.1, GPP7.2, GPP7.3, GPP7.4, GPP7.5, GPP7.6, and GPP7.7. Human resources will be required to develop and support local policy, including provision of staff education, training and compliance monitoring or auditing. Although, it is assumed that these practices are already established in most settings there will be an ongoing need for monitoring to ensure these resource needs continue to be met. GPP7.2 and GPP7.5. There may be additional financial implications related to procurement of disinfectants or combined detergent and disinfectant products that are suitable for use with different care equipment, considering surface compatibility and equipment manufacturer's instructions.

7.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state "none". Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP7.1. This good practice point is informed by seven SIGN 50 Level 4 guidance documents [27, 30, 33, 35, 38, 45, 53] which advise that disinfectant products should be used to decontaminate care equipment whenever an infection risk is present (for example, when contaminated with BBF or exposure to a patient with a suspected or confirmed transmissible infection).) GPP7.2. This good practice point is informed by 11 SIGN 50 level 4 guidance documents [27-29, 33, 34, 47, 49, 53, 56-58] and one guideline, graded AGREE II: Recommend with modifications,[54] that consistently advise that disinfectant products should be selected based on their compatibility with the equipment being decontaminated, as stated in manufacturer's instructions or guidelines. GPP7.3. This good practice point is informed by six SIGN 50 Level 4 guidance documents,[29, 31, 38, 44, 49, 58] that consistently advise that manufacturer instructions should be followed when using a disinfectant to decontaminate non-invasive, reusable, shared care equipment. It is the expert opinion of ARHAI Scotland and its stakeholders that products should be prepared and used according to product

Expert opinion

manufacturer instructions, whilst also considering the specific equipment manufacturers instructions.

GPP7.4. This good practice point is informed by two SIGN 50 Level 4 guidance documents,[27, 33] one propose using detergent to clean non-critical equipment prior to using a low-level disinfectant,[33] while the other suggest considering using 2-in-1 (combined detergent and disinfectant) product.[27] It is ARHAI Scotland and its stakeholders expert opinion that cleaning should involve the use of detergent, unless a combined detergent and disinfectant product is used for decontamination of non-invasive, reusable, shared care equipment.

GPP7.5. This good practice point is informed by two SIGN 50 level 4 guidance,[35, 43] and one European guideline document, graded AGREE II: 'recommend with modifications',[51] that consistently advise that the selection and use of disinfectant should be based on local decision or policy. It is ARHAI Scotland and its stakeholders expert opinion that local policy for use of disinfectant should involve assessment of equipment surface compatibility based on manufacturer's instructions.

GPP7.6 This good practice point is informed by ARHAI Scotland and its stakeholders expert opinion that when disinfecting non-invasive, reusable, shared care equipment, the process should be carried out from the cleanest or least soiled area to the dirtiest or most soiled area.

GPP7.7. This good practice point is informed by six SIGN 50 Level 4 guidance documents,[33, 38, 43, 49, 53, 56] that consistently advise that appropriate steps, including rinsing and drying, should be taken to remove residues of disinfectant agents from non-invasive, reusable, shared patient care equipment after decontamination.

7.10 Value judgements

Summarise value judgements used in creating the Recommendation or Good Practice Point. If none were involved, state "none". Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements

GPP7.1, GPP7.2, GPP7.3, GPP7.4, GPP7.5 GPP7.6, and GPP7.7. No value judgements to note.

7.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation or Good Practice Point. If none was intended, state “none”. Recommendations or Good Practice Points should be clear and specific, but if there is a decision to be vague, acknowledging the reasoning clearly promotes transparency. Reasons for vagueness may include:

- inadequate evidence
- inability to achieve consensus regarding evidence quality
- anticipated benefits or harms, or interpretation of evidence
- legal considerations
- economic reasons
- ethical or religious reasons

Intentional vagueness
GPP7.1, GPP7.2, GPP7.3, GPP7.4, GPP7.5 GPP7.6, and GPP7.7. No intentional vagueness to note.

7.12 Exceptions

List situations or circumstances in which the Recommendation or Good Practice Point should not be applied.

Exceptions
GPP7.1, GPP7.2, GPP7.3, GPP7.4, GPP7.5 GPP7.6, and GPP7.7. No exceptions to note.

7.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
The evidence and recommendations advocate following manufacturers instruction for selecting, preparing, and using disinfectant products. Further research on effectiveness of products using validated methodology, as per BS EN standards, as well as real life application in health and care settings may be required to confirm manufacturer's assessments of efficacy and support comparison across the different products. Moreover, there may be a possibility that use of chemical disinfectant products which meet BS EN standards may contribute to antimicrobial resistance over time. Future research to investigate and quantify the potential risk may be valuable in addressing the current evidence gap.

Research Question 8: Where should non-invasive, reusable, shared care equipment be decontaminated?

A Quality of Evidence

8.1 How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is no available evidence to answer the key question, go to section B.

Comments	Evidence level
Seven guidance documents were included for this research question.[27, 31, 32, 34, 35, 56, 59] • All the included documents were graded SIGN 50 Level 4, expert opinion.[27, 31, 32, 34, 35, 56, 59] Level 4 evidence is subject to methodological and reporting limitations as has not included sufficient systematic methods, thus, it is considered low quality evidence.	7 x SIGN 50 Level 4

8.2 Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the judgement was formed as to the overall direction of the evidence.

Comments
There was a lack of consistency with regards to the optimal location for decontamination of non-invasive, reusable, shared equipment.

Comments

- The UK Department of Health and Social Care recommended adherence to legislation such a Medical Device Regulations for decontamination, as appropriate.[35]
- Five guidance documents, graded SIGN 50 level 4, recommend a separate or designated decontamination area or unit.[31, 32, 34, 35, 56]
- Two SIGN 50 level 4 guidance documents, published by Health Facilities Scotland (HFS) and the Society of Diagnostic Medical Sonography (SDMS), outline that it may be appropriate to decontaminate some equipment at the point of care.[32, 59]
- The Australian NHMRC guidance, graded SIGN 50 level 4, advises that adequate cleaning supplies should be available at or close to the point of care.[27]
- HFS guidance, graded SIGN 50 level 4, advises that decontamination of care equipment can be carried out in ancillary areas, which may include rooms built to function as dirty utility, clean utility, domestic services rooms (DSRs), decontamination facility or disposal room, etc.[59] HFS [59] further propose that decontamination facilities or dirty utility room should include facilities for:
    - cleaning of equipment
    - decontaminating commodes
    - temporarily holding items which require reprocessing
    - disposal of body fluids, and
    - hand hygiene.

Good practices regarding transportation of equipment, to reduce the risk of contamination, were outlined within WHO,[34] CDC,[56] and SDMS [32] guidance, graded SIGN 50 level 4. These include:

- local policy may outline procedures for the transport of equipment to designated decontamination areas.[56]
- transporting equipment as soon as possible after use,[34]
- use of designated or approved containers with clear markings that the box contains dirty items and biohazard stickers.[32, 34]
- clean and dirty equipment should not be transported together, and the containers used to transport equipment should be decontaminated.[34]

Comments
• Both clean and dirty items may be transported parallel to the floor and appropriate processes should be in place to decontaminate the transport carts.[32] • having one-way flow (dirty to clean) and physical separation of clean and dirty areas.[34] • transporting 'clean' equipment in a clean, sterile, and approved container (with clear marking that the box contains clean items).[32, 34]

8.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The country or countries in which the guidance applies are as follows: • UK (n=2)[35, 59] • USA (n=3)[31, 32, 56] • Australia (n=1)[27] • International (n=1)[34] The expert opinion guidance document published within the UK is directly applicable to Scottish health and care settings.[35, 59] The applicability of non-UK guidance documents may be limited where facilities, resources or local policy differ to current Scottish health and care settings. However, these guidance documents were from internationally recognised organisations, and practices in these countries are not anticipated to significantly differ from the UK.

8.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
There were no primary studies included for this research question, therefore, issues such as sample size and methods of sample selection are not relevant.

8.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
Not applicable.

B: Evidence to Decision

8.6 Recommendations

What Recommendations or Good Practice Points are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach

Recommendation	Grading
GPP8.1. If possible, non-invasive, reusable, shared care equipment (for example, blood pressure cuffs, stethoscopes) should be decontaminated at the point of care where they are used.	Good practice point
GPP8.2. Equipment that has been used on an individual with a suspected or confirmed transmissible infection, or within an isolation area, should be decontaminated prior to removal from the area.	Good practice point
GPP8.3. A designated facility or dirty utility room should be provided for decontaminating equipment that cannot be decontaminated at the point of care. This should include facilities for: • cleaning and disinfecting equipment • temporarily holding items which require reprocessing • disposal of body fluids, and	Good practice point

Recommendation	Grading
• hand hygiene.	
GPP8.4. Local policy should outline procedures for decontamination and transport of equipment including clean and dirty flows, segregation of equipment, and use of markings, which may include labels where appropriate (such as those identifying that an item has been decontaminated).	Good practice point

8.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about benefits.

Benefits
GPP8.1. Decontaminating non-invasive, reusable, shared care equipment at the point of care where they are used, may support workforce efficiency, by reducing delays, minimising equipment downtime, and enabling immediate reuse. Also, decontaminating equipment immediately after use may reduce the risk of it being inadvertently reused on another patient or service user without appropriate decontamination being carried out, therefore, reducing the potential risk of cross-contamination. GPP8.2. Decontaminating equipment that has been used on an individual with a suspected or confirmed transmissible infection, or within an isolation area, prior to removal from the area will minimise the risk of contamination and transmission of infectious agents outside the infected patient area. GPP8.3. Temporarily holding and clearly identifying care equipment that require reprocessing in a dedicated decontamination facility or dirty utility room may help minimise contact with used or contaminated equipment and ensure that the equipment is not reused before undergoing appropriate decontamination.

Benefits
GPP8.3 and GPP8.4. Adhering to local policy when decontaminating and transporting equipment to designated decontamination areas, including the use of markings and labels where appropriate supports the standardisation of practice across health and care settings.

Risks and harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about risks and harms.

Risks and harms
GPP8.1 and GPP3.2 There is a risk that decontamination products used at the point of care may not be returned to their designated storage area after use in the care environment, this may pose risks of unintended chemical exposure to patients, service users, staff, and visitors. GPP8.3 Temporarily holding care equipment that require reprocessing in a dedicated decontamination facility or dirty utility room may introduce spatial constrains, which could impact on IPC processes being carried out effectively. There could also be a risk of environmental contamination while transporting equipment to the designated decontamination area. GPP8.3 Improper use of labels, may result in adhesive residue being left on surfaces. This residue can trap and harbour dirt, dust, and microbes, which may subsequently impede effective decontamination processes. This risk should be considered when preparing local decontamination policy.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the:

- individual service user, staff or visitor perspective
- the societal perspective
- or both of the above

Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events or vice versa.

Benefit-Harm assessment
GPP8.1 and GPP8.2. The IPC benefits of decontaminating non-invasive, reusable, shared care equipment at the point of use outweighs the potential risk of chemical exposure or environmental contamination if appropriate process is not followed. GPP8.3. The IPC benefits, along with wider considerations such as the preservation of patient respect and dignity, associated with decontaminating non-invasive, reusable, shared care equipment within a designated decontamination area, if due process is followed, outweighs the potential for environmental contamination during transportation. GPP8.4. The IPC benefits of using labels to mark equipment as decontaminated outweigh the potential risk of microbial contamination from adhesive residue, provided they are applied and removed according to the manufacturer's instructions.

8.8 Feasibility

Is the Recommendation or Good Practice Point implementable in the Scottish context?

Describe (if applicable):

- financial implications
- opportunity costs
- material or human resource requirements
- facility needs
- sustainability issues
- human factors

or any other issues that may be associated with following a Recommendation or Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
GPP8.1 and GPP8.2. There will be staff resource, training and education required to ensure effective decontamination of equipment at the point of care, and to return decontamination products to their storage areas.

Feasibility
GPP8.3 Due to the variation in age and design of the health and care estate throughout NHSScotland, some areas may not fully comply with current national guidance or design standards (for example, the space requirements for designated decontamination areas), which may impact the safe and effective delivery of infection prevention and control processes. Therefore, there may be additional cost required to upgrade these areas to ensure compliance with current national guidance and design standards. GPP8.4. Human resources would be required to develop and support local policy provision, staff education, training, and compliance monitoring (for example, auditing). Although, it is assumed that these practices are already established in most settings, there will be an ongoing need for evaluation to ensure these resource needs continue to be met. The procurement of markers or labels may also incur additional financial cost.

8.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP8.1. This good practice point is informed by two SIGN 50 Level 4 guidance documents,[32, 59] that consistently advise that some care equipment (for example, blood pressure cuffs, stethoscopes) can be decontaminated at the point of care. It is ARHAI Scotland and its stakeholders expert opinion that non-invasive, reusable, shared care equipment should be decontaminated at the point of care where they are used, if possible. GPP8.2. This good practice point is informed by ARHAI Scotland and its stakeholders expert opinion that equipment that has been used on an individual with a suspected or confirmed transmissible infection, or within an isolation area, should be decontaminated prior to removal from the area. GPP8.3. This good practice point is informed by six SIGN 50 Level 4 guidance documents,[31, 32, 34, 35, 56, 59] that consistently advise that a separate designated area

Expert opinion
or unit is required for decontamination of some non-invasive, reusable, shared care equipment. GPP8.4. This good practice point is informed by a SIGN 50 Level 4 guidance document that advise that local policy may outline procedures for the transport of equipment to designated decontamination areas.[56] It is ARHAI Scotland and its stakeholders expert opinion that local policy should outline procedures for decontamination and transport of equipment to designated decontamination areas, including use of markings and labels where appropriate.

8.10 Value judgements

Summarise value judgements used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
GPP8.1, GPP8.2, GPP8.3 and GPP8.4. No value judgements to note.

8.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation or Good Practice Point. If none was intended, state “none”. Recommendations or Good Practice Points should be clear and specific, but if there is a decision to be vague, acknowledging the reasoning clearly promotes transparency. Reasons for vagueness may include:

- inadequate evidence
- inability to achieve consensus regarding evidence quality
- anticipated benefits or harms, or interpretation of evidence
- legal considerations
- economic reasons
- ethical or religious reasons

Intentional vagueness
GPP8.1, GPP8.2, GPP8.3, and GPP8.4. No intentional vagueness to note.

8.12 Exceptions

List situations or circumstances in which the Recommendation or Good Practice Point should not be applied.

Exceptions
GPP8.1, GPP8.2, GPP8.3, and GPP8.4. No exceptions to note.

8.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None.

Research Question 9: When should non-invasive, reusable, shared care equipment be decontaminated?

A Quality of Evidence

9.1 How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is no available evidence to answer the key question, go to section B.

Comments	Evidence level
There were 24 pieces of evidence include to answer this research question.[25, 27-33, 36-38, 43-45, 51-58, 60, 61] • Twenty-two guidance documents were graded SIGN 50 Level 4, expert opinion.[25, 27-33, 36-38, 43-45, 52, 53, 55-58, 60, 61] Level 4 evidence is subject to methodological and reporting limitations as it has not included sufficient systematic methods, thus, is considered low quality evidence. • Two guidelines were graded AGREE II: 'Recommend with modifications'.[51, 54] There were several limitations identified with these publications. Tacconelli et al. used low-quality primary studies, including studies with a bundled IPC approach to inform recommendations. There is also a lack of clarity regarding the process of review by external stakeholders, as well as the expertise of those stakeholders, and limited detail was provided about patient representative(s).[51] Loveday et al. also had several limitations, including being 10 years since the last update, limited rigour of development, and there were no references in the section related to equipment decontamination.[54] Therefore,	2 x AGREE II: Recommend with modifications 22 x SIGN 50 Level 4

Comments	Evidence level
recommendations relevant to this research question from both guidelines are considered as expert opinion despite the documents being graded as AGREE: 'Recommend with modifications'. There was no primary evidence of sufficient quality identified as relevant for this research question.	

9.2 Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the judgement was formed as to the overall direction of the evidence.

Comments
• There is consistency across 13 guidance documents, graded SIGN 50 level 4 and two guidelines, graded AGREE II: 'Recommend with modifications', that patient care equipment should be decontaminated between patient use (that is, after use and before use on another patient).[27, 29-33, 36, 38, 44, 45, 51, 53-56] • Three guidance documents, graded SIGN 50 level 4, consistently recommend that patient care equipment should be decontaminated when visibly soiled.[37, 52, 58] • Two guidance documents, graded SIGN 50 level 4, recommend decontamination of equipment before loaning, decommissioning, recycling and disposal.[25, 60] • NHS England cleanliness guidance, graded SIGN 50 level 4, suggests consideration for decontamination of equipment which is not in use.[43] • MHRA guidance, graded SIGN 50 level 4, recommends that when to decontaminate equipment should be based on manufacturers guidance.[60] Frequency of decontamination There was no overall consistency regarding the frequency of decontamination of non-invasive reusable shared care equipment.

Comments

- The NHS England standards for cleanliness, graded SIGN 50 level 4, suggest that one nationally set frequency of decontamination may not be appropriate, given the differing needs of every healthcare organisation.[43]
- Four guidance documents, graded SIGN 50 level 4, were consistent in suggesting that the frequency of decontaminating equipment may differ depending on the level of associated risk of contamination or transmission.[27, 43, 57, 61]
- NHS England standards for cleanliness and Scottish standards for cleanliness, both graded SIGN 50 level 4, recommend that risk assessment should be conducted to determine decontamination schedules or adaptations to decontamination schedules.[43, 61]
- Five guidance documents, graded SIGN 50 level 4, provided different examples of baseline or example frequencies of decontamination for specific equipment types, without consistency.[27, 43, 44, 55, 56]
- A SIGN 50 level 4 CDC guidance, for the prevention and control of multi-drug-resistant organisms, states that bedrails and other frequently touched items should be decontaminated ‘more frequently’ than non-frequently touched items.[55]
- A CDC guidance document, graded SIGN 50 level 4, states that non-critical care equipment should be decontaminated ‘regularly’, described as weekly or after each use, as appropriate.[31]
- Two guidance documents, graded SIGN 50 level 4, recommend daily cleaning and decontamination of non-invasive, reusable, shared care equipment, while in use.[37, 52]

9.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The country or countries for which the included evidence applies are as follows: • UK (n=8)[25, 30, 36, 43, 52, 54, 60, 61] • USA (n=10)[31, 32, 37, 38, 44, 45, 55-58] • Australia (n=2)[27, 53] • Canada (n=1)[29] • Europe (n=2)[28, 51] • Australasian (n=1)[33] Extant guidance published within the UK is directly applicable to Scottish health and care settings.[25, 30, 36, 43, 52, 54, 60, 61] The applicability of non-UK guidance documents may be limited where facilities, resources or local policy differ to current Scottish health and care settings. However, these guidance documents were from internationally recognised organisations, and practices in these countries are not anticipated to significantly differ from the UK.

9.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
There were no primary studies found in relation to this research question therefore issues such as sample size and methods of sample selection are not applicable.

9.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
Not applicable.

B: Evidence to Decision

9.6 Recommendations

What Recommendations or Good Practice Points are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach

Recommendation	Grading
GPP9.1 Decontamination of non-invasive, reusable, shared care equipment should take place: • as soon as practicable after use • between use on each individual • when visibly soiled	Good practice point

Recommendation	Grading
• after blood or body fluid contamination • following the resolution of an outbreak • before and after inspection, servicing or repair • before being loaned out and following return • before decommissioning, recycling and disposal • at regular, pre-defined intervals as part of an equipment cleaning schedule.	
GPP9.2 Local decontamination policy development should involve conducting risk assessments to determine appropriate decontamination schedules or necessary adaptations for non-invasive, reusable, shared care equipment, based on the level of associated infection risk. Any deviation from the manufacturer's decontamination instructions should be clearly documented and justified in accordance with local governance procedures.	Good practice point

9.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or Good Practice Point on service users, visitors, and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about benefits.

Benefits
GPP9.1. Decontaminating non-invasive, reusable, shared care equipment at the appropriate times supports standardisation of practice, reduces equipment downtime, and may minimise any potential infection risk posed to staff and patients handling and using this equipment.

Benefits
GPP9.2. Conducting risk assessments to inform local policy will ensure that appropriate decontamination schedules are established for health and care settings. This supports maintaining specific standards of cleanliness of non-invasive, reusable, shared care equipment and ensures that decontamination efforts are proportionate to actual risk. It also promotes the consistent application of infection prevention practices and supports sufficient and appropriate allocation of resource.

Risks and harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about risks and harms.

Risks and harms
GPP9.1 and GPP9.2. No risks anticipated.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the:

- individual service user, staff or visitor perspective
- the societal perspective
- or both of the above

Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events or vice versa.

Benefit-Harm assessment
GPP9.1 and GPP9.2. Only benefits identified.

9.8 Feasibility

Is the Recommendation or Good Practice Point implementable in the Scottish context?

Describe (if applicable):

- financial implications
- opportunity costs
- material or human resource requirements
- facility needs
- sustainability issues
- human factors

or any other issues that may be associated with following a Recommendation or Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
GPP9.1 and GPP9.2. Human resources would be required to develop and support local policy provision, staff education, training, and compliance monitoring (for example, auditing). Although, it is assumed that these practices are already established in most settings there will be an ongoing need for evaluation to ensure these resource needs continue to be met.

9.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP9.1 This good practice point is informed by 20 SIGN 50 Level 4 guidance documents,[25, 27, 29-33, 36-38, 44, 45, 51-56, 58, 60] that advise that non-invasive, reusable, shared care equipment should be decontaminated as soon as practicable after use and between patient use,[27, 29-33, 36, 38, 44, 45, 51, 53-56] when visibly soiled,[37, 52, 58] before loaning, decommissioning, recycling and disposal.[25, 60] It is ARHAI Scotland and its stakeholders expert opinion that non-invasive, reusable, shared care equipment should be decontaminated after blood or body fluid contamination, following the resolution of an outbreak, before inspection, servicing or repair, following repair and at regular, pre-defined intervals as part of an equipment cleaning schedule. GPP9.2. This good practice point is informed by six SIGN 50 Level 4 guidance documents [27, 31, 43, 55, 57, 61] that recommend that risk assessment should be

Expert opinion
conducted to inform decontamination schedules or adaptations to decontamination schedules, as appropriate. It is ARHAI Scotland and its stakeholders expert opinion that any deviation from the manufacturer's recommended decontamination instructions must be clearly documented and justified in accordance with local governance procedures.

9.10 Value judgements

Summarise value judgements used in creating the Recommendation or Good Practice Point. If none were involved, state "none". Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
GPP9.1 and GPP9.2. No value judgements to note.

9.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation or Good Practice Point. If none was intended, state "none". Recommendations or Good Practice Points should be clear and specific, but if there is a decision to be vague, acknowledging the reasoning clearly promotes transparency. Reasons for vagueness may include:

- inadequate evidence
- inability to achieve consensus regarding evidence quality
- anticipated benefits or harms, or interpretation of evidence
- legal considerations
- economic reasons
- ethical or religious reasons

Intentional vagueness
GPP9.1 and GPP9.2. No intentional vagueness to note.

9.12 Exceptions

List situations or circumstances in which the Recommendation or Good Practice Point should not be applied.

Exceptions
GPP9.1 and GPP9.2. No exceptions to note.

9.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None.

Research Question 10: Who has responsibility for decontaminating non-invasive, reusable, shared care equipment?

A Quality of Evidence

10.1 How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is no available evidence to answer the key question, go to section B.

Comments	Evidence level
Eleven pieces of evidence were included for this research question.[25, 30, 34, 35, 43, 47, 54, 58, 60-62] • Ten guidance documents, including a Scottish Government Health Department Letter, were graded SIGN 50 Level 4, expert opinion.[25, 30, 34, 35, 43, 47, 58, 60-62] Level 4 evidence is subject to methodological and reporting limitations as it has not included sufficient systematic methods, thus, is considered low quality evidence. • One guideline document was graded AGREE II: 'Recommend with modifications'.[54] This document has several limitations including being 10 years since the last update, limited rigour of development, and there were no references in the section related to equipment decontamination. Therefore, recommendations relevant to this research question from this guideline are considered as expert opinion despite the document being graded as AGREE: 'Recommend with modifications'.	1 x AGREE II: Recommend with modifications 10 x SIGN 50 Level 4

Comments	Evidence level
There was no primary evidence of sufficient quality identified as relevant for this research question.	

10.2 Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the judgement was formed as to the overall direction of the evidence.

Comments
• A Health Department letter [HDL(2005)07] published by the Scottish government advises that sisters or senior charge nurses are responsible for ensuring safe working conditions within their clinical environment, including the authority to require local cleaning services.[62] Although there was a lack of consistency, three Scottish guidance documents,[25, 47, 61] graded SIGN 50 level 4, outline various roles and responsibilities related to decontamination of equipment. • SHTM 2030 outlines the responsibilities of the user with regards to use of a washer disinfector.[47] • SHTN 00-04 sets out general roles and responsibilities for users, management, technical specialists and others specific to decontamination of care equipment and medical devices in Scottish health and care settings.[25] The users' responsibilities includes checking equipment is fit for use, calibration, or maintenance as appropriate, managing IPC issues as appropriate, ensuring safe storage. • Specific roles regarding decontamination are provided within the NHSScotland national cleaning services specification 01-02.[61] The UK Department of Health and Social Care (DHSC), NHS England, and UK Medicines and Healthcare Products Regulatory Agency (MHRA) also provide recommendations regarding different cleanliness responsibilities.[35, 43, 60] However, these guidance documents have a wide coverage, are not specific to equipment decontamination alone, and apply in NHS England settings. • The UK MHRA highlight that the user will have primary responsibility for the way they treat the device and the state in which it is left.[60]

Comments

- There was consistency within five UK guidance documents, graded SIGN 50 level 4, that multiple staff may be responsible for different elements of equipment decontamination and that all staff should be clear on the specific responsibilities for decontaminating equipment.[25, 30, 36, 60, 61]
- There was consistency within five guidance documents, graded SIGN 50 level 4,[25, 34, 35, 47, 58] and a guideline document, graded AGREE II: 'Recommend with modifications'[54] that staff should be appropriately trained in decontamination and relevant protocols.

10.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments

The country or countries for which the included evidence applies are as follows:

- UK (n=9)[25, 30, 35, 43, 47, 54, 60-62]
- USA (n=1)[58]
- International (n=1)[34]

The expert opinion guidance document published within the UK is directly applicable to Scottish health and care settings.[25, 30, 35, 43, 47, 54, 60-62]

The applicability of non-UK guidance documents may be limited where facilities, resources or local policy differ to current Scottish health and care settings. However, these guidance documents are from internationally recognised organisations, and practices in these countries are not anticipated to significantly differ from the UK.

10.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
There were no primary studies found in relation to this research question therefore issues such as sample size and methods of sample selection are not applicable.

10.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
Not applicable.

B: Evidence to Decision

10.6 Recommendations

What Recommendations or Good Practice Points are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach

Recommendation	Grading
GPP10.1 A senior staff member or named individual, for example sister, or senior charge nurse, should have	Good practice point

Recommendation	Grading
overall responsibility for ensuring safe working conditions, including the decontamination of non-invasive, reusable, shared care equipment.	
GPP10.2 Multiple staff may be responsible for different elements of equipment decontamination. A local decontamination policy should be in place to define which staff or groups of staff are responsible for the decontamination of non-invasive, reusable, shared care equipment.	Good practice point
GPP10.3 All staff should have a clear understanding of their specific responsibilities for decontaminating non-invasive, reusable, shared care equipment and should be appropriately trained to perform relevant decontamination protocols.	Good practice point

10.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or Good Practice Point on service users, visitors, and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about benefits.

Benefits
GPP10.1, GPP10.2, GPP10.3. Adherence to these good practice points will support effective decontamination of non-invasive, reusable, shared care equipment. GPP10.1. Appointing a senior staff member or named individual to have overall responsibility for having in place appropriate decontamination processes for non-invasive, reusable, shared care equipment may help ensure that processes are clearly defined, upheld, and effectively monitored. This will also aid adherence to the health and safety at work legislation ensuring safe systems at work are in place.

Benefits
GPP10.2. Having a local decontamination policy in place may facilitate clarity on which staff or groups of staff are responsible for the decontamination of non-invasive, reusable, shared care equipment, which may aid consistent practice and compliance. GPP10.3. Providing staff with clearly defined responsibilities and appropriate training in the decontamination of non-invasive, reusable, shared care equipment may support compliance with relevant regulations, increase staff confidence and help ensure that equipment is decontaminated appropriately.

Risks and harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about risks and harms.

Risks and harms
GPP10.1, GPP10.2, GPP10.3. None anticipated.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the:

- individual service user, staff or visitor perspective
- the societal perspective
- or both of the above

Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events or vice versa.

Benefit-Harm assessment
GPP10.1, GPP10.2, and GPP10.3. Only benefits identified.

10.8 Feasibility

Is the Recommendation or Good Practice Point implementable in the Scottish context?

Describe (if applicable):

- financial implications
- opportunity costs
- material or human resource requirements
- facility needs
- sustainability issues
- human factors

or any other issues that may be associated with following a Recommendation or Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
GPP10.1, GPP10.2, GPP10.3. There will be associated human resource and materials requirement to provide staff training and education, development and review of local decontamination policies and oversight to support effective decontamination and storage of non-invasive, reusable, shared care equipment.

10.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP10.1. This good practice point is informed by the Scottish Government Health Department letter [HDL(2005)07] which advises that sisters or senior charge nurses are responsible for ensuring safe working conditions within their area of responsibility, including the authority to require local cleaning services.[62] It is ARHAI Scotland and its stakeholders expert opinion that this should be extrapolated to decontamination of non-invasive, reusable, shared care equipment. GPP10.2. This good practice point is informed by five guidance documents, graded SIGN 50 level 4, that multiple staff may be responsible for different elements of equipment decontamination and that all staff should be clear on their specific responsibilities for decontaminating equipment.[25, 30, 36, 60, 61] ARHAI Scotland and its

Expert opinion
stakeholders believe it is beneficial to have a local policy in place that clearly defines specific staff responsibilities for decontamination of non-invasive, reusable, shared care equipment. GPP10.3. This good practice point is informed by nine guidance documents, graded SIGN 50 level 4, [25, 30, 34-36, 47, 58, 60, 61] and a guideline document, graded AGREE II: 'Recommend with modifications',[54] that consistently advised that all staff should be clear on their specific responsibilities for decontaminating equipment and should be appropriately trained to perform relevant decontamination protocols.

10.10 Value judgements

Summarise value judgements used in creating the Recommendation or Good Practice Point. If none were involved, state "none". Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
GPP10.1, GPP10.2, and GPP10.3. No value judgements to note.

10.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation or Good Practice Point. If none was intended, state "none". Recommendations or Good Practice Points should be clear and specific, but if there is a decision to be vague, acknowledging the reasoning clearly promotes transparency. Reasons for vagueness may include:

- inadequate evidence
- inability to achieve consensus regarding evidence quality
- anticipated benefits or harms, or interpretation of evidence
- legal considerations
- economic reasons
- ethical or religious reasons

Intentional vagueness
GPP10.1, GPP10.2, and GPP10.3. These good practice points are intentionally vague, recognising that job titles, staffing frameworks, and types of equipment in use will vary significantly across different heath and care settings.

10.12 Exceptions

List situations or circumstances in which the Recommendation or Good Practice Point should not be applied.

Exceptions
GPP10.1, GPP10.2, and GPP10.3. No exceptions to note.

10.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None to note.

Research Question 11: Where should non-invasive, reusable, shared care equipment be stored following decontamination?

A Quality of Evidence

11.1 How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is no available evidence to answer the key question, go to section B.

Comments	Evidence level
Twelve publications were included for this research question.[25, 27, 29, 31-33, 36, 38, 48, 53, 58, 59] • All 12 guidance documents were graded as SIGN 50 Level 4, expert opinion. Level 4 guidance is subject to methodological and reporting limitations, thus is considered low quality evidence. Five of these publications are specific to certain equipment types or settings, including ultrasound transducers,[32, 33, 38] equipment used in optometry settings,[53] and medical devices.[48] These documents may not apply to other types of equipment or settings.	12 x SIGN 50 Level 4

11.2 Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the judgement was formed as to the overall direction of the evidence.

Comments

There was a degree of consistency within SIGN 50 Level 4 evidence as summarised in the following points:

- clean and dirty items should not be stored together to avoid the contamination of clean equipment.[29, 32, 58]
- Two guidance documents advise that care equipment should be stored based on its level of disinfection.[38, 48]
- Two guidance documents propose that the storage provided should not compromise the level of decontamination achieved.[27, 48]
- Four guidance documents advise that storage should provide protection from environmental contaminants or accidental contamination.[25, 33, 36, 48]
- Two guidance documents advise that suitable storage for ultrasound transducers may include covers, boxes, or cabinets [32, 33] while an optometry specific guidance document advised covered containers or covers for optometry equipment.[53]
- Two ultrasound specific guidance also recommend that items should be clearly labelled detailing the date of storage, maximum storage duration and level of disinfection that the equipment has undergone.[32, 33]

Consistency could not be assessed given that only one piece of evidence (SIGN 50 Level 4) was included for some suggestions regarding storage of equipment. This evidence can be summarised as follows:

- Adequate storage facilities were described as well ventilated, providing protection from dust, moisture, insects, temperature and humidity.[31]
- A USA guidance document, specific to ultrasound transducers, advises that storage and the maximum duration of storage should align with intended use and manufacturer instructions.[32]
- Scottish Guidance on Safe Management of Medical Devices and Equipment outline that storage areas should be clean and in a good state of repair and that storage should follow policy and guidance.[25]
- It is also advised that all healthcare premises should have a storage area for large items of equipment, such as beds, mattresses, hoists, wheelchairs, and trolleys which are clean but not in use.[59]

11.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The included guidance was created for the following country or countries: • UK (n=4)[25, 36, 48, 59] • USA (n=4)[31, 32, 38, 58] • Australia (n=2)[27, 53] • Australasia (n=1)[33] • Canada (n=1)[29] The expert opinion guidance document published within the UK is directly applicable to Scottish health and care settings. Non-Scottish guidance documents may not be fully applicable as designs of health and care settings, and equipment storage, may differ across countries. However, these guidance documents are from internationally recognised organisations, and practices in these countries are not anticipated to significantly differ from the UK.

11.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
There were no primary studies found in relation to this research question therefore issues such as sample size and methods of sample selection are not applicable.

11.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
Not applicable.

B: Evidence to Decision

11.6 Recommendations

What Recommendations or Good Practice Points are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach

Recommendation	Grading
GPP11.1. Equipment that has been decontaminated should be stored separately from dirty or used equipment to prevent the contamination of clean equipment.	Good practice point

Recommendation	Grading
GPP11.2. Storage of non-invasive, reusable, shared care equipment should align with manufacturer's instruction.	Good practice point
GPP11.3. Storage areas or facilities should be clean, well ventilated, and in a good state of repair, providing protection from dust, moisture, insects, temperature, humidity and environmental contaminants or accidental contamination.	Good practice point
GPP11.4. All health and care premises should have a storage area for large items of equipment, such as beds, mattresses, hoists, wheelchairs, and trolleys which are clean but not in use.	Good practice point

11.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation or Good Practice Point on service users, visitors, and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about benefits.

Benefits
GPP11.1, GPP11.2, GPP11.3, and GPP11.4. This will ensure equipment that has been decontaminated are adequately stored, remain fit for purpose, and reduce risk of contamination. GPP11.2. Following manufacturer's instructions for storage may reduce the risk of damage to equipment.

Risks and harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation or Good Practice Point were followed correctly. Be explicit and clear about risks and harms.

Risks and harms
GPP11.1, GPP11.2, GPP11.3, and GPP11.4. None anticipated.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the:

- individual service user, staff or visitor perspective
- the societal perspective
- or both of the above

Recommendations or Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events or vice versa.

Benefit-Harm assessment
GPP11.1, GPP11.2, GPP11.3, and GPP11.4. Only benefits identified.

11.8 Feasibility

Is the Recommendation or Good Practice Point implementable in the Scottish context?

Describe (if applicable):

- financial implications
- opportunity costs
- material or human resource requirements
- facility needs
- sustainability issues
- human factors

or any other issues that may be associated with following a Recommendation or Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
GPP11.1, GPP11.2, GPP11.3, and GPP11.4. There will be associated human resource required in terms of defining storage area, keeping the storage area clean, training staff, and ensuring compliance with safe storage practices. Designated appropriate space will be required for storage within each facility. This may be challenging due to local restrictions on space or location.

11.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP11.1. This good practice point is informed by three SIGN 50 level 4 guidance documents that advise that clean and dirty items should not be stored together to avoid contamination of clean equipment.[29, 32, 58] GPP11.2. This good practice point is informed by ARHAI Scotland and its stakeholders expert opinion that storage of non-invasive, reusable, shared care equipment should align with manufacturers instruction. GPP11.3. This good practice point is informed by five SIGN 50 level 4 guidance documents that advise that storage areas or facilities should be clean, well ventilated, and in a good state of repair, providing protection from dust, moisture, insects, temperature, humidity and environmental contaminants or accidental contamination.[25, 31, 33, 36, 48] GPP11.4. ARHAI Scotland and its stakeholders agree with a SIGN 50 level 4 guidance advise that health and care premises should have a storage area for large items of non-invasive, reusable, shared care equipment, such as beds, mattresses, hoists, wheelchairs and trolleys which are clean but not in use.[59]

11.10 Value judgements

Summarise value judgements used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
GPP11.1, GPP11.2, GPP11.3, and GPP11.4. No value judgement to note.

11.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation or Good Practice Point. If none was intended, state “none”. Recommendations or Good Practice Points should be clear and specific, but if there is a decision to be vague, acknowledging the reasoning clearly promotes transparency. Reasons for vagueness may include:

- inadequate evidence
- inability to achieve consensus regarding evidence quality
- anticipated benefits or harms, or interpretation of evidence
- legal considerations
- economic reasons
- ethical or religious reasons

Intentional vagueness
GPP11.1, GPP11.2, GPP11.3, and GPP11.4. No intentional vagueness to note.

11.12 Exceptions

List situations or circumstances in which the Recommendation or Good Practice Point should not be applied.

Exceptions
GPP11.1, GPP11.2, GPP11.3, and GPP11.4 No exceptions to note.

11.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None to note.

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Appendix 1 – Definitions

Term used	Description	Evidence
Recommendation	In general, 'Recommendations' should be supported by high- to moderate-quality evidence. In some circumstances, however, 'Recommendations' may be made based on lower quality evidence when high-quality evidence is impossible to obtain, and the anticipated benefits strongly outweigh the harms or when the Recommendation is required by Legislation or Mandatory Guidance.	Sufficient evidence (SIGN 50 level 1++, 1+, 2++, 2+, 3, 4* AGREE Recommend AGREE Recommend (with Modifications)) Legislation, or mandatory guidance
Good Practice Point	Insufficient evidence or a lack of evidence to make a recommendation but identified best practice based on the clinical/technical experience (expert opinion) of the Working Group, with a clear balance between benefits and harms.	Insufficient evidence + Working Group expert opinion OR No evidence + Working Group expert opinion
No Recommendation	Both a lack of pertinent evidence and an unclear balance between benefits and harms.	No evidence

* A Recommendation cannot be developed when there is only SIGN 50 level 4 evidence available.

The considered judgement form and recommendation system are adapted from the following three sources:

- Update to the Centers for Disease Control and Prevention and the Healthcare Infection Control Practices Advisory Committee Recommendation Categorization Scheme for Infection Control and Prevention Guideline Recommendations. (2019)
- Scottish Intercollegiate Guidelines Network (SIGN). A guideline developer's handbook. (2019)

- Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Handbook. (2013)