Interim guidance on alternative antisepsis products for minor procedures: joint recommendations from the Australasian College for Infection Prevention and Control (ACIPC), the Australasian Society for Infectious Diseases (ASID), and the Australian Vascular Access Society (AVAS)

Premise:
This document, developed through collaboration between the Australasian Society for Infectious Diseases, the Australasian College for Infection Prevention and Control, and the Australian Vascular Access Society, provides interim guidance for healthcare providers on the evaluation and use of substitute products for skin and surface antisepsis prior to minor invasive/percutaneous procedures including insertion and retention of vascular access devices. It does not include guidance for skin preparation prior to major or minor surgical procedures performed under general or regional anaesthesia. ***This document is intended to provide adjunctive guidance to existing guidelines to assist with local risk assessment and policy development during an interim period where the availability of products commonly used for antisepsis in Australasia may be compromised.***

It is recommended that when undertaking a risk assessment, healthcare facilities and clinicians should consider the following recommendations and guidance in the context of their local situation (including availability and ongoing supply of current products in use), and in conjunction with both procedure-related and patient-related risk factors for infection (Figure 1).

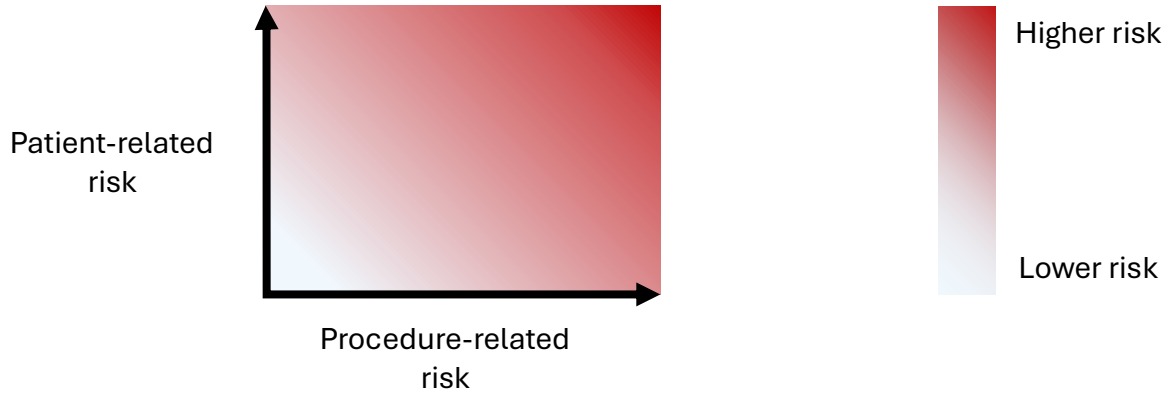

Figure 1: Consider both procedure- and patient-related risk factors when undertaking a risk assessment

Recommendation	Strength of recommendation
For all procedures requiring skin antisepsis, adherence to aseptic technique is essential.	Strong recommendation Level III-3 evidence Consensus guidelines
When considering replacements for products that are unavailable, it is recommended that like-for-like products are used where possible. For example, single-use preparations (e.g. swab stick) of 2% chlorhexidine in 70% alcohol is substituted by another single-use preparation of 2% chlorhexidine in 70% alcohol. *Commentary: When assessing and comparing substitute products, the following factors may influence practicality of use (e.g. drying time) and efficacy, and should be considered: a) the active ingredients; b) volume for administration; c) packaging. Randomised studies comparing iodophor-based or alcohol-alone products to chlorhexidine-in alcohol have generally shown inferior outcomes for procedures involving insertion and retention of vascular catheters. While other products may be available and marketed as alternatives, head-to-head comparisons with clinical outcomes are generally lacking. In the absence of clear evidence, it is recommended that like-for-like replacement products are used where possible, and where these are also unavailable, a risk assessment is undertaken for use of alternative products.*	Strong recommendation Level II/IV/V evidence Consensus guidelines
When considering alternative products, undertake a risk assessment that includes both procedure-related and patient-related risk factors for infection (Figure 1). *Commentary: Examples of procedure-related risk factors include the presence of a retained medical device, procedures involving sites with a higher microbial burden (e.g. femoral vs jugular insertion site), and high-consequence procedures (e.g. lumbar puncture vs venepuncture). Patient-related risk factors may be generic (e.g. immunocompromise), or specific to a particular procedure (e.g. difficult intravenous access). A risk assessment should also be undertaken when preserving limited supply of antisepsis products to ensure optimal products are available for higher risk contexts.*	Strong recommendation Level V evidence Expert opinion

5% alcohol-based povidone-iodine solution should continue to be used for patients with hypersensitivity to chlorhexidine-containing products. If insertion is close to or through mucous membranes, use 10% aqueous povidone-iodine. *Commentary: Povidone-iodine products have generally resulted in inferior outcomes compared to chlorhexidine-in-alcohol for insertion and retention of vascular catheters. While true hypersensitivity to chlorhexidine is rare, for patients with reported hypersensitivity, povidone-iodine in alcohol is the preferred alternative. Although products containing lower concentrations of chlorhexidine have also shown superior outcomes compared to povidone-iodine, reactions are most often due to either anaphylaxis or contact dermatitis and are likely to occur irrespective of the chlorhexidine content.*	Strong recommendation Level IV evidence Consensus guidelines
Where bottled solution products containing preparations of 2% chlorhexidine in 70% alcohol may be used as a substitute for single-use preparations, it is recommended that additional contingency measures be implemented to minimise the risk of bottle contamination and inadvertent injection of antiseptic solution. *Commentary: Although single-use bottles are generally preferred, when using bottled solution products as an alternative during periods of low availability of antiseptic products, additional measures should be undertaken to reduce risks with multiple use of these products. Examples* of mitigation measures include:* • *Use smaller volume bottles where possible* • *Clearly mark bottles with the date and time when opened and ensure bottles are discarded 24 hours after opening* • *Avoid inserting swabs and applicators into bottles to minimise the risk of microbial contamination* • *Have clearly separate processes for skin antisepsis products and injectable medications e.g. discard equipment after skin preparation prior to drawing up injectable medication, and have all injectable medication drawn up into pre-labelled sterile syringes* *It is usually recommended that non-injectable fluids including chlorhexidine-in-alcohol preparations for skin decontamination should not be decanted into open containers on a sterile procedure area to avoid accidental injection of chlorhexidine. For this reason, commercially prepared swabs and swab sticks containing chlorhexidine-in-alcohol are generally preferred. However, if using bottled solution products in place of swabs and swab sticks, the solution should be decanted into a small sterile tray within an aseptic field before being applied using aseptic technique. Establishing processes to separate antisepsis products and injectable medications are critical to prevent accidental injection of antisepsis products.* ** The examples listed are based on expert opinion and intended as a guide. Implementation should be based upon local risk assessment.*	Moderate recommendation Level IV/V evidence Guideline statement

For minor procedures such as lumbar punctures and pleural/ascitic taps that do not require prolonged retention of a catheter, products containing lower concentrations of chlorhexidine-in-alcohol (e.g. 0.5% or 1%) or povidone-iodine in alcohol may be used as a substitute for 2% chlorhexidine in 70% alcohol. *Commentary: Although clinical trials have suggested chlorhexidine-in-alcohol may result in a lower surface microbial burden than povidone-iodine products, superiority in clinical outcomes following minor diagnostic procedures (e.g. lumbar puncture, pleural aspirate) and regional anaesthesia administration has not been established. For most uses of chlorhexidine-in-alcohol antisepsis products, comparisons of different concentrations of chlorhexidine have not been directly undertaken. Consider use based on a risk assessment including patient- and procedure-related risk factors.*	Moderate recommendation Level V evidence Expert opinion
70% alcohol products (e.g. alcohol prep pads) can be used for: • **Antisepsis for temporary skin breach without a retained catheter e.g. venepuncture,** • **Cleaning skin prior to subcutaneous drug administration where required e.g. enoxaparin.** • **Microbial decontamination of needleless connector hubs ("scrub the hub")** *Commentary: Clinical data to inform optimal products are generally lacking or are of low quality for these indications. If chlorhexidine-in-alcohol products are not readily available, 70% alcohol products may be acceptable alternatives for temporary intravenous catheters e.g. for administration of radiographic contrast or radionuclide tracer, where the catheter can be immediately removed following the intended use.*	Moderate recommendation Level V evidence Expert opinion
Administration of vaccines and medications via subcutaneous or intramuscular injection does not necessarily require skin antisepsis preparation unless visibly dirty. *Commentary: If the skin is visibly clean, limited data suggest there is no additional benefit from alcohol skin cleaning prior to vaccine administration. Routine use of alcohol wipes may increase the incidence of local injection site reactions due to tracking in with the vaccine when incompletely dried.*	Strong recommendation Level II evidence Consensus guidelines
All antiseptic products used for skin preparation should be allowed to dry completely to achieve optimal antimicrobial effect prior to performing an invasive procedure. *Commentary: It should be noted that different products (including different brands containing the same active antiseptic components) may have different formulations, packaging and volumes of administration which can result in different drying times.*	Strong recommendation Level V evidence Consensus guidelines

Further questions and guidance:	Strength of recommendation
Q: Can povidone-iodine in alcohol or other products be routinely used as an alternative to chlorhexidine-in-alcohol? *A: The use of povidone-iodine as an alternative to chlorhexidine-in-alcohol depends on the procedure, but the expert group opinion is that where possible, like-for-like products should be used in preference.* *For insertion of vascular access devices with a prolonged dwell time, multiple studies have shown superiority of chlorhexidine-in-alcohol products over povidone-iodine-based products.* *For procedures involving temporary skin breach without a retained catheter, robust clinical data are generally lacking. Products containing other active ingredients have been marketed overseas and in Australia for skin antisepsis, though in the absence of clinical outcome data from head-to-head comparisons, a risk assessment should be undertaken when considering these as alternatives.*	Moderate recommendation Level II/IV evidence Expert opinion
Q: Can products containing alternative concentrations of chlorhexidine-in-alcohol be considered as substitutes for 2% chlorhexidine-in-alcohol? *A: Preparations containing 2% chlorhexidine-in-alcohol have been the most studied and widely used products. However, several studies have tested lower concentrations of chlorhexidine-in-alcohol products and shown superiority over povidone-iodine products using composite and surrogate endpoints. The expert group opinion is that products containing 2% chlorhexidine-in-alcohol are preferred, though if not readily available, alternative products containing a lower concentration of chlorhexidine may be used. In some specialty population groups (e.g. preterm and extremely low birth weight neonates), lower concentrations of chlorhexidine are frequently used – as with all substitute products, a risk assessment should be undertaken when considering an alternative product, with a like-for-like product (i.e. same concentration of active ingredients, same formulation etc.) used preferentially as a replacement.*	Moderate recommendation Level II/V evidence Expert opinion

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Endorsed by:

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ASID Australasian Society for Infectious Diseases

AVAS Australian Vascular Access Society

Appendix: Strength of Recommendations

Strength of recommendation	
Strong recommendation	Recommendations applicable in all contexts whenever possible
Moderate recommendation	Recommended in most situations, depending on context and local risk assessment
Weak recommendation	Consider based on local risk assessment
Level of evidence	
I	Evidence from a systematic review of all relevant randomised controlled trials (RCTs)
II	Evidence from at least one well-designed randomised controlled trial
III-1	Evidence from well-designed controlled trials without randomisation
III-2	Evidence from comparative studies (including systematic reviews) including controls without randomisation e.g. cohort studies, case-control studies, or interrupted time series with a control group
III-3	Evidence from comparative studies with historical controls, or cohort studies without a control group
IV	Evidence from case reports or case series
V	Expert opinion without critical appraisal, or based on physiology, laboratory research or clinical principles
Supporting evidence	
Consensus guidelines	Recommendations consistent with multiple evidence-based national/international guidelines
Guideline statement	Recommended in guideline statement published by government and/or based on expert opinion
Expert opinion	Recommended by expert group