

PART B: SUPPLEMENTARY TECHNICAL, SAFETY AND COST INFORMATION:

Part B contains important safety and cost information and incorporates information from the WHO Guidelines on Hand Hygiene in Health Care (2009).

The case for alcohol-based handrubs in health care

At present, alcohol-based handrubs are the only known means for rapidly and effectively inactivating a wide array of potentially harmful microorganisms on hands.

WHO recommends alcohol-based handrubs based on the following factors:

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 health care-associated infection
5. Minimization of risks from adverse events because of increased safety associated with better acceptability and tolerance than other products.

(Source: WHO Guidelines on Hand Hygiene in Health Care 2009)

Background to WHO alcohol-based handrub formulations

According to the available evidence on efficacy, tolerability and cost-effectiveness, WHO recommends using an alcohol-based handrub for routine hand antisepsis in most clinical situations. Health-care facilities currently using commercially-available handrubs, liquid soaps and skin care products sold in disposable containers should continue this practice, provided that the handrubs meet recognised standards for microbicidal efficacy (ASTM or EN standards) and are well accepted/tolerated by the health-care workers. It is obvious that these products should be regarded as acceptable, even if their contents differ from those of WHO-recommended formulations described within this document. WHO recommends the local production of the following formulations as an alternative when suitable commercial products are either unavailable or too costly.

To help countries and health-care facilities to achieve system change and adopt alcohol-based handrubs, WHO has identified formulations for their local preparation. Logistic, economic, safety, cultural and religious factors have all been carefully considered by WHO before recommending such formulations for use worldwide.

Efficacy

It is the consensus opinion of a WHO expert group that WHO-recommended handrub formulations can be used both for hygienic hand antisepsis and for presurgical hand preparation.

Hygienic handrub

The microbicidal activity of the two WHO-recommended formulations was tested by WHO reference laboratories according to EN standards (EN 1500). Their activity was found to be equivalent to the reference substance (isopropanol 60% v/v) for hygienic hand antisepsis.

Presurgical hand preparation

Both WHO-recommended handrub formulations were tested by two independent reference laboratories in different European countries to assess their suitability for use for pre-surgical hand preparation, according to the European Standard EN 12791. Although formulation I did not pass the test in both laboratories and formulation II in only one of them, the expert group is, nevertheless, of the opinion that the microbicidal activity of surgical antisepsis is still an ongoing issue for research as due to the lack of epidemiological data there is no indication that the efficacy of n-propanol (propan-1-ol) 60% v/v as a reference in EN 12791 finds a clinical correlate. It is the consensus opinion of a WHO expert group that the choice of n-propanol is inappropriate as the reference alcohol for the validation process because of its safety profile and the lack of evidence-based studies related to its potential harmfulness for humans. Indeed, only a few formulations worldwide have incorporated n-propanol for hand antisepsis.

Considering that other properties of WHO recommended formulations, such as their excellent tolerability, good acceptance by health-care workers and low cost are of high importance for a sustained clinical effect, the above results are considered acceptable and it is the consensus opinion of a WHO expert group that the two formulations can be used for surgical hand preparation. Institutions opting to use WHO-recommended formulations for surgical hand preparation should ensure that a minimum of three applications are used, if not more, for a period of 3–5 minutes. For surgical procedures of more than 2 hours duration, ideally surgeons should practise a second handrub of approximately 1 minute, even though more research is needed on this aspect.

Key lessons learned from around the world

Many settings around the world successfully undertook local production of the two WHO-recommended formulations. Throughout Part B, additional information is presented where relevant, in table form, based on feedback from 11 sites located in Bangladesh, Costa Rica, Egypt, Hong Kong SAR, Kenya, Mali, Mongolia, Pakistan (two sites), Saudi Arabia, and Spain. Further, detailed information is available within the WHO Guidelines on Hand Hygiene in Health Care (2009)