20th Expert Committee on Selection and Use of Essential Medicines
Peer Review Report

[Alcohol-Based HandRub (ABHR)]

(1) Does the application adequately address the issue of the public health need for the medicine?
   Yes X
   HCAIs (infections acquired in health-care settings) are the most frequent adverse event in health-care delivery worldwide. Hundreds of millions of patients are affected by HCAIs worldwide each year, leading to significant mortality and financial losses for health systems. Infection prevention and control (IPC) measures for those providing direct and non-direct care to patients with suspected or confirmed cases of infectious diseases is the key for stopping outbreaks and saving lives in health care settings.

(2) Have all important studies that you are aware of been included in the application?
   Yes X
   A full range of articles is listed in the following web sites
   http://www.who.int/gpsc/journals_articles/en/

(3) Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed use?
   Yes X

   1. Evidence-based, intrinsic advantages of fast-acting and broad-spectrum microbicidal activity with a minimal risk of generating resistance to antimicrobial agents;
   2. Suitability for use in resource-limited or remote areas with lack of accessibility to sinks or other facilities for hand hygiene (including clean water, towels, etc.);
3. Capacity to promote improved compliance with hand hygiene by making the process faster, more convenient and immediately accessible at the point of patient care;
4. Economic benefit by reducing annual costs for hand hygiene, representing approximately 1% of extra-costs generated by healthcare associated infection
5. Minimization of risks from adverse events because of increased safety associated with better acceptability and tolerance than other products.

WHO Guidelines on Hand Hygiene in Health Care 2009

(4) Is there evidence of efficacy in diverse settings and/or populations?

   No  X

(5) Has the application adequately considered the safety and adverse effects of the medicine? Are there any adverse effects of concern, or that may require special monitoring?

   Yes  X

Minimising occupational hand dermatitis and accidental eye contact
Preventing fire hazards,
Intentional ethanol abuse may be a problem as with any other alcohol-containing products.
As for accidental ingestion by children, only minor effects were reported in less than 4% of cases with nothing serious.
While those concerns regarding toxicity in children are valid, ABHR can be used safely, with supervision, and the potential for benefits by reduced illness transmission likely outweighs potential for toxicity from accidental ingestion.
They should not be used for children younger than 2 years of age.

http://dpic.org/article/professional/alcohol-based-hand-sanitizer-safety
ADDITIONAL CONSIDERATIONS:

(6) Are there special requirements or training needed for the safe, effective and/or appropriate use of the medicine?

   Yes  X

   This is provided by WHO manuals and local health guidelines
   “Clean Care is Safer Care Programme”
   Service Delivery and Safety Department
   “5 May 2015 WHO Call to Action”

(7) Are there any issues regarding the registration of the medicine by regulatory authorities? (e.g., recent registration, new indications, off-label use)

   Yes  X

   ABHR is not currently registered as a medical product in all countries, despite a WHO public health recommendation to use ABHR. Ethanol is listed in both the US and EU pharmacopeia as a medicine ingredient. Additionally, in the US, ABHRs are regulated by FDA as OTC drugs. There is a drug monograph, which describes both approved actives (ethanol) and approved claims related to validated performance.
   In Canada and Australia, ABHRs are similarly defined but as "natural health products" or "therapeutic goods" respectively. The regulatory requirements in both cases are very similar to drug products and the governing bodies are medical regulators.
   In Europe, ABHRs are biocides, however in Germany they are still classified as medicines.

(8) Is the medicine recommended for use in a current WHO GRC-approved Guideline (i.e., post 2008)?

   Yes  X

   Interim Infection Prevention and Control Guidance for Care of Patients with Suspected or Confirmed Filovirus Haemorrhagic Fever in Health-Care Settings, with Focus on Ebola

   Guideline on Hand Hygiene in Health Care in the Context of Filovirus Disease Outbreak Response Rapid advice guideline November 2014
   Ref: WHO/HIS/SDS/2014.15
Please comment briefly on issues regarding cost and affordability of this medicine.

Alcohol-based handrubs meeting acceptable standards are produced mainly in the USA and Europe. They exist reliably in health care in most developed countries. These are from manufacturers such as Gojo Industries, Deb group, DebMed, 3M, Saraya, Ecolab, BBraun, Bode-Chemie. However, production and therefore availability does not exist in all regions, with the African and South-East Asian regions being those least served due to a number of known barriers. It must be noted that local production of the WHO-recommended handrub formulations has been encouraged and implemented in some countries.

(Who Guide to Local Production: WHO-recommended Handrub Formulations Revised April 2010)

Any additional comments?

They can be summarized by this WHO statement (http://www.who.int/gpsc/tools/faqs/system_change/en/)

The availability of a product which renders the hands safe in terms of transmission of pathogens, and which can be used at the very place where pathogens are transmitted, has revolutionized hand hygiene improvement strategies in the modern age. For this reason, alcohol-based handrubs are considered to fulfil the highest standards of safety in relation to the prevention of cross-infection. At the present time, the most efficacious, well-tolerated and well-researched product which can be placed ergonomically and safely at the point of care is an alcohol-based handrub. This system change facilitates the right action to occur at the right time and in the right way. It is unlikely, although not impossible, that running water, soap and towels will be installed right next to each patient’s bed, or be available at the point of care in an affordable and practical way. Soap and water handwashing is however less efficacious, more time-consuming, and less well tolerated by skin than alcohol-based handrubbing.

In countries where access to sinks is limited or non-existent, alcohol-based handrubs offer a method of preventing cross-infection which can be implemented in the short-term alongside a longer term strategy of sink installation.
(11) Please summarise the action you propose the Expert Committee takes.

Since there is a need for ALCOHOL-BASED HANDRUBS and since both their efficacy and safety are well established, I will recommend their addition to the EML and EMLc. They should be made widely available and thus affordable.