Skin Antiseptics: Frequently Asked Questions (FAQ)

Selection, Handling, Application, Use and Storage of Patient Skin Antiseptic Products for Invasive Procedures Outside of the Operating Room
If you have any questions or comments contact IPC at ipcsurvstdadmin@ahs.ca.

Frequently asked questions

Questions	Responses

1. What is the background for the BPR for Selection, Handling, Application, Use and Storage of Patient Skin Antiseptic Products for Invasive Procedures Outside of the Operating Room, e.g., development and consultation questions?	The BPR was developed in 2014 and updated in 2019 in collaboration with a Working Group led by the Health Technology Assessment and Innovation (HTAI) team and included Surgical SCN, and IPC Physician reps to:
	• provide recommendations for the selection, handling, application, use and storage of patient skin antiseptic products;
	• standardize patient skin antiseptic products for invasive procedures inside and outside the operating room:
	  ○ The IPC BPR applies to invasive procedures outside of the operating room.
	  ○ The Adult Surgical Patient Skin Preparation in the Operating Room/Treatment Areas Practice Direction Manual Policy and Direction Manual applies provincially to invasive procedures in the operating room Insite > Home > Teams > Department of Surgery – Calgary > Policies & Procedures > Surgical Services > Surgical Suites.
	  ○ Follow AHS topic-specific documents for patient skin antiseptics for other purposes as outlined on page of the IPC BPR.
	• reduce the risk of skin antiseptic contamination and infection transmission.

2. Are skin antiseptics sterile?	• Antiseptic agents commonly used for skin preparation for line insertions etc., are not usually sold as "sterile" products, e.g., alcohol, chlorhexidine-alcohol, povidone iodine, povidone iodine-alcohol prep pads. • There are some skin antiseptics that are sold as sterile, and they will be labeled as such, e.g., alcohol pads. • Skin antiseptics approved by Health Canada are manufactured according to the Good Manufacturing Practices Guideline. • Good manufacturing processes are in place so that the potential opportunity for bacterial contamination of the antiseptic during manufacturing is very low/negligible. Antiseptics are not necessarily sterile as the process would render them ineffective but their packaging, e.g., bottle etc. is generally sterile. For further details refer to: • Health Canada. Guidance Document for Human-Use Antiseptic Drugs. 2019. Minister of Health, Health Products and Food Branch, section 6.3.5. • A White Paper by Dr. Michelle Alfa online: Quality of 3M Canada Skin Antiseptic Drug Products.
3. Can open aqueous skin antiseptics such as povidone iodine be used past the 7-day expiry recommended in the BPR for Selection, Handling, Application, Use and Storage of Patient Skin Antiseptic Products for Invasive Procedures Outside of the Operating Room?	No. Do not use aqueous skin antiseptics past the 7-day expiry recommended in the BPR for Selection, Handling, Application, Use and Storage of Patient Skin Antiseptic Products for Invasive Procedures Outside of the Operating Room. Rationale: • The BPR recommendation for 7-day expiry after opening for aqueous skin antiseptics such as povidone iodine was made after discussion/ consultation with IPC Leadership to minimize waste of product while supporting patient safety. • Aqueous skin antiseptics do not contain a preservative so seven days was selected as a safe use period once the container is open versus 30 days for solutions with alcohol, i.e., CHG 2% and alcohol 70% solution. • Manufacturers minimize the risk of intrinsic contamination by following Good Manufacturing Practices while manufacturing the skin antiseptic. However, after the bottle is open contamination can occur. To ensure product integrity manufacturers such as 3M label their

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Questions	Responses
	bottles (even the 500 ml size) single-use and recommend discarding after use on a single patient. • 2014 Health Canada alert on safe use of topical antiseptics: "These products can be considered safe and effective; however, if proper care is not taken when using them, they can become contaminated and cause serious, subsequent infections." • FDA recommendation for label changes and single-use skin antiseptics "Extrinsic contamination occurs when microorganisms are introduced in association with product use. For example products can become contaminated when diluted with nonsterile water, or transferred for storage into nonsterile containers." • 7 days was determined to be a reasonable time frame to reuse an open bottle of aqueous skin antiseptics as long as the skin antiseptic is handled and stored in an aseptic manner. • Open bottles should be discarded sooner if contamination is suspected. Refer to BPR, Section 5 page 4 for details.

4. Why does the BPR recommend discarding CHG 2% with alcohol 70% 30 days after opening?	In consultation with IPC leadership, the BPR recommends discarding alcohol skin antiseptic solutions, i.e., chlorhexidine 2% with alcohol 70%, 30 days after opening.
	• IPC selected the 30-day timeframe for safe reuse of an open bottle of CHG2% with alcohol 70% antiseptics based on United States Pharmacopeia (USP) and other evidence-informed guidelines. The timeframe provides a reasonable end-date for usage when the skin antiseptic is handled and stored in an aseptic manner.
	  ○ The alcohol 70% may help reduce the risk of bacterial growth.
	• The USP General Chapter 797 Guidebook to Pharmaceutical Compounding – Sterile Preparations. Second Edition recommends multi-dose vials be discarded within 28 days of opening.
	• Canadian Pediatric Association. 2018. Position Statement. Infection Prevention and Control in Pediatric Office Settings https://www.cps.ca/en/documents/position/infection-prevention-and-control-in-paediatric-office-settings#ref2
	  ○ Because antiseptics can be contaminated during use, single-use products are preferable. When multiple-use containers are used, label them with the date and discard after 28 days of use.
	• Manufacturers minimize the risk of intrinsic contamination by following Good Manufacturing Practices while manufacturing the skin antiseptic; however, after the bottle is opened contamination can occur. To ensure product integrity, manufacturers such as 3M label their bottles (even the 500 ml size) single-use and recommend discarding after use on a single patient.
	• 2014 Health Canada alert on safe use of topical antiseptics: "These products can be considered safe and effective; however, if proper care is not taken when using them, they can become contaminated and cause serious, subsequent infections."
	• FDA recommendation for label changes and single-use skin antiseptics "Extrinsic contamination occurs when microorganisms are introduced in association with product use, e.g., products can become contaminated when diluted with nonsterile water, or transferred for storage into nonsterile containers."
	• 30 days allows easier calculation of discard date when bottle is opened and dated.
	• Open bottles should be discarded sooner if contamination is suspected. Refer to BPR, Section 5 page 4 for details.

5. Can alcohol 70% skin antiseptic wipes be used for IV starts?	Yes. While CHG 2% with alcohol 70% is the preferred skin antiseptic, alcohol 70% may be used. From The Vascular Access Device Infusion Therapy- Before You Begin Insite > Home > Tools > Clinical Guidance Viewer > CC Topics > Clinical Care Topics > Vascular Access Device Infusion Therapy > Infection Prevention & Control (IP&C), page 4: AHS Approved Antiseptic Agents

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	70% Isopropyl Alcohol — Use if patient has allergy to chlorhexidine 70% alcohol requires a 1 minute friction application, no residual antibacterial activity Dry time 30 seconds
6. Why are single-use skin antiseptics preferred?	• Single-use skin antiseptics reduce the risk of contamination during use (extrinsic contamination) as the open package is discarded after use and not kept for multiple uses. • Use of single-use skin antiseptic formats is promoted as best practice by experts such as ORNAC, FDA, Infusion Nurses Society, Association for Professionals in Infection Control (APIC), and AORN.
7. What is the difference between extrinsic and intrinsic contamination?	• **Intrinsic contamination** occurs when microorganisms are introduced into a product during the manufacturing process. Cases of intrinsic contamination have been identified in which microorganisms have been isolated from pharmaceutical water supplies and nonsterile manufacturing environments. Once introduced into the product during manufacturing, these microorganisms may remain viable and multiply. (FDA Q and A, Q3.) • **Extrinsic contamination** occurs when microorganisms are introduced during product use, e.g., products can become contaminated when diluted with nonsterile water or transferred for storage into nonsterile containers. • Open containers can be a source of contamination if they are not consistently handled in an aseptic manner and stored in a closed container in a clean area. 2014 Health Canada alert on safe use of topical antiseptics: "These products can be considered safe and effective; however, if proper care is not taken when using them, they can become contaminated and cause serious, subsequent infections."
8. Why do AHS guidance documents vary regarding preferred skin antiseptic?	Skin antisepsis recommendations vary according to patient population; where the skin antiseptic is being applied; and the procedure being performed, e.g., neonates versus adults; mucous membranes versus intact skin; surgery, vascular access or urinary catheter management, e.g., CHG 2% and alcohol 70% is contraindicated for mucous membranes.
9. Can we use benzalkonium chloride wipes for urinary catheter management?	• No. Benzalkonium chloride wipes are not listed as a potential skin antiseptic in the urinary catheter management document, Insite > Home >Tools > Clinical Guidance Viewer > Clinical Care Topics (A-Z) > Urinary Catheter Management > Principles of Urinary Catheter Management > Infection Prevention and Control, page 3: AHS approved antiseptic agents for urinary catheter management. • Benzalkonium chloride wipes are used by the patient to clean themselves prior to collecting a urine sample for C&S. Rationale: • Midstream urine collection for C&S guidance recommends that the patient cleanse the genital area with towelettes. The purpose of this cleansing (and avoiding touching inside of sterile container) is that the specimen will be not be contaminated during the collection process. ○ **Midstream urine sample** - clean with towelette x 2, void in toilet small amount, void in container small amount (+/-30ml), void rest in toilet. • In contrast, skin antisepsis/preparation per Alberta Health Services Urinary Catheter Management: Insite > Home > Tools > Clinical Guidance Viewer > Clinical Care Topics (A-Z) > Urinary Catheter Management > Principles of Urinary Catheter Management, Infection Prevention and Control, is meant to provide appropriate skin antisepsis and support aseptic insertion of a urinary catheter into the bladder. These actions help reduce the risk of catheter associated urinary tract infection (CA-UTI) which is the most important common risk of urinary catheterization and is linked to increased morbidity and mortality.
10. Regarding the BPR Selection, Handling, Application, Use and Storage of Patient Skin Antiseptic Products for Invasive Procedures	Follow the manufacturers' recommendations including equipment recommendations, e.g., warming cupboard and controlled temperature parameters. Heat may change the chemical properties and efficacy of the antiseptic agent. (ORNAC, 2017)

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Outside of the Operating Room, Section 7 on Warming: How are skin antiseptics safely warmed?	BPR recommendations: • Never heat or warm flammable skin antiseptics, e.g., chlorhexidine 2% with alcohol 70%. • Warm non-flammable, unopened, skin antiseptic solutions only if the product label provides directions on how to safely do so. • Never warm skin antiseptics in a microwave oven or an autoclave.

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