

CADTH Reference List

Disinfection Caps for Patients Requiring Central Access Lines

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Key Messages

- Four systematic reviews (3 with meta-analyses), 3 randomized controlled trials, and 14 non-randomized studies were identified regarding the clinical effectiveness of disinfection caps on central access lines.
- No evidence-based guidelines were identified regarding the use of disinfection caps on central access lines in pediatric or neonatal patients.

Research Questions

- 1. What is the clinical effectiveness of disinfection caps on central access lines?
- 2. What are the evidence based guidelines regarding the use of disinfection caps on central access lines in pediatric or neonatal patients?

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were disinfection caps and catheters. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English-language documents published between January 1, 2011 and January 8, 2021. Internet links were provided, where available.

Selection Criteria and Summary Methods

One reviewer screened literature search results (titles and abstracts) and selected publications according to the inclusion criteria presented in Table 1. Full texts of study publications were not reviewed. The Overall Summary of Findings section was based on information available in the abstracts of selected publications. Open-access full-text versions of evidence-based guidelines were reviewed when abstracts were not available and relevant recommendations were summarized.

Results

Four systematic reviews¹⁻⁴ (3 with meta-analyses¹⁻³), 3 randomized controlled trials,⁵⁻⁷ and 14 non-randomized studies⁸⁻²¹ were identified regarding the clinical effectiveness of disinfection



Table 1: Selection Criteria

Criteria	Description				
Population	Q1: Patients who require central line access (central venous catheters; adult, pediatric, or neonatal patients)				
	Q2: Pediatric and neonatal patients who require a central line access				
Intervention	Disinfection caps (i.e., alcohol-impregnated devices; "alcohol containing caps," "antiseptic barrier cap," "disinfecting port protectors")				
	Q1: No disinfection cap or a regular cap; standard of care				
Comparator	Q2: Not applicable				
	Q1: Clinical effectiveness (e.g., decreased infection, risks, side effects, adverse outcomes, safety)				
Outcomes	Q2: Recommendations regarding the use of disinfection caps on central line access; recommendations regarding which populations require disinfection caps				
Study Designs	Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies, evidence-based guidelines				

caps on central access lines. No health technology assessments or evidence-based guidelines were identified.

Additional references of potential interest that did not meet the inclusion criteria are provided in Appendix 1.

Overall Summary of Findings

Four systematic reviews¹⁻⁴ (3 with meta-analyses¹⁻³), 3 randomized controlled trials,⁵⁻⁷ and 14 non-randomized studies⁸⁻²¹ were identified regarding the clinical effectiveness of disinfection caps on central access lines. A detailed summary of the identified studies can be found in Table 2. Eighteen studies (4 systematic reviews, 1-4 2 randomized controlled trials, 5,6 and 12 non-randomized studies⁸⁻¹⁹) assessed adult patients or did not specify patients' ages. One systematic review with meta-analysis¹ found using disinfection caps was associated with reduced catheter-associated bloodstream infections compared to manual disinfection with alcohol wipes. Eleven studies (2 systematic reviews with meta-analyses, ^{2,3} 1 randomized controlled trial,⁵ and 8 non-randomized studies^{8,9,12,15-19}) reported disinfection caps were associated with reduced central line-associated bloodstream infections (CLASBI). Authors of a non-randomized study assessing hematological and oncological patients noted that although CLASBI rates were higher in the alcohol disinfection caps group compared to the standard caps group, a multivariate analysis indicated that the disinfection caps were not a statistically significant independent protective factor against CLASBIs, and the alcohol disinfection caps group also did not significantly different from the control group on time to CLASBI.8 Another non-randomized study of oncology patients found that the reduction in CLASBI rates following the implementation of disinfection caps was only seen in high-risk patients, not in general oncology patients. 12 One systematic review 4 found that alcohol disinfection caps were associated with reduced infections. Two studies (a randomized controlled trial⁶ and a non-randomized study¹⁴) found that disinfection caps were associated with reduced bloodstream infections (BSI). One non-randomized study¹³ found disinfection



caps to be associated with reduced catheter-related sepsis and another non-randomized study¹¹ reported no cases of phlebitis. One randomized controlled trial⁶ reported no device-related adverse events.

Three studies (1 randomized controlled trial⁷ and 2 non-randomized studies^{20,21}) assessed neonatal and/or pediatric patients. The randomized controlled trial⁷ found that, in a population of pediatric hematology-oncology patients, introducing disinfection caps was not associated with a reduction in CLASBIs, but was associated with a decrease in positive blood culture incidence. They also reported that no adverse events were observed.⁷ One non-randomized study²⁰ found a non-statistically significant reduction in CLASBIs with the implementation of antiseptic barrier caps in neonatal and pediatric intensive care units, with a larger decline in the neonatal unit compared to the pediatric unit. The other non-randomized study²¹ reported a decrease in bloodstream infections in a pediatric hospital after introducing disinfection caps.

No evidence-based guidelines were found regarding the use of disinfection caps on central access lines in pediatric or neonatal patients. Therefore, no summary can be provided.

Table 2: Summary of Included Studies

First author, year	Study characteristics	Intervention(s) and comparator(s)	Relevant outcomes assessed	Author's conclusions
		Systematic reviews		
Flynn et al. (2019) ¹	Study Design: Systematic review and meta-analysis Population: NR N = 10 relevant studies	Intervention: Alcohol disinfection caps Comparator: 70% alcohol wipes	CABSI	Alcohol disinfection caps were associated with significantly fewer CABSIs than alcohol wipes (RR: 0.43).
Shore et al. (2018) ²	Study Design: Systematic review and meta-analysis Population: General hospital patients and patients in an intensive care setting N = NR	Intervention: Alcohol disinfection caps Comparator: Standard care ^a	CLASBI	Alcohol disinfection caps were associated with significantly fewer CLASBIs in general hospital patients (IRR: 0.43) and in intensive care patients (IRR: 0.29).
Voor In't Holt et al. (2017) ³	Study Design: Systematic review and meta-analysis Population: Patients in a hospital setting that used antiseptic barrier caps on hubs of central access lines with access to the bloodstream N = 9 relevant studies included in review; 7 included in meta-analysis	Intervention: Antiseptic barrier cap Comparator: Manual disinfection	CLASBIs	Antiseptic barrier caps were associated with a significant reduction in CLASBIs (IRR: 0.59).



First author, year	Study characteristics	Intervention(s) and comparator(s)	Relevant outcomes assessed	Author's conclusions
Moureau and Flynn (2015) ⁴	Study Design: Systematic review Population: NR N = 140 studies and 34 abstracts	Intervention: Alcohol disinfection caps Comparator: NR	Infection	Studies reported statistically significant reductions in infection (48% to 86%) when alcohol disinfection caps were used.
	Randomized contro	olled trials — Adult patient	ts or not specified	
Tasdelen Ogulmen and Ates (2020) ⁵	Study Design: Randomized controlled trial Population: NR N = 95 patients	Intervention: Isopropyl alcohol disinfection caps Comparator: Standard caps	CLABSIs	The control group's risk of infection was significantly higher (13.7 times) compared to the intervention group.
Hymes et al. (2017) ⁶	Study Design: 12-month, prospective, cluster-randomized, multicentre, open-label trial Population: hemodialysis patients with central venous catheters (CVC) N = 2470 patients (intervention = 1,245, control = 1,225)	Intervention: ClearGuard HD antimicrobial barrier caps Comparator: Standard caps	BSI, hospitalizations for BSI (admissions, hospitalized days), device-related adverse events	Use of ClearGuard caps was associated with significantly improved outcomes compared to standard caps: 56% lower BSI rate over 12 months, 69% lower BSI over the last 6 months, 43% fewer hospital admissions for BSI, and 51% fewer hospitalization days for BSI. No device-related adverse events were reported.
	Randomized controll	ed trials — Neonatal and/	or pediatric patients	
Milstone et al. (2020) ⁷	Study Design: 24-month, cluster-randomized, 2-period, crossover clinical trial Population: Pediatric hematology-oncology patients N = NR	Intervention: 70% isopropyl alcohol disinfection caps Comparator: Usual care	CLABSI, positive blood culture incidence, adverse events	The use of alcohol disinfection caps was not associated with a reduction in CLABSI incidence, but was associated with significantly lower positive blood culture incidence. No adverse events were reported.
Non-randomized studies — Adult patients or not specified				



First author, year	Study characteristics	Intervention(s) and comparator(s)	Relevant outcomes assessed	Author's conclusions
Cruz-Aguilar et al. (2020) ⁸	Study Design: Pre-post observational study Population: Hematologic and oncologic patients N = 598 patients (intervention = 309, control = 289)	Intervention: 70% isopropyl alcohol disinfection caps Comparator: Preimplementation practice	CLABSI	Alcohol disinfection caps were associated with a significantly lower CLABSI rate compared to control, but the multivariate analysis indicated antiseptic caps were not a significant independent protective factor for CLABSI. No significant difference was found between groups on time to CLABSI.
Martino et al. (2017)9	Study Design: Pre-post observational study Population: Patients in a burn intensive care unit N = NR	Intervention: Alcohol- impregnated central venous line port protector Comparator: Pre- implementation practice	CLABSIS	After introducing the alcohol disinfection caps, the rate of CLABSI infection per 1,000 line days decreased from 7.3 to 3.05.
Cameron-Watson (2016) ¹⁰	Study Design: Pre-post observational study Population: Hospital patients N = NR	Intervention: Alcohol disinfection devices (Curos) Comparator: Preimplementation practice (manual disinfection)	Vascular access device-related bacteremia	After alcohol disinfection caps were introduced and staff compliance was 80% or more, vascular access devicerelated bacteremia rates decreased by 69%.
Gutierrez et al. (2016) ¹¹	Study Design: Non-randomized experimental study Population: Patients attending day hospital oncology unit, with central venous or peripheral venous access lines with needleless connectors for antineoplastic treatment delivery N = 29 patients (intervention = 16; control = 13)	Intervention: Passive disinfection caps (Luer SwabCap) Comparator: Standard disinfection method	Phlebitis	No cases of phlebitis were observed.



First author, year	Study characteristics	Intervention(s) and comparator(s)	Relevant outcomes assessed	Author's conclusions
Kamboj et al. (2015) ¹²	Study Design: Pre-post observational study Population: Patients attending a tertiary care cancer centre in high-risk units (hematologic malignancy wards, hematopoietic stem cell transplant units, and intensive care units) and general oncology units N = NR	Intervention: Passive disinfection cap Comparator: Pre- implementation practice	Hospital-acquired CLABSI	Implementation of the passive disinfection cap was associated with a significant 34% decrease in hospital-wide hospital-acquired CLABSI, occurring only among high-risk patients and not in general oncology patients.
Wheatley et al. (2015) ¹³	Study Design: Pre-post observational study Population: Inpatients receiving parenteral nutrition via a peripherally inserted central catheter or dedicated port of CVC N = NR	Intervention: Alcohol disinfection caps (Curos) Comparator: Preimplementation practice	Catheter-related sepsis	Five months after introducing alcohol disinfection caps, the incidence of line infection per 1,000 line days fell significantly from 6.17 to 0.00.
DeVries et al. (2014) ¹⁴	Study Design: Pre-post observational study Population: Patients at Methodist Hospitals N = NR	Intervention: Isopropyl alcohol disinfection caps Comparator: Pre-implementation practice	BSI	BSI rate dropped by 43% for peripheral IV catheters, 50% for central lines, and 45% overall after introducing the disinfection caps; the drops for the central lines and overall were statistically significant.
Merrill et al. (2014) ¹⁵	Study Design: Pre-post observational study Population: Patients at a trauma Level I centre with peripheral and central lines N = NR	Intervention: Luer-lock disinfectant cap with 70% alcohol Comparator: Pre- implementation practice	CLABSI	Rate of CLABSIs decreased significantly by more than 40% after introducing the disinfection caps.
Stango et al. (2014) ¹⁶	Study Design: Pre-post observational study Population: Patients of an oncology unit at an acute care hospital N = NR	Intervention: Disinfection cap Comparator: Pre- implementation practice	CLABSI	After measures were introduced to improve compliance with cap use, CLABSIs began to decline, with 50% fewer CLABSIs occurring within the first 21 months after implementation.



First author, year	Study characteristics	Intervention(s) and comparator(s)	Relevant outcomes assessed	Author's conclusions
Wright et al. (2013) ¹⁷	Study Design: 3-phased (phase I: baseline, phase II: intervention, phase III: removal of intervention), multi-facility, quasi-experimental study Population: Adult patients with peripherally inserted central catheters inserted during hospitalization with 5 + consecutive line days N = 799 patients (phase I = 252, phase II = 364, phase III = 183)	Intervention: Alcohol disinfection cap (with 70% alcohol) Comparator: Pre- implementation practice (standard scrub)	CLABSI	From phase I to phase II, CLABSI rates per 1,000 line days decreased significantly from 1.43 to 0.69, then increased back to 1.31 during phase III when disinfection caps were removed and replaced with standard caps.
Ramirez et al. (2012) ¹⁸	Study Design: Non- randomized pre-post design Population: Adult care intensive care units N = NR	Intervention: Alcohol disinfection cap Comparator: Preimplementation practice (manual disinfection using alcohol swabs)	CLABSI	CLABSI rates reduced from 1.9 to 0.5 during the 1-year trial period.
Sweet et al. (2012) ¹⁹	Study Design: Pre-post observational study Population: Adult patients with a CVC at a tertiary care hospital's oncology unit N = NR	Intervention: Alcohol disinfection cap Comparator: Preimplementation practice (manual disinfection using alcohol wipes)	CLABSI	After alcohol disinfection caps were introduced, CLABSIs per 1,000 line days decreased significantly from 2.3 infections to 0.3.
	Non-randomized st	tudies — Neonatal and/or	pediatric patients	
Helder et al. (2020) ²⁰	Study Design: Pre-post observational study Population: Infants and children in neonatal and pediatric intensive care units N = 2,248 patients	Intervention: Antiseptic barrier caps Comparator: Pre- implementation practice (manual disinfection)	CLABSI	CLABSI rates per 1,000 catheter days declined non-significantly from 3.15 to 2.35 after introducing antiseptic caps, or an incidence reduction of 22%. CLABSI reduction was slightly larger in the neonatal intensive care unit than the pediatric intensive care unit.



First author, year	Study characteristics	Intervention(s) and comparator(s)	Relevant outcomes assessed	Author's conclusions
Pavia and Mazza (2016) ²¹	Study Design: Pre-post observational study Population: Patients at pediatric hospital that serves many patients with short bowel syndrome N = NR	Intervention: Alcohol disinfection cap Comparator: Pre- implementation practice	BSI	Introduction of alcohol- dispensing caps was associated with lower BSI rates.

BSI = bloodstream infection; CABSI = catheter-associated bloodstream infections; CLASBI = central line-associated bloodstream infections; venous catheter; IRR = incidence risk ratio; NR = not reported; RR = risk ratio.

CVC = central

References

Health Technology Assessments

No literature was identified.

Systematic Reviews and Meta-analyses

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Randomized Controlled Trials

Population — Adult Patients or Not Specified

- Tasdelen Ogulmen D, Ates S. Use of alcohol containing caps for preventing bloodstream infections: A randomized controlled trial. J Vasc Access. 2020 Aug 27:1129729820952961. Medline
- Hymes JL, Mooney A, Van Zandt C, Lynch L, Ziebol R, Killion D. Dialysis catheter-related bloodstream infections: a cluster-randomized trial of the ClearGuard HD antimicrobial barrier cap. Am J Kidney Dis. 2017 Feb;69(2):220-227. Medline

Population – Pediatric Patients

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Non-Randomized Studies

Population - Adult Patients or Not Specified

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Population — Neonatal and/or Pediatric Patients

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Guidelines and Recommendations

No literature identified.



Appendix 1: References of Potential Interest

Previous CADTH Reports

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Health Technology Assessments

Technology Brief

 National Institute for Health and Care Excellence. ClearGuard HD Antimicrobial Barrier Cap for preventing haemodialysis catheter-related bloodstream infections. (Medtech innovation briefing MIB234) 2020; https://www.nice.org.uk/advice/mib234. Accessed 2021 Jan 14.

See: Clinical and technical evidence - Overall assessment of the evidence

Randomized Controlled Trials

Alternative Comparator — Comparison Between Two Brands of Disinfection Caps

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Alternative Intervention — Multifaceted Intervention Including Disinfection Caps

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Unclear Methodology

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Non-Randomized Studies

Alternative Intervention — Disinfecting Swabs Using Alcohol and Chlorhexidine

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Alternative Intervention — Multifaceted Intervention Including Disinfection Caps

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Unclear Comparator

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Guidelines and Recommendations

Alternative Population — Not Specific to Neonatal or Pediatric Patients

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Unclear Methodology and Alternative Population — Not Specific to Neonatal or Pediatric Patients

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Methodology - Expert Opinion

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Review Articles

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