Health Protection Scotland

NHS National Services Scotland

Process Document: Existing and emerging technologies used for decontamination of the healthcare environment

Evidence Grading and Recommendations

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Evidence Grading

Health Protection Scotland (HPS) applies strict inclusion and exclusion criteria to select the research studies used to provide evidence for environmental decontamination technologies. Articles should have undergone a formal peer-review process to ensure that the necessary information (e.g. population characteristics, outcome measures) is reported. This process also ensures that sources of funding and potential conflicting interests are declared, and that original data are not being represented in a misleading format.

It is assumed that confirmation of a product meeting the required regulatory standards (e.g. BS EN ISO standards) will already have been demonstrated prior to testing within a clinical setting. Therefore, this type of evidence will not be considered by HPS when formulating clinical recommendations.

HPS uses a combination of two different systems for grading evidence relevant to environmental decontamination technologies: the Scottish Intercollegiate Guidelines Network (SIGN) 50 methodology[1] (Table 1), and a modified version of the McDonald-Arduino evidentiary hierarchy[2] (Table 2). Together, these two systems classify evidence on the basis of both study design (e.g. randomised controlled trial) and outcome measure (e.g. reduction in microbial bioburden). Such a combination allows the evidence to be graded on multiple parameters of quality.

Whereas SIGN **level 1** denotes the highest quality of evidence, it is in fact the inverse for the McDonald-Arduino hierarchy, in that **level V** that is the highest category. Accordingly, SIGN **level 4** and McDonald-Arduino **level I** indicate the poorest quality of evidence.

For example, a randomised controlled trial that demonstrated in-use bioburden reduction would be graded as SIGN **level 1** and McDonald-Arduino **level II**, while a before-and-after study that demonstrated reduced microbial pathogen acquisition in an outbreak setting would be graded as SIGN **level 3** and McDonald-Arduino **level IV**. A more patient-relevant outcome measure may therefore compensate for a less-than-ideal study design.

The novel intervention should be evaluated against a suitable comparison group, i.e. an environmental decontamination technology recommended by national guidelines for a given procedure in a given setting. For example, it is recommended in the NHSScotland National Infection Prevention and Control Manual[3] (NIPCM) that both routine and terminal decontamination of patient rooms under transmission-based precautions (i.e. patients isolated for communicable diseases such as *Clostridium difficile*) should involve the use of a detergent, followed by disinfection with a chlorine-releasing agent at a concentration of 1,000 parts per million (ppm) available chlorine. Similarly, the NIPCM recommends that both routine and terminal decontamination of patient rooms under standard infection control precautions (i.e. all patients without a communicable disease) should involve the use of a detergent without disinfection,

except for sanitary fittings which require disinfection with a chlorine-releasing agent at the above concentration.

Quaternary ammonium compound disinfectants or novel decontamination technologies (e.g. hydrogen peroxide spray) are therefore **not** considered suitable comparison groups – studies using these technologies as comparison groups would typically be excluded from HPS literature reviews. Likewise, studies comparing new technologies against a chlorine-releasing agent at a concentration considerably above or below 1,000 ppm available chlorine would be excluded.

Importantly, a study that evaluated the use of a novel technology against a detergent (without use of a disinfectant) could still provide evidence of effectiveness for use under standard infection control precautions, but not transmission-based precautions. Such a study would be included within a HPS literature review, although it would only contribute to the recommendations for specific uses of that technology.

Table 1: The Scottish Intercollegiate Guidelines Network (SIGN) 50 methodology for assigning levels of evidence.

SIGN 50 Evidence Grading		
Level of Evidence		Description
1	++	High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
	+	Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
	-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2	++	High-quality systematic reviews of case-control or cohort studies High-quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
	+	Well-conducted case-control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
	-	Case-control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3		Analytic studies without a concurrent comparison group, e.g. before-and-after studies, interrupted time series Non-analytic studies, e.g. case reports, case series
4		Expert opinion, e.g. editorial commentaries, guidelines without a clear methodology

Table 2: The McDonald-Arduino evidentiary hierarchy for assigning levels of evidence.

McDonald-Arduino Hierarchy	
Level of Evidence	Description
V	Demonstration of reduced microbial pathogen acquisition (colonisation or infection) by patients via **non-outbreak** surveillance testing and clinical incidence
	Studies conducted in non-outbreak scenarios that provide evidence of reduced microbial pathogen acquisition by patients offer the highest quality evidence to support new technologies. Any difference between colonisation and infection rates is **not** indicative of environmental contamination levels, but may imply variability in host resistance to the infectious agent.
IV	Demonstration of reduced microbial pathogen acquisition (colonisation or infection) by patients via **outbreak** surveillance testing and clinical incidence
	Studies conducted in outbreak scenarios are limited by the observation that microbial pathogen acquisition will inevitably decrease over time, as a consequence of regression towards the mean. Similarly, the emergence of an outbreak stimulates greater surveillance testing, leading to an artificial increase in acquisition rates after the outbreak has been recognised. Typically the data collected before initiation of the outbreak is less comprehensive than the data subsequently collected.
III	Demonstration of in-use bioburden reduction that may be clinically relevant
	For example, this might include a reduction in hand contamination of healthcare workers. This indicates that healthcare workers' hands are less likely to be transiently colonised by microbial pathogens through contact with the patient care environment. Clinical relevance implies that not only is there a reduction of in-use bioburden, but there is also an accompanying reduction in pathogen transmission.
II	Demonstration of in-use bioburden reduction effectiveness
	This requires environmental sampling within the healthcare environment. Typically measured as the reduction in colony-forming units (CFUs) when using culture methods, or relative light units (RLUs) when using ATP bioluminescence. Unlike microbial colony counts, ATP bioluminescence measures organic material rather than viable micro-organisms and is therefore less specific. In-use testing indicates whether a technology will continue to be effective under non-ideal circumstances outside of the laboratory setting.
I	Laboratory demonstration of bioburden reduction efficacy
	Typically measured in $\log_{10}$ reductions, e.g. 3 $\log_{10}$ reduction = 99.9% reduction in microbial colony count. However, $\log_{10}$ reductions are relative values rather than absolute values – unless baseline levels of contamination are comparable, they cannot inform as to whether one technology is more effective than another. A control group is therefore essential under these circumstances.

Recommendations

SIGN amended their grading system for recommendations in 2013; however, HPS continues to use the SIGN 50 (1999-2012) ABCD system[1] (Table 3) for grading recommendations as this is more suitable for the types of evidence underpinning the recommendations of HPS literature reviews and is more fully understood by our stakeholders.

Grades of recommendation are initially derived from the SIGN levels of evidence, as outlined in Table 3. However, considered judgement of the evidence is undertaken, with the consequence that the grade of recommendation may be upgraded or downgraded on the basis of the McDonald-Arduino hierarchy. For example, a body of applicable and consistent evidence including studies rated as **level 2+** might be accorded a **grade D**, rather than a **grade C**, if the studies were entirely laboratory-based instead of being conducted in a clinical setting.

Due to the nature of the extant professional literature on decontamination technologies, the appraisal of evidence often yields a SIGN ranking of **grade C**, **grade D**, or **GPP (Good Practice Point)**. In part this is due to ethical restrictions which prevent randomised clinical trials or other types of quantitative research being conducted on certain aspects of decontamination, especially in relation to disease outbreaks. Furthermore, decontamination technologies are often trialled in a multi-interventional format – resulting in it not being possible to assess the efficacy of any single intervention.

Despite this, these lower grades do not necessarily mean that the recommendation is weak. Instead, it highlights that it is not possible for the review to make definitive recommendations based on high-level evidence because there is a paucity of such research. All literature reviews are subject to assessment by a representative panel of experts and subject specialists; therefore, final recommendations also take into account existing best professional practice.

Following assessment of the extant scientific literature, evidence tables are compiled summarising each item and discussing its impact on/contribution to the specified topic area. Evidence tables are used in conjunction with the SIGN 50 considered judgement form to synthesise and draft recommendations based on the volume, consistency and applicability of the available evidence. Following a period of consultation, final recommendations are agreed by consensus; if consensus is not reached, a final decision is taken to a vote overseen by the chair.

Table 3: The Scottish Intercollegiate Guidelines Network (SIGN) 50 methodology for assigning grades of recommendation.

SIGN 50 Recommendation Grading	
Grade of Recommendation	Description
A	At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; *or*
	A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*
	Extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; *or*
	Extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4; *or*
	Extrapolated evidence from studies rated as 2+
Good Practice Point (GPP)	Recommended best practice based on the clinical experience of the guideline development group

References

Scottish Intercollegiate Guidelines Network. SIGN 50: A Guideline Developer's Handbook. Accessed: 30/06/2017.
http://www.sign.ac.uk/

McDonald LC and Arduino M. Climbing the evidentiary hierarchy for environmental infection control. Clinical Infectious Diseases 2013;56(1):36–9.

NHS National Services Scotland. National Infection Prevention and Control Manual. Accessed: 30/06/2017.
http://www.nipcm.hps.scot.nhs.uk/