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Nonsterile Glove Use

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Abbreviations

HCW health care worker
LOI late-onset infection

MRSA methicillin-resistant Staphylococcus aureus

NICU neonatal intensive care unit

NSG nonsterile glove

RCT randomized controlled trial

SR systematic review

VRE vancomycin-resistant enterococci



Key Messages

- In acute care settings with low-risk of infection transmission, discontinuing contact precautions (i.e., gloves and gown) may result in similar rates of hospital-acquired methicillin-resistant Staphylococcus aureus (MRSA) and may lower the risk of hospital-acquired vancomycin-resistant enterococci (VRE), compared to scenarios in which such precautions were employed.
- Rates of late-onset infections in a neonatal intensive care unit were similar when standard infection control precautions were used compared with universal glove use.
- Two guidelines recommend that nonsterile gloves should be worn for nonsterile procedures when it
 is anticipated that there will be contact with blood, body fluids, non-intact skin, mucous membranes,
 lesions, or hazardous drugs and chemicals; for environmental cleaning; and when contact
 precautions for infection control are in effect.

Context and Policy Issues

The use of nonsterile gloves (NSGs) reduces the risk of contamination of hands of health care workers (HCWs) after patient contact^{1,2} and, presumably, the transmission of pathogens between patients. Canadian clinical practice guidelines recommend the use of gloves when contact with body fluids is anticipated and when contact precautions are in place for a patient who has tested positive for a pathogen requiring such precautions.³ Gloves should be changed between patient contacts and hand hygiene should be performed before putting on gloves and immediately after removing gloves.³

While glove use is necessary to prevent cross-contamination and transmission of pathogens in many acute care settings and situations, excess glove use contributes to increased medical waste and environmental contamination, which has been exacerbated by the COVID-19 pandemic.⁴⁻⁶ Using gloves when it is not indicated can occur in up to 50% of patient contacts and such use can lead to missed opportunities for hand hygiene, potentially resulting in cross-contamination.⁷⁻⁹ Inappropriate use of gloves combined with inadequate hand hygiene after use may result in the transmission of pathogens to the patient via gloved hands.⁹ Contaminated NSGs have been associated with a hospital-wide outbreak of *Paenibacillus spp* pseudobacteremia,¹⁰ suggesting that even unused gloves can become contaminated. Unnecessary glove use in this type of scenario may result in harm to patients that may not otherwise occur.

Occupational skin disease in HCWs is common and has been associated with occupational "wet work" including repetitive handwashing and the use of disposable gloves. 11-13 The rate of skin disease related to personal protective equipment such as gloves has been reported as almost doubled in HCWs compared with non-HCWs. 11

Recent calls to reduce NSG use cite overuse and consequent cost implications, occupational skin disease, medical waste, and environmental contamination as rationale for advocating appropriate glove use. 14,15 While NSGs are indicated in many health care settings, it is important to determine the appropriate circumstances for the use and non-use of NSGs to develop effective education campaigns.



The objective of this report is to evaluate and summarize the evidence for the effectiveness of non-use of NSGs in inpatient settings compared with use of NSGs during activities with low risk of infection transmission. The report will describe the manner in which NSG use can impact patient outcomes, which may help to inform future initiatives aiming to reduce overuse of NSGs.

Research Questions

- 1. What is the clinical effectiveness of non-use versus use of nonsterile gloves for individuals receiving inpatient care considered at low risk of infection transmission?
- 2. What are the evidence-based guidelines regarding the use of nonsterile gloves for individuals receiving inpatient care considered at low risk of infection transmission?

Methods

Literature Search Methods

An information specialist conducted a literature search on key resources including MEDLINE, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), the Cochrane Database of Systematic Reviews, the International HTA Database, and the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search approach was customized to retrieve a limited set of results, balancing comprehensiveness with relevancy. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. Search concepts were developed based on the elements of the research questions and selection criteria. The main search concepts were nonsterile gloves and health care. CADTH-developed search filters were applied to limit retrieval to health technology assessments, systematic reviews (SRs), meta-analyses, indirect treatment comparisons, any types of clinical trials or observational studies, and guidelines. The search was completed on July 24, 2023, and limited to English-language documents published since January 1, 2018.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in <u>Table 1</u>.



Table 1: Selection Criteria

Criteria	Description
Population	Individuals receiving inpatient care at low risk of infection transmission
Intervention	Q1: Non-use of nonsterile gloves Q2: Nonsterile gloves
Comparator	Q1: Use of nonsterile gloves Q2: Not applicable
Outcomes	Q1: Clinical benefits and harms (e.g., contamination events, infection transmission, health care staff safety, and hand hygiene practices) Q2: Recommendations regarding the appropriate use of nonsterile gloves in hospitals (e.g., appropriate use, best practices to reduce infection transmissions, supplemental hygiene practices)
Study designs	Health technology assessments, systematic reviews, randomized controlled trials, nonrandomized studies, evidence-based guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in <u>Table 1</u>, if they were duplicate publications, or if they were published before 2018. SRs in which all relevant studies were captured in other more recent or more comprehensive SRs were excluded. Guidelines with unclear methodology were also excluded.

Critical Appraisal of Individual Studies

The included publications were critically appraised by 1 reviewer using the following tools as a guide: A MeaSurement Tool to Assess systematic Reviews 2 (AMSTAR 2)¹⁶ for systematic reviews, the Downs and Black checklist¹⁷ for randomized and nonrandomized studies, and the Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument¹⁸ for guidelines. Summary scores were not calculated for the included studies; rather, the strengths and limitations of each included publication were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 496 citations were identified in the literature search. Following screening of titles and abstracts, 455 citations were excluded and 41 potentially relevant reports from the electronic search were retrieved for full-text review. Six potentially relevant publications were retrieved from the grey literature search for full-text review. Of these potentially relevant articles, 43 publications were excluded for various reasons, and 4 publications met the inclusion criteria and were included in this report. These comprised 1 SR, 1 pilot randomized controlled trial (RCT), and 2 evidence-based guidelines. Figure 1 presents the PRISMA¹⁹ flow chart of the study selection. Additional references of potential interest are provided in Appendix 5.



Summary of Study Characteristics

Four relevant reports were identified comprising 1 SR,²⁰ 1 pilot RCT,²¹ and 2 evidence-based guidelines.^{22,23} A summary of study characteristics for each is included below. Additional details regarding the characteristics of included publications are provided in <u>Appendix 2</u>.

Study Design

The SR was published in 2021 and included 15 nonrandomized, quasi-experimental studies and 2 prospective, observational studies evaluating rates of methicillin-resistant *S. aureus* (MRSA) and vancomycin-resistant enterococci (VRE) with the discontinuation of contact precautions (i.e., gloves and gown) for patients testing positive for MRSA and VRE in acute care settings.²⁰ The SR included studies that were published no more than 10 years before and including August 2019.²⁰

One single-centre pilot crossover RCT was published in 2023.²¹ This study, based in a neonatal intensive care unit (NICU), compared the rate of late-onset infections (LOIs) during 6 months of standard infection control precautions (i.e., hand hygiene, glove use only when in contact with bodily fluids) with the rate of LOIs during 6 months of universal gloving (NSGs before any contact with any patient). The centre was randomly assigned to the order of treatment with a 2-week washout period between treatment arms.

One guideline was published in 2021 jointly by the Healthcare Infection Society and Infection Prevention Society in the UK.²² An SR of controlled trials, cohort studies, interrupted time series studies, case control studies, diagnostic accuracy studies, and controlled before-after studies was conducted to inform the recommendations. The quality of the evidence was graded using SIGN Methodology, Cochrane Effective Practice and Organization of Care Risk of Bias, and the Joanna Briggs Institute Critical Appraisal Checklist for Quasi-Experimental Studies. The evidence was graded using the following ratings: high, moderate, low, and very low, based on the characteristics of the studies included in the evidence base. The wording of the recommendations reflected their rating. For example, a strong recommendation used the word "must" if failure to follow the recommendation may have serious consequences. A conditional recommendation used the word "consider" if the evidence did not support a strong recommendation but indicated that the intervention may be beneficial in some circumstances. Final recommendations were based on external consultation with relevant stakeholders.

One guideline was published in 2022 by the Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) Scotland Infection Control team.²³ An SR of all study types was conducted to inform the recommendations. The quality of the evidence was graded using SIGN Methodology. Evidence grades ranged from 1++ (highest quality) to 4 (lowest quality). The highest grade of recommendation was "Mandatory," which reflected directives from government policy, regulations, or legislation. The lowest grade was "Category C," which was based solely on expert opinion. Final recommendations were based on external consultation with relevant stakeholders.

Both guidelines included recommendations that were outside the scope of this review. Only recommendations for glove use were included in this report.



Country of Origin

The lead author of the SR was from the US. 20 The primary studies included in the SR were conducted in the US (n = 15), Canada (n = 1), and France (n = 1). The pilot RCT was conducted in Canada. 21 One of the evidence-based guidelines was developed for Scotland 23 and the other for the UK as a whole. 22

Patient Population

All studies, including those included in the SR, were conducted in acute care settings. The setting for most (11 of 17) of the studies in the SR was the entire hospital, while the other 6 studies were conducted in specific units of a hospital (i.e., leukemia, bone marrow transplant, and lymphoma service of a cancer institute; hospital intensive care units; trauma service; a skilled care unit of hospital).²⁰ No other information with regard to patient characteristics was provided.

The pilot RCT was conducted in a NICU and included a total of 750 neonates.²¹ Baseline characteristics were similar between treatment groups. Among the entire cohort, 61% were male and 39% were female, gestational age at birth was approximately 34 weeks, and 0% to 76.9% had at least 1 risk factor for infection.

The target population of both evidence-based guidelines is hospital inpatients of all age groups, and the intended users are infection prevention and control teams as well as HCWs providing patient care in acute care settings.^{22,23}

Interventions and Comparators

Interventions reported in the SR were the discontinuation of contact precautions (i.e., gown and gloves) for patients testing positive for MRSA or VRE.²⁰ Fifteen studies discontinued contact precautions for patients testing positive for MRSA, 11 studies discontinued contact precautions for patients testing positive for VRE, and 9 studies discontinued contact precautions for both patients testing positive for MRSA and VRE.²⁰ The time period before discontinuation of contact precautions was used as the comparator.²⁰

The intervention assessed in the pilot RCT was universal use of NSGs before any contact with a patient, and the comparator was the use of standard precautions, which included glove use only in the context of contact with bodily fluids.²¹

Both guidelines assessed a wider variety of interventions than the scope of this review. Specific to this review, the guidelines addressed appropriate settings for glove use in general,²³ appropriate settings for NSG use,²³ and glove use for minimizing the transmission of MRSA.²²

Outcomes

The outcome measures reported in the SR were rates of laboratory-confirmed hospital-associated MRSA infection (11 studies) and rates of laboratory-confirmed hospital-associated VRE infection (7 studies) before and after cessation of contact precautions.²⁰ Random-effects and fixed-effects models were used to determine the pooled risk ratios of hospital-associated infection rates with contact precautions compared to rates without contact precautions.²⁰

The outcomes reported in the pilot RCT were rates of LOIs in NICU patients.²¹ LOI episodes were categorized as follows: sterile-site LOI (i.e., culture-positive meningitis, bacteremia, urinary tract infection) and nonsterile-



site LOI (culture-negative meningitis, single blood culture positive with coagulase-negative staphylococci, abdominal infection, pneumonia, clinically diagnosed cellulitis, and "culture-negative" sepsis). This study also assessed compliance with hand hygiene.

One guideline considered new laboratory-confirmed MRSA infections as the outcome in making recommendations for the use of contact precautions for patients with MRSA (i.e., gloves and gown).²² One guideline reported no primary evidence for glove use, and instead relied on expert opinion to make recommendations.²³

Summary of Critical Appraisal

Systematic Review

The SR used a comprehensive literature search strategy and 2 reviewers to select studies, which increased the likelihood that all relevant studies were included; however, only studies of moderate quality were identified for inclusion.²⁰ The meta-analysis included all studies and, while there was a discussion of bias, there was no formal assessment of the impact of bias on results.²⁰ Excluded studies were not listed; however, the rational for exclusion was reported and each excluded study was cited in the reference list.²⁰

Primary Clinical Study

The study objectives, variables of interest, and main outcomes were clearly described in the pilot RCT.²¹ The authors listed and compared the presence of potential confounding factors between treatment groups, which can provide assurance that the groups were similar before the study and that the difference between the groups is the intervention.²¹ Study personnel who conducted the retrospective chart review were blinded to the treatment arm to reduce the risk of observer bias.²¹ While this study was a randomized crossover trial, rather than individual patients being randomized, the single centre was randomly assigned in terms of the order of treatment arms. This means that different patients were included during each of the time periods the treatment arms were in effect, and risk of infection may have been different during each of the time periods. There was no sample size or power calculation, as this pilot study was meant to inform the development of a larger multicentre RCT.²¹

Evidence-Based Guidelines

The main limitation of both evidence-based guidelines was the lack of clinical data on which to base recommendations that were relevant to this review. While both guideline development groups used a systematic approach to gather and evaluate the evidence and to develop recommendations for the use of gloves in acute care settings, there was little evidence identified, and thus all of the relevant recommendations from 1 guideline²³ and 1 of 2 recommendations from the other guideline²² were based on expert opinion.

Additional details regarding the strengths and limitations of included publications are provided in Appendix 3.

Summary of Findings

Appendix 4 presents the main study findings.



Clinical Effectiveness of Nonsterile Glove Use

Pooled data from the SR found a statistically significant difference in the rates of hospital-associated VRE infection, with evidence suggesting lower rates of hospital-associated VRE infection after cessation of contact precautions, compared with the time period during which contact precautions (i.e., gown and gloves) were used in hospitalized patients.²⁰ The SR also found no evidence of a difference in the rate of hospital-associated MRSA infection before and after cessation of contact precautions.²⁰

The pilot RCT found the rate of LOI in the NICU was similar with universal glove use for all patients compared to standard precautions.²¹ In addition, the odds of hand hygiene compliance before and after patient contact was significantly lower in the study arm using universal gloving compared to that using standard precautions alone.²¹

Guidelines Regarding the Use of NSGs

Recommendations for Glove Use in Acute Care Settings

One guideline made several recommendations regarding the use of gloves and standard infection control precautions in acute care settings, which were all based on expert opinion with no supporting evidence from primary studies.²³

This guideline recommends that disposable gloves be worn to protect the health care worker and/or the patient if there is risk of contact with blood, body fluids, non-intact skin, mucous membranes, lesions and/or vesicles, hazardous drugs and chemicals, and that gloves should be worn during environmental cleaning and cleaning of used medical equipment.²³

Gloves are not recommended for administering immunizations unless recommended by vaccine manufacturers or there is risk of contact with body fluids or non-intact skin.²³

In cases where gloves are worn, it is recommended that NSGs are used for nonsterile procedures (e.g., patient examination), communal care equipment, environmental cleaning, and administering immunizations (where gloves are indicated).²³

Recommendations for Glove Use Specific to MRSA in Acute Care Settings

One guideline recommends that standard infection prevention and control precautions be used in the care of all patients to minimize the risk of MRSA transmission (based on expert opinion).²²

One guideline conditionally recommends that providers consider using contact precautions (i.e., gloves and gown) for direct contact with patients known to be colonized or infected with MRSA or their immediate environment.²² If contact precautions are used, it is recommended that gloves be changed between care procedures and that hand hygiene be performed after glove removal.²² This recommendation was based on limited primary clinical evidence from 2 RCTs and 7 quasi-experimental studies with inconsistent results.²²



Limitations

This report is limited by the quantity and quality of evidence available on the use and non-use of NSGs for individuals receiving inpatient care considered at low risk of infection transmission. While the 2 guideline documents used a systematic method of gathering evidence on which to base their recommendations, very few relevant studies were identified.^{22,23} The only RCT included in this review was a pilot project conducted to determine the feasibility of designing a large, multicentre RCT.²¹ While the results showed no statistically significant differences in rates of infection between standard precautions and universal gloving, the study reported no sample size calculation, and it is unknown whether it was powered to detect a difference between treatment arms.²¹ Completion and publication of the findings from the full study (i.e., a large, multicentre, cluster crossover RCT), will further inform the safety and benefits of NSG use in the NICU.

The SR examining the effect of discontinuation of contact precautions (I.e., gloves and gown) for MRSA and VRE was well conducted and of high quality; however, only studies of moderate quality were identified for inclusion.²⁰ Surveillance of these pathogens was variable among the studies, and 2 of the included studies discontinued active surveillance of VRE (i.e., screening) during the study period.²⁰ Thus, it is impossible to know whether a reduction in the rate of VRE was due to the intervention or due to lack of measurement of the outcome.

No studies were identified that examined the impact of NSGs in direct comparison with non-use of NSGs on contamination events or transmission of infections. Little evidence was found for the impact of NSG use on hand hygiene practices. Furthermore, no comparative evidence was found for the impact of gloves outcomes such as occupational skin conditions.

There was considerable heterogeneity in the evidence evaluating NSG use. The SR included studies that evaluated the discontinuation of contact precautions, which include both gloves and gowns.²⁰ Thus, conclusions cannot be made about glove use alone. It was not reported in the SR whether the gloves used were NSGs, and none of the included studies explicitly stated that the care activities were considered to have a low risk of infection transmission; rather, it was inferred that the care being provided was considered at low risk of infection transmission based on the use of "standard precautions" as the alternative intervention (i.e., hand hygiene before and after patient contact). The use of standard infection control precautions implies that the use of gloves would be based on risk of exposure to body fluids.²³ Finally, the populations included in the studies are mixed, with the pilot RCT specific to neonates²¹ while the studies included in the SR were mainly whole-hospital settings.²⁰ The 2 guideline documents were directed toward all inpatients in acute care settings regardless of age.^{22,23}

Conclusions and Implications for Decision- or Policy-Making

The body of evidence comparing non-use of gloves versus use of gloves in acute care settings where there is low risk of infection transmissions is limited and of moderate quality. One SR assessed rates of nosocomial MRSA and VRE infections before and after discontinuation of contact precautions (i.e., gloves



and gown) for such infections.²⁰ One pilot RCT compared the rate of LOIs in neonates during a period when standard infection control precautions were used versus a time period when universal gloving of HCWs was employed.²¹ Finally, 2 evidence-based guidelines included recommendations for the use of gloves for infection control in acute care settings.^{22,23}

Recommendations for the Use of Gloves in Acute Care Settings

In general, gloves should be worn to protect the HCW and patient when it is anticipated that there will be contact with blood, body fluids, non-intact skin, mucous membranes, lesions, or hazardous drugs and chemicals, and for environmental cleaning (1 guideline, based on expert opinion).²³

It is recommended that NSGs be worn under the following circumstances (1 guideline, based on expert opinion):²³

- during nonsterile procedures
- when using communal care equipment
- · during environmental cleaning
- · when administering immunizations, if indicated.

Specifically related to MRSA, it is conditionally recommended to consider using contact precautions (i.e., gloves and gown) for direct contact with patients testing positive for MRSA or their immediate environment.²² This recommendation was based on inconsistent evidence that did not support a strong recommendation, but the intervention may be beneficial in some circumstances.

Clinical Effectiveness of the Non-Use of NSGs

The included SR demonstrated a lower risk of VRE infection and no statistically significant difference in the risk of MRSA infection with discontinuation of contact precautions (i.e., gloves and gown) for patients in acute care settings.²⁰ This evidence suggests that in situations with low-risk of infection transmission, non-use of gloves and gowns may have little to no difference in the rate of hospital-acquired MRSA infections, and may lower the rate of hospital-acquired VRE infections; however, it is important to consider the limitations of this evidence when interpreting these findings (e.g., evidence from 1 SR based on a limited number of moderate-quality nonrandomized studies).

In a neonatal population, no statistically significant differences were found in the rates of LOIs with standard infection control precautions (i.e., use of gloves with risk of contact with bodily fluids) compared with time periods in which gloves were used before any contact with the patient.²¹ This suggests that universal gloving may have little added benefit in the prevention of LOIs in the NICU compared with standard infection control precautions (e.g., hand hygiene).

Generalizability

The evidence and recommendations summarized in this review are generalizable to the Canadian health care context. One study included in the SR and the pilot RCT were conducted in Canada.^{20,21} In addition,



the recommendations for the use of gloves in general²³ and specific to MRSA²² are similar to those in the Canadian infection control guidelines published before 2018 (i.e., outside the time frame of this review).³

Considerations for Future Research

A substantial research gap exists for good-quality prospective RCTs that evaluate the effectiveness of NSGs in comparison with no gloves in terms of transmission of pathogens. Researchers should consider that the current findings of equivalence between NSGs and standard infection control precautions should be confirmed with well-conducted RCTs to better inform decisions regarding NSG use when providing inpatient care considered at low risk of infection transmission. Finally, the design of education campaigns or interventions to reduce misuse and overuse of gloves in acute care settings should be guided by an evidence-informed understanding of the drivers of glove-use behaviour.

Implications for Clinical Practice

In acute care settings, when providing care considered at low risk of infection transmission, standard precautions (e.g., hand hygiene,²⁰ or glove use only when there is a risk of contact with bodily fluids²¹) may offer a similar level of protection against infection,^{20,21} or may have the potential to lower the risk of certain infections²⁰ when compared to the use of contact precautions²⁰ (i.e., gloves and gown) or the universal use NSGs.²¹ However, decision-makers should also consider the limitations of this evidence (e.g., based on a limited number of moderate-quality studies, the heterogeneity of the evidence).

While guidelines recommend wearing gloves to protect HCWs and patients from exposure to bodily fluids, the misuse and overuse of gloves can be a problem in health care settings. Fixcessive glove use when not medically necessary may add an unnecessary expense to the already high cost of health care, contribute to unnecessary medical waste, and contribute to adverse skin effects in wearers. Hand eczema or contact dermatitis in the previous year has been found to be common in HCWs, and higher levels of glove use are associated with harm to skin integrity. In addition, glove use can negatively impact compliance with hand hygiene, which has the potential to impact the transmission of pathogens. However, no evidence was identified that met the criteria for this review that directly compared the impact of non-use versus use of NSGs on health care staff safety (e.g., dermatitis).

Decision-makers may also wish to consider the environmental impacts of NSG use. Medical waste has become an increasing concern, as it contributes to environmental pollution. Physiochemical analysis showed weathered gloves released leachable substances, including microparticles, organic matter, and heavy metals contaminating drinking water and the food chain,^{4,5} potentially resulting in a number of health effects in humans and animals.⁵



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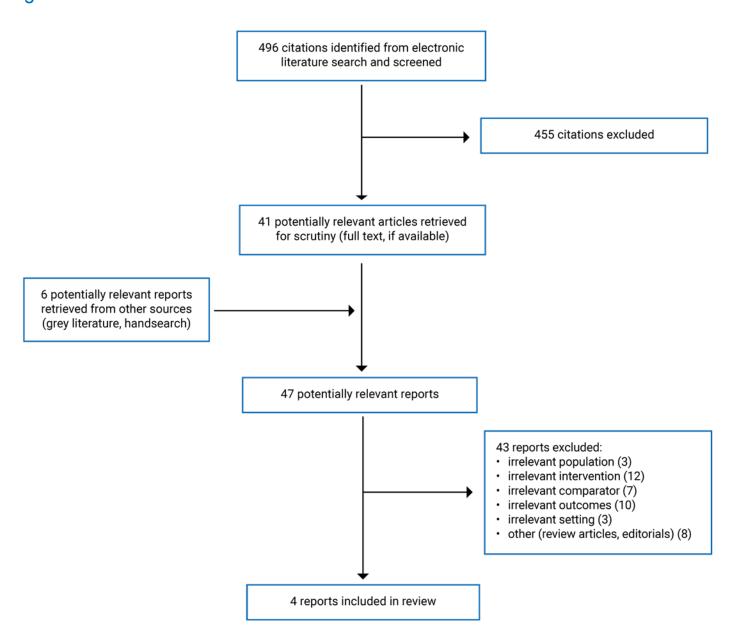


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Appendix 1: Selection of Included Studies

Figure 1: Selection of Included Studies





Appendix 2: Characteristics of Included Publications

Note that this appendix has not been copy-edited.

Table 2: Characteristics of the Included Systematic Review

Study citation, country, funding source	Study designs and numbers of primary studies included	Population characteristics	Intervention and comparator(s)	Clinical outcomes, length of follow-up
Kleyman et al. (2021) ²⁰ Country: US Funding source: HCA Healthcare	Nonrandomized quasi- experimental before and after comparison studies (n = 15) Prospective observational studies (n = 2)	Study setting: • Entire hospital (n = 11) • Leukemia, bone marrow transplant, and lymphoma service of a cancer institute (n = 1) • Hospital ICU (n = 3) • Trauma unit (n = 1) • Skilled care unit (n = 1) All of the studies required per-protocol hand hygiene with alcohol base hand rub. In 2 of the studies contact precautions were replaced by chlorhexidine bathing. There was no description of patient characteristics.	Intervention: Cessation of contact precautions (gown and gloves) for hospital inpatients with MRSA or VRE Comparator: Contact precautions (gown and gloves) for hospital inpatients with MRSA or VRE	Outcomes: Rate of hospital-associated MRSA infection Rate of hospital-associated VRE infection Follow-up: range, 0.5 to 10 years

ICU = intensive care unit; MRSA = methicillin-resistant S. aureus; VRE = vancomycin-resistant enterococci.

Table 3: Characteristics of Included Primary Clinical Study

Study citation, country, funding source	Study design	Population characteristics	Intervention and comparator(s)	Clinical outcomes, length of follow-up
Khan et al. (2023) ²¹ Country: Canada Funding source: Hamilton Health Sciences New Investigator Fund	RCT with crossover Random assignment of treatment arms to order of treatment with 2-week washout period between treatments Single centre Pilot study to assess feasibility of conducting a multicentre cluster RCT crossover study	Includes: Infants admitted to the NICU for a minimum of 2 days Excludes: Infections requiring contact precautions (i.e., gloves and gown) Standard arm: n = 390 Male: 61.0% Female: 39.0% Mean gestational age at birth (weeks): 34.41 (SD = 4.8) Mean birth weight (g): 2,452.76 (SD = 95.5) Prenatal steroid use: 74.9% Risk factors for infection: 0.3% to 76.9%	Intervention: Nonsterile gloves before any contact with any patient (i.e., universal gloving) for 6 months Comparator: Standard precautions (i.e., hand hygiene; glove use only when in contact with bodily fluids) for 6 months	Hand hygiene compliance Compliance to gloving Late-onset infection prevalence and rate Types of pathogens detected, prevalence of patients who had additional precautions (isolation) Follow-up: 2 intervention periods lasting 6 months each



Study citation, country, funding source	Study design	Population characteristics	Intervention and comparator(s)	Clinical outcomes, length of follow-up
		Glove arm: n = 360		
		Male: 57.8%		
		Female: 42.2%		
		Mean gestational age at birth (weeks): 34.11 (SD = 4.7)		
		Mean birth weight (g): 2,332.03 (SD = 35.7)		
		Prenatal steroid use: 71.5%		
		Risk factors for infection: 0% to 76.9%		

NICU = neonatal intensive care unit; RCT = randomized controlled trial; SD = standard deviation.



Table 4: Characteristics of Included Guidelines

Intended users, target population	Intervention and practice considered	Major outcomes considered	Evidence collection, selection, and synthesis	Evidence quality assessment	Recommendations development and evaluation	Guideline validation
			National Services Sc	otland (2022) ^{23,24}		
Intended users: Staff involved in the prevention and control of infection in Scotland Target population: Health and care settings	Glove use in general Nonsterile glove use	NR	Targeted systematic literature review using a defined 2-person systematic methodology Search strategy developed using the PICO framework Searched databases include MEDLINE, Embase, and CINAHL	One reviewer critically appraised each included study. A second reviewer carried out a check of a minimum of 30% of included studies. Critical appraisal of individual studies completed using SIGN 50 methodology (refer to Table 5). Quality assessment of guidelines were assigned using AGREE grades of recommendation, ranging from "Would not recommend" to "Strongly recommend."	Consensus-based recommendations were drafted by the guideline development group and agreed upon through discussion. Recommendations were given a grade to highlight the strength of supporting evidence (refer to Table 6).	External consultation and feedback All comments from registered stakeholders were addressed and changes were made to the final literature review and recommendations.
			Coia, et al.	(2021) ²²		
Intended users: Clinical staff involved in patient care in health care settings and IPAC teams Target population: Prevention	All aspects related to the infection prevention and control of MRSA	Transmission of MRSA	MEDLINE, CINAHL/ EMCare and Embase) were searched for articles published between July 2004 and February 2021 using a defined search strategy. Studies were selected for inclusion	Studies were critically appraised independently by 2 reviewers. SIGN Methodology Cochrane Effective Practice and Organization of Care Risk of Bias	Consensus-based recommendations were drafted by the guideline development group and agreed upon through discussion. The wording of the evidence statements and the recommendations reflected	Four-week external consultation and feedback Feedback from stakeholders was addressed and changes were made to the final literature review and recommendations.



Intended users, target population	Intervention and practice considered	Major outcomes considered	Evidence collection, selection, and synthesis	Evidence quality assessment	Recommendations development and evaluation	Guideline validation
of MRSA transmission and managing patients colonized or infected with MRSA in health care settings			independently by 2 reviewers. Data extraction was completed by 1 reviewer and checked by a second reviewer.	Joanna Briggs Institute Critical Appraisal Checklist for Quasi- Experimental Studies	the strength of the evidence and its classification. ^a	

IPAC = infection prevention and control; MRSA = methicillin-resistant S. aureus; NR = not reported.

a"Use" or similar wording was used if the benefits outweigh harms, and the intervention is cost-effective, reflecting a strong recommendation. "Consider" was used if the evidence did not support a strong recommendation, but the intervention may be beneficial in some circumstances, reflecting a conditional recommendation for the intervention.



Table 5: SIGN 50 Levels of Evidence^{23,24}

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

RCT = randomized controlled trial.

Table 6: Grades of Recommendation^{23,24}

Grade	Description	Levels of evidence
Mandatory	Recommendations that are directives from government policy, regulations, or legislation	NA
Category A	Based on high to moderate quality evidence	SIGN level 1++, 1+, 2++, 2+, AGREE strongly recommend
Category B	Based on low to moderate quality of evidence which suggests net clinical benefit over harm	SIGN level 2+, 3, 4, AGREE recommend
Category C	Expert opinion	SIGN level 4
No recommendation	Insufficient evidence to make a recommendation	NA

AGREE = Appraisal of Guidelines for Research and Evaluation; NA = not applicable.



Appendix 3: Critical Appraisal of Included Publications

Note that this appendix has not been copy-edited.

Table 7: Strengths and Limitations of the Systematic Review Using AMSTAR 216

Strengths	Limitations
Kleyman et	al. (2021) ²⁰
 The research question was not explicitly stated but all elements of PICO could be inferred from the introduction section The review methods were planned in advance of the study – the authors used an established SR and meta-analysis protocol from Cochrane guidelines (i.e., PRISMA guidelines) The search strategy was recent in relation to publication of review The authors searched more than one database, reported a search of grey literature, and hand searched reference lists of relevant publications Two reviewers/data extractors independently reviewed articles for inclusion and extracted data, while a third reviewer helped resolve discrepancies The method for pooling data was appropriate; the authors used random-effects model and included an analysis of heterogeneity Interpretation of the results considered the risk of bias in included studies 	 There was no justification for the selection of study designs The methods did not include a list of keywords searched Excluded studies were not listed but the rational for exclusion was reported and each excluded study was cited in the references Funding source was not reported for included studies The meta-analysis included studies at moderate risk of bias and there was no assessment of the impact of bias on the results The authors reported they did not "notice" any risk of publication bias and there was no analytical evidence to support this statement (there was a reference to a figure in an appendix; however, the figure was missing).

AMSTAR 2 = A MeaSurement Tool to Assess systematic Reviews 2; PICO = population, intervention, comparator, outcome; PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses.



Table 8: Strengths and Limitations of the Clinical Study Using the Downs and Black Checklist¹⁷

Strengths	Limitations		
Khan et al. (2023) ²¹			
 The study objectives, main outcomes, patient characteristics, interventions, and potential confounders were clearly described Participants were representative of the source population Study personnel conducting the retrospective chart review to assess neonatal infections were blind to treatment arm Infants recruited sequentially, with 100% of parents consenting to their neonates participating in the study 	 Individuals were not randomized, rather the NICU was randomized in terms of order of treatment arm (i.e., standard care for the first 6 months, glove use for the second 6 months with a 2-week washout period between treatment arms) It was not possible to blind health care workers to treatment arm Compliance with gloving in the glove arm ranged from 48% (before contact with the patient's environment) to 86% (glove removal after contact with body fluid) There was no adjustment for confounding even though there were differences in some risk factors for infection between groups (e.g., the proportion of neonates receiving hydrocortisone and probiotics) No sample size calculation or power calculation was provided 		

NICU = neonatal intensive care unit.

Table 9: Strengths and Limitations of Guidelines Using AGREE II¹⁸

National Services Scotland (2022) ²³	Coia et al. (2021) ²²		
main 1: Scope and purpose			
Yes	Yes		
Yes	Yes		
Yes	Yes		
Domain 2: Stakeholder involvement			
Yes	Unclear		
No	Yes		
Yes	Yes		
Domain 3: Rigour of development			
Yes	Yes		
Yes	Yes		
	Yes Yes Yes Yes in 2: Stakeholder involvement Yes No Yes ain 3: Rigour of development Yes		



Item	National Services Scotland (2022) ²³	Coia et al. (2021) ²²	
The strengths and limitations of the body of evidence are clearly described.	Yes	Yes	
10. The methods for formulating the recommendations are clearly described.	Yes	Yes	
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	Yes	Yes	
12. There is an explicit link between the recommendations and the supporting evidence.	Yes	Yes	
13. The guideline has been externally reviewed by experts before its publication.	Yes	Yes	
14. A procedure for updating the guideline is provided.	Yes	Yes	
Domain 4: Clarity of presentation			
15. The recommendations are specific and unambiguous.	Yes	Yes	
16. The different options for management of the condition or health issue are clearly presented.	Yes	Yes	
17. Key recommendations are easily identifiable.	Yes	Yes	
]	Domain 5: Applicability		
18. The guideline describes facilitators and barriers to its application.	No	No	
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	Yes	Yes	
20. The potential resource implications of applying the recommendations have been considered.	No	Yes	
21. The guideline presents monitoring and/or auditing criteria.	No	Yes	
Domain 6:Editorial independence			
22. The views of the funding body have not influenced the content of the guideline.	Yes	Unclear	
23. Competing interests of guideline development group members have been recorded and addressed.	Yes	Yes	

AGREE II = Appraisal of Guidelines for Research and Evaluation II.



Appendix 4: Main Study Findings

Note that this appendix has not been copy-edited.

Table 10: Summary of Findings by Outcome — Clinical Effectiveness of NSG Use

Oharda attacking and			
Study citation and study design	Method of measurement	Result	Notes
Kleyman et al., 2021 ²⁰ Systematic review or meta-analysis n = 15, quasi-experimental before and after studies n = 2, prospective observational studies Rates of hospital-associated infections were calculated from laboratory-confirmed infections Random-effects and fixed-effects models were used to determine the pooled RRs of hospital-associated infection rate with stopping contact precautions compared to that with contact precautions (i.e., gloves and gown)	Rates of hospital-associated MRSA infection, cessation of contact precautions compared to using contact precautions: RR = 0.84 (95% CI, 0.71 to1.01); P = 0.06	No difference was detected in the rate of MRSA infection before and after discontinuation of contact precautions.	
	Rates of hospital-associated VRE infection, cessation of contact precautions compared to using contact precautions: RR = 0.82 (95% CI, 0.72 to 0.94); P = 0.005	The risk of VRE infection was lower after discontinuation of contact precautions compared with the time period during which contact precautions were used.	
Khan et al., 2023 ²¹ Crossover randomized trial (pilot study) Compliance with hand hygiene (both arms) and glove compliance (glove arm) were monitored by audit Data on LOI³ were collected by retrospective chart review of all cases that received antibiotics for more than 3 days	LOI prevalence: Glove arm: 11.4% Standard arm: 8.7% LOI rate: Glove arm: 8.2 per 1,000 person-days Standard arm: 6.7 LOI per 1,000 person-days IRR = 1.22 (95% CI, 0.84 to 1.78); P = 0.293	LOI rates were not different between the glove arm and the standard arm.	
	Hand hygiene compliance: standard arm vs. glove arm Before initial patient contact or contact with patient environment: OR = 1.86 (95% Cl, 1.34 to 2.59); P < 0.001 Before aseptic procedure: OR = 1.73 (95% Cl, 1.00 to 3.01); P = 0.051 After body fluid exposure risk: OR = 1.11 (95% Cl, 0.62 to 1.98); P = 0.727 After patient contact or contact with patient environment: OR = 1.65 (95% Cl, 1.27 to 2.14); P < 0.001	Hand hygiene compliance was lower in the glove arm.	

CI = confidence interval; IRR = incidence rate ratio; LOI = late-onset infection; MRSA = methicillin-resistant *S. aureus*; NSG = nonsterile glove; OR = odds ratio; RR = relative risk; VRE = vancomycin-resistant enterococci.

^aLOI events met the following criteria: 1) occurring after 2 days of life to exclude early-onset infection events related to in utero environments or delivery; 2) had at least 2 compatible signs and symptoms (including temperature instability, hemodynamic changes, respiratory distress, and increased inflammatory markers, change in feeding tolerance, or lethargy); 3) had at a minimum; blood cultures sent for analysis; 4) antibiotic treatment for more than 4 days to eliminate inclusion of episodes of suspected but not clinically or microbiologically proven infection as no clinically significant infections are treated for < 4 days.



Table 11: Summary of Recommendations in Included Guidelines

Recommendations and supporting evidence	Quality of evidence and strength of recommendations			
National Serv	rices Scotland (2022) ²³			
When or where should gloves be worn?				
"The use of gloves should be based on an assessment of the risk of contact with blood, body fluids (including but not limited to secretions and/or excretions), non-intact skin, mucous membranes, lesions and/or vesicles, hazardous drugs and chemicals, e.g. cleaning agents: Where such a risk exists, gloves should be worn to protect the healthcare worker and/or the patient." (p. 28) ²³	SIGN level 4, or opinion of NIPC group Grade C recommendation (NIPCM grades of recommendations)			
No primary evidence; 34 guideline documents citing expert consensus.				
"Gloves should not be worn as a substitute to hand hygiene." (p. 28) ²³ No primary evidence; 2 expert opinion guidelines.	SIGN level 4, or opinion of NIPC group Grade C recommendation (NIPCM grades of recommendations)			
"Unless recommended by vaccine manufacturers, it is not usually necessary to wear gloves for administering immunisations unless: It is anticipated that there may be exposure to blood or body fluids	SIGN level 4, or opinion of NIPC group Grade C recommendation (NIPCM grades of recommendations)			
 The health care worker has non-intact skin on their hands The person receiving the immunisation has non-intact skin" (p. 28)²³ 				
No primary evidence; 4 expert opinion guidelines.				
"Gloves should be worn during environmental cleaning and cleaning of used medical equipment." (p. 29) ²³ No primary evidence; 18 guideline documents citing expert consensus.	SIGN level 4, or opinion of NIPC group Grade C recommendation (NIPCM grades of recommendations)			
When should nonsterile examination gloves b	be worn and are they specified for specific procedures?			
"Non-sterile gloves should be worn for non-sterile procedures (e.g. patient examination)." (p. 29) ²³ No primary evidence; 11 expert opinion guidelines.	SIGN level 4, or opinion of NIPC group Grade C recommendation (NIPCM grades of recommendations)			
"Non-sterile gloves should be worn for communal care equipment and environmental cleaning." (p. 29) ²³ No primary evidence; 11 expert opinion guidelines.	SIGN level 4, or opinion of NIPC group Grade C recommendation (NIPCM grades of recommendations)			
'When indicated, non-sterile gloves should be used for administering immunizations." (p. 30) ²³ No primary evidence; 11 expert opinion guidelines.	SIGN level 4, or opinion of NIPC group Grade C recommendation (NIPCM grades of recommendations)			
Co	pia (2021) ²²			
To what extent are contact precautions (i.e., gloves and gown) effective in minimizing the transmission of MRSA?				
"Use standard infection prevention and control precautions in the care of all patients to minimize the risk of MRSA	Strong recommendation ("Use" was used if most practitioners, commissioners, or service			



Recommendations and supporting evidence	Quality of evidence and strength of recommendations
transmission." (p. S26) ²² 1 expert opinion guideline.	users would choose an intervention if they were presented with the same evidence.)
"For patients known to be colonized/infected with MRSA, consider using contact precautions ^b for direct contact with the patient or their immediate environment. If contact precautions are used, gloves and aprons must be changed between care procedures and hand hygiene must be performed after glove removal." (p. S26) ²² Evidence from 2 cluster RCTs showed inconsistent results. Incidence of new MRSA acquisitions was either similar using contact precautions compared with universal gloving or lower with universal gloving compared with contact precautions. Evidence from 1 interrupted time series showed a reduction in MRSA acquisition associated with rapid screening, contact precautions and isolation compared to no isolation and standard precautions while 1 interrupted time series showed decrease in MRSA infection rates associated with discontinuing contact precautions for known MRSA patients. Five uncontrolled before/after studies found no difference in the rate of MRSA acquisition associated with discontinuation of contact precautions for known MRSA patients.	Conditional recommendation ("Consider" was used if the evidence did not support a strong recommendation, but that the intervention may be beneficial in some circumstances.)

MRSA = methicillin-resistant *S. aureus*; NIPC = National Infection Prevention and Control; NIPCM = National Infection Prevention and Control Manual; NR = not reported; RCT = randomized controlled trial.

*Standard infection prevention and control precautions were defined as staff washing their hands before and after direct contact with the patient and their immediate environment, and any susceptible site on the patient.²²

^bContact precautions was defined as gloves and gown worn when touching patients' intact skin or surfaces in close proximity to the patient.²²



Appendix 5: References of Potential Interest

Note that this appendix has not been copy-edited.

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