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Guidelines

Automated room decontamination: report of a Healthcare Infection Society Working Party

A.J. Beswick [a], C. Fry [b], C.R. Bradley [c,†], T. Pottage [b], S. Sharpe [d], C.F. Haill [e], M.A. Mugglestone [f,*], A. Bak [f], G.L. Marsden [f], A. Bennett [b], M. Garvey [c], A.P.R. Wilson [g]

[a] Health and Safety Executive, UK
[b] UK Health Security Agency, UK
[c] University Hospitals Birmingham NHS Foundation Trust, UK
[d] Black Country Healthcare NHS Foundation Trust, UK
[e] University Hospitals Plymouth NHS Trust, UK
[f] Healthcare Infection Society, London, UK
[g] University College London Hospitals NHS Foundation Trust, UK

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Executive summary

This report provides advice to hospital managers, hospital-based service providers, infection prevention and control (IPC) teams and end users who intend to employ automated room decontamination devices as part of their IPC regimens. Conventional cleaning and disinfection approaches are long established and can be very effective if thorough, but recently automated systems have become available that offer the effectiveness and safety to supplement manual methods. Some chemicals such as formaldehyde have had a place within the contained laboratory setting for many years but are too toxic for use in patient areas. Biocidal ultraviolet C light has long been used to treat water systems, but whole-room treatment systems have become available following improved electrical safety and componentry.

Although suppliers of fumigation systems have offered decontamination services for over 20 years, new companies have entered the marketplace providing a greater choice of machine designs, catering for different budgets and usage requirements. As a result of the growth in equipment availability the choice is now much greater. This brings consumer benefits but can also be confusing to the potential end user, who might not be familiar with the wealth of technical specifications for these specialized systems.

This report is independent and aims to provide useful, generic information that will help healthcare professionals make a well-informed choice if they are intending to buy or rent/lease the automated technology. The aim is to provide guidance on the types of device available, the various active

* Corresponding author. Address: Healthcare Infection Society, Montagu House, 7E Wakefield Street, London WC1N 1PG, UK. Tel.: +44 (0)207 7130273.
E-mail address: moira.mugglestone@his.org.uk (M.A. Mugglestone).
† Deceased 25 August 2020.

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chemicals (where relevant), the biocidal mechanism underpinning the technology, suggested information to be sought from the supplier before purchase, and general precautions recommended for the safe and effective use of the equipment.

Recommendations

Consider use of an automated decontamination device as a supplement to manual cleaning in the context of rising or high prevalence of nosocomial infection, such as *Clostridioides difficile*, meticillin-resistant *Staphylococcus aureus*, or vancomycin-resistant enterococcus.

Consider use of hydrogen peroxide vapour or pulsed-xenon ultraviolet light in room surface decontamination during an outbreak of *C. difficile* infection when other modalities have failed to reduce acquisition.

Good practice points

- Manual cleaning should be completed to the same high standard regardless of the subsequent use of automated cleaning devices.
- On first use of a fumigant or ultraviolet light in a specific room design, efficacy of sealing should be monitored to ensure safety.
- Prioritize different cleaning systems to the type of infection of the most recent room occupant by use of a red/amber/green rating based on local nosocomial infection rates.
- Remove foam materials from the room if fumigant is used unless sealed under an impervious cover.
- Before purchasing or renting a system, run a mock decontamination cycle in a hospital room to determine turnaround times.
- After purchasing an ultraviolet-light decontamination system, consider the impact on surface finishes such as whitened polyvinyl chloride (PVC) before purchasing other equipment, and ask the equipment supplier to confirm compatibility.
- Monitor levels of fumigant or ultraviolet light at regular intervals during the contract to ensure efficacy.
- When adopting a new automated system or disinfecting a new room design, conduct microbiological culture tests (if permitted in the hospital) or take in-use environmental swab tests before and after disinfection to confirm efficacy.

Lay summary

Acquiring an infection in hospital is undesirable, especially if the infection is resistant to antibiotic treatment. Manual cleaning and disinfection of patient rooms and areas in which care is delivered can leave surfaces contaminated with microorganisms (such as bacteria or viruses) that might lead to infection. This report considers the effectiveness of automated (or no-touch) decontamination devices used in addition to ordinary cleaning and disinfection in patient areas. For example, the microbiological benefit versus time taken for automated decontamination of patient rooms between one patient vacating the room and another occupying it. The main types of devices considered are those using ultraviolet light or hydrogen peroxide for the decontamination process. The report describes which devices are recommended in which circumstances, as well as practical advice on their procurement and operation. Although the devices are effective the benefit in terms of preventing patient infections needs further research.

A glossary explaining key terms used in the report is presented in Appendix A.

Introduction

Infection prevention and control (IPC) measures in healthcare settings include manual cleaning (using detergent) and disinfection (using a chemical agent such as bleach). For simplicity, such procedures (which can take many and varied forms) are referred to as 'manual cleaning/disinfection' in this report. The procedures can be implemented one or more times per day and when patient rooms and other clinical areas are vacated (the latter being referred to as terminal cleaning/disinfection). The effectiveness of manual cleaning/disinfection depends on the thoroughness of designated procedures and the adherence of the cleaners to those procedures. Microbiological contamination of surfaces in the healthcare environment that persists due to incomplete manual cleaning/disinfection increases the risk of healthcare-associated infection, particularly for people with weakened immune systems. A potential solution is an enhanced approach to environmental surface decontamination, including those offered by automated (no-touch) room decontamination devices and systems.

This Healthcare Infection Society (HIS) guidance incorporates a systematic evidence review evaluating the effectiveness of automated approaches to room decontamination in healthcare settings compared with manual cleaning/disinfection. The automated decontamination techniques considered include ultraviolet light, either as ultraviolet C (UV-C) or pulsed-xenon ultraviolet (PX-UV) systems, and hydrogen peroxide, either as hydrogen peroxide vapour (HPV) or aerosolized hydrogen peroxide (AHP). HPV and AHP are distinguished by the concentration of hydrogen peroxide used in the decontamination process: HPV is used for systems employing 30—35% hydrogen peroxide whereas AHP refers to systems using 5—6% hydrogen peroxide [1]. Micro-organisms used to evaluate automated decontamination in healthcare settings include both Gram-positive and Gram-negative bacteria associated with healthcare-associated infection, for example, *Acinetobacter* spp., *Clostridioides difficile*, meticillin-resistant *Staphylococcus aureus* (MRSA), and vancomycin-resistant enterococcus (VRE). The primary focus of the systematic evidence review underpinning the guidance is an evaluation of the effectiveness of automated decontamination in preventing infection or colonization, either in relation to specific microorganisms or particular types of infection, for example, surgical site infection or device-associated infection (including catheter-associated urinary tract infection (CAUTI), and central line-associated bloodstream infection (CLABSI)). The evidence review highlights published research evaluating the effectiveness of automated decontamination in terms of reducing microbiological environmental contamination in healthcare settings. The guidance overall was intended to address practicalities related to the selection and implementation of an automated decontamination system. These

considerations were based on the expertise and experience of the Working Party convened by HIS to develop the guidance.

Guidance development team

Acknowledgements

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Source of funding

There was no external funding for development of the guidance.

Disclosure of potential conflicts of interest

All members of the Working Party completed conflict-of-interest forms in line with HIS policy. No material conflicts of interest were identified.

Relationship of authors with sponsor

HIS commissioned the Working Party to develop the guidance. Several authors are members of HIS (A.Be., A.P.R.W., C.F., C.F.H. and M.G.) or HIS staff (A.Ba., G.L.M. and M.A.M.).

Responsibility for the guidance

The views expressed in the report are those of the authors and have been endorsed by HIS following an external consultation process.

Working Party report

What is the Working Party Report?

The report comprises recommendations related to automated room decontamination in healthcare settings. The methodology used to develop the recommendations combines a systematic evidence review and synthesis and expert opinion (see Section Methodology for further details).

Why do we need a Working Party Report for this topic?

The need for guidance was prompted by a recognition that many hospitals are either already operating or preparing to purchase automated decontamination systems. Suppliers of such systems act in an intensely competitive market with no independent oversight in terms of responsibility for comparing systems and advising on their application. The guidance was intended to include practical advice for prospective purchasers considering implementation of an automated decontamination system (for example, as part of a tender process).

What is the purpose of the Working Party Report's recommendations?

The main purpose of the recommendations is to inform IPC practitioners about the options available for automated room decontamination in healthcare settings. The report includes research recommendations, highlighting gaps in knowledge and evidence.

What is the scope of the guidance?

The guidance covers automated systems for decontaminating environmental surfaces in healthcare settings. It does not cover decontamination of equipment, devices, or the air in healthcare facilities. The guidance was largely developed with hospitals in mind, but the recommendations might be useful in other healthcare settings where microbiological environmental contamination and associated risk of a healthcare-associated infection is of concern.

What is the evidence for the guidance?

The guidance topic was proposed by the former HIS Scientific Development Committee (whose remit was transferred to the HIS Guidelines Committee in 2019) and approved by the HIS Council. The Working Party's considerations regarding the effectiveness of automated room decontamination devices were based on a systematic review and evidence synthesis of peer-reviewed research literature, including quality assessment of the evidence using validated techniques. The members of the Working Party used their experience and expertise to supplement analysis of the published literature regarding the practicalities of selecting and implementing automated decontamination systems.

Who developed the guidance?

The Working Party comprised infectious diseases/microbiology clinicians, other IPC specialists such as infection control nurses, microbiologists, engineers and facilities managers specializing in healthcare cleaning. HIS staff with expertise in systematic reviewing prepared the evidence synthesis.

Who is the guidance for?

Any healthcare practitioner may use the guidance and adapt it as needed. Users will include clinical staff and IPC teams. The guidance aims to provide recommendations for all health and care settings and to include the available evidence for all settings where microbiological environmental contamination of surfaces is of concern. However, the studies included in the evidence review and synthesis were predominantly conducted in hospital settings. The Working Party believes that whereas many sections of the guidance are especially relevant to hospitals, some evidence and recommendations could be extrapolated to other health and social care settings such as nursing homes.

How is the guidance structured?

The rationale for the advice is presented in the context of the supporting evidence identified through systematic literature searches or, in the case of the practicalities of selecting and implementing an automated decontamination system, the expert opinion of the Working Party. Evidence statements summarize the results of the systematic literature searches and evidence synthesis. The phrasing and classification of recommendations reflects the strength of the supporting evidence or reliance on expert opinion. It should be noted that the guidance is of a general nature and that an employer should consider the specific conditions of each individual place of work and comply with all applicable legislation, including the Health and Safety at Work etc. Act 1974 (see https://www.legislation.gov.uk/ukpga/1974/37/contents) and provisions for the regulation, supply, and use of biocides (see https://www.hse.gov.uk/biocides/).

How frequently will the guidance be reviewed and updated?

The guidance will be reviewed at least every four years and updated if changes are necessary or if new evidence emerges that requires a change in practice.

Aim

The primary aims of the guidance were to evaluate the effectiveness of different approaches to automated room decontamination in healthcare settings and to support decision-making regarding the practicalities of selecting and implementing a particular approach. A secondary aim was to identify areas in need of further research.

Implementation of the guidance

How can the guidance be used to improve clinical effectiveness?

The guidance can be used to inform local IPC advice and in the procurement process for automated room decontamination devices. It provides a framework for audit for quality improvement in maintaining a safe patient environment.

How much will it cost to implement the guidance?

Automated room decontamination devices represent significant revenue and capital expenditure which will need to be balanced against potential reduction in hospital-acquired infection and improved quality of life for patients. Similar benefits can be achieved by increasing investment in standard cleaning.

Summary of audit measures

The following expressed as percentage compliance:

- All rooms receive enhanced disinfection (either automated or additional manual cleaning) where a patient with *C. difficile* infection has been discharged or transferred.
- All rooms given the appropriate level of cleaning according to the patient pathogens present and not derogated due to patient accommodation pressures.

Supplementary tools

Continuing professional development (CPD) questions and model answers for self-assessment are presented in Appendix B.

Methodology

Overview

The processes and methods used to develop the systematic evidence review evaluating the effectiveness of automated approaches to decontamination were based on those described in the National Institute for Health and Care Excellence (NICE) guidelines manual [2]. The review question was expressed in the patient—intervention—comparator—outcome (PICO) framework as presented in Table I.

Data sources and search strategy

Three electronic databases (Embase, MEDLINE, and CINAHL) were searched for published articles using medical subject headings (MeSH) and free-text terms. Reference lists from published reviews identified in the literature searches were used to identify additional studies to be considered for inclusion in the guidance review. No date or language restrictions were applied as part of the searches, which were completed in

Table I
The review question formulated using the PICO framework

Population/setting	Intervention	Comparator	Outcomes
Patients in any healthcare setting	Use of an automated device to decontaminate a patient room or other clinical area	No cleaning, manual cleaning/disinfection or another automated decontamination device	Patients — infection or colonization with any pathogen
Additional evidence: micro-organisms, including those experimentally inoculated			Micro-organisms — microbial count (on any surface)

PICO patient-intervention-comparator-outcome.
Exclusion criteria: studies describing decontamination of equipment or devices; automated devices used for decontamination of air; non-comparative clinical outbreak studies; studies reporting a total count, but not specific types of micro-organisms.

February 2021. Further details of the searches are presented in Appendix C.

Study eligibility and selection criteria

Published articles identified through the literature searches were screened for relevance against the PICO framework. One reviewer examined titles, abstracts, and full texts of all records identified through the searches. A second reviewer checked at least 10% of records earmarked for exclusion at each stage of screening. Disagreements were first discussed between the two reviewers and, if consensus was not reached, a third reviewer was consulted. The results are presented in the study selection flowchart in Appendix D. A list of studies excluded after full-text screening is presented in Appendix E.

Data extraction, preliminary analysis, and quality assessment

The characteristics of included studies were summarized in the evidence tables presented in Appendix F. For each included study, data were extracted into an evidence table by one reviewer and a second reviewer checked the data extraction for 10% of studies. Priority was given to studies reporting the clinical outcomes of infection or colonization, whereas additional studies reporting only environmental sampling outcomes were highlighted in a separate evidence table.

The preferred outcome measure for extraction of clinical outcomes was the incidence rate in each treatment arm, since these are used to calculate incidence rate ratios (IRRs) for interventions and comparators in the same study. An IRR of one implies no difference between the incidence rates for two treatments under comparison, whereas an IRR less (greater) than one implies a reduction (increase) in the incidence rate relative to the reference treatment (which, for the purposes of this evidence review, was defined as the most conservative approach to manual cleaning/disinfection evaluated in each study). Further details relevant to the calculation of incidence rates and IRRs are described in Appendix F.

Included studies reporting the clinical outcomes of infection or colonization were appraised for quality using checklists recommended in the NICE guidelines manual [2]. Critical appraisal was conducted by one reviewer, and appraisal outcomes for at least 10% of studies were checked by a second reviewer. The results of study-level quality appraisal are presented in Appendix G, with results stratified (organized) by study design.

Network meta-analysis

Network meta-analysis (NMA) was considered relevant for quantitative synthesis of the clinical outcomes of infection or colonization because of the multiplicity of automated approaches to decontamination under consideration. Whereas pairwise meta-analysis allows comparison of two treatments (for example, treatment A versus treatment B), NMA allows a unified (and therefore more powerful and informative) comparison of three or more treatments (for example, treatment A versus treatment B, treatment A versus treatment C, and treatment B versus treatment C). Studies involving head-to-head comparisons of treatments provide direct evidence related to those treatment comparisons; however, NMA also allows indirect evidence to be incorporated in the analysis (for example, one study comparing treatments A and B directly and another study comparing treatments A and C directly provide indirect evidence for the comparison of treatments B and C).

In this evidence review, NMA was planned to allow comparison of a variety of automated decontamination systems with manual cleaning/disinfection and with each other. By contrast, previously published meta-analyses have been restricted to pairwise comparisons of either ultraviolet light or hydrogen peroxide systems with manual cleaning/disinfection (for example, Marra *et al.* [3] and Dong *et al.* [4]). NMA is becoming more widely used within guideline development, and the statistical methodology used in this evidence review mirrors that used in the NICE guideline development programme [5]. Generic code for Bayesian NMA using the statistical software WinBUGS (see https://www.mrc-bsu.cam.ac.uk/software/bugs/the-bugs-project-winbugs/) was adapted for the analyses conducted for the guidance (see below) [6]. The statistical package R (see https://www.r-project.org/) was used for graphical presentation of NMA data structures.

The NMAs conducted as part of this evidence review met good practice criteria [7] covering: creation of network diagrams and examination of the geometry of each network and implications for the analysis (for example, in terms of risk of bias); adjustments for correlated outcomes in multi-arm studies (studies evaluating three or more treatments); model fitting (including assessment of convergence in the Bayesian computational framework); model checking (for example, using deviance residuals); interpretation of results both as IRRs for all pairwise treatment contrasts supported by the network and by considering surface under cumulative ranking (SUCRA) scores for individual treatments; and exploration of model assumptions including transitivity (by comparing study designs in relation to the PICO framework) and inconsistency (by comparing direct and indirect treatment effect estimates) where possible. Further details of these aspects of the methodology are presented in Appendix H.

IRRs for all pairwise treatment contrasts supported by each network were calculated as part of NMA model-fitting. IRRs are easier to interpret than the $\log_e$-IRRs and associated standard errors (SEs) that formed the data inputs for the NMAs (see Appendix H). Posterior distributions for the IRRs were summarized in terms of medians and 95% credible intervals (CrIs; analogous to 95% confidence intervals (CIs) used in frequentist approaches to statistical inference). Treatment rankings were also calculated for each iteration of model-fitting, and these were summarized using SUCRA scores expressed as percentages such that a treatment uniformly ranked most (least) effective over all iterations would have a score of 100% (0%).

Rating of evidence and recommendations

Evidence synthesized in the guidance review was assessed for quality at outcome level using the approach known as Grading of Recommendations Assessment, Development and Evaluation (GRADE; see https://www.gradeworkinggroup.org/for details). The resulting GRADE tables are presented in Appendix I, with results stratified by the micro-organisms associated with infection or colonization, or type of infection (surgical site infection, device-associated infection, or infection specific to a body organ or system). Using GRADE, the overall quality of the evidence for

each clinical outcome of infection or colonization was classified as very low, low, moderate, or high.

Evidence statements for the clinical outcomes of infection or colonization were constructed by combining the outcome-level classification of evidence quality determined using GRADE and the following terms reflecting the overall confidence in using the evidence to formulate recommendations:

- strong evidence – further research is unlikely to alter confidence in the estimated effect
- moderate evidence – further research might alter the estimated effect and its strength
- weak evidence – further research is very likely to alter the estimated effect and its strength
- inconsistent evidence – current studies report conflicting evidence and further research is very likely to alter the estimated effect.

In accordance with the GRADE approach, the Working Party's recommendations related to the clinical outcomes of infection or colonization were phrased to reflect the strength of the evidence and the Working Party's confidence in using it as the basis for developing recommendations.

Where there was little or no evidence related to the clinical outcomes of infection or colonization that could be used to guide recommendations, the Working Party used informal consensus to formulate good practice points based on their collective experience and expertise. The Working Party also used this approach to formulate advice regarding the practicalities of choosing and implementing automated decontamination systems. In addition, the Working Party formulated recommendations for further research to address identified gaps in the evidence.

Consultation process

Feedback on the draft guidance was received from the HIS Guidelines Committee and through consultation with relevant stakeholders. The draft report was placed on the HIS website for 10 working days along with the HIS standard response form, including a conflict-of-interest disclosure form. The availability of the draft guidance was communicated via e-mail and social media. Stakeholders were invited to comment on the format, content, local applicability, patient acceptability, and recommendations. The Working Party reviewed stakeholder comments and collectively agreed revisions in response to the comments (see Appendix J). Comments received from individuals who disclosed conflicts of interest, or who did not submit a conflict-of-interest disclosure form, were not considered by the Working Party.

Rationale for recommendations

Which automated room decontamination devices are effective for reducing microbial burden and preventing infection or colonization in healthcare settings?

Search results and study selection

The literature searches, which were performed in accordance with the search terms in Tables C.1 and C.2, identified 1041 articles; a further 13 articles were identified by hand-searching reference lists, etc. (see Figure D.1). One thousand and one articles were eventually excluded, with those considered at the full-text stage being listed in Table E.1 together with reasons for exclusion. A total of 53 articles were selected for inclusion, representing 29 distinct studies reporting clinical outcomes (see Table F.1) [8–39] and 21 further studies reporting only environmental sampling outcomes involving either detection of clinically occurring environmental contamination [40–53] or experimental inoculation of surfaces [54–60] (see Table F.2).

Among the 29 studies reporting clinical outcomes, some focused specifically on infection and one focused specifically on colonization; the remainder focused on acquisition (infection or colonization without distinguishing between the two). Subsequent sections of this report are, therefore, structured and phrased according to the clinical outcomes of infection or acquisition. The evidence identified for inclusion covered infection or acquisition due to specific micro-organisms or groups of micro-organisms, surgical site infection, device-associated infection, and infection specific to body organ or system (see below for further details).

The most frequently evaluated automated room decontamination systems in terms of clinical outcomes were UV-C (eight studies [8,15,25,29,32,34,35,38]), PX-UV (13 studies [10,13,14,16,17,20–22,25,26,28,37,39]), and HPV (six studies [11,18,19,23,24,33]). AHP was compared with manual cleaning/disinfection in one study [27], as was a visible (indigo and white) light continuous disinfection system [30]. Most studies focused on the use of automated decontamination devices after manual cleaning/disinfection (most frequently in the context of terminal cleaning/disinfection of patient rooms). However, one study [29] compared UV-C at every terminal discharge to UV-C only at terminal discharge of patients with *C. difficile* infection.

Assessment of methodological quality

Two of the studies reporting clinical outcomes were conducted as controlled trials [8,12], five were conducted as controlled before–after studies [20,28,30,33,37], seven were conducted as interrupted time series [13,15,24,27,29,34,38], and the remainder were conducted as quasi-experimental (uncontrolled before–after) studies [10,11,14,16–19,21–23,25,26,32,35,39]. Where controlled before–after studies reported adjusted IRRs these were used to calculate data inputs for the relevant NMAs (see Appendix H). Methodological quality assessments for the included studies are presented according to study design in Tables G.1, G.2, G.3, and G.4, respectively.

Network meta-analysis

NMA was performed for the clinical outcomes of infection or acquisition due to *Acinetobacter* spp. (four studies [8,28,32,35]), *C. difficile* (18 studies [8,10–13,16,17,19,22–26,32–34,37,39]), MRSA (12 studies [8,12,16,17,19,20,27,28,32,33,35,39]), and VRE (10 studies [8,12,13,17,19,32,33,35,37,39]). The data inputs for the NMAs (including $\log_e$-IRRs and associated SEs) are presented in Tables H.1, H.2, H.3 and H.4, respectively. One multi-arm study [8] was included in several of the NMAs. This study compared four treatments: UV-C after bleach disinfection; UV-C after standard manual cleaning/disinfection; bleach disinfection; and standard manual cleaning/disinfection. Where relevant, the NMAs incorporated adjustments for correlations between IRRs involving the three alternatives to standard manual cleaning/disinfection in this study. Another study [25] evaluated both UV-C and PX-UV through comparisons with manual

cleaning/disinfection, but these comparisons were conducted in different hospitals and contributed statistically independent IRRs to the relevant NMA. One study comparing different approaches to manual cleaning/disinfection [12] was also included in several of the NMAs. This ensured that the approaches to manual cleaning/disinfection represented in the analyses reflected the wide variety of approaches that might be used in practice (see Appendix H). However, the purpose of the analyses was not to compare the effectiveness of different approaches to manual cleaning/disinfection *per se*.

Network diagrams corresponding to each NMA are presented in Figure H.1. The automated approaches to decontamination represented in the NMAs were UV-C, PX-UV, HPV, and AHP. The total number of patient-days represented in the networks of evidence was greatest for *C. difficile* (more than 3.5 million patient-days), lower for MRSA and VRE (~1.5 million patient-days each), and lowest for *Acinetobacter* spp. (~170,000 patient-days). None of the included studies involved head-to-head comparisons between different approaches to automated decontamination. The resulting star networks, in which the only direct comparisons were those between automated decontamination systems and the reference treatment (manual cleaning/disinfection), did not allow investigation of the consistency assumption underpinning each NMA, but the width of the 95% CrIs for indirect treatment effect estimates was taken into account when determining GRADE quality ratings for the domain of imprecision (see Appendix H). The transitivity assumption that also underpins each NMA was expected to hold because it was plausible that any automated decontamination system could have been implemented in any of the study settings represented in the networks of evidence.

The numerical results (IRRs for relevant treatment contrasts and SUCRA scores) from the NMAs are presented in Tables H.5, H.6, H.7, H.8 and H.9. The IRRs (and 95% CrIs) are presented graphically in Figure 1.

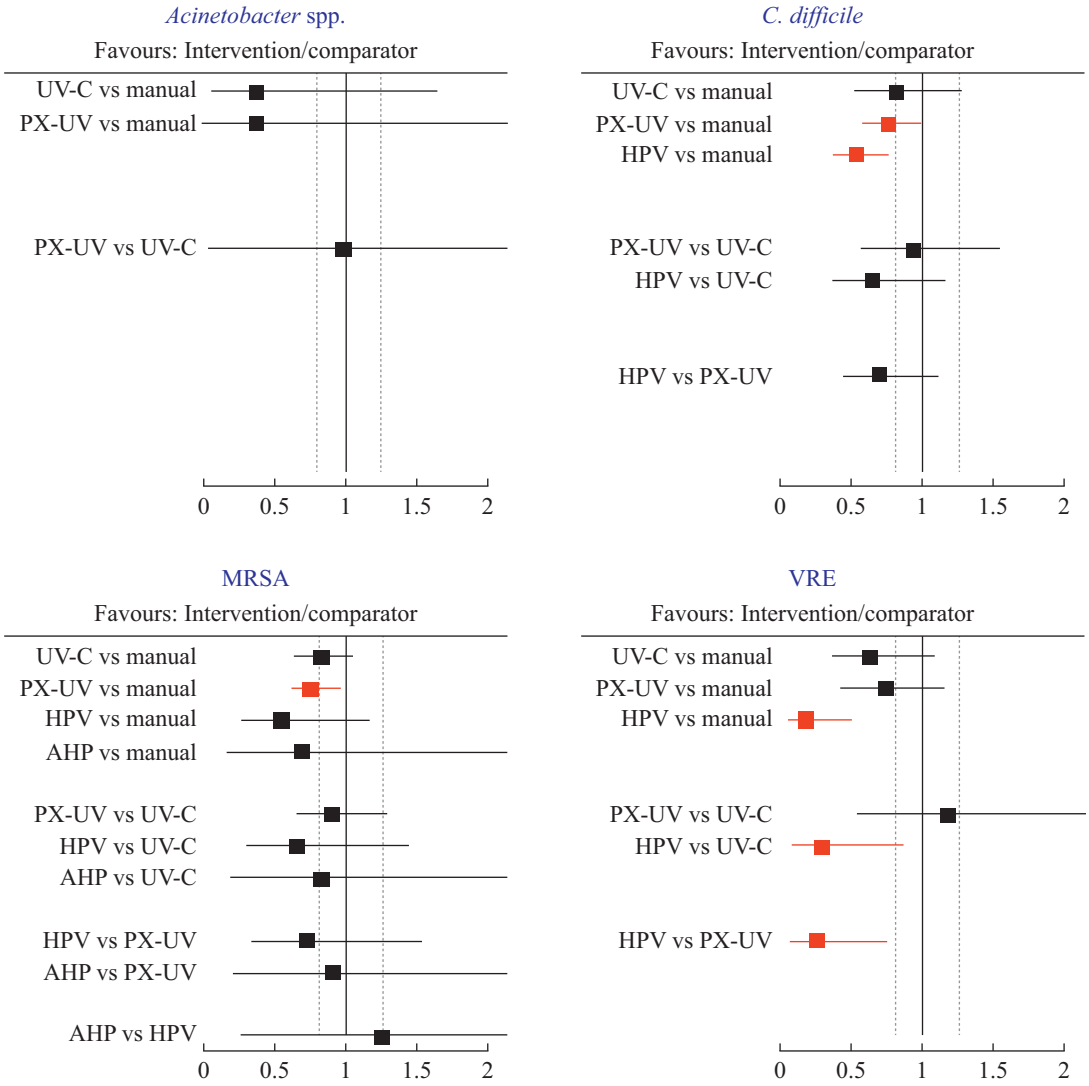

Figure 1. Forest plots for network meta-analysis of the clinical outcomes of infection or acquisition. IRRs with 95% CrIs that do not cross the line of no effect (IRR = 1) shown in red; upper limits of 95% CrIs truncated at ~2 (see Appendix H for exact results); dashed vertical lines show thresholds for defining imprecision (IRR = 0.8 and IRR = 1.25). AHP, aerosolized hydrogen peroxide; CrI, credible interval; HPV, hydrogen peroxide vapour; IRR, incidence rate ratio; MRSA, meticillin-resistant *Staphylococcus aureus*; PX-UV, pulsed-xenon ultraviolet; UV-C, ultraviolet C; VRE, vancomycin-resistant enterococcus.

GRADE tables

A separate GRADE table was constructed for each type of evidence identified for the clinical outcomes of infection or acquisition. Thus, GRADE tables were produced for infection or acquisition due to the specific micro-organisms *Acinetobacter* spp., *C. difficile*, *Klebsiella pneumoniae*, MRSA, *Pseudomonas aeruginosa*, *Stenotrophomonas maltophilia*, and VRE (see Tables I.1, I.2, I.3, I.4, I.5, I.6 and I.7, respectively) and for the groups of micro-organisms Enterobacterales (including extended-spectrum β-lactamase-producing (ESBL) Enterobacterales see Table I.8), multidrug-resistant Gram-negative rods (MDR-GNR; see Table I.9), extended-spectrum β-lactamase-producing Gram-negative bacteria (ESBL-GNB; see Table I.10), and multidrug-resistant Gram-negative bacteria (MDR-GNB; see Table I.11). The GRADE tables related to infection or acquisition due to specific micro-organisms refer to NMA results where relevant. Further GRADE tables summarize evidence for surgical site infection (see Table I.12), device-associated infection (CAUTI, CLABSI, and ventilator-associated pneumonia; see Table I.13), and infection of specific body organs or systems (enteric infection, respiratory infection, skin and soft tissue infections, and urinary tract infection (UTI); see Table I.14).

All the evidence was assigned an overall quality rating of very low or low. Frequently occurring reasons for downgrading the quality of individual outcomes were serious risk of bias (as identified through the methodological quality assessments based on study design referred to above) and serious (or very serious) imprecision (where 95% CrIs or CIs for relative treatment effects such as IRRs or odds ratios (ORs) crossed one (or both) prespecified thresholds of 0.8 and 1.25).

Evidence statements

Acinetobacter spp. infection or acquisition. There was weak evidence from an NMA based on a controlled trial [8], a controlled before–after study [28] and two uncontrolled before–after studies [32,35] that using UV-C or PX-UV in addition to manual cleaning/disinfection might reduce the incidence of *Acinetobacter* spp. infection or acquisition in subsequent patients compared with manual cleaning/disinfection alone. However, the reductions were not statistically significant, nor was the difference in effectiveness between UV-C and PX-UV (UV-C versus manual cleaning/disinfection, IRR = 0.376 (95% CrI 0.068 to 1.638); PX-UV versus manual cleaning/disinfection, IRR = 0.370 (95% CrI 0.023 to 5.755); PX-UV versus UV-C, IRR = 0.987 (95% CrI 0.046 to 26.310)). Treatment rankings (from best to worst) based on SUCRA scores were as follows: UV-C (SUCRA = 36%); PX-UV (SUCRA = 34%); and manual cleaning/disinfection (SUCRA = 11%).

Clostridioides difficile infection or acquisition. There was moderate evidence from an NMA based on two controlled trials [8,12], two controlled before–after studies [33,37], three interrupted time series [13,24,34], and 11 uncontrolled before–after studies [10,11,16,17,19,22,23,25,26,32,39] that using UV-C, PX-UV or HPV in addition to manual cleaning/disinfection reduced the incidence of *C. difficile* infection compared with manual cleaning/disinfection alone (UV-C versus manual cleaning/disinfection, IRR = 0.822 (95% CrI 0.525 to 1.258); PX-UV versus manual cleaning/disinfection, IRR = 0.761 (95% CrI 0.571 to 0.972); HPV versus manual cleaning/disinfection, IRR = 0.532 (95% CrI 0.372 to 0.755); PX-UV versus UV-C, IRR = 0.925 (95% CrI 0.553 to 1.531); HPV versus UV-C, IRR = 0.646 (95% CrI 0.373 to 1.145); HPV versus PX-UV, IRR = 0.699 (95% CrI 0.458 to 1.108)). Treatment rankings (from best to worst) based on SUCRA scores were as follows: HPV (SUCRA = 72%); PX-UV (SUCRA = 42%); UV-C (SUCRA = 32%); and manual cleaning/disinfection (SUCRA = 6%).

There was inconsistent evidence regarding *C. difficile* infection from an interrupted time series [29] comparing UV-C at every terminal discharge to UV-C only at terminal discharge of patients with *C. difficile* infection. In a bone marrow transplant unit, using UV-C at every terminal discharge reduced the baseline incidence of *C. difficile* infection and slowed the rate of increase over time compared with using UV-C only at terminal discharge of patients with *C. difficile* infection. The change in baseline incidence was statistically significant, but not the change in the rate of increase over time (segmented regression change in intercept, $P = 0.044$; change in slope, $P = 0.417$).

Klebsiella pneumoniae infection or acquisition. There was weak evidence regarding *K. pneumoniae* infection from two uncontrolled before–after studies [32,35] comparing UV-C to manual cleaning/disinfection. There were no statistically significant differences between UV-C and manual cleaning/disinfection.

Meticillin-resistant Staphylococcus aureus infection or acquisition. There was weak evidence from an NMA based on two controlled trials [8,12], three controlled before–after studies [20,28,33], an interrupted time series [27], and six uncontrolled before–after studies [16,17,19,32,35,39] that using UV-C, PX-UV, HPV, or AHP in addition to manual cleaning/disinfection reduced the incidence of MRSA infection or acquisition compared with manual cleaning/disinfection alone. The reduction was statistically significant with PX-UV, but not with UV-C, HPV, or AHP, nor when comparing differences in effectiveness between UV-C, PX-UV, HPV, and AHP (UV-C versus manual cleaning/disinfection, IRR = 0.838 (95% CrI 0.656 to 1.052); PX-UV versus manual cleaning/disinfection, IRR = 0.760 (95% CrI 0.621 to 0.966); HPV versus manual cleaning/disinfection, IRR = 0.554 (95% CrI 0.272 to 1.150); AHP versus manual cleaning/disinfection, IRR = 0.701 (95% CrI 0.170 to 2.677). Treatment rankings (from best to worst) based on SUCRA scores were as follows: HPV (SUCRA = 81%); PX-UV (SUCRA = 60%); AHP (SUCRA = 56%); UV-C (SUCRA = 44%); and manual cleaning/disinfection (SUCRA = 11%).

Pseudomonas aeruginosa infection or acquisition. There was moderate evidence from an uncontrolled before–after study [35] that using UV-C in addition to manual cleaning/disinfection did not significantly reduce the incidence of *P. aeruginosa* infection compared with manual cleaning/disinfection alone (IRR = 0.871 (95% CI 0.634 to 1.197)).

There was weak evidence from an uncontrolled before–after study [16] that using PX-UV in addition to manual cleaning/disinfection did not significantly reduce the incidence of multidrug-resistant *P. aeruginosa* acquisition compared with manual cleaning/disinfection alone (IRR = 0.670 (95% CI 0.032 to 13.947)).

Stenotrophomonas maltophilia infection or acquisition. There was weak evidence from an uncontrolled before–after study [16] that using PX-UV in addition to manual cleaning/

disinfection did not significantly change the incidence of *S. maltophilia* acquisition compared with manual cleaning/disinfection alone (IRR = 2.511 (95% CI 0.562 to 11.218)).

Vancomycin-resistant enterococcus infection or acquisition. There was moderate evidence from an NMA based on two controlled trials [8,12], two controlled before–after studies [33,37], an interrupted time series [13], and five uncontrolled before–after studies [17,19,32,35,39] that using UV-C, PX-UV or HPV in addition to manual cleaning/disinfection reduced the incidence of VRE infection or acquisition compared with manual cleaning/disinfection alone. The reduction was statistically significant with HPV, but not with UV-C or PX-UV; HPV also reduced the incidence of VRE infection or acquisition compared with UV-C and PX-UV and these reductions were statistically significant (UV-C versus manual cleaning/disinfection, IRR = 0.626 (95% CrI 0.376 to 1.075); PX-UV versus manual cleaning/disinfection, IRR = 0.740 (95% CrI 0.427 to 1.139); HPV versus manual cleaning/disinfection, IRR = 0.180 (95% CrI 0.060 to 0.482)). Treatment rankings (from best to worst) based on SUCRA scores were as follows: HPV (SUCRA = 74%); UV-C (SUCRA = 42%); PX-UV (SUCRA = 31%); and manual cleaning/disinfection (SUCRA = 3%).

Enterobacterales infection or acquisition. There was weak evidence from an uncontrolled before–after study [16] that using PX-UV in addition to manual cleaning/disinfection did not significantly change the incidence of ESBL Enterobacterales acquisition compared with manual cleaning/disinfection alone (IRR = 1.674 (95% CI 0.152 to 18.460)).

Multidrug-resistant Gram-negative rod infection or acquisition. There was weak evidence from an uncontrolled before–after study [16] that using PX-UV in addition to manual cleaning/disinfection did not significantly change the incidence of MDR-GNR acquisition compared with manual cleaning/disinfection alone (IRR = 1.674 (95% CI 0.504 to 5.559)).

There was weak evidence from a controlled before–after study [33] that using HPV in addition to manual cleaning/disinfection did not significantly change the incidence of MDR-GNR acquisition compared with manual cleaning/disinfection alone (IRR = 0.715 (95% CI 0.307 to 1.667)).

Extended-spectrum β-lactamase-producing Gram-negative bacterial infection or acquisition. There was moderate evidence from an uncontrolled before–after study [19] that using HPV in addition to manual cleaning/disinfection reduced the incidence of ESBL-GNB acquisition compared with manual cleaning/disinfection alone. The reduction was statistically significant (IRR = 0.063 (95% CI 0.008 to 0.500)).

Multidrug-resistant Gram-negative bacterial infection or acquisition. There was moderate evidence from an uncontrolled before–after study [17] that using PX-UV in addition to manual cleaning/disinfection reduced the incidence of MDR-GNB acquisition compared with manual cleaning/disinfection alone. The reduction was statistically significant (IRR = 0.81 (95% CI 0.66 to 0.98)).

Surgical site infection. There was inconsistent evidence regarding surgical site infection from an uncontrolled before–after study [14] comparing PX-UV to manual cleaning/disinfection. Among class 1 (clean wound) surgical procedures, using PX-UV in addition to manual cleaning/disinfection reduced the incidence of surgical site infection. The reduction was statistically significant (IRR = 0.553 (95% CI 0.334 to 0.918)). However, among class 2 (clean contaminated wound) procedures, using PX-UV in addition to manual cleaning/disinfection increased the incidence of surgical site infection. The increase was not statistically significant (IRR = 1.230 (95% CI 0.632 to 2.393)).

There was moderate evidence from a controlled before–after study [30] that using visible (indigo and white) light in addition to manual cleaning/disinfection reduced the incidence of surgical site infection compared with manual cleaning/disinfection alone. The reduction was statistically significant (adjusted OR = 0.22 (95% CI 0.05 to 0.90)).

Device-associated infection. There was weak evidence regarding device-associated infection from an uncontrolled before–after study [16]. Using PX-UV in addition to manual cleaning/disinfection, there was no statistically significant change in the incidence of CAUTI or CLABSI compared with manual cleaning/disinfection alone ($P = 0.23$ and $P = 0.20$, respectively).

There was weak evidence regarding CLABSI from an interrupted time series [29] comparing UV-C at every terminal discharge to UV-C only at terminal discharge of patients with *C. difficile* infection. In a bone marrow transplant unit, using UV-C at every terminal discharge reduced the baseline incidence of CLABSI and slowed the rate of increase over time compared with using UV-C only at terminal discharge of patients with *C. difficile* infection. The change in baseline incidence was statistically significant, but not the change in the rate of increase over time (segmented regression change in intercept, $P = 0.048$ and change in slope, $P = 0.204$).

There was weak evidence regarding ventilator-associated pneumonia from an uncontrolled before–after study [16]. Using PX-UV in addition to manual cleaning/disinfection, there was no statistically significant change in the incidence of ventilator-associated pneumonia compared with manual cleaning/disinfection alone ($P = 0.12$).

Infection of specific body organs or systems. There was weak evidence regarding infection of specific body organs or systems from an uncontrolled before–after study [21] comparing PX-UV to manual cleaning/disinfection. Using PX-UV in addition to manual cleaning/disinfection, there were no inferential analyses reported regarding the incidence of enteric infection compared with manual cleaning/disinfection alone. However, there were statistically significant differences in the incidence of respiratory system infections, skin and soft tissue infections, and UTIs ($P = 0.017$, $P = 0.014$, and $P = 0.014$, respectively).

There was weak evidence regarding respiratory viral infection from an interrupted time series [29] comparing UV-C at every terminal discharge to UV-C only at terminal discharge of patients with *C. difficile* infection. In a bone marrow transplant unit and an oncology unit, using UV-C at every terminal discharge did not significantly change the baseline incidence of respiratory viral infection or the rate of increase over time compared with using UV-C only at terminal discharge of patients with *C. difficile* infection.

Interpretation of the evidence

Outcomes that matter most. The Working Party focused on the clinical outcomes of infection or acquisition as these reflect the direct impact on patients in healthcare settings when exposed to microbiological environmental contamination. In many studies infection and acquisition were not distinguished, although all included studies that evaluated *C. difficile* reported infection as the clinical outcome. The Working Party included evidence regarding surgical site infection, device-associated infection and infection of specific body organs or systems while noting that this does not identify specific target micro-organisms.

Quality of the evidence. All the evidence was of very low or low quality, reflecting potential for bias in the design, analysis and reporting of individual studies, and in many cases imprecise estimates of treatment effects (as reflected by wide CrIs/CIs or those that crossed predetermined thresholds for precision). The Working Party emphasized the potential for bias when reporting study results in research funded by manufacturers of devices being evaluated.

One study evaluated the effectiveness of AHP compared with manual cleaning/disinfection [27], but AHP was used only in single-occupancy rooms while hydrogen peroxide was applied manually in shared rooms. The quality of the evidence from this study was, therefore, downgraded for indirectness; the consequence of the indirectness would be to dilute any real effect of AHP compared with manual cleaning/disinfection alone.

In accordance with the overall quality of the evidence, the Working Party formulated weak/conditional recommendations for practice (that is, starting with the verb 'consider').

Benefits and harms. The NMA results suggest that using the different forms of automated decontamination (UV-C, PX-UV, HPV and AHP) in addition to manual cleaning/disinfection have some benefits compared with manual cleaning/disinfection alone.

There was moderate evidence of benefit against *C. difficile* infection, with HPV and PX-UV having statistically significant effects; the effect of UV-C was also in the direction of benefit but was not statistically significant.

There was moderate evidence of benefit against VRE infection or acquisition, with HPV having a statistically significant effect; the effects of UV-C and PX-UV were also in the direction of benefit although not statistically significant. HPV was associated with statistically significant reductions in the incidence of VRE infection or acquisition compared with UV-C and PX-UV. This might reflect the persistence of VRE in clinical environments and the ability of HPV to reach all surfaces whereas UV light might be subject to shadowing effects, etc.

No evidence was identified in relation to the effectiveness of HPV when considering *Acinetobacter* spp. infection or acquisition. The evidence identified for *Acinetobacter* spp. was regarded as weak: the included studies were small and this resulted in effect estimates for UV-C and PX-UV being very imprecise and not statistically significant.

There was weak evidence of benefit against MRSA infection or acquisition, with PX-UV having a statistically significant effect; the effects of UV-C, HPV and AHP were also in the direction of benefit but were not statistically significant.

The Working Party's overall conclusion from the NMAs was that, where evidence was available, HPV was consistently most effective based on SUCRA scores; conversely, UV-C was generally the least effective of the automated approaches to decontamination, while still providing a marginal reduction in infection or acquisition of clinically relevant micro-organisms compared with manual cleaning/disinfection alone. The Working Party noted that the findings were consistent with in-vitro research demonstrating that ultraviolet light delivers a lower $\log_{10}$-kill rate than does hydrogen peroxide [61]. However, the bacterial load used in these studies far exceeds that likely to be encountered in the environment [51].

Most of the single-study analyses related to clinical outcomes with UV-C, PX-UV, or HPV, although one study evaluated the effectiveness of visible (indigo and white) light. The incidence of clinical events was reduced in some single-study reports, but the reductions were statistically significant in very few cases (for example, infection or acquisition due to ESBL-GNB, MDR-GNB and surgical site infection). A recent systematic review with 43 included articles found insufficient assessment of patient outcome because many were before–after studies and sponsored by industry; most were confounded by other infection control or audit interventions [62].

The Working Party emphasized that the theoretical superiority of HPV reflected the increased effectiveness in killing spores demonstrated in laboratory studies [61], but that practical considerations might outweigh the theoretical advantages, for example, room turnaround times and training of operational staff. Use of lower concentrations of hydrogen peroxide might be attractive in practice, as would use of an alternative automated decontamination method allowing rapid re-entry of patient rooms. These considerations are explored further in Sections Procuring an automated room decontamination device and Using an automated room decontamination device.

Cost-effectiveness and resource use. The implementation of automated decontamination devices to enhance terminal cleaning of patient rooms and other clinical areas will have a cost impact. The exact costs will be dependent on the particular type of device.

The cost consequences of healthcare-associated infection might be reduced using automated decontamination, particularly in elderly populations or clinical groups with weakened immune systems, and this might influence settings in which automated decontamination devices are recommended. Although the Working Party did not undertake a formal economic evaluation, the cost-effectiveness of automated decontamination is explored further in Section How cost-effective are automated room decontamination devices.

Other considerations. The Working Party highlighted the scarcity of evidence regarding the effectiveness of automated decontamination using AHP and visible (indigo and white) light. Although the literature searches were broad enough to identify clinical evidence related to high-intensity narrow-spectrum (HINS) light, steam, and ozone, no such evidence was identified.

The evidence for *Acinetobacter* spp. displayed moderate heterogeneity, possibly due to the clinical outcomes of infection or acquisition being defined somewhat differently across the included studies. By contrast, the definitions of *C. difficile*, MRSA, and VRE infections or acquisitions were more consistent across studies (see Appendix H for further details).

The evidence identified by the Working Party involved direct (head-to-head) comparisons only with manual cleaning/disinfection. Comparisons between different automated room decontamination devices were, therefore, made through indirect comparisons in the corresponding NMAs; the resulting effect estimates were subject to much uncertainty (as reflected in the GRADE imprecision domain). The study designs encountered in the evidence might reflect difficulties in implementing different automated decontamination systems in the same setting.

Recommendations. Consider use of an automated decontamination device as a supplement to manual cleaning in the context of rising or high prevalence of nosocomial infection, such as *C. difficile*, MRSA, or VRE.

Consider use of hydrogen peroxide vapour or pulsed-xenon ultraviolet light in room surface decontamination during an outbreak of *C. difficile* infection when other modalities have failed to reduce acquisition.

Procuring an automated room decontamination device

How cost effective are automated room decontamination devices?

The decision on which equipment to purchase or rent will depend on user needs, budget and service contract provisions. Contractors commonly have a preferred system, but the choice needs to be reviewed for effectiveness by the client. Cost is likely to be a key influencer, as well as the profile and reputation of the manufacturer. Some devices cost in excess of £50,000 to purchase outright from larger suppliers. Service contracts are an added cost but might often be attractive as the supplier company will risk assess use, train staff and include the cost of consumables. There is insufficient published information to recommend specific decontamination systems on the basis of cost savings due to reduced infections [62].

What are the considerations for the relative benefits of hiring versus buying a device?

The relative cost of purchase compared with lease should be investigated with prospective contractors. Options might include outright purchase, long-term hire or loan, rental or rental period with the option to purchase at the end. There may be benefits in terms of mitigating breakdown costs between the different purchase options. Differences between the different service options and related response times to breakdowns or repairs should be ascertained. The contractor should offer potential upgrades to the system as new developments occur but there may be additional costs best managed with a rental arrangement. However, in a hire or lease arrangement, there need to be adequate safeguards in place if the company goes into liquidation. The expected life-span of the equipment is an important consideration in the case of purchase.

Does the system come with guarantees, service agreements and recommendations on whether it requires recalibration, and, if so, the frequency of this?

In the procurement process, the lengths of time that standard guarantees can be extended should be determined with the associated costs. The breadth of the guarantee (parts, labour, manufacture fault and operator fault) should be ascertained. If there any disputes, the resolution process and the cover — for example, misuse by operators — is important. The published response time for callouts and supportive data on average response times is essential information during an outbreak or equipment failure. The requirements for the client when calling out an engineer must be clearly understood, particularly whether an order number is required to cover those items that might not be covered by a guarantee or warranty. The provisions for the replacement of faulty equipment must be agreed. The client will need to confirm the recommended period or number of uses after which the system should be recalibrated or checked by the provider and the associated cost.

What key information should be requested from the manufacturer?

Medical engineering, infection control, facilities management and procurement services should be consulted in all decisions regarding adoption of new devices as most information will be gathered by those departments as part of due diligence in the tendering process. All responsible suppliers/manufacturers should be able to provide the following information to the end user for any purchased system.

- Written instructions on the correct use of the system, including safety-related information on the storage and handling of any hazardous chemicals required for filling the machine.
- A full demonstration of the safe operation of the machine. A certificate for those receiving training should be provided as a record.
- Electrical safety information.
- Validation information relating to any known levels of efficacy of the system against defined groups of microorganisms. National standards will be available shortly (see https://standardsdevelopment.bsigroup.com/projects/2019-00332#/section).
- For the device, ease of use, quality control and functionality and reliability.

In the case of fumigants, the supplier should provide a monitoring device for end users to check residual levels of fumigant in treated areas prior to full room re-entry. Such monitors should be calibrated against the fumigant in use and should be accompanied by a calibration certificate. Premature entry by cleaning staff may result in adverse effects.

Regarding device maintenance and product life, the following should be established:

- whether maintenance and repair are undertaken by the supplier or a third party
- data showing the frequency of breakdown (on an annual basis) following purchase of equipment and itemized into the types of faults with the system
- availability and source of spare parts, and the timeframe for accessing spare parts
- whether the provider has systems in place for decontamination of any equipment or materials used in the maintenance of equipment during visits to other organizations
- the shelf life of any consumables used with the system and the length of time after manufacturing consumables are stored prior to shipping.

The proposed method of monitoring effectiveness should enable comparison between each treatment and should automatically record treatments carried out. The following information should be provided:

- the means of recording within the system and how data are transferred and to whom
- the security measures in place to safeguard any data
- the ease of use, required education of users, supply of training (users vary but may be dedicated staff from the supplier or client staff who have been trained in the use of the equipment)
- an operational manual for ongoing reference
- safety measures such as lock or tamper-proofing, physical or software setting of the system, adjustment of the programme for room size, recording of every operation and setting, means of monitoring any leakage from the room or to monitor the system while in use
- accessories supplied or recommended such as air vent covers, door seals, tape, hand-held hydrogen peroxide vapour gas monitors.

Room-sealing devices are essential for both fumigant and ultraviolet-light systems, with signage to warn patients and staff that an area or room is being treated. Monitoring devices to determine the level of active agent and any leakage are desirable. Accessories should be provided to allow the system to be transported easily.

What are the limitations of automated room decontamination devices?

Automated room decontamination can assist IPC activities within the hospital setting by adding assurance to existing cleaning/disinfection procedures. They can treat areas that might not otherwise receive regular cleaning attention, for example, the treatment of high-level surfaces and, using fumigants, undersides of furnishings [27,63].

In addition, when used at higher intensity, some of these systems might offer effective interventions during outbreaks, allowing hospital areas to be treated and returned to normal operational conditions more rapidly than might otherwise be possible. There is greater confidence in the standards of surface disinfection achieved [24].

Automated room decontamination systems are not designed to be used in isolation or as a standalone solution to hard surface disinfection of hospital ward and clinical treatment areas. Surfaces such as floors, tables, wash areas or toilets still require physical cleaning. This basic requirement removes organic soiling, making surfaces appear acceptably clean and facilitates a more effective fumigation process or permits better access of ultraviolet light. Biocidal processes using chemicals or ultraviolet light are more effective when associated organic soiling is removed or reduced. Due to toxicity, both hydrogen peroxide and ultraviolet systems are used in single patient rooms and not in shared ward bays. Although temporary single-bed enclosures have been tested, none has been widely adopted.

For systems using a fumigant, performance is affected by [63]:

- the size and sealability of the treated area — leaks may result in failure to maintain effective levels of fumigant in the decontamination process and threaten the safety of those potentially exposed in surrounding areas
- the type and levels of fumigant delivered into the treated area
- the physical nature of the gas, vapour, or aerosolization — for example, small droplets will only reach shadowed areas if the particles generated are small enough to be buoyant and to mix well in the treated room air; a truly gaseous product will not suffer such problems
- the nature of challenge micro-organisms (and concentration) that require eradication; for example, *C. difficile* spores are likely to be more difficult to kill than *P. aeruginosa* vegetative cells; however, some vegetative micro-organisms might be more resistant than spores due to physiological characteristics such as catalase production
- the presence of cold surfaces in rooms, such as outside windows and doors, might increase localized condensation of vapourized product, limiting deposition (micro-condensation) of fumigant on to other surfaces in the room
- some equipment in a treated area might be sensitive to the effects of raised chemical and moisture levels, limiting the areas of use — for example, avoiding microelectronics, mild steel, and porous surfaces such as wood and textiles
- presence of organic matter can reduce penetration of the fumigant or break it down.

Similarly, ultraviolet light systems have limitations, which include [63]:

- shadowing effects produced by surface soiling or furniture and room geometry
- reduced biocidal effect due to distance of the contaminant from the ultraviolet light source
- type and energy level of ultraviolet light delivered
- position and number of units used to treat the area (that is, triangulation and overlap effects of three systems enhance effectiveness)
- age of the units, which will affect the energy level of the ultraviolet light emission
- presence/absence of low-level light units which can influence floor-level energy delivery — a luminometer can be used for quality purposes as an independent measure
- penetration of glass might be uncertain.

Using an automated room decontamination device

What standard of manual cleaning/disinfection should be evident before using an automated device?

The use of automated decontamination equipment does not negate the need for physical cleaning of healthcare surfaces. When used alongside traditional (manual) cleaning/disinfection methods the two represent distinct but recognized hygiene approaches that seek to achieve the same endpoint — a safe, clean hospital environment. Both are generally used to deliver effective IPC [63].

The purpose of environmental cleaning is to remove debris and organic matter. For a fully effective physical process, a properly prepared environment, trained and competent staff, ergonomically designed equipment, and chemical contact are all required. The time taken to clean a patient room between successive occupations depends on the space, en-suite facilities, ventilator grills, radiators, and the general condition of

the area. Turnaround can be reduced by effective collaboration between clinical and domestic staff. A standard operating procedure detailing staff responsibilities will improve efficiency and set expectations of management.

A visual inspection undertaken jointly by clinical and domestic supervisors who are competent at inspections will ensure the standard is achieved consistently. Routine ward-based cleaning of solid surfaces, such as bed frames, bedside cabinets, over-bed tables and bathroom areas, is typically undertaken using approaches specified in national guidance. For example, in the UK, professionals should refer to National Standards of Healthcare Cleanliness 2021 [64] and the standard for providing a clean and safe hospital environment [65]. An initial physical cleaning step, using detergent and warm water, is followed in high-risk areas by wiping over the same areas with a disinfectant, either using disposable wipes or a freshly prepared solution of a chlorinated disinfectant.

The standard achieved by manual cleaning can be assessed by a rapid test for adenosine triphosphate (ATP), which is present in all organic material but not a direct measure of bacterial, viral, or sporal loading on a surface. Presence of ATP can be linked to improvements in training in cleaning processes and improving the cleanliness of surfaces.

Automated decontamination systems, whether chemical or ultraviolet light-based, are likely to work less effectively if surfaces are visibly dirty [61,63]. This is because, in the case of chemical fumigants, organic residues will react with micro-condensed disinfectant on material surfaces and might neutralize it, reducing its activity before it can impact on contaminating micro-organisms. Physical soiling can shield micro-organisms exposed to ultraviolet light, masking the contaminants from full exposure to the treatment and again reducing the beneficial impact. Treated surfaces should first be cleaned to maximize the enhanced hygiene offered by automated decontamination [63].

Good practice point

- Manual cleaning should be completed to the same high standard regardless of the subsequent use of automated cleaning devices.

Is there a potential risk of bacterial resistance to the decontamination method?

Fumigant automated decontamination systems may deliver: a true gas such as ozone or chlorine dioxide; heat-generated vapour (for example, hydrogen peroxide or formaldehyde); or cold-generated fogs or dry mists from aqueous liquid disinfectants such as hydrogen peroxide, quaternary ammonium compounds and peracetic acid [66–69]. The delivery system should ensure that the disinfectant chemicals reach the targeted area, with active agents typically designed to give a powerful oxidizing effect on pathogenic micro-organisms. This effect damages microbial cell structures, including cell membranes and internal cellular components such as nucleic acids. The levels of chemical delivery are high and even spores are not immune to most oxidizing treatments. Some protection might be conferred where micro-organisms are associated with high levels of organic soiling (for example, faeces or blood), but this should not occur if physical cleaning of surfaces has been undertaken. Penetration of any liquid contaminant is challenging for most fumigation systems. In addition, complex room structures/furnishings and tubular (hollow) objects limit fumigant ingress and result in reduced effectiveness.

Ultraviolet-based systems rely on energy delivery to surfaces, rather than chemical action, to disrupt target cells that lie within the line of sight of the treatment unit(s) [61]. All ultraviolet-based biocidal treatments are therefore limited by the amount of shadowing of surfaces intended for treatment. The evidence for successfully treating surfaces not in line of sight or for using methods of ultraviolet reflection under or around static objects remains mixed. As with fumigation delivery, any organic co-contaminants that confer physical protection to the micro-organisms will shield them from ultraviolet exposure, thus reducing the effectiveness of the treatment. The positioning of the emitters accounts for most differences in bactericidal efficacy between systems [55]. Physical cleaning therefore remains an important prerequisite to environmental decontamination involving ultraviolet-light treatment delivery.

What are the health and safety considerations of using automated room decontamination devices?

Automated room decontamination devices comprise fumigation systems and devices used to deliver biocidal ultraviolet light (UV-C and PX-UV). Most published research focuses on treatment efficacy, rather than safety. However, there are health and safety issues that require consideration prior to deploying the equipment.

The chemicals delivered by fumigation systems are harmful if exposure occurs during use. Products may be based on hydrogen peroxide, ozone, or chlorine dioxide. Hydrogen peroxide can be present as the only active substance or in combination with other components such as silver or peracetic acid. Systems delivering this chemical may achieve hydrogen peroxide concentrations of several hundred parts per million (ppm) in air, whereas the workplace exposure limit (WEL) for this chemical in the UK is just 1 ppm for long-term exposure and 2 ppm for short-term exposure [70,71]. Similarly, other widely used fumigants, such as ozone, have a low WEL (ozone = 0.2 ppm). The potential for harmful chemical exposure is, therefore, clear and should be controlled. The whole process should be risk assessed, with procedures in place to ensure the room is sealed to retain the fumigant, preventing room entry during treatment, monitoring for fumigant leaks during and after treatment, and effective fumigant removal and room aeration to complete the process. There is no justification for unnecessarily exposing staff or patients to harmful chemicals during fumigation treatments.

The availability of the correct gas monitoring equipment is crucial to ensuring appropriate measurements can be made during or after the treatment process [72]. These items typically cost a fraction of the price of the fumigation equipment and their use is central to safe working with any fumigant [70].

As with other forms of high-intensity light, biocidal ultraviolet light is potentially harmful and can damage the eyes and skin if they are exposed [73,74]. Ultraviolet-light carousels vary in terms of their energy delivery, but all are designed to cause cellular damage to micro-organisms and should, therefore, be used with control measures in place to prevent human exposure. As with fumigation systems, it is important to avoid entry of the area during treatment. Modern carousels may be fitted with motion sensors that immediately turn off the system if any motion is detected in the room. In addition, ultraviolet light

does not usually penetrate double-glazed windows, although any assumption that glass is protecting an observer outside the room should be checked with a light meter capable of measuring ultraviolet emissions between 100 and 280 nm. There have been anecdotal reports of some ultraviolet-light systems generating localized ozone around high-energy lamps, but this effect would need to be investigated if suspected. Ozone could, if present even at low residual levels after treatment, potentially cause respiratory irritation for those exposed.

Good practice point

— On first use of a fumigant or ultraviolet light in a specific room design, efficacy of sealing should be monitored to ensure safety.

How easy is the equipment to use, what standard of education are users expected to have, and what training and training materials are supplied?

The operation of earlier systems could be complex and sometimes required open handling of potentially harmful chemicals. However, in modern machine designs, disinfectants are often supplied in sealed or smart cartridges, or decanting of chemicals is minimized with use of protective gloves and eye protection [75].

The operational interfaces on both fumigation and ultraviolet-light systems may range between 'on—off' switch activation with a timer delay to allow staff to safely leave the room, to more complex touchscreen interfaces with multiple programmes. Regardless of the method, all systems should be provided with effective training from the supplier.

What indicators should trigger use of an automated device?

IPC teams in collaboration with domestic services will determine the appropriate use of hydrogen peroxide and ultraviolet light systems in addition to standard manual cleaning. The indication to use hydrogen peroxide, ultraviolet light or other systems in addition to manual cleaning will depend on the terms of the contract agreed with the suppliers, cost and availability of staff, as well as a risk assessment of the pathogenicity of the organisms that caused infection in the last occupant of the room. Prevalence of, or outbreaks due to, certain pathogens may be deemed higher priority for additional room disinfection by local IPC teams. Automated devices are not usually practicable in shared bays, unless the area is free of patients and staff and can be sealed. Where available, hydrogen peroxide cleaning may be used following discharge of patients with *C. difficile*, norovirus, multi-resistant organisms, such as acinetobacter, carbapenem-resistant Enterobacterales and tuberculosis, and viral haemorrhagic fever [33,51]. Turnaround times are usually between 3 and 4 h depending on local circumstances. An ultraviolet-light cleaning system may be used following occupation by a patient with norovirus or rotavirus, COVID-19, MRSA, *Streptococcus* group A, extended-spectrum β-lactamase producers, VRE and during outbreaks of infection not successfully managed by increased manual cleaning (or any of the above if hydrogen peroxide is not available) [8,9,55]. Turnaround times are shorter (1.5—2 h) but depend on local circumstances. In the absence of either fumigant or ultraviolet-light systems, a second manual clean can reduce environmental contamination and transient flora acquired on the hands of staff to a similar degree [76].

Good practice point

— Prioritize different cleaning systems to the type of infection of the most recent room occupant by use of a red/amber/green rating based on local nosocomial infection rates.

What are the requirements in terms of engineer audit and user audit?

Prior to any work commencing, it is important to audit the information provided with the device, which should include the engineering and calibration protocols/results that the generator has undergone, with any corrective measures.

Validation data should be generated to demonstrate that an effective cycle can be completed in each enclosure prior to the generator's use for decontamination. Biological indicators should be positioned around the enclosure and an effective fumigation process determined by the inactivation of the indicators. For validation purposes, the enclosure should be set up to replicate actual use, allowing optimization of cycle conditions before use in the target area. The room design and set-up should be as similar as possible to that intended for use, or a room in the target area temporarily set aside for the test. Usually a 3—5 $\log_{10}$ reduction in bacterial numbers is required in the healthcare environment [63]. As the devices provide disinfection — not sterilization — survival of some micro-organisms may be acceptable, provided any residual levels can be tolerated.

Data generated from the automated decontamination device can be used to document an effective cycle, preferably every time, together with surface cultures (before and after) or biological indicators if available (see Section How often should testing be performed?) [54,55,77]. Some devices provide a printout of the different parameters used during a cycle as a record to form part of audit to ensure that the decontamination process is effective and repeatable. Other devices provide real-time feedback on a display screen that can be checked against records to ensure that the correct parameters have been achieved. For devices that need to be inside the enclosure and do not have a visible display during operation, it is important to ensure that there is a method of accurately determining that a cycle has been completed successfully — for example, a download from the device to a computer to check that the cycle has been completed. All cycle-monitoring data should be adequately organized (by reporting date, location, cycle type, etc.) to allow processes to be audited. Some providers have maintenance audit and calibration checks within their contract with the client. Fumigant chemicals should be used within date and some smart systems may not accept out-of-date cartridges.

Can extra equipment be placed in the room during decontamination?

Any future standard fumigation or ultraviolet-light test is likely to avoid the placement of additional equipment or furnishings in the treated area, other than the fumigation machine and test coupons. In practice, other items such as furniture will be present and other equipment needing decontamination may be placed in the room [78]. The number of items should be controlled to a reasonable level following the supplier's advice. However, some items are difficult to disinfect because of their shape — for example, convoluted or tubular — or, if too many items are moved into the room, then

the surface area to treat may exceed the dose of fumigant supplied or in the case of UV-C result in excessive shadowing. For fumigant systems, porous materials will absorb the active agent and off-gas (see Section 8.3.8).

How does effectiveness of decontamination compare for hard and soft surfaces?

During automated chemical disinfection processes, porous materials should be removed from rooms for reasons related to effectiveness and safety. If common porous materials such as textiles, foams, and cardboard are left in a room they can absorb fumigant chemicals during treatment. These are released slowly afterwards, a process known as off-gassing. This phenomenon might influence fumigant performance on surfaces, with overall effectiveness becoming less certain than if all surfaces are non-porous. If all surfaces in a room are smooth and impervious, then this problem will be avoided because fumigant levels in the treated area will be more predictable [66]. Seemingly protected items such as foam-filled mattresses with waterproof covers might still absorb chemical fumigant via zip closure [79]. Foam-filled items are best removed from the room and treated separately with wet surface disinfectant.

Even when a fumigation system has a chemical removal step this might not remove all fumigant from porous materials. These can continue to off-gas chemicals beyond treatment completion and chemical levels might rise above WELs. For this reason, it is recommended that a portable sensor is used to check fumigant levels at the point of room re-entry, even when such levels are expected to be safe. In some situations, small 'pockets' of the fumigant may remain (for example, under solid surfaces, where aeration might not fully take place).

In contrast to fumigant chemicals, ultraviolet light does not penetrate porous surfaces such as sheets, upholstery and curtains. In addition, any shadowing effect caused by a material's porosity, shape, and softness is likely to inhibit the exposure of contaminants to the full ultraviolet dose [80,81]. This will in turn cause uncertainty in machine performance and would require site-specific validation to confirm that required microbiological kill is being achieved. There is no reason why softer or more porous materials cannot be left in a room being treated with ultraviolet light, but the success of the treatment would be dependent on the amount of light energy hitting exposed surfaces; harder, more even surfaces are always easier to treat with light-based technology.

Good practice point

- Remove foam materials from the room if fumigant is used unless sealed under an impervious cover.

How many times can the device be used in a room?

There is no imposed or recognized limit on how many times a device can be used in a particular room or treatment space. Multiple treatments would be expected, depending on the nature of the room's use. The room and its resident equipment should be able to tolerate the intended treatment, preferably be free from porous or absorbent materials, and any 'leaky' areas of the room should be sealed if fumigant chemicals are to be used. Losses might not only reduce the effectiveness of the treatment but might also allow the seepage of fumigant into sensitive areas outside the intended treatment location. Such considerations should be built into an appropriate risk assessment for the treatment of any room, healthcare or otherwise.

There are reports of certain types of fumigant chemicals damaging surfaces after only small numbers of treatments, and the powerful oxidizing effect of the chemicals is the most likely cause [82]. HPV and chlorine dioxide gas have been implicated especially because of their corrosive properties, especially when unwanted condensate pools on surfaces or inside sensitive equipment [83—85]. Consideration should also be given to seals around doors, utilities such as pipes and cables passing through walls, etc., where sealant or bespoke seals around these items will be required to contain fumigant chemicals. Such seals may deteriorate over multiple treatments, requiring examination and testing to ensure that no leaks have appeared in the fabric of the room. For non-specialized areas that are treated repeatedly, the risk is greater than in laboratories where the fabric of the room has been designed to tolerate such treatments.

Similar principles can be applied to ultraviolet-light treatments, in that multiple treatments can be delivered if required, but it should be confirmed that materials in a room can tolerate the energy delivery over time. Ultraviolet light would not be expected to have major cumulative effects on room infrastructure and integrity (wall and ceiling materials, seals around doors, windows, etc.), although some polymers (including some plastics) might be affected after prolonged exposure.

Does decontamination degrade room equipment?

There have been reports of equipment and surfaces being damaged by repeated automated disinfection treatments. Electronic equipment, stainless steel, powder-coated paint, anodized metals and enamelled surfaces have reportedly suffered damage. Metal corrosion, surface tarnishing, material colour 'bleaching' and enamel loss have all been described, with hydrogen peroxide and chlorine dioxide treatments implicated most frequently.

These effects have been an end-user concern since fumigation treatments became more commercially focused in the 1990s, and system suppliers have sought to demonstrate safety and reproducibility, publishing a number of articles to support their use with sensitive materials [84]. The potential for bias in such articles should, however, be considered, especially in terms of funding from or association with device manufacturers. Most chemical fumigation systems operate at relative humidity levels in excess of 65%, and this level of moisture alone might be incompatible with some types of complex electrical equipment [86]. Where high humidity meets cold surfaces, such as external walls and windows in a treated room, condensation can pool in a form that contains the concentrated active chemical [66]. This might in turn cause damage to paint work and some metals, particularly after repeated treatments [87].

For biocidal ultraviolet light, the rate and extent of any material degradation is also likely to relate to the levels of ultraviolet energy delivered, usually measured in Joules (J) or mJ/cm^2 of surface treated. Prolonged exposure has been associated with damage in endoscope storage facilities [88].

The compatibility of any surface materials or equipment should be discussed with the equipment suppliers prior to procurement or embarking on room treatments.

Are there any limitations on use of the active agent on some materials (including compatibility with equipment used in intensive care units)?

In areas where microelectronic circuitry is present, such as critical care equipment, there is potential for damage to metals and delicate circuit boards by the fumigant [84,86]. Proving that this will not occur requires validation and prior testing on similar equipment and may not be feasible. The integrity of plastic and rubber used in seals on or within equipment might be susceptible to degradation because of chemical exposure. If there is any doubt about the impact of fumigant chemicals on sensitive and important equipment, the automated device supplier should be consulted before any treatment is undertaken.

High-intensity ultraviolet light is less likely to damage internal electronic componentry but might affect surface finishes such as whitened PVC [88,89]. The flexibility of some softer materials such as sealants might also be affected, resulting in shrinkage and cracking. The extent of this damage will depend on the material composition, the intensity of ultraviolet energy delivery and the frequency of treatments. If there is any doubt, the automated device supplier should be consulted before any treatment is undertaken.

Good practice point

— After purchasing an ultraviolet-light decontamination system, consider the impact on surface finishes such as whitened PVC before purchasing other equipment, and ask the equipment supplier to confirm compatibility.

Do damaged surfaces need to be sealed before use of the device?

Normally impervious surfaces that already show signs of cracks, fissures, and flaking may be further damaged by fumigation. Surface imperfections can allow colonization by micro-organisms that avoid exposure to the active agent. Removal of damaged items from the area to be treated is advisable. Trying to seal off surfaces with plastic or tape will trap fumigant or the contamination.

For ultraviolet-light treatment, sealing of surfaces is not necessary and the problem relates more to the ability of light energy to penetrate a breach or depression in an otherwise smooth surface. Unevenness due to pitting and flaking is likely to cause small shadowing effects, which means that full ultraviolet energy delivery to the damaged region cannot be assumed.

Can a device be used in rooms with positive or negative pressure ventilation?

Under normal circumstances a ventilation system that maintains a positive or negative air pressure in a clinical workspace would be switched off during fumigation treatment. Most ventilation control is based on total air loss, that is, feeding air in and out of the room space at a pre-set flow rate to refresh and mix the air and achieve the required air flow and pressure conditions. The movement of air can rapidly dilute fumigant in the room and would reduce treatment effectiveness. In addition, a room maintained at positive pressure would be at higher risk of leaking toxic fumigant chemicals. Keeping the ventilation running and simply blocking off the vents could adversely affect air pressurization in other critical areas such as isolation rooms [90,91]. For these reasons, and to control the fumigation process, the room ventilation should be turned off during these procedures, unless a room air recirculation function is available.

For ultraviolet-light systems any air flow or air pressure changes should not undermine the performance of the light-based treatment, although if expected air pressure changes are well above or below ambient then it would be prudent to check with the equipment supplier to ensure no damage to the system electronics is likely.

What measurements are required when calculating the dose of active chemical for the room size? Is this carried out by the supplier/manufacturer or can the machine be programmed by the user?

Many modern automated fumigation systems have a user-control panel (touchscreen) or remote PC/tablet operation that allows the machine to be programmed with the required treatment conditions. The machine control software might already be pre-programmed with a variety of cycle conditions. Although different manufacturers take different approaches to machine set-up, the volume of the room to be treated is often the basis for calculating fumigant chemical delivery, with the machine automatically calculating the required dosage once these dimensions have been entered into the software. For some simpler and less expensive machines, where software programming might be absent, an 'on—off' approach is often used, with a set volume of liquid disinfectant added to the machine prior to treatment. The amount of disinfectant would typically be informed by the supplier, a user manual, or both. In the event of a purely gaseous product being used, such as ozone generated from ambient air, there is no requirement for liquid disinfectant calculations and the duration of delivery is again likely to be calculated from treated area volume. Before using any fumigation system, detailed advice should be sought from the supplier regarding the set-up and use of the system. This is likely to vary between different rooms, especially if room geometry varies. The cycle should be validated when used for the first time using representative micro-organisms if possible.

The amount of energy delivered by different ultraviolet-light devices is likely to vary and will be dependent on the energy output from ultraviolet-light units, the number of units present on the device, the number of devices used to treat a room and the distance of the ultraviolet-light emission system from the target surface. Detailed advice should be sought from the suppliers regarding the positioning and duration of use for these systems, which is likely to vary from room to room.

What is the cycle time?

The term 'cycle time' is often used to describe the time required for an automated decontamination device to go from start to finish of its treatment, at the point where staff and patients can safely re-enter the treated area.

For chemical systems this normally includes clearing and sealing of the room, followed by placement of the system in an agreed position and:

- a room air-conditioning step — where the room air might be treated in some way before delivery of the disinfectant (for example, reduction of humidity); this step is often absent for smaller devices

- the fumigant delivery step – where the fumigant is sprayed or pumped into the room: some systems will inject until a set point is reached; others will inject a certain volume of the fumigant
- the dwell or exposure time – where the fumigant chemical remains in the air, or is deposited on to surfaces, often mixed by the delivery system fan or some other means; some advanced systems will constantly 'top up' the fumigant levels during this period, to maximize treatment effectiveness
- the removal or aeration step – this might be an active chemical removal phase completed by the same machine that delivers the chemical or it might involve mechanical ventilation being reactivated to dilute and remove the chemical and promote its breakdown; indeed it might involve a suitably protected operator entering the treated area and opening external windows to facilitate natural aeration of the room (this option requires the use of appropriate personal protective equipment, namely respirator, skin and eye protection, and should be avoided if possible or used only as a last resort or emergency procedure).

Cycle times might vary from ~1 h to several hours, or even overnight, depending on the circumstances and the type of chemical in use. The aeration period may need to be extended due to incomplete removal of the fumigant from the room by the automated device in the time allowed, therefore it is necessary to monitor the level prior to entry with a calibrated handheld monitor.

For ultraviolet-light systems the cycle steps are far simpler and generally shorter. There are normally no chemical residues generated and so no requirement for a 'removal' step. Typical treatment steps would be:

- placement of the ultraviolet-light unit(s) in the room and covering of windows/closure of doors to prevent any risk of human exposure for those outside the treated area
- safe activation of the system once the room is clear of staff and patients; this is normally achieved using a timer delay of 1 min or more, to allow machine activation and then time for room clearing
- the delivery step – this typically lasts 15–30 min, but might involve stopping the system thereafter, relocating it and then repeating the treatment, to make sure all areas receive equal coverage
- room re-entry once the treatment is complete, removal of machines and re-occupation; most modern ultraviolet-light systems have motion sensors attached as a safety feature, such that the machine will shut down if any movement is detected in the room during treatment.

For a single-occupancy patient room of typical size, what is the time requirement for the process from completing manual cleaning/disinfection to being able to enter the room to set up for the next patient?

Following physical cleaning of a room, the duration of the fumigation process might vary considerably between systems and is influenced by the type of room [66,67]. To complete the full cycle time, 3–4 h may need to pass before a small side room of 40 m^3 can be safely re-entered (see Section When is it safe to go back into the room?) [90]. Consideration should be given to the use of a gas detector to ensure safe levels of fumigation are met before re-occupation; alternatively detailed calculations should be made with periodic testing to determine the time requirement. A longer period would be required for a large room or if the fumigant were difficult to clear (for example, due to unusual room geometry or because insufficient room aeration is available to clear the fumigant).

Good practice point

– Before purchasing or renting a system, run a mock decontamination cycle in a hospital room to determine turnaround times.

What is required to prepare a patient room or other clinical area for treatment?

For fumigation, where non-sealable treatment and clinical work areas are being fumigated, the following should be implemented:

- physical cleaning to remove dust and biological fluids
- removal of any porous materials, such as textiles, cardboard or paper; it is advisable to remove foam mattresses, even if they have waterproof covers, as some fumigants are extremely penetrative and might come out of the foam later; otherwise ensure that there are no cracks in the covering and that any zips are fully closed, leaving the mattress on its side to allow access to contaminated surfaces
- mechanical ventilation to the treated area should be switched off or at least vents covered
- ventilation inlet and exhaust vents should be occluded to prevent fumigant loss into ductwork; if poorly sealed there may be unsafe leakage to areas beyond the room to be treated and reduced fumigant levels within the room
- if a room has a false ceiling then care should be taken to ensure that fumigant is not trapped above it and that the fumigant cannot leak into upper floors via ceiling spaces; advice should be taken from equipment suppliers or other decontamination specialists to avoid risk of human exposure due to false ceilings
- the room should be sealed as far as possible around door gaps and windows; gas-impermeable tape should be used and normally obtained from the equipment supplier; waterproof duct tape is advisable for use but can leave residues on surfaces after removal; do not use gaffer tape
- a portable, accurate gas monitor should be available to the operator to check door seals periodically for leakage and to take corrective action if leakage is detected; the monitor can be used to assist safe room re-entry at the end of treatment
- the machine should be switched off from outside the room, either by remote control or by running the power lead outside the treated area; this gives the operator final control in the event of an emergency or unforeseen equipment failure.

For ultraviolet-light treatment of clinical areas the following should be implemented:

- any windows to the room should be covered to avoid exposure of those outside the room to ultraviolet light; this is strongly recommended even if the equipment supplier

indicates that the high-energy ultraviolet light cannot travel through glass
- the ultraviolet-light unit(s) should be positioned away from heat-sensitive objects and where maximum light delivery can be achieved over contaminated surfaces
- the machine should be switched off from outside the room, either by remote control or by running the power lead outside the treated area; as above, this gives the operator final control
- anyone re-entering the room should wear approved ultraviolet-light protective spectacles and opaque hand protection to avoid the risk of accidental exposure to the high-energy light; these should be removed only after the system is confirmed as having been powered down.

Can the wavelength of ultraviolet light or concentration of chemical be measured during use?

Calibrated hand-held meters are available for both chemical and light emission measurement. For fumigation systems these are important for safety reasons during room re-entry, to check that the air is clear, but otherwise are normally used only for experimental purposes when measuring the specific level of fumigant might be important (usually read as ppm or mg/m^3). Evidence for the success of any routine treatment is obtained either by placing bacterial indicators in the treated area to indicate biocidal kill, or by using before—after swab checks from treated surfaces if bacterial indicators cannot be used (for example, in hospital wards). However, levels of chemical fumigant or ultraviolet light are not a guarantee of overall treatment effectiveness. The ultimate indicator is the impact the treatment has on existing surface contaminants or on bacterial indicators placed strategically in the room.

Some automated decontamination systems provide real-time feedback regarding the concentration of fumigant chemicals in the room, but such measurements might not always be reliable because accuracy of electrochemical sensors can decline when exposed to high concentrations of chemicals.

Some light-based technologies record the amount of energy delivered per unit area of treated surface. Ultraviolet-light emissions are more usually measured using a portable ultraviolet light irradiance and exposure meter, which might be placed in a room during treatment to confirm energy delivered to different surfaces. Because ultraviolet-light systems are either on or off, and normally have a defined delivery period and no residual effects, light meters are not normally required for safe re-entry to the treated area.

Good practice point

— Monitor levels of fumigant or ultraviolet light at regular intervals during the contract to ensure efficacy.

When is it safe to go back into the room?

Automated room decontamination technologies are designed to kill microbial cell structures and as such the treatments are normally toxic or harmful to other life. For fumigation systems the chemicals used mostly have low WELs, some of less than 1 ppm [71,92], above which adverse health effects are likely to occur. Hydrogen peroxide, chlorine dioxide, ozone, quaternary ammonium compounds, peracetic acid and formaldehyde all fall into this harmful chemical classification and the silver added to some hydrogen peroxide products can have associated exposure risks, depending on its source. For oxidizing chemicals, the exposure effects can escalate from acute eye and throat irritation at levels just above the WEL, to major toxicity and permanent damage to the lungs and mucous membranes following exposure to high levels of fumigant. Any exposure should therefore be avoided.

Most of the above chemicals, with the exception of quaternary compounds, can be monitored using real-time calibrated hand-held monitors. The monitoring equipment should be used prior to fumigated room re-entry even if the equipment supplier states that the device can remove chemicals from treated areas at the end of cycles. This process is not always successful and is highly dependent on the size, design and contents of the area to be treated. Some service providers are prepared and equipped to re-enter rooms with full personal protective equipment, including respiratory protective equipment, to open external windows or to open air vents to aid aeration, but this is not recommended for other users.

For ultraviolet-light equipment, rooms should always be locked and re-entered only when light-emitting systems are switched off. Some systems have audible alarms or voice alerts when the cycle is completed and ideally these systems should be linked to motion sensors that are interlocked to the ultraviolet-light device and will switch it off if anyone enters the room.

Is a material safety data sheet available for the active agent?

Material safety data sheets (MSDSs) contain information for each of the chemical groups discussed in this report, although for quaternary ammonium compounds — a large group of related chemicals — the generic reference chemical is often benzalkonium chloride. An MSDS should always be provided by the automated decontamination device supplier and should be relevant to the chemicals that accompany their machine or should come from the disinfectant supplier if purchased separately. The MSDS contains all essential hazard and toxicity information about the active chemical and actions to be taken if exposure occurs; it thus provides important information that can be used to help prepare risk assessments for chemical handling. WEL information for most of the chemicals used is available from open, reliable sources such as the HSE website [92].

Equipment associated with ultraviolet-light emissions might also be accompanied by an MSDS or other technical information that describes the product and any known hazard. However, if the specific item does not contain hazardous substances or substances of very high concern as defined, for example, by European Community (EC) WELs, then an MSDS might not be legally required (under EC law).

Decision algorithm

A decision algorithm for procedures involving fumigation or ultraviolet light is presented in Figure 2. The advantages and disadvantages of different fumigants [1] should be used to guide the choice between them.

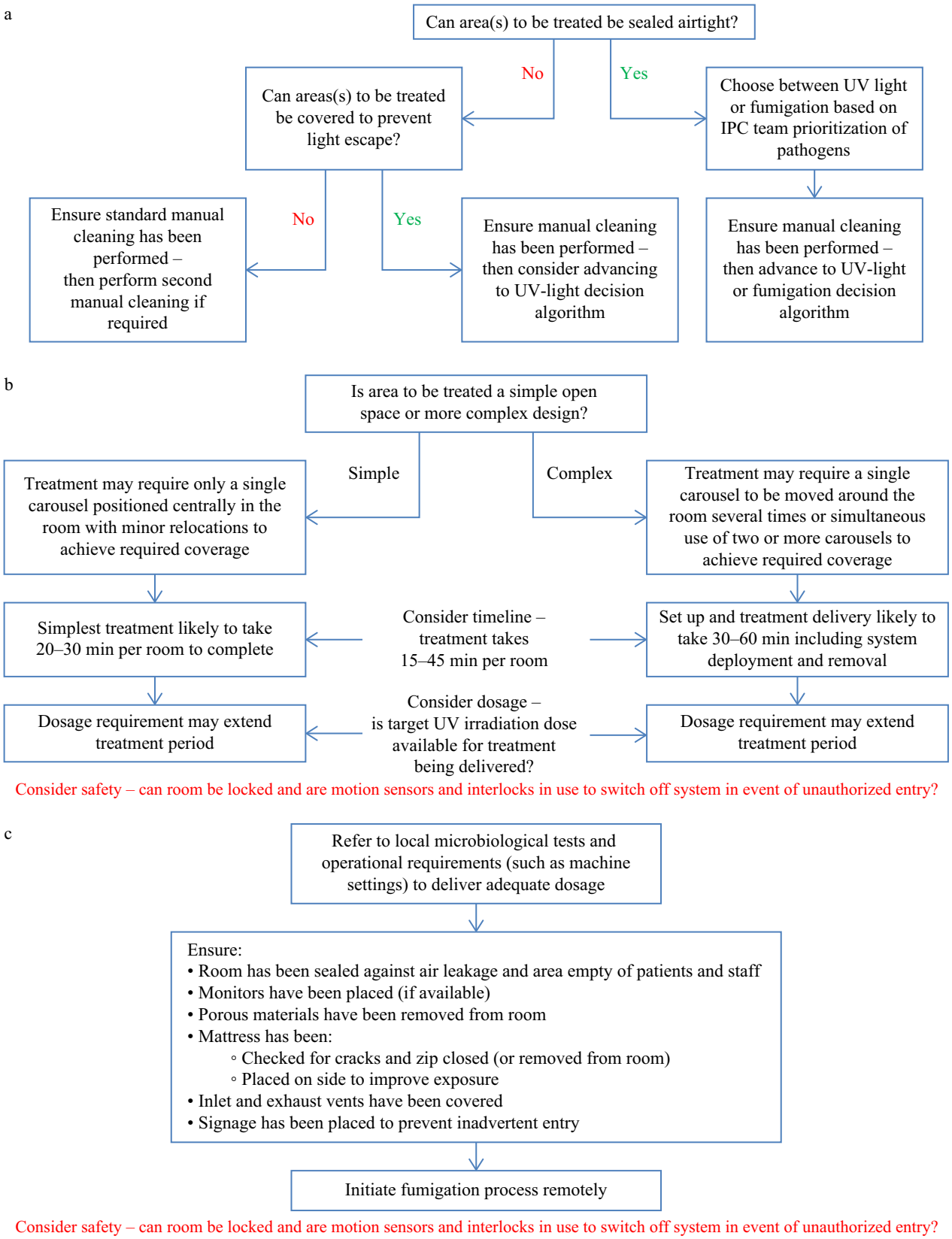

Figure 2. Decision algorithm for automated room decontamination systems. (a) Ultraviolet light versus fumigation. (b) Ultraviolet-light decision algorithm. (c) Fumigation decision algorithm. * IPC infection prevention and control; UV ultraviolet.

Microbiological testing

What is the effectiveness of the device against pathogens including spores?

Automated room decontamination devices are effective against a wide range of pathogens including spores, although differences exist between them (see Section Is there a potential risk of bacterial resistance to the decontamination method?). However, the chosen automated decontamination method should be tested within the area in which it is intended to be deployed, using a microbiological test challenge. Microbiological tests of detection of common pathogens can be used in practice as a measure but the use of $\log_{10}$ reductions in target micro-organisms is more informative, providing a better indication of equipment efficacy against a defined level of challenge.

What considerations are important in terms of bacterial colony count, target $\log_{10}$ reduction and cleanliness threshold definition?

Automated room decontamination devices are designed to reduce the bioburden on surfaces (or in room air), but do not guarantee eradication of micro-organisms [91,93]. Within the UK healthcare setting the desired $\log_{10}$ reduction in target micro-organisms — typically measured as colony forming units (cfu) — is normally a 3—5 $\log_{10}$ reduction for British and European Standards disinfection tests [55,80]. Further standards are due to be published shortly (see https://standardsdevelopment.bsigroup.com/projects/2019-00332#/section).

Because automated room decontamination devices are designed to be used alongside traditional (manual) cleaning/disinfection methods, the levels of microbiological environmental contamination present are unlikely to exceed 10^5 micro-organisms on a given surface area [94—97]. Some overseas authorities require hospital disinfectants to achieve at least a 6 $\log_{10}$ reduction of certain vegetative bacteria *in vitro*. This is clearly higher than the concentration typically found on hospital surfaces but may provide further assurance that the disinfectant will be effective even under the more unpredictable conditions of the real world [98]. For this reason, commercial spore challenges of 10^6 *Geobacillus stearothermophilus* per coupon, or alternatively coupons seeded with *Bacillus atrophaeus*, continue to be used as a measure of fumigation success [99]. The bacterial endospores of *G. stearothermophilus*, while not directly reflecting some contaminating agents found, are used as biological indicators because they provide a consistent and well-understood challenge for automated decontamination systems. They are easy to handle and process, and being in Tyvek pouches and growing at 60 °C helps to limit any potential contamination during handling. Testing against spores of *C. difficile*, without vegetative organisms, is preferable but more complex and restricted to research [100]. Contaminating micro-organisms are rarely seen in isolation and are usually associated with surface soiling. The physical soiling levels normally used for standard testing approaches might include the addition of milk powder or protein soilant such as bovine serum albumen (BSA). BSA would, for example, be typically added at high (0.3%) or low (0.03%) concentrations, depending on the test challenge requirement.

What considerations are important in terms of penetration of dry biofilm and environmental soil?

In the natural environment micro-organisms rarely exist in the absence of associated organic residues. Within the healthcare setting these residues might take the form of environmental dust, urine or faecal material or blood. These associated organic materials can protect harmful micro-organisms, inhibiting the access of disinfectant treatments [68,101]. For ultraviolet-light treatments heavy soiling that has not been physically cleaned away might shadow underlying surfaces, again limiting the effect of the delivered treatment. Disinfection test methods require the addition of organic soil to make the test more realistic. The soil is usually added to test micro-organisms in the form of animal protein (albumin) or milk residues, to simulate organic soil in the real-world healthcare setting. Once dried down with test micro-organisms on the surface of test carriers these residues can present a dried 'film' that can be a difficult challenge for automated decontamination procedures [55].

What are the essential requirements for a microbiological test to establish effectiveness in the clinical environment?

Laboratory tests might have been used to support the claims for microbiological efficacy made by the manufacturer, but the user should conduct verification tests in their clinical environment.

There are two options for testing. The first involves using a swab or sponge to sample defined areas such as mattress covers, tables and patient chairs within the clinical area where the system is to be used. Sampling should be before and after cleaning and after use of the automated decontamination device. This will give an indication of the efficacy of cleaning as well as the automated system [97]. A template could be used (for example, defined as an 5×5 cm^2 area) so that the results can be quantified rather than just recording presence/absence. The swab or sponge is placed in a defined volume of recovery medium (containing an appropriate neutralizer if required), vigorously agitated and defined volumes plated on to a nutrient media (for total viable counts) or a selective media (if a specific organism is being investigated).

The second option requires test carriers (for example, stainless steel discs or other representative materials found in the area to be treated) to be inoculated with specific test bacteria or bacterial spores. The addition of 0.03% albumin will mimic low soiling and is described in EN standards for assessing the efficacy of chemical disinfectants [55]. The culture is allowed to dry before placing in defined locations within the area to be treated. After processing, the carriers plus a control that has not been exposed are recovered and placed into a defined volume of recovery media and colonies counted after incubation. As a simpler, qualitative approach carriers can be recovered directly into appropriate culture broth and incubated to record presence/absence, rather than using quantitative culture methods.

The advantages and disadvantages of each option are summarized in Table II.

If the manufacturers of the automated decontamination device have previously validated the system with *G. stearothermophilus* or *B. atrophaeus* and claim efficacy against these spores then commercial spore strips are available for these tests.

Good practice point

— When adopting a new automated system or disinfecting a new room design, conduct microbiological culture tests (if

Table II
Options for microbiological testing of effectiveness of automated decontamination systems in clinical settings

Option	Procedure	Advantages	Disadvantages
1	Detection of naturally occurring contamination before and after the decontamination process	Relatively simple to carry out	The level of naturally occurring contamination detected might be unpredictable so difficult to express results as a $\log_{10}$ reduction
2	Using artificially contaminated carriers with defined numbers of specific micro-organisms	Allows for a $\log_{10}$ reduction in test micro-organisms to be assessed	Expertise on preparation of carriers might be required as these are not available commercially for all micro-organisms

permitted in the hospital) or take in-use environmental swab tests before and after disinfection to confirm efficacy.

How often should testing be performed?

It is advisable to perform testing in a variety of room sizes when the system is first commissioned or introduced, after any maintenance or servicing of the system and possibly, if used during an outbreak, to establish that the implicated micro-organism is being eradicated. Any change to the internal structure of regularly treated areas might also justify repeat validation. If the surface area within a room increases, more fumigant chemical would then be needed to deposit the same concentration of disinfectant on to all surfaces.

What checks are required to show dissemination of antimicrobial agents used in automated room decontamination devices (such as those required to show all surfaces have been treated adequately)?

This section is mainly relevant for fumigation systems, where contact of the antimicrobial agent with all surfaces is essential to ensure effectiveness of the system. It is advisable to use a chemical indicator test strip specific to the antimicrobial agent as proof of process every time the system is used. Chemical indicator strips are available for agents such as hydrogen peroxide which could be placed in defined locations within the area to be treated. Most available chemical indicators involve a colour change when the fumigant is in contact with the strip. The colour change will initiate on contact and might not be concentration dependent but will indicate that the agent has been in contact with target surfaces. Alternatively, dosimeters are available for some agents and could be used to establish distribution to hard-to-reach surfaces and the dose of the antimicrobial agent. Some gaseous decontamination generators will monitor the enclosure for the presence of the chemical fumigant when air is returned to the generator.

For ultraviolet-light systems, the main risk is shadowing, particularly in a room with furniture or a complex design. Meters and data logs are incorporated into some machines. Disposable indicators using photoactive ink are more convenient than radiometers [102]. The manufacturer/supplier of the system should provide recommendations/advice on the most suitable method to use for their system.

Further research

The Working Party identified the following as priorities for future research.

- Randomized multicentre comparative trials to determine relative effectiveness of different automated systems in preventing nosocomial infection or acquisition, including *C. difficile*, MRSA and multidrug-resistant Gram-negative pathogens.
- A randomized multicentre study comparing use of automated systems following one cycle of manual cleaning with two cycles of standard manual cleaning and no automated cleaning.
- Automated systems that can be used in patient bays without risk of toxicity to patients or staff.
- Economic evaluation of automated systems in terms of acquisition/leasing, repair, staffing, turnaround and monitoring in different healthcare environments.
- Cleaning agents for manual cleaning that show temporary colour to demonstrate areas missed by cleaners.
- Effects of repeated exposure of plastics used in the healthcare environment to chemical or ultraviolet-light disinfection.
- Measurement of residual levels of fumigant in different environments and ventilation rates, particularly in the presence of foam mattresses.
- Development of disposable tests to demonstrate efficacy against *C. difficile* spores rather than surrogates.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jhin.2022.01.006.

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