#### **EXECUTIVE SUMMARY**

## **Background**

According to the definition given by CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, a germicide is an agent that can kill microorganisms, particularly pathogenic organisms ("germs"). The term *germicide* includes both antiseptics and disinfectants. *Antiseptics* are germicides applied to living tissue and skin; *disinfectants* are antimicrobials applied only to inanimate objects. In general, antiseptics are used only on the skin and not for surface disinfection, and disinfectants are not used for skin antisepsis because they can injure skin and other tissues.

An antiseptic is a substance which inhibits the growth and development of microorganisms. It may be either bacteriocidal or bacteriostatic. Their uses include cleansing of skin and wound surfaces after injury, preparation of skin surfaces prior to injections or surgical procedures, and routine disinfection of the oral cavity as part of a program of <u>oral hygiene</u>. Some commonly used antiseptics for skin cleaning includes chlorhexidine, iodine compounds, and alcohol.

Currently in the Ministry of Health Drug Formulary, the common antiseptics listed are: 70% alcohol; 4% chlorhexidine gluconate scrub; 5% chlorhexidine gluconate solution; 5% chlorhexidine gluconate solution in 70% alcohol; 10% povidone iodine; and 7.5% povidone iodine scrub.

In the last fifty years we have witnessed a significant increase in the number of antiseptics as well as their usage in the healthcare environment. When used appropriately, antiseptics play an important role in controlling infection and reduce the risk of nosocomial infections.

In view of the new development in the area of antiseptic, there is a need to update the evidence available to support the use of these antiseptics in the Malaysian Ministry of Health. Thus, this Health Technology Assessment was undertaken to review the antiseptics currently used for skin preparations especially prior to procedures such as surgery, central venous catheterization, epidural catheterization, urinary catheterization, intradermal, subcutaneous, and intramuscular injection which will help healthcare providers to identify the best intervention strategies in preventing and controlling infections in clinical settings.

#### **Technical features**

Alcohols exhibit rapid broad-spectrum antimicrobial activity against vegetative bacteria (including mycobacteria), viruses, and fungi but are not sporicidal. They are, however, known to inhibit sporulation and spore germination but this effect is reversible. Another antiseptic, chlorhexidine, is probably the most widely used biocide and antiseptic. This is due in particular to its broad-spectrum efficacy, substantively for the skin, and low irritation. Despite the advantages of chlorhexidine, its activity is pH dependent and is greatly reduced in the presence of organic matter. A new antiseptic, Octenidine dihydrochloride, has activity against Grampositive and Gram-negative bacteria. Octenidine dihydrochloride is used in concentrations of 0.1% to 2.0% and is similar in its action to the Quaternary Ammonium Compounds (QAC's), but is of somewhat broader spectrum of activity. Currently, it is increasingly being used in continental Europe as a QAC's and chlorhexidine substitute in water-or alcohol-based antiseptic for skin, mucosa and wound. A commonly used antiseptic, iodine, is bactericidal, fungicidal, tuberculocidal, virucidal, and sporicidal. Although aqueous or alcoholic (tincture) solutions of iodine have been used for 150 years as antiseptics, they are associated with irritation and

excessive staining. In addition, aqueous solutions are generally unstable; in solution, at least seven iodine species are present in a complex equilibrium, with molecular iodine ( $I_2$ ) being primarily responsible for antimictrobial efficacy. These problems can be overcomed by the development of iodophors ("iodine carriers" or "iodine-releasing agents"); the most widely used are povidone-iodine and poloxamer-iodine in antiseptics.

# **Objective**

To assess the safety, effectiveness, efficacy and cost-effectiveness of antiseptics for skin preparations prior to five procedures commonly performed in clinical practice.

### Methods

Electronic databases such as MEDLINE, PubMed, EBM Reviews-Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, HTA databases, EBM Reviews – NHS Economic Evaluation Database, EBM Full Text-Cochrane DSR, ACP Journal Club and DARE were searched. Critical appraisal of all relevant literature was done using Critical Appraisal Skills Programme (CASP) and evidence was graded according to US/Canadian Preventive Services Task Force.

#### **Results and conclusion**

Twenty four potentially relevant articles were retrieved in full text. Of the twenty four full text articles, seventeen articles were included for effectiveness of antiseptics for skin preparations prior to the identified procedures.

Five systematic reviews, eleven randomised controlled trials and one non randomised trial related to the effectiveness of antiseptics for skin preparations prior to procedures were retrieved. However, there was no health technology assessment report retrieved.

The evidence retrieved showed that 0.1% Octenidine in alcoholic solution, 70% alcohol, 10% povidone iodine, iodophor in alcohol, 0.25% chlorhexidine gluconate, 0.5% chlorhexidine gluconate in 70% alcohol, 4% chlorhexidine gluconate, 2% chlorhexidine gluconate in 70% alcohol and alcohol spray are antiseptics commonly used for skin preparations prior to procedures.

The review showed there was strong evidence that:

- Two percent (2%) chlorhexidine gluconate resulted in significant reduction in microbial colonization of the central venous catheter insertion site and the catheter tip as well as local site infection. However, (0.1%) Octenidine in alcoholic solution was superior to 74% alcohol in preventing the central venous catheter associated infections.
- Zero point five percent (0.5%) chlorhexidine in 70% alcohol resulted in significant reduction in microbial colonization of the epidural catheter insertion site.
- Two percent (2 %) chlorhexidine gluconate in 70% alcohol resulted in significant microbial reduction of the preparation sites prior to surgery and surgical site infection.
- Cleansing the periurethral area with sterile water was not inferior to cleansing with antiseptics prior to urinary catheterization.

There was evidence to show that the use or no use of antiseptics on unsoiled skin prior to intradermal, subcutaneous and intramuscular injection does not decrease or increase the risk of infection.

# 8 RECOMMENDATION

Based on the above review, the following antiseptics are recommended for use prior to the following procedures:

## i) Central venous catheterization:

Two percent (2%) chlorhexidine gluconate in 70% alcohol is the antiseptic of choice prior to central venous catheterization but 0.1% Octenidine in alcoholic solution is potentially beneficial. However, the retrieved evidence shows that 0.1% Octenidine in alcoholic solution was superior to alcohol. More clinical research is warranted.

# ii) Epidural catheterization

Zero point five percent (0.5%) chlorhexidine in 70% alcohol is the antiseptic of choice for skin preparation prior to epidural catheterization.

## iii) Surgery:

Two percent (2 %) chlorhexidine gluconate in 70% alcohol is potentially superior to 4% chlorhexidine and povidone iodine solution and may be the antiseptic of choice for skin preparation prior to surgery

### iv) Urethral catheterization:

The use of either sterile water or antiseptic for skin preparation prior to urethral catheterization is an acceptable practice.

# v) Intradermal, subcutaneous, and intramuscular injection

For unsoiled skin, the use or not use of 70% alcohol swab prior to the above procedures can be practised.