NHS National Services Scotland

Management of non-invasive, reusable, shared Care Equipment Literature Review

Version 2.0

26 March 2026

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

Version history

Version	Date	Summary of changes
V1.0	2021	SICPs Management of Care Equipment and TBPs Management of Care Equipment (and Environmental Decontamination) reviews were amalgamated and updated using a double reviewer methodology. The questions sets were reviewed and the following changes made: **TBPs Management of Care Equipment** Rephrased the previous objective "What measures are required for the management of patient care equipment when applying TBPs in addition to those outlined in SICPs?" to "What is the correct use of single-use and patient-dedicated equipment when applying TBPs?"
V2.0	March 2026	This literature review replaces the Standard Infection Control Precautions and Transmission Based Precautions Literature Review: Management of Care Equipment Version 1.0. • Three-Year Update of the Literature Review • Title updated to align with content of the NIPCM. • Updated using a new methodology as outlined in the NIPCM development process. • The question set was reviewed, and the previously separated SICPs and TBPs specific objectives were combined to focus on "use in health and care settings". • A new research question was added: What legislative requirements or standards should be adhered to when decontaminating non-invasive, reusable, shared care equipment? Databases were searched for evidence published between 2000 and October 2024. Search strategies added as Appendix 1.

Version	Date	Summary of changes
		PRISMA diagram incorporated in Appendix 3.

Approvals

Version	Date Approved	Group or Individual
V1.0	Feb 2021	NPGO Steering Group
V2.0	March 2026	National Policy, Guidance and Evidence (NPGE) Working Group
		Care Home Infection Prevention and Control (CHIPC) Oversight and Advisory Group

Key information

Document title:	Management of non-invasive, reusable, shared care Equipment.
Date published/issued:	26 March 2026
Date effective from:	26 March 2026
Version/issue number:	2.0
Document type:	Literature review
Document status:	Final

Document information

Document information	Description
Description:	This literature review examines the available professional literature on the management of non-invasive, reusable, shared care equipment.
Purpose:	To inform the National Infection Prevention and Control Manual in order to facilitate the prevention and control of healthcare associated infections in NHS Scotland health and care settings.
Target Audience:	All NHS staff involved in the prevention and control of infection in NHS Scotland.
Update/review schedule:	Updated as new evidence emerges with changes made to recommendations as required. Review will be formally updated every 3 years with next review in 2029.
Cross reference:	National Infection Prevention and Control Manual Care Home Infection Prevention and Control Manual
Update level:	Practice – No significant changes to practice. Research – The implications for research are formulated based on a review of the available professional, scientific literature on the infection prevention and control (IPC) aspects or impacts respiratory and cough hygiene in health and care settings.

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Abbreviation list

Acronym	Definition
AGREE II	Appraisal of Guidelines for Research and Evaluation II
BS EN	British/European Standards
COSHH	Control of Substances Hazardous to Health
HAI	Healthcare associated infection
HCW	Healthcare worker
HDL	Health workforce directorate letter
HICPAC	Healthcare Infection Control Practices Advisory Committee
HFS	Health Facilities Scotland
HSE	Health and Safety Executive
IPC	Infection prevention and control
MDRO	Multidrug-resistant organism
NCSS	National Cleaning Services Specification
NIPCM	National Infection Prevention and Control Manual
PFGE	Pulsed field gel electrophoresis
PPE	Personal protective equipment
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCN	Royal College of Nursing
SIGN 50	Scottish Intercollegiate Guidelines Network 50
SHFN	Scottish Health Facilities Note
WGS	Whole Genome sequencing
WHO	World Health Organization

Contents

1 Objective

The aim is to review the extant scientific literature regarding the management of non-invasive, reusable, shared care equipment in health and care settings to inform evidence-based recommendations for practice. The specific objectives of the review are to determine:

1. What legislative requirements or standards should be adhered to when decontaminating non-invasive, reusable, shared care equipment?
2. How should care equipment be categorised?
3. What is the risk of healthcare associated infection (HAI) from non-invasive, reusable, shared care equipment?
4. What is the definition of decontamination for non-invasive, reusable, shared care equipment?
5. How should decontamination methods be categorised?
6. When and how should detergents be used to decontaminate non-invasive, reusable, shared care equipment?
7. When and how should disinfectant be used to decontaminate non-invasive, reusable, shared care equipment?
8. Where should non-invasive, reusable, shared care equipment be decontaminated?
9. When should non-invasive, reusable, shared care equipment be decontaminated?
10. Who has responsibility for decontaminating non-invasive, reusable, shared care equipment?
11. Where should non-invasive, reusable, shared care equipment be stored following decontamination?

2 Methodology

This targeted literature review was produced using a defined systematic methodology as described in the National Infection Prevention and Control Manual (NIPCM): Development Process. The complete search strategy is provided in Appendix 1.

In addition to the exclusion criteria outlined in the NIPCM Development Process, the following exclusion criteria were applied:

- Evidence which focuses on invasive, high-risk medical devices or other patient care equipment, single-use and single-patient use equipment are not within the remit of this review. However, they are discussed to inform the section on categorisation of care equipment.
- Evidence focused on linen or environmental decontamination.
- Research considering novel technology which are covered by other ARHAI Scotland reviews (including wipes, hydrogen peroxide, steam, ATPbio, microfibre, copper surfaces, chlorine dioxide, electrolysed water, UV light, ozone, HINS light, copper and silver solutions) and other novel approaches.
- Outbreak studies which did not provide evidence of confirmed source such as through whole genome sequencing (WGS) or another typing method.
- Studies which provided a brand name but lacked clarity on the type and concentration of the active ingredients.

Personal protective equipment (PPE) is covered more generally within the NIPCM in relation to infection prevention and control (IPC). The use of PPE is regulated by legislation such as the PPE at Work regulations and Control of Substances Hazardous to Health Regulations (COSHH), Health and Safety at Work etc. Act 1974. Regulations applicable to occupational health and/or health and safety at work regarding the use of chemicals or other aspects of decontamination must be followed and are outside of the scope of this review which focuses on IPC.

This literature review considers equipment used in the care of patients and service users in health and care settings under the broad heading of ‘care equipment’. This review focuses on non-invasive, reusable, shared, care equipment which includes beds, mattresses, blood pressure cuffs, stethoscopes, drip stands, commodes,

bedpans, wheelchairs, lockers, and other similar equipment. This is a non-exhaustive list to illustrate examples of non-invasive, shared, reusable care equipment.

Definitions for grades of evidence are provided in Appendix 2. A flowchart, adapted from Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA),[1] is presented in Appendix 3.

3 Discussion

3.1 Implications for practice

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

Twenty-five pieces of evidence were included for this research question.[2-26] This includes 16 standards [2-17] and six regulations[18, 22-26] graded SIGN 50 Level 4 and mandatory respectively. Two UK Health and Safety Executive (HSE) documents, an approved code of practice [20] a guidance document,[19] and Scottish Health Technical Note 00-04 published by NHS Scotland Assure,[21] all graded as SIGN 50 Level 4.

Legislation

The Medical Device regulations apply wherever the care equipment being decontaminated is considered as a 'medical device', per the regulations.[18, 23] The Biocidal Products regulations details provisions for getting an active substance authorised for use in a biocidal product, placing biocidal products on the market and use of biocidal products.[22] The Public Health etc. (Scotland) Act 2008 states that it is the duty of health boards to protect public health, including prevention and control of infectious diseases and provision of facilities for decontamination and disinfection.[25] The Health and Safety at Work etc Act 1974 is the generic health and safety legislation relating to occupation health at work.[26] The Control of Substances Hazardous to Health (COSHH) regulations apply across any settings, as outlined in this legislation (for example the use of chemicals or other decontamination

methods).[24] The protective measures are not IPC-specific, (for example the topic of PPE or other measures) and therefore are not discussed in detail within this literature review.

The UK HSE provide an approved code of practice detailing guidance for performing a risk assessment, prevention and control of hazards which they claim support adherence to COSHH regulations.[20] Another HSE guidance on biocides, including disinfectants, provides relevant regulations on its supply and usage.[19] The Scottish Health Technical Note 00-04, published by NHS Scotland Assure (previously Health Facilities Scotland), provides a summary of relevant guidance, legislation, standards, and policy in Scotland relating to all medical devices and equipment.[21]

Standards

Fourteen included British Standards are generally focused on testing methods and minimum requirements of bactericidal, sporicidal, and virucidal activity of chemical disinfectants and antiseptic products intended for use in medical areas.[2-12, 15-17] These standards state that the manufacturer is required to provide evidence where product claims of effectiveness against microorganisms are made.

British Standard BS EN 14885:2022 provides an overview of multiple standards applicable to 'medical settings'.[17] It aims to support manufacturers and others in outlining the appropriate standards to be used and assessed (by regulatory authorities) with regards to products and any claims for that specific product. It recommends that to make a claim about disinfectant properties, products should adhere to the multiple standards outlined in table 1 (page 20) of that document.[17] Specifically that products (which make a disinfectant claim) should have fully met the requirements of the multiple standards covering bactericidal, fungicidal, virucidal, yeasticidal and sporicidal activity. Test organisms for these activity claims are listed in full in Appendix 4. This standard explains that factors such as the test organism's relative resistance, relevance to practical use, handling properties, and microbiological safety were considered in choosing representative test organisms. However, the tests involve analysing product efficacy in a laboratory setting (suspension and surface tests); thus, the BS EN tests may have limited generalisability to real world settings.

The 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, and sterilised in health and care settings.[14] 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.[13]

However, these British Standards are subject to limitations, including a lack of detail about the methodology for producing these documents and a focus on laboratory-based test methods which may not be indicative of product usage in real-world settings. It is also unclear if included standards include non-invasive, reusable, shared care equipment, as an exhaustive list of equipment and a rigorous definition of 'instrument' was not provided. Appendix 4 provides a non-exhaustive list of relevant standards and legislation that may be applicable for the decontamination of non-invasive, shared, reusable care equipment. At the time of writing, these discussed standards were the most recent versions available. It should be noted, however, that these are subject to amendment and that the standards discussed here may not represent all standards which apply to equipment decontamination.

Conclusion

There are no specific legislative requirements or standards for decontaminating non-invasive, reusable, shared care equipment in health and care settings, with most of the included evidence focussing on medical devices generally and on disinfectant product claims. However, adhering to applicable legislation is mandatory and following relevant standards provides a consistent and transparent methodology for assessing microbiological efficacy of disinfection products, noting limited applicability of laboratory test methods to real-world clinical settings.

3.1.2 How should care equipment be categorised?

In total, 16 pieces of evidence were included for this research question.[18, 21, 23, 27-39] Of these, 14 guidance documents were graded SIGN 50 Level 4.[21, 27-39] Level 4 guidance is subject to methodological and reporting limitations and is considered low-quality evidence, underpinned by expert opinion. Two further publications are graded mandatory as they are EU and UK legislation.[18, 23] The included guidance is

applicable across all health and care settings, except for Rathore et al.[38] which is specific to paediatric ambulatory care settings and may have limited applicability.

Medical devices are explicitly defined in UK [23] and EU[18] regulations and summarised by NHS Scotland Assure [21] and the Medicine and Healthcare products Regulatory Agency (MHRA).[27] The UK medical device legislation states that "devices are classified as belonging to Class I, IIa, IIb or III in accordance with the classification criteria set out in Annex IX of Directive 93/42".[23] The EU directive which replaces 93/42/EEC (2017/745) states that a medical device is "any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process, control of conception".[18]

According to Scottish Health Technical Note 00-04,[21] there is no clear definition for the term 'medical equipment', with both medical equipment and medical device considered subcategories of health technology.[21] Health technology is defined as "the application of organised knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life".[21] They further explain that medical equipment is generally used in the direct or indirect care of patients and can include equipment that is not regulated as a medical device.[21]

There are three broad categories of care equipment (including medical devices) identified in extant guidance,[21, 31, 36, 37] This includes:

- Single-use
- Single-patient use
- Reusable (invasive or non-invasive)

This literature review is focussed on reusable non-invasive shared patient care equipment. To provide context, some information is given on each of the other categories for this research question only.

Single-use

Three UK expert opinion guidance documents, published by the Department of Health and Social Care (DHSC) and Royal College of Nursing (RCN), define 'single-use' care equipment as equipment that is intended to be used once for one patient or service user and then discarded.[31, 36, 37] Single-use care equipment should not be re-used or reprocessed and then re-used.[21, 31, 37]

Equipment intended for single-use is marked with the symbol: [21, 31]

Single-patient use

According to three UK expert opinion guidance documents, published by the DHSC and RCN, single-patient use care equipment is intended to have designated use for one single patient or service user and may be used multiple times for that individual, as appropriate.[31, 36, 37] The device may undergo some reprocessing and decontamination between each use on the one patient, according to the manufacturer's instructions.[31, 36, 37]

Reusable equipment – invasive or non-invasive

Reusable care equipment may be considered as invasive or non-invasive.[18, 36] Invasive equipment refers to care equipment that in whole or partially penetrates inside the body for example through a body orifice or through the surface of the body.[36] As per EU Regulation 2017/745, care equipment that does not penetrate (partially or fully) into the body and is in contact with intact skin only, is considered as non-invasive.[18]

To better define reusable equipment, the Spaulding's classification has been referred to or adapted by many organisations including the World Health Organization (WHO),[35] Centers for Disease Control and Prevention (CDC),[32] NHS Scotland

Assure [21] and others.[28-30, 33, 34, 39] This system categorises reusable medical devices and other care equipment as critical, semi-critical or non-critical according to the infection risk associated with their intended use and the subsequent level of decontamination required to render them safe for reuse.

Critical equipment that enters sterile tissue, the cavity or the blood stream is generally considered as high risk due to the potential for cross transmission.[21, 28-30, 32, 33, 35, 38, 39] Semi-critical equipment is described as having contact with non-intact skin and/or mucous membranes and is considered as medium or moderate risk for cross transmission.[21, 30, 32-35, 38, 39] This may include equipment that has contact with another device which has contact with non-intact skin or mucous membranes.[33] Whereas, non-critical equipment may be considered as low risk as it defines equipment in contact with intact skin but not with mucous membranes.[21, 28-30, 32-35, 38, 39]

There is a lack of consistency in extant guidance regarding the name and scope of the three risk-based classifications of reusable care equipment. The UK Department of Health and Social Care (DHSC) reports that reusable care equipment may also be classified as low (intact skin), medium (mucous membrane and contaminated items), high (close contact with non-intact skin or mucous membrane and devices that enter the body) risk.[37] The Royal College of Nursing (RCN) also separate reusable equipment into categories of risk (high, intermediate, and low).[31] The RCN categories generally align with the UK DHSC,[37] with 'intermediate' in place of 'medium', similar to WHO guidance [35] which refers to semi-critical as intermediate.

There is a lack of clarity regarding the classification of equipment which has contact with blood and body fluids but not with mucous membranes or non-intact skin. The WHO base their classifications on the Spaulding system, however, they include equipment which is in contact with blood and body fluids as semi-critical or intermediate level equipment.[35] It is unclear if this differs to other descriptions based on the Spaulding classifications which state that semi-critical equipment includes those which have contact with mucous membranes and/or non-intact skin. An exhaustive list of equipment examples was not provided in the included guidance documents. It is therefore difficult to determine the categorisation of equipment such as commodes or similar equipment that has likely contact with blood and body fluids.

One CDC guidance that specifically mentions commodes and bedpans places them in the category of 'non-critical'.[32] This contrasts to guidance by the WHO, DHSC and the RCN which lists commodes, urinals or bedpans as semi-critical.[31, 35, 37] Therefore, it is unclear if equipment which has contact with blood and body fluid, but is initially in contact with intact skin should be considered as semi-critical or non-critical.

Conclusion

In summary, there was no clear definition for the term 'medical equipment', identified in extant guidance, it is often used interchangeably with medical devices, with both terms considered subcategories of health technology. For this review, the focus is on medical devices and/or medical equipment that are non-invasive, reusable, shared, and those not intended for single-use or single-patient use.

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

Four outbreak studies, graded SIGN 50 Level 3, were included for this research question.[40-43] This research question specifically aimed to identify evidence of transmission events involving care equipment as the source or reservoir; studies demonstrating contamination of equipment alone were therefore not included. Although studies that implement IPC measures in bundles meet the NIPCM Development process exclusion criteria, they have been included for this research question because the specific aim is to identify evidence of transmission events via equipment to demonstrate HAI transmission risk. Four types of non-invasive, reusable, shared care equipment were considered as a vector of transmission in the identified outbreaks, including EKG (ECG) leads,[43] breast milk pumps,[42] breast milk thawing or warming devices,[40] and blood pressure cuffs.[41]

Gras-le Guen et al. in their outbreak investigation study, associated 31 cases of *Pseudomonas aeruginosa* infection (14 symptomatic, 17 colonised) in neonates within a neonatology and neonatal intensive care unit in France to a contaminated milk bank pasteuriser, used for thawing bottles of human donor milk.[40] The outbreak

strain (*P. aeruginosa* O10), isolated from all infected patients, matched isolates from the milk bank pasteuriser and units' bottle warmer, as confirmed by pulsed field gel electrophoresis (PFGE). The author's hypothesis is that the milk bank pasteuriser was contaminating the outside of bottles during thawing, leading to onward transmission. However, no details were provided as to whether there was a cleaning or decontamination process in place for this device, and if failure to adhere to such process contributed to proliferation of the outbreak strain. The outbreak was controlled by discontinuing use of the contaminated milk bank pasteuriser and bottle warmer along with intensified aseptic techniques during bottle handling. Other IPC measures in place were not clear and details of what an intensified aseptic technique entailed was not provided. This outbreak took place between the years 2000 to 2001 in France and may not reflect current IPC practices or be applicable to a Scottish healthcare setting.

An outbreak investigation study by Alfandari et al. described how Velcro-closing blood pressure cuffs facilitated a carbapenem-resistant *Acinetobacter baumannii* (CRAB) outbreak in a French hospital ICU.[41] The outbreak started after a patient that presented with CRAB pneumonia was managed with 'strict isolation' precautions in the ICU and was discharged. A series of environmental sampling failed to identify source, and a series of cleaning and disinfection, including terminal cleaning, and IPC education failed to control the outbreak. Further environmental sampling led to isolation of CRAB from the Velcro of two blood pressure cuffs, which had been subjected to disinfection and aerosolized hydrogen peroxide exposure. PFGE revealed the presence of two different clones, the outbreak clone (Clone 1) was identified in 14 patients, 12 of whom were in the ICU, and matched with the cuff Velcro and index case isolates. Clone 2 was identified in five patients (two in the ICU), in different wards, with no hospitalisation overlap and without a specific source. All models of blood pressure cuffs Velcro were changed to wholly submersible ones for improved disinfection purposes. The authors suggest initial direct transmission could have happened as all colonised or infected patients had a few days of hospitalisation overlap, however, this suggests the strict isolation precautions for managing the first case were unsuccessful. They also hypothesise that colonised Velcro cuffs may have acted as a fomite vector, contributing to the spread of infection from patient to patient, however, there was no information provided to

establish shared usage patterns and if this facilitated transmission between cases. Moreover, this outbreak took place in France between year 2011 and 2012 and may not reflect current IPC practices in Scottish health and care settings.

Engür et al. described an outbreak of *Acinetobacter baumannii* in a Turkish hospital neonatal intensive care unit, associating this with contaminated breastmilk pumps.[42] Authors described the breastmilk pump as "hospital-grade", used by more than one mother with their own disposable milk collection kits, and cleaned daily with a surface disinfectant (unclear what product). The outbreak initially involved two neonates (one two-days old and one premature) with respiratory distress syndrome and *A. baumannii* positive blood samples, with similar antibiograms, within two days of one another. Further investigation identified five other neonates who had *A. baumannii*-positive nasopharyngeal aspirate and expressed milk samples. In contrast, a neonate whose mother used her own electric breast pump had negative cultures (patient 8). Culture of the shared breast milk pump, used by all infected patients' mothers, was *A. baumanni*-positive while the electric breast pump used by patient 8's mother was negative. PFGE confirmed that all the isolates were derived from a common ancestor. Control measures included cleaning the electrical unit and outer surface of the equipment after each individual use, ensuring strict adherence to hand hygiene protocols through monitoring, providing new milk collection kits and terminal disinfection of the unit with sodium hypochlorite. However, the authors could not identify the exact source of this organism and only speculate that the mother of the index case might have contaminated the pump because it was the first time that any Acinetobacter species has been isolated in the NNU. Moreover, inadequate cleaning and decontamination practices were inferred, as authors claim they only started cleaning the electrical unit and outer surface of the equipment after each individual use when a positive culture from the breast milk pump was obtained. Furthermore, this outbreak took place in Turkey in 2009, thus, may not reflect current IPC practices regarding breast pump use in Scottish health and care settings.

Falk et al. described a vancomycin-resistant *enterococci* (VRE) outbreak in an eight-bed burns ICU (BICU) in Texas, USA.[43] This involved widespread environmental contamination in patient rooms, other areas of the BICU, and instruments used on patients such as EKG leads, stethoscopes, and pulse oximeters. Initial control measures included decontamination of surfaces using two

quaternary ammonium products, contact precautions (with all HCW wearing gloves and gowns and washing hands with 4% chlorhexidine), and providing staff training. However, the outbreak restarted when an electrocardiogram (EKG) lead on a patient, from which cultures had not previously been taken, had a positive culture for VRE, the patient then tested positive three days later. Further investigation identified that the patient who previously occupied the new case room was VRE-positive, and PFGE confirmed that clinical isolates of the cases and EKG lead matched. Following decontamination of the EKG lead there were no further patient cases identified. However, further environmental samples in the BICU yielded positive results, with enhanced cleaning needed to eradicate the widespread contamination and end the outbreak. Moreover, this outbreak happened between 1996 and 1997 in a USA hospital, which may not reflect current cleaning or other IPC practices in Scottish health and care settings. There were also multiple positive VRE environmental samples (338 of 2844) suggesting possible failures in decontamination practices on the ward.

Conclusion

In summary, the few included studies suggest there is a risk of indirect infection transmission from a variety of non-invasive, reusable, and shared care equipment. However, the exact direction of transmission in these studies could not be determined. The evidence-base is subject to publication bias as other equipment may have been associated with outbreaks but not published. Research Question 2 provides more information on the categories of reusable care equipment and the potential risk of transmission. The imposed exclusion criteria also rule out studies in which equipment may have been a potential source or reservoir, but typing was not carried out to investigate this, therefore, the potential risk from those equipment are overlooked. A list of studies excluded after critical appraisal is presented in Appendix 1.

3.1.4 What is the definition of decontamination for non-invasive, reusable, shared care equipment?

Ten guidance documents, graded SIGN 50 Level 4 expert opinion, were included for this research question.[21, 28-32, 35-37, 44] SIGN 50 Level 4 guidance is subject to methodological and reporting limitations as it has not included sufficient systematic methods.

Decontamination was described as an umbrella term which outlines the varied elements or methods involved in the removal, destruction, or inactivation of microorganisms, which may be used in combination in health and care settings.[21, 28-32, 35-37]

According to six SIGN 50 level 4 guidance documents, published in the UK, decontamination involves cleaning, disinfection and/or sterilisation.[21, 29, 31, 36, 37, 44] Any, all, or a combination of these may be considered as 'decontamination'. The NHS England National Cleaning Standard refers to disinfection and cleaning only in the decontamination of non-critical care equipment.[44] Cleaning, disinfection and sterilisation is described in more detail within Research Question 5: 'How should decontamination methods be categorised'.

Conclusion

In summary, decontamination for non-invasive, reusable, shared care equipment is described in extant guidance as a process of removal, destruction, or inactivation of microorganisms, through any or a combination of cleaning, disinfection and/or sterilisation.

3.1.5 How should decontamination methods be categorised?

Seventeen guidance documents, all graded SIGN 50 Level 4 expert opinion, were included to answer this research question.[28-35, 37, 38, 44-50] SIGN 50 Level 4 guidance is subject to methodological and reporting limitations as it has not included sufficient systematic methods.

The included guidance documents categorise decontamination methods into cleaning, disinfection, and sterilisation.[28-35, 37, 38, 44-50] These categories are described below.

Cleaning

Across the included guidance documents (n=9), cleaning is generally described as the physical removal of contamination.[28-31, 35, 37, 44, 45, 50] Cleaning is described as the first step of decontamination which is designed to remove contamination to the extent required for further processing (disinfection or sterilisation, as required),[28, 29, 31, 34, 35, 38, 44, 46, 50] or further use.[34, 35, 44, 46, 50] This means that cleaning may be conducted in the absence of disinfection or sterilisation and should be carried out before disinfection or sterilisation.

Cleaning is described as involving physical or mechanical action to remove contamination from an object.[28, 30, 31, 35, 37, 44-46, 48-50] This may involve:

- friction – rubbing, scrubbing,[28, 44] or
- fluids – use of liquid or fluid to remove soiling, [28, 44] or
- mechanical action – use of a washer-disinfector[48, 49]

There is consistency across 11 guidance documents that cleaning may involve the use of detergents.[28-31, 35, 38, 44, 46-48, 50] A WHO guidance document defines detergent as a product which reduces surface tension and disrupts fat and organic matter.[35] It is designed to remove contamination, not to disinfect it. There may be many types of detergents with different compositions and ingredients. Enzymatic cleaners and cleaning chemicals are described within two SIGN 50 level 4 guidance documents, produced by the WHO and the American College of Emergency Physicians (ACEP), and outlined as potentially involved in the initial cleaning stage of decontamination.[35, 46] WHO states that this type of product may be beneficial where blood or exudates may have dried or hardened.[35] ACEP highlights some types of product that may be used, but it is not clear if one is preferred.[46]

Disinfection

Disinfection is consistently described within nine SIGN 50 level 4 guidance documents as the process of destroying viable microorganisms using thermal or chemical methods.[28, 31, 34, 37, 38, 44-46, 48] Three SIGN 50 level 4 guidance documents

indicate that disinfection may be carried out using an automated process such as a washer-disinfector.[47-49]

Disinfection is described as resulting in the destruction of most microorganisms. Nine guidance documents, graded as SIGN 50 Level 4 expert opinion, highlight that disinfection may not result in the destruction of some viruses and some bacterial spores.[28, 31-33, 35, 37, 38, 44, 46] However, the efficacy of a disinfectant or disinfection method may be separated into two [30, 33] or three [28, 29, 32, 34, 35, 38, 46] categories, including low level,[28-30, 32-35, 38, 46] high level,[28-30, 32-35, 38, 46] and intermediate level disinfection.[28, 29, 32, 34, 35, 38, 46]

High level disinfection is generally described as destroying or removing most pathogenic material, other than where there are large numbers of endospores.[28-30, 33]

Intermediate level disinfection is described as a middle level, destroying most microorganisms including mycobacteria, most spores, virus, and fungi.[29, 32, 34]

Low level disinfection is generally described as the inactivation of vegetative bacteria, enveloped and some non-enveloped viruses and most fungi.[28-30, 32, 33] Two guidance documents suggest that low level disinfection may often be achieved in 10 minutes or less.[32, 33]

Sterilisation

The term sterilisation is defined within the included expert opinion guidance as the decontamination process in which microorganisms are rendered fully destroyed/inactivated meaning that the equipment is free of virus, fungi and bacteria, including spores.[28-30, 34-36, 38, 44, 45, 47] There are different methods which may result in the sterilisation of equipment, including automated processes, such as using sterilisers.[29, 35, 44, 47, 49] Heat may also be used to achieve sterilisation in the form of steam or dry heat,[29, 35, 38, 47] or chemicals in the form of gas or liquids.[29, 33, 35, 38, 47]. The standards required for sterilisation are specified in BS EN ISO 14937:2009.[51] Sterilisation may be considered as a specific process based on these standards and associated regulations, it is unlikely to be routinely undertaken when decontaminating non-invasive, reusable, shared patient care equipment. Therefore, it is not covered in detail within this review.

Conclusion

In summary, there are three principal categories of decontamination: cleaning, disinfection, and sterilisation. There are a range of methods and chemicals which may be considered for use as appropriate per legislation and standards.

3.1.6 When and how should detergents be used to decontaminate non-invasive, reusable, shared care equipment?

Sixteen pieces of evidence were included to answer this research question.[28-35, 38, 39, 44, 47, 48, 52-54] Of these, 15 guidance documents were graded SIGN 50 Level 4 expert opinion.[28-35, 38, 39, 44, 47, 48, 53, 54] SIGN 50 Level 4 guidance is subject to methodological and reporting limitations as it has not included sufficient systematic methods.
A guideline document published by Tacconelli et al. was graded AGREE II: 'Recommend with modifications'.[52] There was no primary evidence of sufficient quality identified for this research question. Evidence which provides results for a combined process of detergent use and disinfection are considered within Research Question 7.

Four of the included guidance documents were created for a UK [31, 44, 47, 53] setting as well as one, published by Health Facilities Scotland, which is applicable to Scottish health and care settings.[48] Four documents were published for an international,[35] Australasian,[34] or European [29, 52] setting. The remaining documents were published in the USA,[32, 33, 38, 39] Australia [28, 54] and Canada.[30] In terms of relevance to equipment or settings, four of the included guidance documents are specific to ultrasound transducers or ultrasound equipment,[29, 33, 34, 39] one is specific to optometry settings [54] and one is specific to ambulatory paediatric settings.[38] These guidance may not be fully applicable to other equipment or settings.

Considerations for when to use a detergent

As indicated by Research Question 5, cleaning may be considered as a first or only step in decontamination, before reuse, or before disinfection, sterilisation, or other aspects of decontamination. There was consistency across 11 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.[28-35, 39, 52, 53] 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.[44, 52]

The use of a detergent was outlined as part of the decontamination process for various care equipment types including; non-invasive ultrasound transducers,[33, 34, 39] other ultrasound equipment,[29, 34] bed and bed rails,[28, 30] blood pressure cuffs,[28, 30, 38, 53] stethoscopes,[38, 53] stands and brackets (for example for holding catheters or to facilitate administration of intravenous drug therapy),[28] pulse oximeter probes and cables,[30, 53] electrocardiographic cables,[53] hoists,[28] mattresses,[28] commodes or bedpans,[28, 30] and toys or games in direct contact with patients or their environment.[30] However, it should be noted that these were provided as examples rather than an exhaustive list. An exception to this was the guidance documents which focused on ultrasound equipment specifically.[33, 34, 39]

Considerations for selecting a detergent

There is consistency within the included literature, based on expert opinion guidance (n=7, SIGN 50 level 4), that detergents should be selected based on their compatibility with the equipment being decontaminated, as advised by the equipment manufacturer's instructions.[28, 30, 32-35, 48]

A small number (n=3) of guidance documents, graded SIGN 50 Level 4, list different product types that may be considered for use during 'cleaning'. The detergents are listed broadly as neutral pH cleaners, approved soaps, and enzyme soaks.[32, 38] However, specific detail on effectiveness of these products and which products were most effective were not provided.

The exact type of detergent that should be used to clean specific non-invasive, reusable, shared equipment was not clearly outlined within the included evidence. However, three SIGN 50 Level 4 guidance documents propose that factors to consider when selecting detergents should include the type of contamination or soiling (such as with blood);[35, 47] efficacy, cost, time, complexity, and designated

location for reprocessing;[33] as well as the water quality, temperature of water, and availability of cleaning products.[35]

Considerations for how to use a detergent

There was a lack of clarity regarding the correct way to use detergents. This may be related to there being multiple types of detergent available. Two guidance documents, Australian IPC guidelines [28] and WHO guidance on decontamination and reprocessing of medical devices,[35] recommend that detergents should be prepared (for example dilution with water) and used according to the manufacturer's instructions. With regards to how equipment may be cleaned when using a detergent, there were some general principles of cleaning suggested in the literature. These include:

- Manual cleaning, such as using friction, where indicated.[32, 35]
- Submersion where compatible with equipment and appropriate.[35]
- The use of brushes, damp soft, non-linting cloths or gauze pads, where appropriate.[35, 39]
- Disassembling equipment prior to decontamination, where appropriate.[35]
- Changing water for each cleaning 'session' or when visibly soiled.[35] 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.[32] Standards related to washer-disinfector use are provided by Health Facilities Scotland (HFS), included within Scottish Health Technical Memorandum (SHTM) 2030.[48]
- Rinsing of equipment after 'cleaning' with a detergent,[28, 32, 35, 54] followed by drying of equipment.[29, 35, 54]

The following was also outlined within the NHS England National standards of healthcare cleanliness:[44]

- 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
- 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 clothes, wipes, and hands

Although there was no consistency in the evidence base, these suggestions represent good practices which may be applicable where they align with manufacturer's instructions. However, they may not be specific to cleaning with detergent and appear to apply generally to decontamination, where appropriate.

Conclusion

In summary, there was consistency across the included literature that detergents should be considered for use during the 'cleaning' of non-invasive, shared reusable care equipment. However, the selection of a specific type of detergent should be based on the manufacturer's instructions (including the equipment and detergent manufacturer), the type of contamination, water type and availability. There was a lack of clarity regarding the correct way to clean non-invasive, reusable, shared care equipment with detergent. However, it was recommended that detergents should be used according to the manufacturer's instructions including contact time, dilution, etc. There are general principles of good cleaning practices based on expert opinion in extant guidance. However, these were not specific to cleaning with a detergent.

3.1.7 When and how should disinfectant be used to decontaminate non-invasive, reusable, shared care equipment?

Twenty-six sources of evidence were included to answer this research question.[21, 28-39, 44-48, 50, 52, 54-59] Two guidelines were graded AGREE II: Recommend with modifications,[52, 55] and twenty-four guidance documents were graded SIGN 50 Level 4 expert opinion.[21, 28-39, 44-48, 50, 54, 56-59] SIGN 50 Level 4 guidance is subject to methodological and reporting limitations as it has not included sufficient systematic methods.

Considerations for when to use a disinfectant

There was a lack of clarity regarding whether a disinfectant should be used each time a piece of equipment is decontaminated or if it should only be indicated by a risk assessment. 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.

Local decision or policy

Two UK guidance documents, graded SIGN 50 level 4, and a European guidance document, graded AGREE II: 'recommend with modifications' (though the details related to decontamination were considered as primarily expert opinion), state that the use and selection of a disinfectant should be based on local decision or policy.[36, 44, 52]

Routine use

Twelve guidance documents, graded SIGN 50 level 4, suggest that disinfection of equipment may be conducted as part of routine decontamination processes.[29, 30, 32-34, 39, 45, 46, 50, 54, 57, 59] These publications were primarily associated with USA settings and four were endorsed by the CDC.[32, 50, 57, 59] This included general recommendations across equipment types and specific mention of equipment such as toys,[30, 45] ultrasound transducers,[29, 33, 39, 46] bedpans and commodes,[30, 57] and mattresses.[44, 50] A CDC guidance document advocates the routine use of disinfectants for decontaminating care equipment arguing that medical equipment surfaces (for example blood pressure cuffs, stethoscopes) can become contaminated with infectious agents and contribute to the spread of healthcare associated infections, therefore they should be disinfected with Environmental Protection Agency (EPA)-registered disinfectants.[50]

Conversely, four guidance documents, graded SIGN 50 level 4, suggest that decontamination may involve disinfection 'if indicated'.[21, 28, 31, 37] One guidance document from the Australasian Society for Ultrasound in Medicine suggest that a detergent should be used to clean non-critical equipment and that this "may" be followed with a low-level disinfectant.[34] This suggests that there may be some instances where disinfection is not required in addition to detergent use but specific

indications for increasing or decreasing the level of decontamination are not provided.

Low level disinfection

As indicated in Research Question 5, disinfection is often split into categories (low, medium or intermediate, and high-level disinfection). It is suggested within eight SIGN 50 level 4 guidance documents 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.[29, 30, 32-35, 39, 46] A policy statement from the American Academy of Pediatrics 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.[38]

Enhanced disinfection

Seven SIGN 50 level 4 guidance documents advise enhancement to more regular use of disinfectants [28, 46] or a higher level of disinfection for certain circumstances, based on the perceived risk.[31, 34, 36, 39, 54] Such as, where a patient has a suspected or confirmed infection,[28, 37, 54] including when undergoing contact precautions,[28] where a patient has a multidrug resistant infection,[28, 56] and during outbreaks.[28, 31]

The following were also reported to be considered when determining the level of disinfection, and disinfectant, required:

- if equipment will be used for immunocompromised patients[37]
- where a procedure is considered as high risk for aerosolization of infective agents[39, 46]
- the level of contamination, where items have contact or likely contact with blood and/or body fluids[31, 37, 46]
- where it is recommended that products with efficacy against mycobacteria and bloodborne pathogens [39, 46] or that a suitable high-level disinfectant be used[34]

Considerations for selecting a specific disinfectant

Twelve sources (11 SIGN 50 level 4 guidance documents and one guideline, graded AGREE II: Recommend with modifications) are consistent in advising that the products selected should be compatible with the equipment being decontaminated, as stated in the manufacturer's instructions.[28-30, 34, 35, 48, 50, 54, 55, 57-59] A CDC guidance document, graded SIGN 50 level 4, further advises that high level disinfectants should not be used on non-critical equipment where it does not align with manufacturer's instructions.[50] Disinfectants are covered by COSHH regulations and, as such, will be subject to a risk assessment before use.[24] Research Question 1 provides more details about legislation and standards relevant to the use of disinfectants in Scotland. The CDC also 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.[50]

According to the World Health Organization (WHO), 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.[35] The effectiveness of a disinfectant was also reported to be impacted by factors such as contact (exposure) time, concentration of the agent, and the quality and quantity of microorganism's present, including their resistance.[35] This is important as some disinfectants may have an undesirable reaction and in some cases dangerous reaction to other products. An example of this is chlorine releasing agents that encounter ammonia or acid may release toxic chlorine gases.[35] Another example may include the inactivation of quaternary ammonium compounds when exposed to some enzymatic cleaners and detergents.[47]

There was no consistency regarding the specific type of product that should be used for disinfection. Chlorine-releasing agents are recommended for use during outbreaks in haemodialysis units,[28] when there is visible contamination with blood,[28, 32] though tuberculocidal products were also considered as appropriate.[32] The epic3 guidelines suggest that chlorine-based products may be considered during outbreaks, but no formal recommendation was provided by the authors on this

subject.[55] Chlorine-releasing agents were also advised for the decontamination of mattresses and were recommended as a type of low-level disinfection at concentration 1:500 dilution of sodium hypochlorite.[38]

A CDC guidance document, graded SIGN 50 level 4, highlights that alcohols have 'generally underrated germicidal characteristics'; when used at an optimum concentration [60-90% (v/v) in water] ethyl- and isopropyl alcohol were considered as tuberculocidal, virucidal, fungicidal and rapidly bactericidal against vegetative bacteria.[32] However, alcohols were described as not sporicidal, can damage some equipment (shellac, rubber and plastics), and may not be effective over larger surfaces.[32, 35, 50] Four guidance documents, graded SIGN 50 level 4, also outline that the intended use of some types of products may be limited. This included limited use of formaldehyde-alcohol,[32] formaldehyde,[35] concerns related to the use of glutaraldehyde,[35, 44] and not considering 3% iodophors and phenolics as high-level disinfectants,[32] limiting their use for incubators.[50]

Considerations for how to use a disinfectant

The included literature outlined several considerations for the use of a disinfectant when decontaminating patient care equipment, including non-critical, reusable, shared care equipment within health and care settings. As highlighted within Research Question 4 and 6, cleaning (with the use of a detergent product as appropriate) should take place as standard before disinfection to remove residual proteinaceous material which may reduce the effectiveness of disinfection or sterilisation.[57] 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.[28]

Where a disinfectant is used within a health and care environment, six guidance documents, graded SIGN 50 level 4, advise that manufacturer's instructions should be followed.[30, 32, 39, 45, 50, 59] This would include disinfectant concentration, [32, 34, 50] recommended dilution, [31, 33] contact time [32] and any other aspects of using the product, for example, when considering if submersion or immersion or wiping of equipment is appropriate.[39]

While there was consistency that manufacturer's instructions should be followed, four guidance publications did provide suggestions for additional considerations.[32, 34, 35, 50] Three guidance documents, graded SIGN 50 level 4, recommend that the 'correct' concentration of a chemical disinfectant should be used.[32, 34, 50] It was also advised that a fresh solution is prepared for each decontamination.[34] The WHO advise that solutions should be replaced after each cleaning 'session', but the definition of a session is unclear.[35] The principles for cleaning that are outlined above (Research Question 6) may also apply to the use of disinfectants. Rinsing of equipment after decontamination with a disinfectant to remove residues from disinfectant agents was consistently recommended.[34, 39, 44, 50, 54, 57] This was advised for various types of equipment including toys that may be mouthed,[45, 57] ward bed mattresses,[44] incubators,[50] and transducers.[34, 39]

Finally, it was advised that equipment should be dried following decontamination of the equipment.[34, 54] This may be conducted depending on the local policy, equipment type and manufacturer's instructions such as, using a single-use, dry, clean, non-linting cloth,[34, 54] or via air drying.[54] However, these guidance documents were specific to ultrasound equipment [34] and optometry settings.[54]

Conclusion

In summary, the included literature outlines several factors to consider when using disinfectants for the decontamination of non-invasive, shared, reusable patient care equipment. This includes adhering to local policy and procedures, ensuring the compatibility of all products for use with each other and on each piece of equipment (per manufacturer's instructions), and an assessment of the risk. There was a lack of consistency regarding the efficacy of different products, though it was consistently recommended that the products selected should be compatible with the specific equipment being decontaminated, per the manufacturer's instructions.

There was no one method of using a disinfectant consistently recommended within extant guidance. This may be due to variation in different types of non-invasive, reusable, shared equipment and disinfectants that can be used for decontaminating them. However, there was consistency within the included guidance that a disinfectant should be used in accordance with the instructions provided by the

manufacturer, including for the correct dilution, recommended contact time and concentration.

3.1.8 Where should non-invasive, reusable, shared care equipment be decontaminated?

Seven guidance documents were included for this research question, all graded SIGN 50 Level 4.[28, 32, 33, 35, 36, 57, 60] These guidance documents are subject to methodological limitations and are primarily based on expert opinion. Two of the included guidance documents were produced for UK settings,[36, 60] three were USA-specific,[32, 33, 57] one for Australian settings;[28] and one for across international settings, published by the WHO.[35] The applicability of these documents may be limited where facilities 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. Legislation governs the use and management of medical devices.[36] See Research Question 1 and Appendix 4 for details of legislation and standards which may apply to Scottish settings.

There is no exact location stated within the included guidance with regards to decontamination of non-invasive, shared, reusable care equipment. Five guidance documents, graded SIGN 50 level 4, refer to either a separate or designated decontamination area or unit,[32, 33, 35, 36, 57] while two guidance documents, published by Health Facilities Scotland and the Society of Diagnostic Medical Sonography, outline that it may be appropriate to decontaminate some equipment at the point of care.[33, 60]

Health Facilities Scotland (HFS) 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.[60] The Australian NHMRC advises that adequate cleaning supplies should be available at or close to the point of care.[28] HFS propose that decontamination facilities or dirty utility room should include facilities for:[60]

- cleaning of equipment
- decontaminating commodes

- temporarily holding items which require reprocessing
- disposal of body fluids
- hand hygiene

HFS further recommend that there should be adequate space and facilities for holding, reprocessing or disposal of bedpans, urinals and emesis (vomit) bowls.[60] Large dedicated deep utility sinks should be available for the disposal of contaminated wastewater and for the decontamination of materials (for example cloths, bucket) used in the decontamination of equipment.[60]

Where appropriate, transportation of equipment may be considered to reduce the risk of contamination. A CDC guidance document, graded SIGN 50 level 4, advises that local policy may outline procedures for the transport of equipment to designated decontamination areas.[57] Other considerations, described within the literature, include transporting equipment as soon as possible after use,[35] use of designated or approved containers with clear markings that the box contains dirty items and biohazard stickers.[33, 35] Similarly, transporting 'clean' equipment in a clean, sterile, and/or approved container (with clear marking that the box contains clean items) is suggested by two guidance documents, graded SIGN 50 level 4.[33, 35] The WHO advise that clean and dirty equipment should not be transported together, and the containers used to transport equipment should be decontaminated.[35]

Conclusion

In summary, there is no consistency in extant guidance regarding the specific location in which non-invasive, reusable, shared care equipment should be decontaminated. There is consistency in WHO and CDC guidance that a designated area may be appropriate in some circumstances, transportation of equipment to designated decontamination areas may also be needed to reduce the risk of contamination. Others suggest that cleaning supplies should be made available at point of care.

3.1.9 When should non-invasive, reusable, shared care equipment be decontaminated?

In total, 24 pieces of evidence were included to answer this research question.[21, 28-34, 37-39, 44-46, 52-59, 61, 62] Of these, 22 guidance documents were graded as SIGN 50 Level 4 as they were based primarily on expert opinion.[21, 28-34, 37-39, 44-46, 53, 54, 56-59, 61, 62] Two guidelines were graded AGREE II: 'Recommend with modifications'.[52, 55] There were several limitations identified with these publications including limited evidence on decontamination, suggesting the included recommendations for this topic were based on expert opinion, as well as a lack of clarity regarding stakeholder involvement [52] and a lack of rigour of development for their literature review.[55]

Eight of the included evidence sources were produced for a UK setting, [21, 31, 37, 44, 53, 55, 61, 62] two of these specific to Scottish health and care settings.[21, 62] Thirteen were published guidance for the USA,[32, 33, 38, 39, 45, 46, 56-59] Australia,[28, 54] and Canada,[30] as well as two international guidance for European [29, 52] and one for Australasian settings.[34] These guidance documents are from internationally recognised organisations, and decontamination practices in these countries are not anticipated to significantly differ from the UK. Several publications were over 10 years old which may reduce applicability where practice may have changed over time.[45, 52, 53, 55]

There was consistency across 19 evidence sources (17 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),[28, 30-34, 37, 39, 45, 46, 52, 54-57, 59] and when visibly soiled.[38, 53, 59] However, two of these documents were specific to ophthalmology or optometry,[45, 54] and three were specific to ultrasound equipment,[33, 34, 39] therefore, these may not apply to other settings or equipment respectively.

Other specific circumstances where decontamination of equipment was recommended in the literature include before loaning, decommissioning, recycling and disposal;[21, 61] and based on manufacturers guidance.[61] A UK guidance document also suggests consideration for decontamination of equipment which is not in use.[44]

Frequency of decontamination

Four guidance documents, graded SIGN 50 level 4, suggest that the frequency of decontamination may differ depending on the associated risk.[28, 44, 58, 62] 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.[56] Five guidance documents, graded SIGN 50 level 4, provide examples of baseline or example frequencies of decontamination for specific equipment types.[28, 44, 45, 56, 57] A CDC guidance document, graded SIGN 50 level 4, states that standard, non-critical care equipment should be decontaminated 'regularly', described as weekly or after each use, as appropriate.[32] A guidance document for paediatric ambulatory settings recommends that all patient care equipment be decontaminated daily while in use.[38] Similarly, guidance from the association of anaesthetists in Britain and Ireland also recommend daily cleaning of non-invasive, reusable, shared equipment.[53]

However, it is stated within the NHS England Standards for Cleanliness that one nationally set frequency of decontamination may not be appropriate, given the differing needs of every healthcare organisation.[44] While this document is largely focused on environmental cleaning, it is applicable to the decontamination of some non-invasive, reusable, shared equipment.[44] This guidance document and the NHS Scotland National Cleaning Services Specification recommend that risk assessment should be conducted to determine decontamination schedules or adaptations to decontamination schedules.[44, 62] However, an optimum frequency of decontamination for non-invasive, shared, reusable care equipment was not indicated.[44, 62]

Conclusion

In summary, there is consistency in extant guidance that non-invasive reusable shared patient care equipment should be decontaminated between patients (after use and before use on another patient) and when visibly soiled. Extant guidance advises that the frequency of decontamination should consider the level of infection transmission risk. Conversely, some sources outline that equipment may be decontaminated daily or weekly depending on usage. Other indications for

decontamination include before loaning, repair, decommissioning or disposal as well as per manufacturer's instructions, where appropriate.

3.1.10 Who has responsibility for decontaminating non-invasive, reusable, shared care equipment?

Eleven pieces of evidence were included for this research question.[21, 31, 35, 36, 44, 48, 55, 59, 61-63] Of these, 10 guidance documents, including a Scottish Government Health Department Letter, were graded SIGN 50 Level 4 expert opinion,[21, 31, 35, 36, 44, 48, 59, 61-63] and one guideline was graded AGREE II: 'Recommend with modifications'.[55] Nine of the included evidence were produced for UK settings [21, 31, 36, 44, 48, 55, 61-63] (including four that are Scottish setting-specific [21, 48, 62, 63]), one for USA,[59] and one for international use.[35] Non-Scottish guidance documents may not be fully applicable as roles and responsibilities may differ across settings and countries. However, these guidance documents were from internationally recognised organisations, and decontamination practices in these countries are not anticipated to significantly differ from the UK.

There was a lack of consistency regarding each of the specific roles and responsibilities of staff with regards to the decontamination of non-invasive, reusable, shared care equipment. Some roles were outlined within the Scottish Government Health Department Letter [HDL(2005)07] which establishes that sisters or charge nurses are responsible for all aspects of environmental cleanliness within their clinical area.[63] This includes the authority to require local cleaning services to address any identified issues.[63]

Two Scottish technical guidance also outline various roles and responsibilities related to decontamination of equipment. The SHTM 2030 outlines the responsibilities of the user with regards to use of a washer disinfector.[48] Whereas the SHTN 00-04 sets out more general roles and responsibilities including for users, management, technical specialists and others specific to decontamination of care equipment and medical devices in Scottish health and care settings.[21] The users' responsibilities include checking equipment is fit for use, calibration or maintenance as appropriate, managing IPC issues as appropriate, ensuring safe storage.[21] More specific roles regarding decontamination are provided within the NHS Scotland

National Cleaning Services Specification 01-02.[62] This guidance considers the role of board lead for domestic services, domestic assistant, domestic supervisor, and domestic manager with regards to environmental cleanliness.[62] However, these guidance documents have a wide coverage and are not specific to equipment decontamination alone.

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.[36, 44, 61] However, these guidance documents have a wide coverage, are not specific to equipment decontamination alone, and apply in NHS England settings. There was consistency within 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 the specific responsibilities for decontaminating equipment.[21, 31, 37, 61, 62] It is also recommended that staff should be appropriately trained in decontamination and relevant protocols.[21, 35, 36, 48, 55, 59]

Conclusion

In summary, there is consistency within the included evidence that multiple persons may be responsible for decontamination but that responsibilities should be clearly defined. There is a lack of consistency regarding each specific role and their responsibilities, however, the responsibilities of the Senior Charge Nurse are outlined by the Scottish Government within the HDL (2005) 07 and other roles are clearly outlined by the Scottish National Cleaning Services Specification.[62, 63]

3.1.11 Where should non-invasive, reusable, shared care equipment be stored following decontamination?

Twelve guidance documents, graded as SIGN 50 Level 4, were included for this research question.[21, 28, 30, 32-34, 37, 39, 49, 54, 59, 60] This type of guidance is considered as low-quality evidence due to a lack of a rigorous systematic development process, with recommendations underpinned by expert opinion which may be subject to bias. Of the included publications, three are for Scottish settings,[21, 49, 60] one produced for the UK,[37] four for the USA,[32, 33, 39, 59] two for Australia,[28, 54] one for Australasia [34] and one for Canada.[30] Non-Scottish guidance documents may not be fully applicable as

designs of health and care settings 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. Five of the publications focus on specific equipment types or settings.[33, 34, 39, 49, 54] Three are specific to ultrasound transducers,[33, 34, 39] one for equipment used in optometry settings,[54] and one for medical devices.[49] These documents may not apply to other types of equipment or settings.

The included guidance documents propose different considerations for storing non-invasive, reusable, shared care equipment following decontamination. Two guidance documents advise that care equipment should be stored based on its recommended level of disinfection.[39, 49] Two guidance documents propose that the storage provided should not compromise the level of decontamination achieved.[28, 49] Four guidance documents further advise that storage should provide protection from environmental contaminants or accidental contamination.[21, 34, 37, 49] It is also advised that clean and dirty items should not be stored together to avoid the contamination of clean equipment.[30, 33, 59]

Other aspects of adequate storage facilities advised in guidance include being well ventilated, providing protection from dust, moisture, insects, temperature and humidity.[32] 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.[33] Two ultrasound specific guidance also recommend that suitable storage options for ultrasound transducers may include covers, boxes and cabinets, and that items should be clearly labelled detailing the date of storage, maximum storage duration and level of disinfection that the equipment has undergone.[33, 34] An optometry specific guidance document advises covered containers or covers for optometry equipment.[54]

Scottish setting-specific guidance provides general good practices, including making sure that storage area is clean and in a good state of repair, and that storage follows local policy and guidance.[21] 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.[60]

Conclusion

In summary, within the included literature, there lacks clear and specific requirements for where non-invasive, reusable, shared care equipment should be stored following decontamination. General principles raised within the guidance include considering the required level of decontamination when storing equipment, where storage should not compromise this; protection should be provided from contamination; and clean and dirty equipment should be stored separately. It is also recommended that storage areas be 'adequate' which may include being clean, well-ventilated as well as in a good state of repair and provide protection from dust, moisture, insects, temperature, and humidity. The space required for equipment, particularly larger items, should also be considered.

3.2 Implications for research

There was no specific standard or legislation for decontaminating non-invasive, reusable, shared care equipment identified. Current legislation is generalised to provide employers and employees with requirements for management of medical devices and dangerous substances and/or chemicals in the workplace, expansion on their appropriate use for IPC within health and care settings may provide more evidence regarding non-invasive, reusable, shared care equipment. The included British Standards are mostly focused on quantitative tests for the evaluation of bactericidal, virucidal, sporicidal, yeasticidal and/or fungicidal activity of chemical disinfectants in the medical area, without specific focus on decontaminating non-invasive, reusable, shared care equipment.

This review identified limited evidence that demonstrates the risk of HAI transmission from non-invasive, reusable, shared care equipment. A body of evidence, mainly outbreak studies, that associated equipment such as mattresses and razors with HAI transmission was excluded from this review because of multiple limitations, including applicability to Scottish or UK settings, lack of evidence to prove direction of transmission and lack of WGS or PFGE to provide confirmation that specific equipment and clinical isolates matched. There is a lack of high-quality primary research around the decontamination of non-invasive reusable shared patient equipment. There were several low quality experimental and outbreak studies which

considered decontamination methods for patient equipment. However, many of these were excluded based on their low-quality methodology and/or focus on reprocessing of high-risk critical equipment, often involving high-level disinfection and sterilisation. There is a larger evidence base which considers the management of medical devices, control of the environment and management of outbreaks but this cannot always be extrapolated to the routine management of care equipment. A list of all studies excluded from the review after critical appraisal, based on their limitations, is provided in Appendix 5.

There remains some debate on the value of using disinfectants for cleaning non-critical, low-risk surfaces and equipment. The CDC and USA literature are in favour of using disinfectants for routine cleaning of equipment while the UK and some European countries support the use of cleaning with detergent only, rather than disinfection unless there is a presence of a recognised risk. High quality studies are needed to provide more substantial evidence on the effectiveness of various cleaning methods including the risk of transmission associated with using detergents versus using detergents and disinfectants as part of routine decontamination.

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3. BS EN 1040: 2005. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics. Test method and requirements (phase 1).
4. BS EN 14561:2006. Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area. Test method and requirements (phase 2, step 2). .
5. BS EN 14562:2006. Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area. Test method and requirements (phase 2, step 2). .
6. BS EN 14563:2008. Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area. Test method and requirements (phase 2, step 2). .
7. BS EN 13727:2012+A2:2015. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity in the medical area. Test method and requirements (phase 2, step 1).
8. BS EN 16615:2015. Chemical disinfectants and antiseptics. Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4- field test). Test method and requirements (phase 2, step 2).
9. BS EN 17126:2018. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area. Test method and requirements (phase 2, step 1).
10. BS EN 16777:2018. Chemical disinfectants and antiseptics. Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area. Test method and requirements (phase 2/step 2).

11. BS EN 17111:2018. Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area. Test method and requirements (phase 2, step 2). .
12. BS EN 14476:2013+A2:2019. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of virucidal activity in the medical area. Test method and requirements (Phase 2/Step 1).
13. PD CEN ISO/TR 24971:2020 – TC. Medical devices. Guidance on the application of ISO 14971.
14. BS EN ISO 17664-1:2021 – TC. Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices - Critical and semi-critical medical devices.
15. BS EN 17387: 2021. Chemical disinfectants and antiseptics. Quantitative test for the evaluation of bactericidal and yeasticidal and/or fungicidal activity of chemical disinfectants in the medical area on non-porous surfaces without mechanical action. Test method and requirements (phase 2, step 2).
16. BS EN 13624:2021 – TC. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area. Test method and requirements (phase 2, step 1).
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Appendix 1: Literature Review Search Strategies.

MEDLINE

Ovid MEDLINE(R) ALL <1946 to February 07, 2024>

1	Decontamination/
2	Detergents/
3	exp Sterilization/
4	(antisept* or clean* or decontamin* or contamin* or antimicrob* or sterili*).ti,ab,kf.
5	(terminal adj3 clean*).ti,ab,kf.
6	(terminal adj3 disinfect*).ti,ab,kf.
7	(discharge adj3 clean*).ti,ab,kf.
8	1 or 2 or 3 or 4 or 5 or 6 or 7
9	diagnostic equipment/
10	equipment reuse/
11	Equipment contamination/
12	durable medical equipment/
13	(equipment adj3 (reus* or communal or share*)).ti,ab,kf.
14	(non*invasive adj3 equipment).ti,ab,kf.
15	medical device*.ti,ab,kf.
16	(single and patient and equipment).ti,ab,kf.
17	9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18	*Communicable Disease Control/
19	*Cross Infection/
20	exp *Disease Transmission, Infectious/
21	*Housekeeping, Hospital/
22	*Infection Control/
23	*Occupational Exposure/
24	(cross infection or healthcare associated infection or health care associated infection).ti,ab,kf.

25	18 or 19 or 20 or 21 or 22 or 23 or 24
26	8 and 16 and 25
27	limit 26 to (english language and yr="2000 - 2024")

Embase

Embase <1974 to 2024 February 07>

1	decontamination/
2	detergent/
3	disinfection/
4	(antisept* or clean* or decontamin* or contamin* or antimicrob* or sterili*).ti,ab,kf.
5	(terminal adj3 clean*).ti,ab,kf.
6	(terminal adj3 disinfect*).ti,ab,kf.
7	(discharge adj3 clean*).ti,ab,kf.
8	1 or 2 or 3 or 4 or 5 or 6 or 7
9	exp *medical device/
10	(equipment adj3 (reus* or communal or share*)).ti,ab,kf.
11	(non*invasive adj3 equipment).ti,ab,kf.
12	(medical device* or diagnostic equipment or medical equipment).ti,ab,kf.
13	(single and patient and equipment).ti,ab,kf.
14	9 or 10 or 11 or 12 or 13
15	communicable disease control/
16	cross infection/
17	exp *disease transmission/
18	hospital service/
19	infection control/
20	occupational exposure/
21	(cross infection or healthcare associated infection or health care associated infection).ti,ab,kf.
22	15 or 16 or 17 or 18 or 19 or 20 or 21
23	8 and 14 and 22

24	23 not conference*.so,pt.
25	limit 24 to (english language and yr="2000 -Current")
26	limit 25 to "remove medline records"

CINAHL

S25	S8 AND S15 AND S23 – English language
S24	S8 AND S15 AND S23 – 2000-2024
S23	S8 AND S15 AND S23
S23	S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR 22
S22	((TI (cross infection OR healthcare associated infection OR health care associated infection)) OR (AB (cross infection OR healthcare associated infection OR health care associated infection)) OR (SU (cross infection OR healthcare associated infection OR health care associated infection))))
S21	MH "Occupational Exposure"
S20	MH "Housekeeping Department"
S19	MH "Infection Control"
S18	MH "Disease Transmission+"
S17	MH "Cross Infection"
S16	MH "Communicable Diseases"
S15	S9 OR S10 OR S11 OR S12 OR S13 OR 14
S14	(TI (single) AND (patient) AND (equipment))
S13	((TI medical device*) OR (AB medical device*) OR (SU medical device*)))
S12	((TI non#invasive N3 equipment) OR (AB non#invasive N3 equipment) OR (SU non#invasive N3 equipment))
S11	((TI (equipment N3 (reus* OR communal OR share*))) OR (AB (equipment N3 (reus* OR communal OR share*))) OR (SU (equipment N3 (reus* OR communal OR share*))))
S10	MH "Equipment and Supplies"
S9	MH "Equipment Reuse"
S8	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7
S7	((TI discharge N3 clean*) OR (AB discharge N3 clean*) OR (SU discharge N3 clean*)))

S6	((TI terminal N3 disinfect*) OR (AB terminal N3 disinfect*) OR (SU terminal N3 disinfect*))
S5	((TI terminal N3 clean*) OR (AB terminal N3 clean*) OR (SU terminal N3 clean*))
S4	((TI (antisept* OR clean* OR decontamin* OR contamin* OR antimicrob* OR sterili*)) OR (AB (antisept* OR clean* OR decontamin* OR contamin* OR antimicrob* OR sterili*)) OR (SU (antisept* OR clean* OR decontamin* OR contamin* OR antimicrob* OR sterili*)))
S3	MH "Detergents"
S2	MH "Sterilization and Disinfection"
S1	MH "Decontamination, Hazardous Materials"

Appendix 2: Evidence gradings

SIGN 50 Evidence levels

The SIGN 50 methodology was used to appraise and grade primary studies and expert opinion guidance documents.

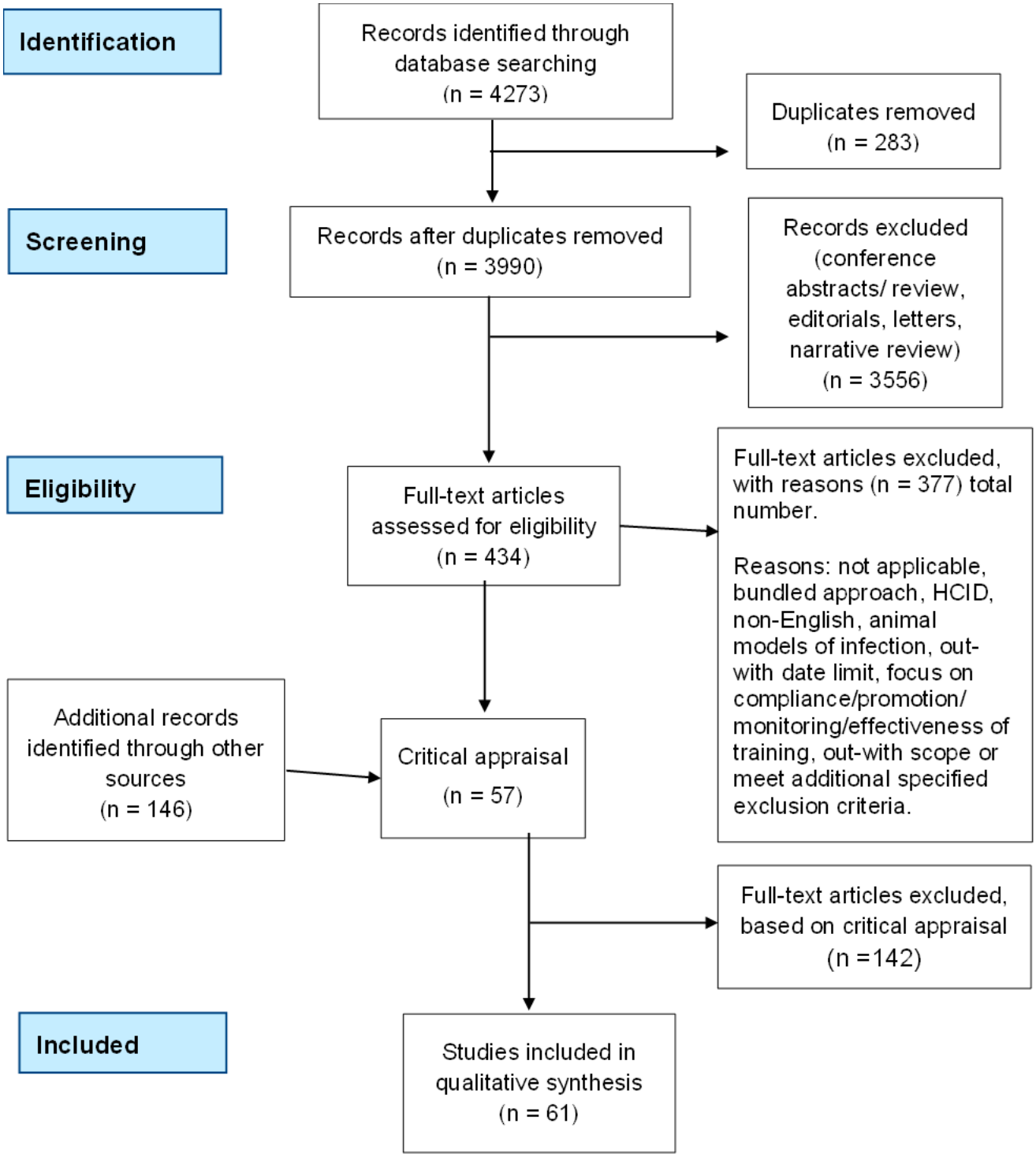
Grade	Description
1++	High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias.
1-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High-quality systematic reviews of case-control or cohort studies. High-quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2-	Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies, for example, case reports, case series
4	Expert opinion

AGREE II Evidence levels

The AGREE II tool was used to appraise guidelines which were based on a systematic review of evidence, and experts have formulated the recommendations/ statements.

Grade	Description
AGREE II 'Recommend'	This indicates that the guideline has a high overall quality and that it can be considered for use in practice without modifications.
AGREE II 'Recommend with modifications'	This indicates that the guideline has a moderate overall quality. This could be due to insufficient or lacking information in the guideline for some items. If modifications are made the guideline could still be considered for use in practice, when no other guidelines on the same topic are available.
AGREE II 'Do not Recommend'	This indicates that the guideline has a low overall quality and serious shortcomings. Therefore, it should not be recommended for use in practice.

Appendix 3: PRISMA flow diagram



Appendix 4: Standards pertaining to equipment decontamination.

This appendix provides a non-exhaustive list of standards pertaining to equipment decontamination. The standards listed represent the most recent versions available at the time of publication. Please note, however, standards are subject to amendments and the most recent versions should always be sourced and used in practice.

Standard/Legislation	Title	Description	Publication Date
BS EN 1040:2005	Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics — Test method and requirements (phase 1).	Applicable to multiple settings including medical. Supersedes 1040:1997. This standard provides a summary of testing methods and minimum requirements of bacterial activity for chemical disinfectants and antiseptic products (that form homogenous, physically stable preparation when diluted with water). Test organisms: (*pseudomonas* and *staphylococcus aureus* and media/reagents. Reduction: ≥ 5 decimal log reduction.	2005
BS EN 13727: 2012+A2:2015	Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity in the medical area —	Applicable to medical settings. Supersedes 13727:2012+a1:2013. This standard provides a summary of testing methods and minimum requirements of hygienic handrub, hygienic washes, surgical handrub, surgical handwash, instrument	2015

Standard/Legislation	Title	Description	Publication Date
	Test method and requirements (phase 2, step 1).	disinfection by immersion, surface disinfection by wiping, spraying, flooding or other means. Test Organisms: *Enterococcus hirae*, *pseudomonas aeruginosa* and *staphylococcus aureus*. Reduction: > 5 decimal log reduction.	
BS EN 14885:2022	Chemical disinfectants and antiseptics — Application of European Standards for chemical disinfectants and antiseptics.	Supersedes 14885:2018. This standard is applicable where chemical disinfectants and antiseptics may be used in areas and situations where disinfectants and antiseptics are medically indicated. This standard provides and overview and lists other relevant standards to consider.	2022
BS EN 16615:2015	Chemical disinfectants and antiseptics — Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4- field test) — Test	This standard is reported to apply to products intended for use in medical (reported to cover such areas as hospitals, clinics of schools, nursing homes and more) areas for disinfecting non-porous surfaces including medical device by wiping (even if not covered by 93/42/EEC). Test organisms: *Pseudomonas aeruginosa, Staphylococcus aureus, Enterococus hirae and Candida albicans.* Reduction: ≥ 5 decimal log	2015

Standard/Legislation	Title	Description	Publication Date
	method and requirements (phase 2, step 2).	reduction (*P. aeruginosa, S. aureus, E. hirae*) and >4 decimal log reduction (*Candida albicans)*.	
BS EN 13624:2021	Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area — Test method and requirements (phase 2, step 1).	Supersedes 13624:2013. This standard is applicable to products used in medical area in the fields of hygienic handrub, hygienic handwash, surgical handrub, surgical handwash, instrument disinfection by immersion, and surface disinfection by wiping, spraying, flooding or other means. Test organisms: *candida albicans, aspergillus brasiliensis*. Reduction: >4 decimal log reduction.	2021
BS EN 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices Part 1: Critical and semi-critical medical devices.	Supersedes the 17664-1:2017. This document provides minimum standards for manufacturers producing medical device that will be cleaned, disinfected, sterilised including items (including single use) decontaminated before use and any that may be reprocessed. The focus of the standard appears to be on the detail manufacturers should provide.	2021

Standard/Legislation	Title	Description	Publication Date
BS EN 14476:2013+ A2:2019	Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of virucidal activity in the medical area. Test method and requirements (Phase 2/Step 1).	Applicable to products intended for use in medical areas. Test methods and minimum requirements for virucidal activity of chemical disinfectant and antiseptic products.	2019
BS EN 17126:2018	Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area. Test method and requirements (phase 2, step 1).	Applicable to products intended for use in medical areas. This provides a test method and the minimum requirements for sporicidal activity of chemical disinfectant.	2018
BS EN 16777:2018	Chemical disinfectants and antiseptics. Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area. Test	A test method and minimum requirements for virucidal activity of chemical disinfectants and antiseptics used for disinfecting non-porous surfaces such as medical device surfaces, without mechanical action.	2018

Standard/Legislation	Title	Description	Publication Date
	method and requirements (phase 2/step 2).		
BS EN 17387:2021	Chemical disinfectants and antiseptics. Quantitative test for the evaluation of bactericidal and yeasticidal and/or fungicidal activity of chemical disinfectants in the medical area on non-porous surfaces without mechanical action. Test method and requirements (phase 2, step 2).	Applicable to medical settings. Test methods and minimum requirements for bacterial, yeasticidal and fungicidal activity of chemical disinfectant products where disinfection is medically indicated.	2021
PD CEN ISO/TR 24971:2020	Medical devices. Guidance on the application of ISO 14971.	This document provides guidance on the development, implementation, and maintenance of a risk management system for medical devices according to ISO 14971:2019.	2020
BS EN 14561:2006	Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the	This document provides minimum standards regarding the use of chemical disinfectants and antiseptics in medical settings. It provides phase 2 of test methods for instruments decontaminated via immersion, but it	2006

Standard/Legislation	Title	Description	Publication Date
	medical area. Test method and requirements (phase 2, step 2).	does note that it applies even if they are not covered by the EU Directive on Medical Devices.	
BS EN 14562:2006	Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area. Test method and requirements (phase 2, step 2).	This document provides minimum standards regarding the use of chemical disinfectants for instruments with fungicidal or yeasticidal activity described within the scope. It provides phase 2 of test methods for instruments decontaminated via immersion, but it does note that it applies even if they are not covered by the EU Directive on Medical Devices.	2006
BS EN 14348:2005	Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants. Test methods and requirements (phase 2, step 1).	This document provides minimum standards for “mycobactericidal (or tuberculocidal) activity of chemical disinfectant products that form a homogeneous, physically stable preparation when diluted with hard water — or in the case of ready-to-use products — with water.	2005

Standard/Legislation	Title	Description	Publication Date
BS EN 14563:2008	Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area. Test method and requirements (phase 2, step 2).	This standard provides “test method and the minimum requirements for mycobactericidal or tuberculocidal activity of chemical disinfectant products that form a homogeneous, physically stable preparation when diluted with hard water, or — in the case of ready-to-use products — with water”.	2008
BS EN 17111:2018	Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area. Test method and requirements (phase 2, step 2).	This standard provided minimum standards and methods for chemical disinfectants and antiseptics regarding virucidal activity for instruments used ion a medical area, for produced diluted with water or ready to use.	2018

Appendix 5: Studies excluded following critical appraisal

- Kim, E.J., Park, W.B., Yoon, J.K., Cho, W.S., Kim, S.J., Oh, Y.R., Jun, K.I., Kang, C.K., Choe, P.G., Kim, J.I. and Choi, E.H., 2020. Outbreak investigation of Serratia marcescens neurosurgical site infections associated with a contaminated shaving razors. Antimicrobial Resistance & Infection Control, *9*, pp.1-7.
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- MacDonald K, Bishop J, Dobbyn B, Kibsey P, Alfa MJ. Reproducible elimination of Clostridium difficile spores using a clinical area washer disinfector in 3 different health care sites. American Journal of Infection Control. 2016 Jul 1;44(7):e107-11.
- Speight S, Moy A, Macken S, Chitnis R, Hoffman PN, Davies A, Bennett A, Walker JT. Evaluation of the sporicidal activity of different chemical disinfectants used in hospitals against Clostridium difficile. Journal of Hospital Infection. 2011 Sep 1;79(1):18-22.
- Rutala WA, Peacock JE, Gergen MF, Sobsey MD, Weber DJ. Efficacy of hospital germicides against adenovirus 8, a common cause of epidemic keratoconjunctivitis in health care facilities. Antimicrobial agents and chemotherapy. 2006 Apr;50(4):1419-24.
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- Fraise A. Currently available sporicides for use in healthcare, and their limitations. Journal of Hospital Infection. 2011 Mar 1;77(3):210-2.
- Meyers J, Ryndock E, Conway MJ, Meyers C, Robison R. Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants. Journal of Antimicrobial Chemotherapy. 2014 Jun 1;69(6):1546-50.