



HARTMANN



5 facts to help you select a product for surgical hand disinfection

Why alcohol-based surgical hand rubs
without additional Chlorhexidine provide the
best efficacy, skin tolerability, and safety.





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Fact 1:

In surgical hand disinfection, immediate and sustained activities are more important than persistent effect.

Surgical hand disinfection focuses on reducing the skin's own, resident skin flora on the employees' hands. One reason is that surgical gloves might become punctured during surgery. For preparations for surgical hand disinfection, the efficacy is tested at differing contact times, depending on the test protocol.

Differing test protocols and their relevance to patient safety

European EN 12791 standard

The European norm EN 12971 – a testing method that is recognised by expert associations throughout the world and is used by European manufacturers but also, for example, by WHO to prove the efficacy of their alcohol-based hand rubs – tests the following activities [1]:

- **Immediate activity**

The immediate reduction of the microbial flora on the hands is measured immediately after the application of the preparation.



Practical relevance: High. For the patient to be protected right from the beginning of the surgery, the product has to feature a good immediate activity.

- **Three-hour activity**

The reduction of the microbial flora on the hands is measured after surgical gloves have been worn for three hours after product application.

If the mean values of the measured three-hour \log_{10} reduction factors are superior to the ones of the reference product, the preparation can be claimed to have a sustained activity.

A preparation is considered suitable for surgical hand disinfection in accordance with EN 12791, when the mean values of the measured \log_{10} reduction factors for both the immediate activity and the three-hour activity are not inferior to the ones of the reference product propan-1-ol with a volume concentration of 60 %.



Practical relevance: High. The risk of punctures grows the longer gloves are worn. Around 90 % of all surgeries take a maximum of three hours. During this period of time, the resident skin flora is prevented from growing. Keeping the microbial skin flora that low increases the safety in case the gloves are not changed after at least 150 minutes as recommended [2].

References

1. Chemical disinfectants and antiseptics. Surgical hand disinfection. Test method and requirement (phase 2/step2) EN:12791:2005.
2. New AORN recommendations focus on infection prevention, patient safety. In: OR Manager Vol. 28 No. 6, June 2013.

Differing test protocols and their relevance to patient safety

FDA based on ASTM E-1115

- **Persistent activity**

An FDA-compliant alcohol-based surgical hand rub must meet explicit performance criteria for immediate and six-hour germ reduction based on testing specified by ASTM E-1115 [3]. Persistence is defined by the FDA as not returning to baseline skin flora levels within six hours of application of a disinfectant.

For this, the US-American ASTM E-1115 protocol (surgical hand scrub) tests a cumulative activity: a six-hour value is measured on five consecutive days with a total of eleven applications. The persistent activity, over a longer period, shall inactivate resident microorganisms that grow again after product application and reach the hand surface. And the last of the eleven applications shall yield the highest reduction factor.



Practical relevance: Doubtful. Following the ASTM protocol, the first patient on Monday morning – due to the lower reduction requirements on day 1 – would be less protected than, for example, the patient treated on Friday after the last application.

Also WHO criticises: "...It is, however, difficult to understand why the efficacy of a scrub is required to increase from the first to the fifth day of permanent use. Ethical considerations would suggest that the first patient on a Monday, when the required immediate bacterial reduction from baseline is only 1 log, should be treated under the same safety precautions as patients operated on the following Friday when, according to the TFM requirement, the log reduction has to be 3.0"[4].

References

3. United States Food and Drug Administration. Tentative final monograph for healthcare antiseptic drug products; proposed rule. Federal Register. 1994:31441–31452.
4. World Health Organization. Methods to evaluate the antimicrobial efficacy of handrub and handwash agents and formulations for surgical hand preparation. In: WHO Guidelines on Hand Hygiene in Health Care. First Global Patient Safety Challenge Clean Care is Safer Care. 2009.



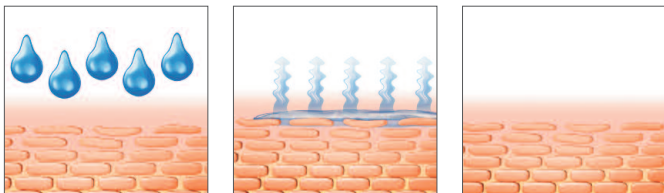
Fact 2:

Alcohol-based hand rubs without antimicrobial additives fulfil all efficacy requirements.

Even though experts, for example those from WHO, question the persistent effect: Products that apply for FDA authorisation need to prove a persistent activity. The FDA does not specify the use of specific persistent ingredients in order to achieve this effect. However, chlorhexidine gluconate (CHG) is often used to yield persistence in surgical hand disinfection. CHG has a different mode of action than alcohol. This mechanism leads to insufficient values for the immediate and sustained efficacy, but also for the persistent effect.

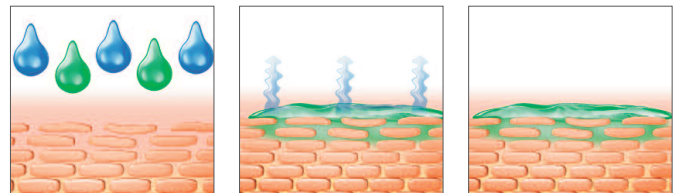
Alcohols' mode of action

The alcohol contained in alcohol-based hand rubs is a volatile substance, which evaporates completely on the hands after the exposure time (Fig. 1-3). Depending on their alcohol content, these preparations achieve a high immediate reduction of the microbial skin flora (both transient and resident flora). This initial high reduction slows down the regrowth of the resident microorganisms and the release to the skin's surface – the microbial skin flora is restored only very slowly.



CHG's mode of action

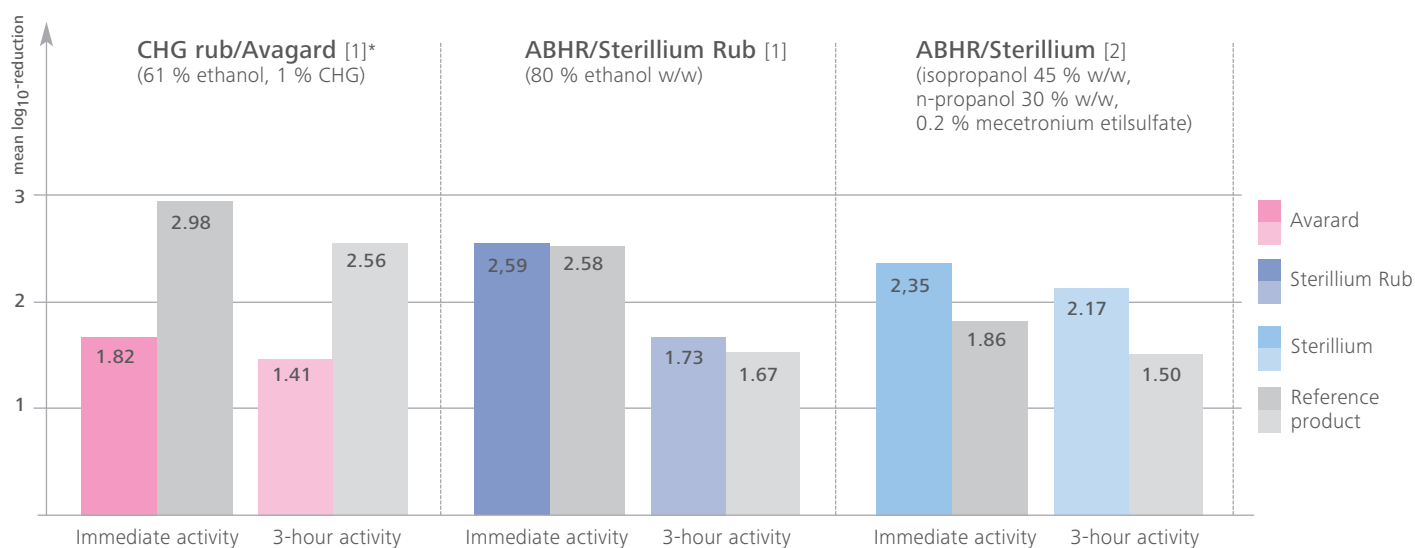
As a non-volatile substance CHG remains on the skin after application and unfolds its activity over a longer period. Microorganisms that reach the skin after hand rub application thus can also be inactivated for a certain period of time (Fig. 4-6). The immediate effect of CHG, however, is rather low.



The initial reduction factor of alcohol-based hand rubs is high enough to fulfil the requirements of the European EN 12791 standard. Moreover, depending on the type and concentration of alcohol, alcohol-based hand rubs can also achieve a persistent activity in accordance with the ASTM E-1115 test protocol. In contrast, some of the CHG-containing products available on the market miss the EN 12791 requirements (see table). Also their persistent activity is overrated as tests were carried out without neutralisation (see box).

A. According to European EN 12791 standard

Tests were carried out according to prEN 12791 (1997).



Reference product: 60 % n-propanol (v/v)

* Following prEN 12791 test method with validated neutralisation (see box)

Specification in Mean log₁₀-reduction (mean + SD): Sterillium Rub and Sterillium show a significantly higher activity than Avagard that contains CHG and the reference alcohol. Avagard does not fulfil the requirements of EN 12791. Both the immediate activity and the three-hour activity are significantly lower than the ones of the reference.

1. Kampf G, Ostermeyer C. Efficacy of two distinct ethanol-based hand rubs for surgical hand disinfection – a controlled trial according to prEN 12791. BMC Infectious Diseases

Both alcohol-based hand rubs (Sterillium® and Sterillium® Rub) are effective according to prEN12791, but the CHG rub Avagard is not. A high alcohol concentration in an alcohol-based hand rub is necessary for a sufficient initial efficacy. Available hand rub products containing CHG usually contain less alcohol. That yields in a lower initial efficacy.

Lack of neutralisation leads to false positive results for CHG

EN 12791 requires to use a neutralisation agent in the sample and diluents, which needs to be validated in accordance with prEN 12054. Background: If non-volatile active ingredients such as CHG are not neutralised, they continue to inactivate microorganisms in the sample, diluent and on the agar plate even beyond the contact time to be tested. The result – the determined number of live microorganisms at a specific time point (e.g. immediate activity) – thus is falsified and overestimated [1, 2, 3] by factors between 0.3 and 1.1 log₁₀ steps. Hence, when considering patient safety, neutralisation is essential.).



1. Rotter, M.L. 1981. Journal of Hospital Infection 2: 273-276

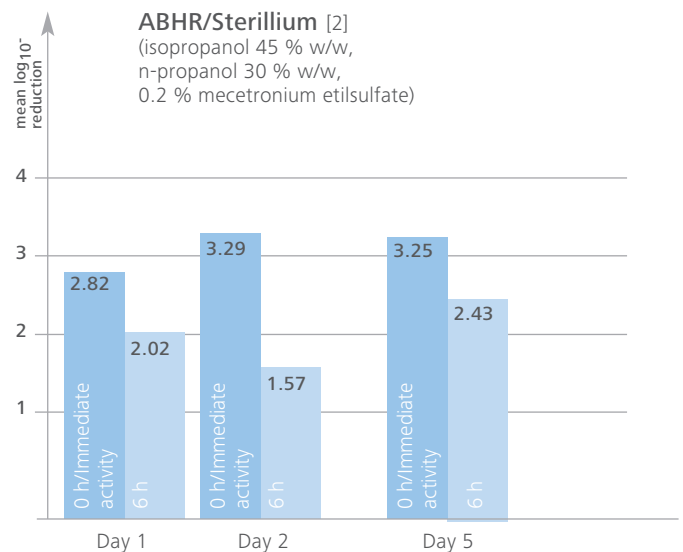
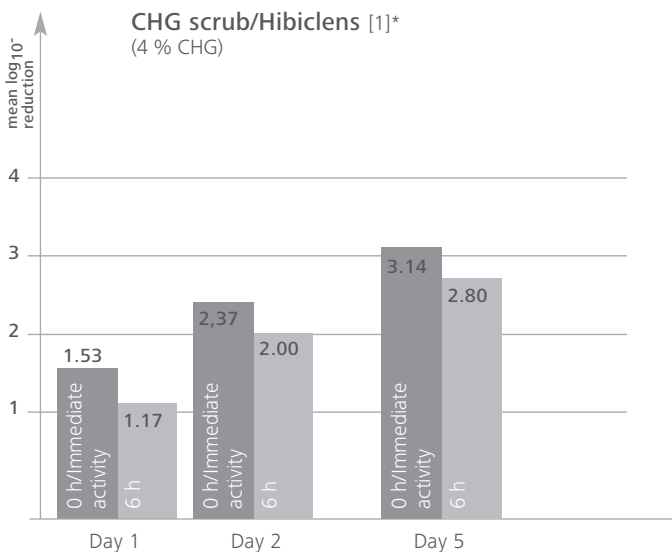
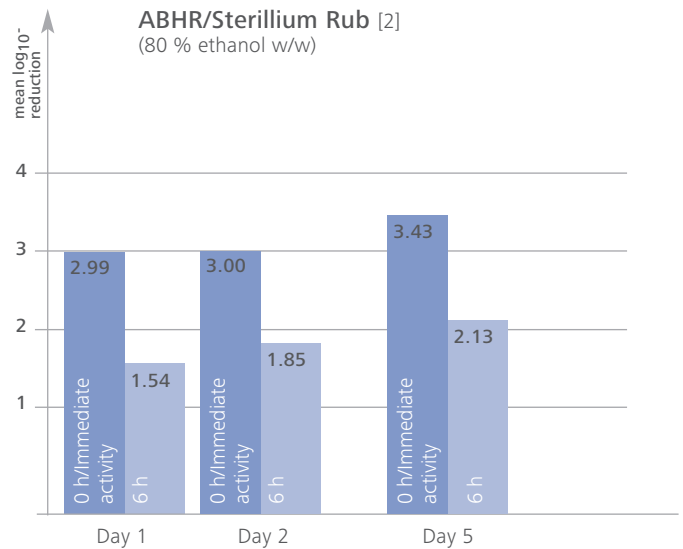
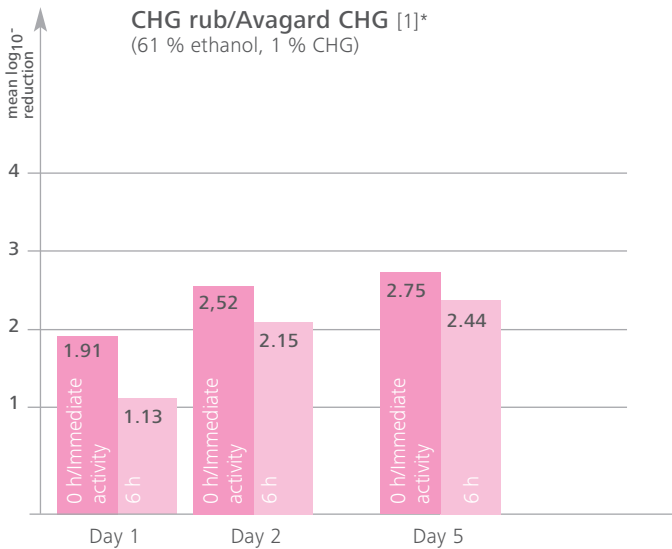
2. Benson, L., L. Bush, and D. LeBlanc. 1990. Infection Control and Hospital Epidemiology 11:595-599.

3. Kampf, G., M. Shaffer, and C. Hunte. 2005. BMC Infectious Diseases 5: 48.

Fact 2:

→ Alcohol-based hand rubs without antimicrobial additives fulfil all efficacy requirements.

B. According to FDA based on ASTM E-1115



*Test method with validated neutralisation following ASTM E 1054-02 (see box)

1. Kampf et al. Efficacy of surgical hand scrub products based on chlorhexidine is largely overestimated without neutralizing agents in the sampling fluid. AJIC January 2013; Volume 41, Issue 1, Pages e1–e 5.
2. Kampf et al. Evaluation of Two Methods of Determining the Efficacies of Two Alcohol-Based Hand Rubs for Surgical Hand Antisepsis. APPL. ENVIRON.MICROBIOL. June 2006, p. 3856–3861 Vol. 72, No. 6.



Conclusions for the efficacy

Sterillium® Rub and Sterillium® fulfill the FDA requirements within a contact time of 2 min and 1.5 min respectively. For comparison the reduction factors of the CHG products (Avagard and Hibiclens) are shown. These CHG products do not provide any benefit in terms of efficacy in hand disinfection compared to an alcohol-based hand rub. Also WHO recommends alcohol-based hand rubs without additional antimicrobial ingredients as gold standard for surgical hand disinfection.

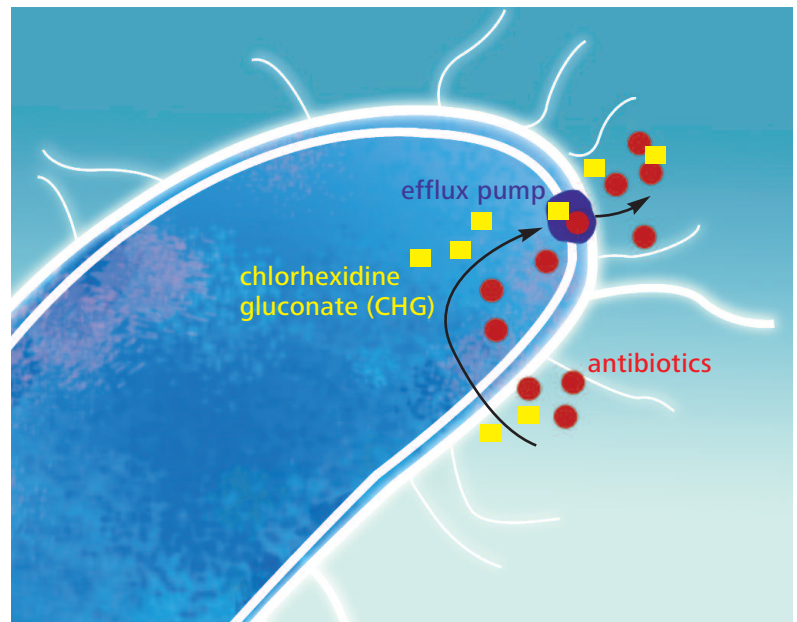
Fact 3:

There is an increased risk for resistance to CHG due to an overall exposure. According to experts most of the CHG exposure would be explained by hand hygiene agents when liquid soaps or alcohol-based hand rubs contain CHG [1].

Many bacteria are increasingly able to survive higher Chlorhexidine concentrations. The unsusceptibility to CHG also promotes resistance to antibiotic agents.

CHG: acquired resistance mechanisms

- **Plasmid-mediated resistance:**
Bacteria can develop certain proteins in their cell wall, so-called efflux pumps that eject the chlorhexidine out of the cell; the bacteria thus become more insusceptible to CHG. The genetic information for this resistance mechanism is on the plasmids – small independent genetic units that are transferred from cell to cell. Thus, there is a risk that these resistance genes spread rapidly.
- **Cross-resistance to antibiotics**
The bacteria's efflux pumps can also eject other antimicrobial substances, e.g. some antibiotics. This leads to cross-resistances. Alcohols have a natural resistance to spores. Bacteria, however, do not develop resistances to alcohols [2].



The bacteria's efflux pumps can also eject other antimicrobial substances, e.g. some antibiotics. This leads to cross-resistances.

Sources

1. Kampf G, Acquired resistance to chlorhexidine – is it time to establish an “antiseptic stewardship” initiative?, Journal of Hospital Infection (2016).
2. Kampf G (Hrsg.) Händehygiene im Gesundheitswesen. Springer-Verlag Berlin Heidelberg. 2003.



Conclusion

The frequent use of CHG in hand rubs does not only result in bacteria becoming insusceptible to CHG-containing disinfectants, but also promotes their resistance to antibiotics.

Fact 4:

When used frequently, chlorhexidine-containing hand rubs hold the risk of skin irritations on hands.

Skin irritations on hands associated with the use of CHG for hand rubs are observed frequently and well documented in studies. However, hypersensitivity reactions can go far beyond skin irritations and assume life-threatening proportions.

Frequent hypersensitivity reaction to CHG

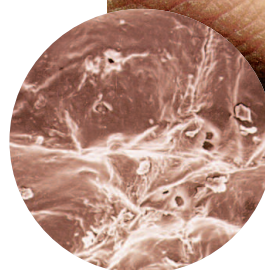
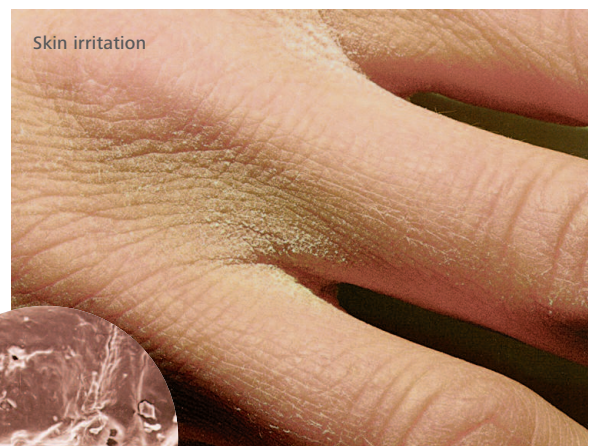
Skin irritations on hands

CHG may trigger skin irritations on intact hands. Adding CHG to alcohol increases the product's potential for irritation [1]. A survey among 1.301 employees of a hospital revealed that the most common cause of skin irritations on the hands was – besides glove use – due to CHG-based solutions [2]. A Japanese study identified hypersensitivity reactions in 89 of 307 healthcare workers that were triggered by CHG as second leading cause after glove use. Contact dermatitis was the most frequent disease here [2]. Most reactions occur with longer, repeated application [3]. Due to the high number of hand disinfection procedures that are necessary throughout the day, CHG-based hand disinfectants pose a high risk of skin irritation.



Sources

1. Händehygiene in Einrichtungen des Gesundheitswesens. Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO) beim Robert Koch-Institut (RKI). Bundesgesundheitsbl 2016 · 59:1189–1220.
2. Sato K, Kusaka Y, Suganuma N, Nagasawa S, Deguchi Y (2004) Occupational allergy in medical doctors. J Occup Health 46: 165-170.
3. Stingeni L1, Lapomarda V, Lisi P. Occupational hand dermatitis in hospital environments. Contact Dermatitis. 1995 Sep; 33(3):172-6.
4. <http://www.ncbi.nlm.nih.gov/pmc/?term=chlorhexidine+anaphylaxis> Accessed on 07 September 2016.



Conclusions for tolerability

CHG-containing hand disinfectants expose users and patients to unnecessarily high risks due to frequent application. The risk of an allergic reaction and an anaphylactic shock always needs to be factored in.

Fact 5:

Using alcohol-based hand rubs for surgical hand disinfection can reduce the costs by more than 70 % compared to surgical hand scrubbing.

Hand scrubbing products with CHG are not only less effective and less skin friendly than alcohol-based hand rubs – they also cost more as shown in a systemic study review [1]. The difference in costs is due to the differing procedures. In contrast to alcohol-based hand rubs, hand scrubbing additionally requires water, sterile towels and, depending on the water quality, also filters to ensure water that is microbiologically clean.

Surgical hand scrubbing: costs according to Tavalacci et al. [1]

Method*	Cost per procedure in € [1]	
Wet hands and forearms, apply 5 ml of antiseptic soap** and wash for one minute, cleaning the fingernails with a brush. Rinse, apply further 5 ml of antiseptic soap** and continue washing for another 2 minutes. 2 x 5 ml antiseptic soap** for about 3 minutes.	Nail brush	0.280
	Antiseptic soap**	0.067
Rinse thoroughly and dry with sheets of sterile paper towel.	Sterile towel	0.700
Use of water filter.	Single use	0.077
	Multipurpose	0.027
Total time 3 minutes	Total costs	
	Alternative:	
	Water filter (single use)	1.124
	Water filter (multipurpose)	1.074

*Study design corresponds to manufacturer specifications, described in the Hibiscrub** datasheet. www.promed.ie/shop/assets/catalog/parts/15645.pdf. Download on 24 September 2016

Surgical hand rubbing: costs according to Tavalacci et al. [1]

Method*	Cost per procedure in € [1]	
Before surgical hand rubbing, clean nails with a brush. Perform surgical hand rubbing with an alcohol-based hand rub** that covers hands, forearms and elbows. Continue rubbing until the hands are dry. Apply more alcohol-based hand rub** and repeat procedure (excl. elbows). 3 x 4.5 ml alcohol-based rub.	Nail brush	0.280
	Alcohol-based handrub**	0.082
	Unmedicated soap (not necessary)	
	Soap hands and forearms once again.	
Total time 3 minutes	Total costs	0.386
Total time 1.5 minutes*	Total costs	0.335

**Sterillium Gel

*Study design differs from current manufacturer specifications: In the study design, the application time of Sterillium Gel was > 3 minutes. The application time of Sterillium Gel when used for surgical hand disinfection, however, is 1.5 minutes (EN 12791) and includes the wrists but not the elbows. Based on the calculation of Tavalacci et al. this would mean another product saving of approx. 4.5 ml per procedure (see total time and costs for 1.5 minutes).
And the calculation of Tavalacci et al. does not consider the cost benefits due to the saving of time thanks to shorter application times and the water saving. For one single surgical hand scrubbing procedure WHO calculated "approximately 20 litres of warm water or 60 litres and more for the entire surgical team" [2].



Conclusions for the efficacy

The use of alcohol-based hand rubs can cut the costs for surgical hand hygiene by more than two thirds compared to handscrub preparations that contain CHG.

Statements

What the Worlds Health Organisation (WHO) says:



“...the continued presence of a microbicidal chemical to produce a persistent effect may be unnecessary in view of the fact that volatile ingredients such as short-chain aliphatic alcohols (e.g. ethanol, isopropanol, and n-propanol) appear fully capable of producing the same effect.” [1]

What the Centers for Disease Control and Prevention (CDC) says:



“Alcohols are effective for preoperative cleaning of the hands of surgical personnel (...) Alcohol-based solutions were more effective than washing hands with plain soap in all studies, and they reduced bacterial counts on the hands more than antimicrobial soaps or detergents in the majority of experiments (...) In addition, the majority of alcohol-based preparations were more effective than povidone-iodine or chlorhexidine.” [2]





What the American Hospital Association (AHA) says:

The AHA that represents 5 000 clinics calls for only using alcohol-based hand rubs: "AHA has been impressed with the efficacy and health benefits of alcohol-based hand rubs, which have proven to reduce healthcare-associated infections (...) Alcohol alone has been demonstrated to be effective for hand hygiene for healthcare personnel (...) We recommend that the persistence/cumulative requirement for waterless, alcohol-based hand antiseptics be eliminated or that an exception for this class/formulation of antimicrobials be created." [3]

What the Robert Koch-Institute (RKI) says:

"There has as yet been no proof that alcohol-based preparations with chlorhexidine as additive possess higher efficacy in terms of the prevention of surgical site infection. Even though some studies show that the addition of chlorhexidine improves the persistent activity, the interpretation of results needs to consider that the chlorhexidine in the sample fluid was not neutralised. Thus, the growth of remaining bacteria may be inhibited, leading to false low numbers of colonies. Hence, the informative value is limited." [4]



References

1. World Health Organization. Methods to evaluate the antimicrobial efficacy of handrub and handwash agents and formulations for surgical hand preparation. In: WHO Guidelines on Hand Hygiene in Health Care. First Global Patient Safety Challenge Clean Care is Safer Care. 2009.
2. Boyce JM1, Pittet D; Healthcare Infection Control Practices Advisory Committee. Society for Healthcare Epidemiology of America. Association for Professionals in Infection Control. Infectious Diseases Society of America. Hand Hygiene Task Force. CDC Guideline for Hand Hygiene in Health-Care Settings Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. Infect Control Hosp Epidemiol. 2002 Dec;23(12 Suppl): S3-40.
3. Letter from Rick Pollack Executive Vice President of the American Hospital Association (AHA) to Mark B. McClellan, M.D., Ph.D. Commissioner Food and Drug Administration (HFA-305)AHA letter to FDA, August 27, 2003.
4. Händehygiene in Einrichtungen des Gesundheitswesens. Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO) beim Robert Koch-Institut (RKI). Bundesgesundheitsbl 2016 · 59:1189–1220.

The benefits of alcohol-based hand rubs without CHG:

1. Better efficacy

Efficacy of CHG is often low and overestimated (lack of neutralization!). A high alcohol concentration in an alcohol-based hand rub is necessary for a sufficient initial efficacy. Available hand rub products containing CHG usually contain less alcohol. That yields in a lower initial efficacy. Therefore WHO recommends alcohol-based hand rubs without additional antimicrobial ingredients as gold standard for surgical hand disinfection.

2. Better dermatological tolerance

CHG triggers skin irritations on intact skin of hands when used frequently and is known to be a contact allergen. The WHO Guidelines refers to many studies that prove the excellent skin tolerability of alcohol-based rubs: "in prospective trials, alcohol-based solutions or gels containing humectants caused significantly less skin irritation and dryness than the soaps or antimicrobial detergents tested" [2].

3. No acquired bacterial resistance

Alcohols act rapidly and in a non-specific manner and destroy the bacterial structure irrevocably. As a consequence, so far no acquired resistances against alcohols have been found in bacteria including multi drug resistant bacteria.

4. Excellent cost effectiveness

Alcohol-based hand rubs don't require water, sterile towels and the use of water filters due to the differing procedures. For this reason alcohol-based hand rubs can cut the costs for surgical hand hygiene by more than two thirds.

References

1. Kampf G, Acquired resistance to chlorhexidine – is it time to establish an "antiseptic stewardship" initiative?, Journal of Hospital Infection (2016)
2. WHO World Health Organization. Methods to evaluate the antimicrobial efficacy of handrub and handwash agents and formulations for surgical hand preparation. In: WHO Guidelines on Hand Hygiene in Health Care. First Global Patient Safety Challenge Clean Care is Safer Care. 2009.



Conclusions:

- In hand disinfection CHG products do not provide any benefit compared to an alcohol-based hand rub.
- CHG-containing soaps and rubs for hands are the biggest or the second biggest contributor to an overall exposure.
- In order to keep the valuable effect of CHG for indications such as the treatment of the CVC puncture site, CHG should be banned from hand hygiene and limited to indications with a definite patient benefit [1].

First Choice: Hand Disinfection with the Sterillium® range

The availability of products in the Sterillium range may vary in different countries and regions.



Sterillium®

The classic of alcohol-based hand disinfection. Successful for over 50 years. The favorite of millions of users around the world thanks to its reliable antimicrobial activity and special skin friendliness.

Sterillium® classic pure

The colourant and fragrance-free variant of the classic Sterillium. Featuring the proven Sterillium skincare complex. Particularly suitable for sensitive skin.

Sterillium® Gel

The highly effective hand disinfection gel with comprehensive antimicrobial activity and a tried-and-tested moisturising complex.

Sterillium® Gel pure

The fragrance-free variant of Sterillium Gel for particularly sensitive skin. Highly effective hand disinfection gel with comprehensive antimicrobial activity and a tried-and-tested moisturising complex.

Sterillium® med

The hand disinfectant with virucidal efficacy within hygienic hand disinfection. Featuring the proven Sterillium skincare complex. Colourant- and fragrance-free.

*efficacy tested with the murine norovirus (MNV)

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Going further
for health