The efficacy of alcohol-based hand disinfectant products

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Over the last few years alcohol-based hand disinfectants have become widely available within health care, providing an alternative means of achieving good hand decontamination. In the hospital setting their advantage over soap and water is that they can be applied in transit to the next patient or task and therefore may help improve compliance with hand decontamination. Within the community setting they provide a suitable alternative to handwashing, particularly where there may be inadequate handwashing facilities. This article considers some issues around their use, namely indications for use, efficacy, and potential for skin damage.

It is well known that hand hygiene is a crucial factor in the control of health care-acquired infections (HCAs) (Pratt et al, 2001). This is because hands may readily become contaminated with transient micro-organisms during the delivery of health care. Transient flora such as *Staphylococcus aureus* are micro-organisms colonising the superficial outer layers of the skin, and may be readily removed by handwashing (Boyce and Pittet, 2002). Equally, where hand hygiene is poor these micro-organisms may be transmitted from the hands of one patient to another. Hands contaminated by the hospital environment may increase their effectiveness over products containing a single alcohol.

Traditionally soap and water, either plain soap or soap incorporating an antimicrobial agent such as chlorhexidine gluconate, have been used for handwashing in an effort to reduce HCAs (Boyce and Pittet, 2002). More recently a number of alcohol-based hand rubs/gels have also become widely available in health care, providing health care workers with another range of hand decontamination products. Their introduction raises a number of issues, such as indications for use, efficacy and potential for skin damage. This article considers some of the evidence available in relation to these issues.

**Indications for use**

National and international guidelines on hand hygiene within health care provide guidance on the use of alcohol-based hand rubs/gels. For example, national evidence-based guidelines commissioned by the Department of Health, on the prevention of HCAI in hospitals, state alcohol-based hand rubs are indicated for use during delivery of health care provided there is no visible dirt or organic matter present on the hands (Pratt et al, 2001). Alcohol-based products cannot adequately penetrate dirt or organic matter to effectively destroy contaminating micro-organisms.

Similarly, the more recently published evidence-based guidelines for preventing HCAI in primary and community care state it is preferable to decontaminate hands between contact with different patients using an alcohol-based hand rub unless hands are visibly soiled (Pelllowe et al, 2003). Furthermore, in the community or the patient’s own home where limited handwashing facilities are available, alcohol hand rubs offer a practical and highly acceptable alternative to handwashing (Pelllowe et al, 2003).

International guidelines provided by the Centers for Disease Control and Prevention in the US also clearly indicate that if hands are not visibly soiled then an alcohol-based hand rub should be used for routine hand decontamination in a variety of health care settings and care activities (Boyce and Pittet, 2002).

Therefore it appears there is a consensus view on the indications for use of alcohol-based hand rubs/gels. They should be used routinely during delivery of patient care provided hands are not visibly soiled.

**Efficacy**

Alcohol-based hand rubs/gels are composed of a variety of active ingredients (Box 1). According to Rotter (2001) n-propanol is the most effective alcohol and ethanol the least effective when compared at equal concentrations. However, Boyce (2000) states that ethanol has greater virucidal efficacy than isopropanol-based products.

Many of the available alcohol hand rubs/gels contain combinations of two of these alcohols, which in theory may increase their effectiveness over products containing a single alcohol.

Others contain alcohol solutions combined with other known antimicrobial agents, such as povidone-iodine, triclosan or chlorhexidine gluconate (Boyce and Pittet, 2002). The addition of other antimicrobial agents can result in an increase in persistent antimicrobial activity (Rotter, 1999), a property that alcohol alone does not have (Pratt et al, 2001).

Alcohol-based hand rubs/gels containing 60-95 per cent alcohol have the greatest efficacy (Boyce and Pittet, 2002). The antimicrobial activity of alcohol solutions within this range is related to their ability to denature proteins (Larson and Morton, 1991). Concentrations of alcohol above 95 per cent are considered less effective because proteins are not readily denatured in the absence of water (Larson and Morton, 1991).
and care population. In addition it may be that the plain soap on the generalisability of the study to the wider health reducing the potential for bias.

Similarly Girou et al (2002) compared the efficacy of hand rubbing with an alcohol-based solution versus handwashing with antimicrobial soap during the delivery of routine patient care, including caring for patients with MRSA. This trial involved 23 health care workers and a total of 114 patient care activities (59 in the alcohol hand rubbing group and 55 in the antimicrobial handwashing group). Imprints were taken of the fingertips and palms of the dominant hands before and after the hand hygiene procedures and bacterial counts were measured.

The researchers found with alcohol hand rubbing the median percentage reduction in bacterial contamination was significantly greater than with handwashing, 83 per cent compared with 58 per cent respectively. The health care workers in the study were randomly assigned to their study group and laboratory staff were blind to which group the imprint samples belonged while undertaking the bacterial counts. Both of these factors help reduce the potential for bias.

However, as with the previous study it may be argued that the sample size was small and the achieved results may not have been directly attributable to the hand decontamination products used and may have been influenced by lack of handwashing for an optimum period of time, as the researchers themselves indicated.

This limitation identified in both studies, namely insufficient time spent on application of soap, actually strengthens the argument for use of alcohol hand rubs, which were also applied for similar lengths of time but proved to have greater efficacy. Therefore, the evidence appears to confirm that alcohol based hand rubs/gels are more effective than soap and water in achieving adequate hand decontamination.

**Efficacy testing**

Before trying to compare different products it is necessary to understand a little of the methodology behind the testing of hand hygiene products. It appears that efficacy testing of alcohol-based hand rubs/gels is a complex issue. A further confounding factor is that scientific studies have not yet established the extent to which microbial reduction on hands is required to minimise the transmission of harmful pathogenic bacteria in the clinical situation (Rotter, 1999; Larson, 1995).

Different test methods are in use in Europe and the US to evaluate the efficacy of hand hygiene products. In Europe the method most widely used is EN 1500 1997. This involves a standardised methodology, including two applications of an alcohol hand rub agent for a maximum of 60 seconds. Hands are then microbiologically tested and bacterial colony counts performed. Products achieving approximately a 4log<sub>10</sub> reduction in micro-organisms are classified as meeting the standard.

In the US efficacy testing is regulated by the Food and

**REFERENCES**


**KEYWORDS** Infection control Hand hygiene Alcohol hand disinfectant

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**BOX 1. THE DIFFERENT ALCOHOLS PRESENT IN HAND RUBS AND GELS**

- Ethyl alcohol/ethanol
- Isopropyl alcohol/isopropanol (propan-2-ol)
- N-propyl alcohol/n-propanol (propan-1-ol)

Boyce and Pittet (2002) confirm that alcohol-based hand rubs have excellent germicidal activity against both Gram-negative and Gram-positive bacteria such as Escherichia coli and methicillin-resistant Staphylococcus aureus (MRSA), along with mycobacteria. They are also effective against certain enveloped (lipophilic) viruses, such as HIV, influenza, respiratory syncytial virus, and herpes simplex virus. Hepatitis B and C are also susceptible to alcohol but are killed less readily and require at least 60-70 per cent alcohol for effectiveness (Sattar et al, 2001).

Less encouragingly, alcohol is not effective against bacterial spores, such as those produced by the diarrhoeal illness-causing bacteria Clostridium difficile and certain non-enveloped (non-lipophilic) viruses, for example enteroviruses (Boyce and Pittet, 2002). However, others such as Larson and Morton (1991) suggest alcohol has some activity against both enteroviruses and rotaviruses.

It appears therefore that overall alcohol-based hand disinfectants containing 60-90 per cent alcohol have good efficacy against a wide range of micro-organisms.

**Soap and water versus alcohol hand rubs and gels**

There are many studies comparing the effectiveness of plain or medicated soaps with hand rubs containing 60-70 per cent alcohol, which have demonstrated the latter are more efficient in achieving a greater reduction in the bacterial counts on health care workers’ hands (Girou et al, 2002; Winnefeld et al, 2000; Rotter, 1999; Zaragoza et al, 1999; Ayliffe et al, 1988). It may be helpful to consider some of these studies in further detail.

In the study conducted by Winnefeld et al (2000) hand hygiene procedures using plain soap and an alcohol-based solution were compared in everyday hospital use. The study involved 52 nurses over an eight-day period using one of the two hand decontamination procedures.

Microbiological hand samples were obtained before and after the hand decontamination procedures. The study found the alcohol-based solution was significantly more effective than liquid soap in removing contaminating transient micro-organisms (p=0.016). It is worth noting that the nurses in the study were randomly assigned to either the plain soap or alcohol hand rub group, thus reducing the potential for bias.

However, the sample size was small, throwing doubt on the generalisability of the study to the wider health care population. In addition it may be that the plain soap group was not as effective in removing contaminating micro-organisms because the participants in this group did not soap their hands for the minimum length of time required, which according to Pratt et al (2001) should be for at least 10-15 seconds.

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Drug Administration (FDA) Tentative Final Monograph for Healthcare Antiseptic Drug Products (TFM) and requires only a 2log_{10} reduction in micro-organisms within five minutes after the first use and a 3log_{10} reduction within five minutes after the tenth use.

Confusingly this indicates that different standards for efficacy testing are in place in Europe and the US and this may explain some of the difficulties in comparative studies. A further confounding issue is the paucity of truly independent studies. Some studies are commissioned by manufacturers of decontamination products and may be open to potential bias as a result.

**Shortcomings of the methods used**

Whether it is necessary to achieve a 4log_{10} (99.99 per cent) reduction as stipulated in EN 1500 to prevent transmission of nosocomial infection does not appear to have been confirmed by scientific studies. A 3log_{10} (99.9 per cent) or a 2log_{10} (99 per cent) reduction as required by the TFM in the US may be sufficient but again is unknown.

In addition EN 1500 testing involves two applications of alcohol. However, in clinical practice only one application is used in accordance with national and international guidelines on hand hygiene.

Furthermore, volunteers are often used for product efficacy testing. However, it may be argued that the normal hand flora of volunteers may not accurately reflect the normal hand flora of health care workers. Therefore, it has to be questioned whether the efficacy testing methodology is itself flawed.

**Rubs versus gels**

Alcohol-based hand decontamination products are available in the form of rubs and gels but is one product type more effective than the other? With the test methodology shortcomings in mind, let us consider this question.

Kramer et al (2002) investigated the antimicrobial efficacy of 10 alcohol hand gels and four alcohol rubs, according to EN 1500. The products were tested using a crossover trial with 15 volunteers who had artificially contaminated hands. The researchers found most of the alcohol hand rubs met the EN 1500 requirements but the alcohol gels did not fulfil this criterion.

However, while EN 1500 requires a 4log_{10} reduction in microbial contamination on hands, scientific evidence is not available to confirm this level of microbial reduction is required to minimise the spread of harmful pathogenic bacteria (Boyce and Pittet, 2002). Furthermore, it may be questioned whether the study was flawed due to a conflict of interest, as one of the researchers was a paid employee of an alcohol hand rub manufacturer included in the trial.

In contrast, more positive results were found in a study conducted by MacDonald et al (2004) who introduced alcohol hand gel into a plastic surgery unit in a district general hospital, for use on socially clean hands between clinical contact with patients. Hand hygiene practice was observed and performance feedback given to staff. Nosocomial acquisition of MRSA was also monitored.

The study found there was a significant reduction in the number of patients newly affected by MRSA (p<0.05). While the conclusion of this study was that performance feedback on hand hygiene practice reduces nosocomial MRSA infection rates, equally it may be argued that the use of alcohol hand gel did play a role in achieving this reduction.

Furthermore, it has to be questioned whether performance feedback alone could have achieved the level of reduction seen in microbial contamination on hands and reduction in MRSA rates, if alcohol hand gel was ineffective in destroying micro-organisms as reported by the previous study.

It appears to date that there is conflicting evidence about the comparative effectiveness of alcohol hand rubs and gels, suggesting further independent and unbiased research is required in this area to help reach a consensus opinion.

**Skin compatibility**

Skin compatibility issues are centred on concerns about the drying effects of alcohol itself and consequent skin damage. The recommendations made by both the national and international guidelines on hand hygiene are that alcohol-based hand hygiene products should contain emollients to counteract their drying effect (Boyce and Pittet 2002; Pratt et al, 2001).

Interestingly a number of studies have been conducted on this issue and several trials have found substantially less skin irritation and dryness when using the alcohol-based products in comparison with plain soap or antimicrobial agents using both subjective and objective measures for assessing skin compatibility (Larson et al, 2001; Boyce et al, 2000; Winnefeld et al, 2000).

Nevertheless, it is recognised that even products containing emollients along with the alcohol may cause a momentary stinging sensation if there are any cuts or abrasions present on the hands (Boyce and Pittet, 2002). Therefore, it is important to keep cuts covered.

**Conclusion**

There is strong evidence to support the use of alcohol-based hand rubs/gels in the fight against health care-acquired infection in both the hospital and community setting. Much research is available supporting their efficacy. Test data on different products is not sufficiently robust or unbiased to recommend one product in preference to another.

Despite some of the limitations of the research discussed it appears alcohol hand rubs/gels offer a quick and ready means for decontaminating hands in both hospital and community settings.

As with all hand decontamination methods it is vital that health care workers use alcohol hand rubs/gels appropriately. This means using them on socially clean hands that are not visibly soiled and that all the surfaces of the hands are adequately covered with the alcohol product to ensure the microbial load on the hands is sufficiently reduced to minimise the risks of transmitting pathogenic micro-organisms to vulnerable patients.