Hand Disinfection and Hand Hygiene

Preliminary remarks

Each section begins with indications and requirements and/or recommendations (highlighted for quick orientation). Justification for the recommendations within each section will be provided at the end of each chapter with reference to the literature.

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1. Hygienic Hand Disinfection

**Indications**

Hygienic hand disinfection must be performed before the nurse/physician has any opportunity to transmit infections to patients by hand and after any potential contamination of the hands. The World Health Organization (WHO) has broken the indications down into five groups (5 moments). These moments refer to hand disinfection in the immediate vicinity of patients:

- prior to patient contact
- prior to tasks requiring aseptic technique and
- after contact with potentially infectious material

and in cases of extended patient contact to hand disinfection

- after each contact with patients
- after each contact with the patients’ direct vicinity.

This applies regardless of whether sterile or non-sterile disposable medical gloves are worn after hand disinfection.

In addition, hand disinfection must be performed after removing sterile or non-sterile disposable medical gloves.

In the following situations, one must consider if hygienic hand disinfection is to be preferred to hand washing due to better skin tolerability:

- after washing the patient (after removal of the protective gloves)
- prior to preparing and distributing food
- after blowing your nose (rhinitis often spreads pathogens, such as the influenza and parainfluenza viruses, rhinoviruses and pneumococci).

It is also practical to involve patients in preventing infections and to explain to them how the five moments distinguished by the WHO can be applied to their situation during the following:

- entering the patient’s room
- leaving the patient’s room
- prior to eating
- after using the toilet
- prior to and after contact with their own wounds, mucous membranes or devices.

**Implementation**

The hand disinfectant (HD) – also called “hygienic handrub” - is applied to dry (!) hands without adding water before or during a procedure and evenly distributed by rubbing the hands together in a defined manner for the duration of the application time stated by the manufacturer, in such a way that the entire palm, i.e. finger tips, nail folds, thumbs, spaces between the fingers and interior and exterior surfaces, is completely wet. Nail folds and fingertips need to be given extra special attention. The palms should remain wet for the length of application time stated by the manufacturer. The application of at least 3 ml of disinfectant solution is sufficient for adequate moisture. The hands must not be dried after the application time has elapsed.
If there is visible contamination on the hands, it can be removed with a paper towel, pulp or the like soaked in the HD. After this, hand disinfection is performed. Alternatively, hand disinfection can be performed twice such that, following the desired hand washing, water is only added after the application time specified for the hand disinfection has elapsed.

**Justification**

**Indication:** Hygienic hand disinfection is considered worldwide to be the most effective single action to break infection chains in health facilities, thus preventing nosocomial infections (NI) in inpatient and outpatient health facilities, and also for persons requiring outpatient treatment and home care [1-10]. Ignaz Philipp Semmelweis’ first publication has already impressively shown the effectiveness of hand hygiene [11, 12]. In addition, hand disinfection stems the spread of multiresistant pathogens, thereby reducing the number of associated colonizations and infections [13-20]. Finally, hand disinfection has been demonstrated to disrupt outbreaks [21-23]. Moreover, hand disinfection contributes to personal protection [24].

The hands of personnel contaminated with pathogens are the most important transmitters of those pathogens [1, 25-31]. Therefore, a hygienic hand disinfection must be performed for patient procedures and when coming into contact with contaminated surfaces. The WHO has summarized the indications into 5 indication groups (“five moments”) as the basis for providing instruction and training on hand disinfection. This should also facilitate recognizing the indications during the work routine [6].

Hygienic hand disinfection should reduce the number of pathogens on the hands (transient flora) to the extent that they are prevented from proliferating. This type of hand disinfection results in a significantly higher reduction in the number of germs than hand washing and thus provides greater safety [32-56]. In addition, the skin is less stressed [57-60].

Whereas hand washing is sufficient for healthy people after a bowel movement, in cases of diarrhea, disinfection may be recommended prior to hand washing, e.g. if there is a high probability of viral pathogens in particular being excreted with partially very low infective doses like with rotaviruses and noroviruses.

Hand disinfection is necessary after removing non-sterile disposable medical gloves since they provide no absolutely reliable protection from hand contamination (risk of perforation), and hands may become contaminated if the gloves are not removed properly. To properly remove the gloves, one takes the finger of the hand that was first uncovered and places it on the wrist of the other hand in the glove, and then pulls the glove off without touching it from the outside. This procedure is often not used out of ignorance. Instead, the gloves are removed by grasping the upper part at the wrist with the thumb and forefinger and pulling down, which inevitably results in contact with the outside surface. This surface may however be contaminated by coming into contact with infectious material.

Hand disinfection is indicated after the removal of medical gloves due to the risk of unseen glove perforations. The hands can then be washed as needed. The disinfectant chosen must be a virucide for procedures involving an increased viral load from non-enveloped viruses (e.g. papillomas, condylomata acuminata). Finally, the use of a skin-care lotion is recommended [61].

Involving the patient in infection protection goes without saying since s/he is the potential recipient and transmitter of nosocomial infections [51]. If s/he is given basic knowledge about how s/he can contribute to his/her own protection, s/he will not only act appropriately, s/he will also feel safer, which ultimately helps in the healing process. Initial experiences have confirmed this approach [62]. Hand disinfection is especially important for patient protection because its preventative benefit has already been demonstrated after being introduced to different population groups [63-68].

**Implementation:** The use of < 2 ml HD significantly reduces the moist surface [69]. The
disinfectant should be rubbed in especially at the fingertips, nail folds and thumbs [70, 71], which is often disregarded [72]. A comparison of the movement sequence specified by DIN EN 1500 [73] with individually chosen hand-rubbing techniques, focused on moistening the palms as mentioned above, showed no advantage for the movement sequence of the testing standard [70]. Therefore the model consisting of six individual steps recommended in the DIN does not have to be followed. However, a rub-in technique that has been practiced is advised, to ensure standardized implementation as much as possible.

2. Surgical Hand Disinfection

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<td>Surgical hand disinfection should be performed by all those working in the operating room, including the staff responsible for the sterile supply.</td>
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<td>Washing with soap is no longer part of surgical hand disinfection. However, one should enter the operating area with clean hands, and hand washing usually occurs when entering a hospital or practice to gain a sufficient amount of time before surgical hand disinfection. The use of brushes should be limited to removing stubborn contaminants. If the sluice room does not have a washing area, but hands must still be washed prior to the surgery due to contaminants, a suitable alternative must be found. Washing with soap is not necessary after subsequent surgical hand disinfection if the hands are not visibly soiled.</td>
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If hand washing is necessary before performing surgical hand disinfection, it should be done 10 minutes before surgical hand disinfection at the earliest, but no later than in the operating sluice room before putting on scrubs. The hands should then be dried with a germ-resistant textile or paper towel. Regardless of whether the hand washing was performed in the operating sluice room or at an earlier time, hygienic hand disinfection should be performed before putting on operating room scrubs so as not to contaminate the scrubs. This procedure should be repeated with each new entry into the operating room.

During surgical hand disinfection, the hands and then the forearms are first made wet within the application time stated by the manufacturer. Then, the HD is vigorously rubbed into both hands in a similar way to hygienic hand disinfection, during which all hand surfaces must be made wet for the duration of the application time for the HD stated by the manufacturer using the rub-in technique practiced. It should be noted that gaps in coverage should be avoided, with particular attention given to the fingertips, nail folds and spaces between the fingers. Further, it should be pointed out that one should not come into contact with non-disinfected areas of the skin during the procedure.

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<td><strong>Indication:</strong> For ethical reasons, there is only indirect evidence for surgical hand disinfection: the postsurgical rate of wound infection was significantly higher with perforated surgical gloves than with non-perforated gloves [74, 75]. Experiments have shown that wounds can have between $10^3$ and $10^4$ colony forming units (CFU) when glove lesions occur with hands that have not been disinfected [76, 77]. In contrast, the number of colony forming units...</td>
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transferred with previously disinfected hands was < 100 CFU [76, 138]. Therefore, prior surgical hand disinfection can keep the number of microorganisms entering the surgical wound with the sweat remaining from the glove (“glove juice”) low if the surgical gloves are damaged during surgery, thus reducing the risk of infection [76-78]. It should be noted that, in accordance with DIN EN 455-1 [79], brand-new, unused, sterile surgical gloves may already be defective in 3 out of 80 or 4 out of 120 gloves tested (i.e. AQL ≤ 1.5). Regardless of this, surgical gloves become perforated, whether noticed or not, in up to 40% of procedures [80], and bacteria transfer could be detected with surgical gloves after a wearing time of 90 minutes [81, 82].

The drastic incident in which a post-surgical outbreak of wound infections was caused by using non-surgical soap instead of an HD containing iodine underscores the importance of surgical hand disinfection [83].

Based on the testing model for surgical hand disinfection, it is assumed that the effect lasts for about 3 hours. However, there are no studies demonstrating that surgical hand disinfection must be performed again after this time.

**Implementation:** It is recommended that hands be washed first before performing surgical hand disinfection for the first time on the day of surgery [84] to reduce the risk of spore load on the hands. There is a particular risk of the hands becoming contaminated with spores after gardening (*Clostridium* and *Bacillus* spp.), but also after a colonoscopy, using the toilet and caring for patients with *C. difficile*-associated diarrhea. A large number of sporulators (primarily *Clostridium* spp.) was found in the glove juice during testing of surgical HD [85]. This finding underscores the need for thoroughly washing the hands once no later than in the operating room sluice before surgical hand disinfection.

An interval of <10 min should be observed between hand washing and surgical hand disinfection. With shorter intervals, the effectiveness of alcohols tends to be or is significantly reduced due to the dilution effect of residual moisture [86-90], so that additionally the increase in the number of pathogens on the hands associated with washing with soap, with [91] or without using a brush [86, 92, 93], may affect the reduced effectiveness. When washing, the hands and forearms should be washed up to the elbows with the fingertips pointed upwards and elbows down for about 30-60 seconds using a hand washing agent. Hands should not be washed for a longer period due to potential skin damage, especially since no further reduction in the resident flora is achieved [94-96].

For surgical disinfection, the hands and forearms should be moistened by using a practiced rub-in technique for the length of application time stated. When disinfecting hands, the areas of skin on the hands should be moistened first, then the forearm up to the elbows and then the hands again. During this phase of hand disinfection, special attention should be given to rubbing in the fingertips, nail folds and spaces between the fingers and achieving complete coverage. The following procedure has been demonstrated to be effective for an application time of 1.5 min [97]. First, both hands should be moistened (10 seconds) and then both forearms in the second step (10 seconds). This is followed by the hand disinfection phase using a rubbing-in technique (70 seconds) [98]. The number of portions applied had no effect on efficacy as long as the hands were kept moist for the duration of the application time for the agent [99]. The hands should be dry before putting on surgical gloves as this reduces the risk of perforation [100] and irritation [101], and the effectiveness of alcoholic hand disinfection is significantly improved if the hands are air dried for one minute [102].
3. Selection of Hand Disinfectants

Formulations of choice for hygienic and surgical hand disinfection are alcohol-based products. The addition of active antiseptic substances is critical and also unnecessary.

For prophylactic (i.e. routine) use, an HD chosen from the list of disinfectants from the Association for Applied Hygiene (VAH) is guaranteed to comply with performance requirements.

In contrast, the list of disinfectants recognized and tested by the Robert Koch Institute (RKI) should be taken as the basis for officially ordered disinfection measures in accordance with § 18 of the IfSG [Protection against Infection Act].

All alcoholic HDs are effective against vegetative bacteria and yeast-like fungi. If there is a risk of proliferation of enveloped viruses, HDs with the statements “limited virucidal” (or “virucidal” for non-enveloped viruses) should be used. If there is a risk of transmitting tuberculosis bacteria, agents should be used that are effective as tuberculocides. However, no additional tuberculocidal, fungicidal or virucidal effectiveness is necessary for surgical hand disinfection.

Since alcohol is non-active on bacterial spores, non-sterile medical protective gloves should be worn if there is a risk of transmitting bacterial spores. Hands should be thoroughly washed with soap after removing the gloves and disinfecting hands.

When selecting an alcohol-based HD, it is important to check if refatting agents have been added to the alcoholic base (refer to statement).

Justification

At the request of the manufacturer and after being evaluated by the VAH’s Disinfectant Committee, the VAH’s annually updated list [103] only includes substances that comply with the VAH’s testing requirements and European standards [104-106]. The requirements of the DVV/RKI guideline or European standards must be met before “limited virucidal” or “virucidal” is claimed [107, 108]. When there is an increased risk to the public, health departments can mandate disinfection to protect against communicable diseases. Only the agents and procedures on the RKI’s list must be used for officially ordered disinfection measures [109]. The concentrations, application times and recommendations (e.g. disinfecting hands twice in the event of massive contamination) thus differ somewhat from the VAH’s list. It should be noted that the testing requirements of both the VAH and RKI do not include tolerability. The range of effectiveness for alcohols includes bacterial pathogens and yeasts; however, bacterial spores are not inactivated. Products that are effective as tuberculocides should be used in the care of patients with open pulmonary tuberculosis [110]. After caring for patients with viral diseases or after contact with materials containing viruses, an HD with the statement “limited virucidal effect” should be used for enveloped viruses, and an HD with “virucidal effect” should be used for unenveloped viruses [110, 111]. Ethanol is more effective against viruses than propanols, while enveloped viruses are caught by all alcohols depending on the concentration. A high concentration of ethanol or synergistic combinations with a low alcohol content are needed to inactivate unenveloped
viruses [112-116]. No sporicidal activity can currently be achieved for all HD alcohols with bearable skin tolerance and practical application time [117, 118]. Therefore, thoroughly washing hands with soap and water is currently recommended after hand disinfection to remove bacterial spores [119]. If there are no handwashing facilities in the patient’s room or associated sanitary module, the nearest washing facility must be sought out, and on the way there contamination of the environment, e.g. doorknobs, must be avoided. Substances containing peracetic acid can be used on a short-term basis when working with spores at the laboratory workbench.

A longer lasting (residual) effect is not necessary to remove pathogens on the hands, and there is no evidence that the preventative effectiveness of hygienic or surgical hand disinfection can be increased with slow-acting additives to an alcohol-based HD. However, when added to alcohols these additives, such as chlorhexidine gluconate, octenindine hydrochloride, polyhexanide, quaternary ammonium compounds such as benzalkonium chloride, phenol derivatives and triclosan, are associated with the risk of reduced skin tolerance, sensitivity and absorptive side effects [120-134, 144]. In rare cases, anaphylactic reactions may already occur as immediate allergic reactions after the first-time use of chlorhexidine, depending on circumstances [135-137]. Resistance may be developed, in part with cross-resistance to antibiotic agents, with long-term use of chlorhexidine, triclosan and benzalkonium chloride [120, 138-143]. Aqueous-based iodophors pose a risk due to the dermal resorption of free iodine by intact skin. Depending on the duration of use, iodine resorption can reach critical iodine concentrations for persons suffering from hyperthyroidism and even those with a normal thyroid. Another disadvantage of aqueous-based iodophors is the required application time of 60 seconds [103]. The following contraindications should be kept in mind when using them, even just once: iodine hypersensitivity, hyperthyreosis, autonomous thyroid adenoma and radioiodine therapy. The use of aqueous-based iodophors on pregnant females or persons with a history of thyroid disease or having a nodous struma is only acceptable if thyroid function is monitored. For longer-term use, monitoring thyroid function is also recommended for persons with a history of healthy thyroid function. Use over months or years should not be considered harmless even in healthy persons due to the risk posed to the thyroid, particularly in cases of nutrition-induced iodine deficiency [145-156]. There is a risk of triggering hyperthyrotic metabolism crises in persons predisposed to autonomous thyroid nodules exceeding a critical volume with relatively small quantities of iodine [145, 157-163]. Thus, neither aqueous nor alcohol-based iodophors are the agent of choice for hand disinfection. Neither are aqueous solutions based on chlorine releasers or peroxides or liquid-active washing substances with antiseptic additives alternatives to using an alcohol-based HD, due to their lower level of effectiveness and poorer skin tolerability compared to alcohol-based substances, their poorer distribution behavior on the skin and longer evaporation time [164-170]. In contrast, the alcohols used for hand disinfection cause no change in the properties of the skin barrier, have no increased potential to irritate skin, even if it has already been irritated, and have no sensitizing effect [171]. Rather, ethanol-based hand disinfection by nursing staff who previously only used antiseptic soaps instead of an alcohol-based HD resulted in skin improvement [166, 167, 170]. Skin tolerability requires the addition of refatting agents to the alcohol base, which should be taken into consideration when choosing the substance [60, 172, 173]. The use of alcohols is not associated with the risk of irritation dermatosis with adequate skin care [60]. Up to now there have been no studies as to whether ethanol and both propanols differ in their tolerability regarding intact skin. A tissue tolerability of 80% for ethanol was better than 60% for propan-2-ol for peritoneal explants [174]. This could be an advantage when used on
irritated or especially sensitive skin. Also, the inhalation toxicity of ethanol is much lower [175-177] even though no toxicity through inhalation was described for the alcohols. Therefore, the use of ethanol-based substances is preferred, especially with vulnerable patients (e.g. newborns, small children, patients with respiratory diseases), above all due to better physiological adaptation (deposit and breakdown of ethanol in the organism). Ethanol and both propanols are only reabsorbed in trace amounts [178, 179] such that there is no systemic risk. Even if ethyl glucuronide is measured as an abstinence marker in the urine while performing commonly practiced hand disinfection, both on the day of implementation and on the morning after use during the night shift, and possibly exceeds the legal limit specified in Germany [180], there is no associated health risk.

4. Hand Washing

The frequency of hand washing should be limited to the minimum required. It is usually done to remove dirt or for aesthetic needs (e.g. after removing disposable gloves to remove hand sweat), and is particularly mandated after using the toilet and prior to eating. If pathogens cannot be killed by hand disinfection, removing loosely adhering microorganisms by hand washing is the only way to remove them, e.g. in cases of contamination by bacterial spores, helminths, Cryptosporidium, oocysts and protozoa.

The subungual spaces should be given particular attention during hand washing. If the water does not automatically turn off, it should be simply turned off with the used hand towel or elbows.

In contrast to washing with soap in a domestic setting, a liquid substance (detergent) from a dispenser is used in medical settings. The detergent should be selected with regard to the lowest possible potential for irritation and sensitivity, including the use of fragrance-free and preservative-free products. A slightly acidic (pH 5.5) or at least pH-neutral cleanser is recommended to protect the skin.

Brushes should not be used routinely but instead only for special contaminants and only for fingernails and nail folds to prevent mechanical damage to the skin on the hand and forearm. Washing hands with soap should be reduced to the absolute minimum, i.e. at the beginning of the shift if necessary, if there is visible dirt, after using the toilet and for aesthetic needs. After washing, careful drying with a soft disposable hand towel is important, especially for the spaces between the fingers.

Soap bars cannot be used for hygienic reasons.

Justification

Hand washing has no demonstrable effect on the incidence of nosocomial infections under the conditions of everyday life on the ward due to soaps having no intrinsic microbiocidal effect. However, in contrast to alcohol-based hand disinfection, hand washing is associated with the risk of skin irritation. Frequent hand washing causes the stratum corneum to swell, which results in the alteration and emulsification of the intercellular lipid bilayers, and the lipids are rinsed away with water-soluble moisturizing factors and antimicrobial protection factors. As a result, the skin dries out, the stratum corneum may split open, the epidermis and cutis may become inflamed with keratinization disorders and the person may end up with irritation dermatosis that in certain circumstances can be difficult to treat [169]. The timespan for the normalization of skin parameters is no longer sufficient if hands that are used a lot on the job are washed four times in one hour [181]. Although skin lipids are also emulsified and pushed out of their structural arrangement by alcoholic disinfectants in the
stratum corneum, substantially they remain on the skin if not rinsed off [60]. A number of experimental findings and application studies have demonstrated better skin tolerability of alcoholic rubbing substances compared to soap [169, 182]. The subungual spaces should be given special attention during hand washing since they contain most of the hand flora [183]. If the water does not automatically turn off, it should be turned off with the used hand towel or the elbow to prevent contamination [189]. Solid soaps are prohibited [184] since contamination with both gram-positive and gram-negative bacteria was demonstrated repeatedly under conditions of use [185-188]. After a liquid soap was introduced, the rate of NI fell from 4.2% to 2.2% in one year [188].

5. Medical Gloves

### Non-Sterile Disposable Medical Gloves

Non-sterile disposable medical gloves should be worn in the foreseeable or likely event of coming into contact with pathogens, as well as in the event of possible contamination by bodily excrement, secretions, excretions and/or blood. As a rule, the gloves should only be used when caring for the same patient and then removed afterwards. If the workflow permits, disposable gloves should be changed in parallel with the indications for hand disinfection, i.e. always when hand disinfection is indicated but gloves are being worn. In exceptional cases, glove-protected hands may be disinfected instead of the gloves being changed if the workflow cannot be guaranteed otherwise, e.g. when taking consecutive blood samples from several patients or when alternating between clean and unclean activities with the same patient. Compatibility with the disinfectant or proof of chemical resistance in accordance with EN 374 is required. The latter is ensured by nitrile gloves, for instance, with the corresponding statement. Gloves must be changed in the event of visible perforation, contamination by blood, secretions or excretions, as well as by unenveloped viruses and after being used to wash a patient. Disposable or reusable textile gloves may be worn during extended periods (e.g. physiotherapy) to collect hand sweat.

If the gloves are taken from a conventional cardboard box, rather than an automatic glove dispenser or a cardboard box that releases the next glove when the first glove is removed and enables the glove to be removed without touching the box and other gloves, hand disinfection should be performed before taking them from the box.

### Protective Gloves as PPE from Chemicals and Microorganisms (PPE Gloves)

Gloves declared to be personal protective equipment (PPE) should be used if there is to be protection from chemicals and microorganisms. This applies when performing disinfection (surfaces, medical devices), for instance.

### Sterile Surgical Gloves

This type of glove should be worn before all invasive procedures requiring barrier measures exceeding basic hygiene measures and when handling sterile medical devices or material. When putting on these gloves, attention should be given to creating a tight seal at the cuffs of the gown.

Both non-sterile disposable medical gloves and surgical gloves should only be worn on completely dry hands; the former should only be worn as often and as long as necessary. Sterile cotton gloves worn under the surgical gloves can counteract moisture accumulation. Natural latex is preferred for surgical gloves. Non-powdered gloves are generally more
tolerable for the skin than powdered gloves. Powdered latex gloves are prohibited due to the high risk of allergy. The use of talcum powder before putting on surgical gloves is not recommended.

Due to the danger of perforation, double-gloving is recommended, depending on the risk. Two freshly sterile surgical gloves must be put on if glove damage occurs during surgery. Hand disinfection should be performed prior to double-gloving. If the perforation occurred at the end of surgery, it may be sufficient to put a freshly sterile glove over the perforated glove.

### Justification

**Non-sterile disposable medical gloves:** These serve primarily to disrupt bacterial chains [190-192] as part of personal protective equipment and also occupational safety equipment. In particular, their use is indicated if the expected pathogens are resistant to alcohol-based HDs, e.g. *C. difficile*, or are especially dangerous, e.g. pathogens causing viral hemorrhagic fever. The necessity of wearing protective gloves when a high level of contamination is expected is based on the fact that, if the hands are highly contaminated with *Escherichia coli* and similarly with methicillin-resistant Staphylococcus aureus (MRSA), two to three log10 still remains on the hands after hand disinfection [193, 194].

Changing disposable gloves is necessary due to the risk of undetected perforations. Since the perforation rate increases with prolonged wearing time and/or strenuous activity, changing gloves is recommended after no later than 15 minutes, e.g. after washing the patient [195].

**PPE gloves:** High-risk gloves (RL686 Category III, with the CE mark, followed by a four-digit number) should be chosen if protection against chemicals is needed [196]. This type of quality is recommended for all gloves used in the healthcare field. It not only indicates the level of protection performance to be expected but, in particular, also the quality (AQL) ensured, which is critical for the expected protection. PPE gloves must meet both the general requirements of EN 420 [197], especially regarding safety, mechanical strength, ergonomics, and resistance to water penetration, as well as the specific requirements concerning intended use, i.e. protection against chemicals and microorganisms in accordance with EN 374 [197-201]. The ASTM standard F1671-07 provides information about resistance to pathogens that are transmitted via the blood, e.g. viruses [202]. Likewise, barrier function testing for cytostatic agents is currently only governed by ASTM D6978-05 [203]. Only gloves with a declared protective effect against chemicals and microorganisms ensure sufficient protection for disinfection.

**Sterile surgical gloves:** When putting on these gloves, special attention should be paid to creating a tight seal around the cuffs of the gown. Wearing a second pair of surgical gloves (double gloving) with an indicator system if possible [204, 205] reduces the risk of damage and thus contamination if glove defects occur, but does not completely prevent them [364]. When wearing only one pair of gloves during visceral surgery, due to the increasing perforation rate over surgery time, a glove change is recommended after no later than 90 minutes for the surgeon and primary assistants and no later than 150 minutes for the secondary assistants and theater nurses [206, 207]. Also, gloves having antibacterial barriers or antibacterial impregnation reduce the transfer of pathogens through perforations [208] and/or the quantity of pathogens on the hands [209]. However, the latter pose an allergy risk. Both hands should be disinfected for a period of 30 seconds before changing damaged gloves during surgery [210, 211].

The recommendation for natural latex is justified on the grounds that no other material currently has the same properties regarding wearing comfort, fit, grip and mechanical load. Powdered latex gloves are prohibited due to the risk of allergy [212]. Talcum powder and substitute products pose the risk of granuloma formation in the operating area [214-217].
This has not been studied for emulsion with corn starch; however, the latter is unnecessary since no effect on the amount of sweat could be detected [218].

**Textile undergloves:** These are thin, disposable or recycled cotton gloves. They can be worn both under non-sterile and sterile disposable medical gloves. Their use to reduce hand sweat during extended wear of protective gloves impermeable to air is given careful consideration in TRBA 250 [184]. Undergloves should be changed together with the disposable medical gloves. Their use has also been demonstrated to be feasible for non-sterile disposable medical gloves as they have a subjectively favorable effect on the skin by absorbing moisture such that nurses and physiotherapists overwhelmingly endorse their routine use in patient care [219].

### 6. Hygienic Requirements for Hand Disinfection

When staff enter the facility and in particular the operating area, their hands and fingernails should be clean. Their nails and nail folds should already have been cleaned at home if the subungual spaces are contaminated. If nails become soiled during work, they can be cleaned with cleaning/disinfection equipment using a soft plastic brush or disposable nail brush. A brush should not be used on the hands and forearms due to the risk of facilitating skin irritation and the associated higher release of pathogens.

Fingernails must be kept short and round and flush with the fingertips. The nail surface should not be cracked, e.g. by chipped or cracked nail polish. Color nail polish should not be worn. Artificial or gel nails must not be worn.

Rings, bracelets, watches or piercings (e.g. dermal anchors) must not be worn on the hands and forearms in all areas where hand disinfection is performed. Ring dosimeters are exempted for personal safety reasons.

There should be no injury to the nail bed or inflammatory processes on the hands prior to surgical procedures. However, with careful consideration of the risks involved, if there are non-inflammatory changes and/or small injuries on the hand, the surgery may be performed with two pairs of gloves worn underneath each other, if necessary after being previously covered with antiseptic ointment and an additional fingerling. If necessary the person is advised to see the company physician.

Skin lesions on the hands should be covered and sealed against pathogens and, if necessary, liquids (with plaster or dressing) to prevent infection and for personal safety when performing non-surgical tasks; protective gloves should be worn over this.

Except for scrubs, all surgical clothing worn in surgical units should have short sleeves so as not to hinder surgical hand disinfection. Sterile protective clothing usually has long sleeves, and its fabric must be impermeable to pathogens and liquids.

### Justification

The requirements for effective hand disinfection have only been studied in part and have mainly come from hygienic risk assessment. Short fingernails flush with the fingertips ensure that the subungual spaces can be cleaned and minimize the risk of glove perforations at the fingertips. Nail polish should not be used because it hinders a visual assessment of the nails, increases colonization on the nails when worn for an extended period and, depending on the age of the lacquer, does not have an adequate disinfectant effect [220].
Artificial nails tempt one to neglect hand hygiene, increase the risk of perforation for disposable medical gloves and facilitate bacterial colonization [221-225]. Artificial nails have been repeatedly identified as the source of nosocomial infections in immune-suppressed patients and outbreaks of postsurgical wound infections [226-232]. Jewelry worn on the hands and forearms, including wedding rings, hinders proper hand hygiene and may become a reservoir for pathogens [233-235], and therefore is not permitted. In addition, wearing wedding rings increases the perforation rate of surgical gloves [204]. However, rings are also not allowed due to the risk of injury [184]. Ring dosimeters are permitted when prepared properly. It is sufficient to disinfect ring dosimeters by immersing them in an alcoholic instrument disinfectant. Afterwards the ring does not have to be rinsed with water; it can be worn again on the disinfected hand after being air dried [236].

For chronic skin diseases, it should be checked whether there is any colonization by potential pathogens and if they can be eradicated, since hands colonized (e.g. with *Serratia marcescens*) can result in an outbreak if the person has psoriasis [237]. The person is advised to see the company physician. One outbreak was caused by a case of severe onycholysis and onychomycosis of the right fingernail with the simultaneous confirmed presence of *Pseudomonas aeruginosa* although latex surgical gloves were worn [238].

### 7. Technical Requirements for Hand Disinfection

#### Hand Washing Station

The hand washing station and its fittings must not lead to the spread of pathogens. A hygienic hand washing station includes a sufficiently large and deep sink with no overflow and with hot and cold water, wall-mounted dispensers for HD and liquid soap, hand care agents, disposable towels and a collection container (wastepaper basket or plastic bag) for used hand towels. Alternatively, disposable textile hand towels (dispensed individually or by retraction) can be considered. Electric hot air hand dryers are unsuitable for health care facilities.

Hand washing stations must be available in or near rooms where diagnostic or invasive procedures are performed, in rooms where preparation for these procedures takes place and near unclean work areas. Each patient room must have a washing facility easily accessible for employees, if possible in the sanitary module. Water faucets must be capable of being operated by a single handle or by sensor, foot or knee activation, due to the risk of recontamination. The water jet should not be directed at the outflow (thereby swirling up pathogens).

#### Hand Disinfectant and Liquid Soap Dispenser

Only products declared to be medical products should be used as HD dispensers in health care. In contrast to liquid soaps, the use-by date of HDs must be documented on the container or separately. Hands-free operation is recommended for both types of dispensers (elbow or proximity sensor).

Dispensers must be serviced so as to prevent them from becoming colonized by microbes. The fixed exterior and interior parts of both types of dispensers must be easily accessible. Contaminants on the exterior housing and all parts accessible without further manipulation, as well as drippings by the outlet, should be removed by surface disinfection.

If, instead of the hospital using hygienically safe disposable containers, it needs to re-fill the dispenser, the dispenser container must first be re-filled in a pharmacy under clean room conditions. The resident doctor may re-fill smaller dispenser bottles him/herself; however,
s/he is required to ensure that all measures guaranteeing safety are performed (preparation, aseptic filling, batch number, documentation).

Disinfectant dispensers must be conveniently available everywhere regular hand disinfection is performed. At a minimum, there should be one dispenser per patient bed in the intensive care and dialysis units and one dispenser per two patient beds and in the sanitary module in the non-intensive care units. Further, dispensers should be provided in clean working areas, on the ward trolley and/or dressing trolley, at the exit to the patient’s room and in sluices. If adequate dispenser provision with wall-mounted dispensers is not possible, mobile dispensers, including portable bottles worn on clothing, can be used.

Disinfectant dispensers with disposable bottles are recommended because re-filling poses a risk of contamination.

**Justification**

**Hand washing station:** Patient sinks may also be used by staff in special situations, provided that they have been equipped with dispensers for hand disinfectant, liquid soap and hand towels. This concerns e.g. washing hands after removing gloves after caring for patients with *C. difficile*-associated diarrhea, or after an unexpected massive contamination of the hands while caring for patients.

Paper towel dispensers are to be preferred to hot-air hand dryers due to the smaller drying effect compared to paper towels, the absence of any mechanical removal of residues (soap residue, flaky skin, remnants of skin flora), the noise load of jet air hand dryers, the higher level of user comfort and, depending on the electric dryer, the risk of spreading pathogens [239-253]. They must facilitate easy removal without the next hand towel and retrieval opening becoming contaminated. Care should be taken that the collection container for used hand towels is emptied regularly. Alternatively, retractive dispensers that automatically feed the textile hand towel can be considered. This type of dispenser unwinds a towel on one roll and rolls it up on another roll after the towel is used [253]. If sensor faucets are used instead of handle-operated faucets, the magnetic valve that releases the stream of water should be checked to make sure it is as close as possible to the level of the faucet, so that no column of water that gram-negative non-fermenting organisms might colonize can stagnate in the faucet, something that has caused outbreaks [254-260].

It is plausible from a hygienic perspective to construct the sink without an overflow, which has been identified as the cause of a spate of *Serratia liquefaciens* infections [261]. The sink drain is an open pathogenic reservoir for patient flora [262]. When water flows in, bacteria are emitted up to 1.50 meters in the vicinity of the wastewater in the outflow. The transfer of bacteria to the hands of the nursing staff during hand washing was demonstrated when the outflow was contaminated with >10^5 CFU/ml [263]. Outflows colonized with *P. aeruginosa* have been identified as a risk factor for the colonization of patients [263, 264]. Outbreaks of *Enterobacter cloacae, P. aeruginosa, Acinetobacter baumannii* and *Serratia* spp. originating from the outflow have been reported [264-267]. An outbreak lasting over five years ended after the outflow was cleaned three times a day and changed [268]. If an outflow plug is desired, it should be easy to disinfect, and therefore not made of rubber or plastic. A cap extending far over the outflow opening is beneficial for screening the aerosol emitted by the inflowing water. Automatic outflow disinfection systems may be indicated for specific units, e.g. for mucoviscidosis patients, in the intensive neonatology unit, and to prevent *Pseudomonas* infections [269].

**Dispenser for hand disinfectant and liquid soap:** The declaration that disinfectant dispensers are medical products requires manufacturers to provide information on proper treatment. Since liquid soap dispensers are not medical products, the user has to determine the treatment on his/her own. The requirement for HDs to document the date of use arises from their classification as medical products by presentation [288, 289].
Neither type of dispensers must give rise to pathogen proliferation. Therefore, the following requirements should be met regardless of the manufacturer and model [270]: hands-free operation, provision of a non-refillable liquid soap or hand disinfectant container (disposable container), option to use liquid soap and hand disinfectant containers from different manufacturers (e.g. Eurospender), as well as prevention of microbial contamination of the pump head during use. The liquid soaps or HDs used in the dispenser, including important manufacturer instructions and filling level, must be identifiable without further manipulation. Soap dispensers should be more critically evaluated than HD dispensers with regard to the risk of microbial colonization [273, 274]. In addition, unlike with disinfectant dispensers, hands are not necessarily disinfected after contact with the outlet of the soap dispenser, but likely rinsed. Therefore, the use of disposable pumps on the container, which are thrown away with the empty container, is beneficial for soap dispensers. Preparation is usually manual; however, machine preparation is possible, albeit at a higher cost [275]. There is no evidence regarding preparation interval. The cleaning service can disinfect the operating handles daily by wiping. The scope and frequency of preparation of the interior surfaces of dispensers should be specified in the in-house hygiene plan. In this process, the results of the microbiological testing of samples routinely taken from dispensers should be taken into account. Obviously no risk of pathogen contamination is documented for hygienically adequate dispensers [271].

Outbreaks caused by contaminated soaps always involved open soap bottles or refillable dispenser systems with no prior preparation but not closed systems [271-274, 276-284]. Experiments have shown that washing with contaminated liquid soap increases the number of gram-negative pathogens on the hands, which can possibly enable proliferation in communal facilities [273]. Soap contamination is possible even when the dispenser is loaded with disposable bottles if the complete dispenser, including the ascending pipe, is not cleaned and disinfected properly [275, 279, 285].

A high level of compliance regarding hand disinfection can only be attained with an optimum provision of hand disinfectant dispensers [7, 286]. Therefore, such dispensers must be present everywhere hand disinfection has to be regularly performed, e.g. at bedsides in the patient’s room and at the exit to the room, on ward trolleys and/or dressing trolleys, in sluices, etc. [287]. The staff should have no other way to access an HD during patient care. Inadequate provision of hand disinfectant dispensers inevitably leads to a neglect of hand hygiene. Therefore, in addition to the provision of hand washing stations prescribed by TRGS 250 [184], the WHO recommends that HDs be provided “at point of care” [6]. If an adequate provision of wall-mounted dispensers is not possible, mobile dispenser systems, including portable bottles worn on clothing, should be provided.

Disinfectant dispensers should be loaded with disposable bottles. The provisions of the Medical Products Law (AMG) should be observed if the dispensers need to be filled. Section 4, Para. 14 of the AMG defines the transfer of medical products from larger containers into smaller containers for dispensers as manufacturing, i.e. the person performing the filling becomes a manufacturer and requires authorization to manufacture in accordance with § 13 [290]. Pharmacies meet the filling requirements by meeting their own professional and technical requirements. There must be manufacturing authorization if the filling is done for commercial reasons, i.e. for surrender to others, such as occurs at the pharmacy. The resident doctor, as the manufacturer and user at the same time, is not subject to the authorization requirement, i.e. s/he may fill smaller dispenser bottles; however, in accordance with § 25, Para. 10 of the AMG, s/he is required to ensure that all safety measures have been taken. These include cleaning and sterilizing the disinfectant container before re-filling, filling under aseptic conditions (sterile workbench), documenting the batch number and/or filling date and making sure that the dispenser was re-filled by trained staff [291]. This procedure is necessary because bacterial spores can survive in alcohol-based disinfectants and may enter a wound this way (risk of gas gangrene and tetanus). After the occurrence of gas gangrene infections, gas gangrene spores were detected in ethanol used for disinfection, and, as a result, the standard recipe (SR) with added hydrogen peroxide was
introduced to eliminate the spores in the ethanol [292]. 1.8% of samples (n=16142) were found to be contaminated during a practical study, including 70% ethanol. Only PVP iodine and iodine tincture were not contaminated at all, which can be attributed to sporicidal effectiveness. The contamination only concerned regional hospitals and no university hospitals [293]. The following risk factors were identified for the contamination: provision by untrained staff, unsuitable containers and extended use.

From a toxicological perspective, no sustained serious side effects are to be expected from the improper use of dispensers in patients’ rooms as long as these only contain alcoholic substances with no residual microbiocidal substances, such as chlorhexidine, quaternary ammonium compounds or iodophors, since patients who are fully mentally responsive are not expected to accidentally ingest toxicologically critical quantities orally. Nevertheless, for legal reasons, it is recommended that the dispenser or dispenser bottles be permanently labelled with a legible warning. For example, this can read: “HD for use on hands only! Do not drink, spray in eyes or apply to mucous membranes. Flammable.” Pictograms can also be used as a warning [286].

8. Skin Protection and Care

Skin protection products are used to protect the skin from stress (e.g. working in wet conditions). These products are used after washing hands, during breaks, after finishing work and during leisure time. More stressful loads on the skin during leisure time (e.g. working in the garden) should be avoided. As a rule, only products with proven effectiveness should be used for skin protection and care. In addition, the allergenicity of the ingredients of these products should be checked, and the products chosen should be fragrance-free and, if possible, also preservative-free. Skin protection products should also not contain urea. Skin protection and care products should be provided in dispensers or tubes due to the risk of contamination.

If the skin is at risk due to a person working in wet environments, including wearing gloves for more than two hours, the employer must provide personal protective equipment (PPE), create operational instructions and a skin protection plan, check the possibility of reducing exposure, and ensure medical care and monitoring in the workplace. If the skin begins to be damaged, the person should immediately consult the occupational health service or a dermatologist.

Justification

Work-related skin diseases have topped the list of occupational diseases for many years [294]. This is due, on the one hand, to improper methods of hand hygiene, i.e. hands are washed too much instead of the person using an alcoholic HD, and, on the other hand, to the inadequate use of skin protection and care products [295, 296]. The employer is legally obligated to provide PPE to prevent occupational dermatosis [297, detailed presentation in 298]. In addition, the preparation of a skin protection plan in accordance with TRGS 401 is recommended [212]. Skin protection and care primarily serve to prevent irritation dermatosis [299-307], but are at the same time a prerequisite for effective hand disinfection [181] since even minor cracks and micro trauma can become a reservoir for pathogens [308, 309].

Rough, cracked skin supports the occurrence of toxic and irritant changes to skin (i.e. attrition dermatitis) [169, 310]. If concentrations of irritants below the clinical threshold repeatedly come into contact with the skin, this can reduce its buffering capacity and impair
its function as a barrier. As a result, noxious agents can penetrate the skin and trigger an inflammatory reaction, which can develop into toxic contact dermatitis. Repeated work-related contact with the irritant may result in hand eczema. In wet environments (> 2 hours of water contact/day, wearing gloves, washing hands > 20 times/day), intercellular substances, in particular epidermal lipids, can be dissolved out of the stratum corneum, creating intercellular gaps [311]. If the skin’s barrier function is already impaired, as with persons suffering from atopic dermatitis, irritants can penetrate the skin more quickly. Hand protection and care must be systematically and consistently performed using products with proven effectiveness to prevent irritant toxic contact eczema [294].

Skin care products should be applied before work and also during breaks if necessary [302, 312]. These products promote skin regeneration [313, 314] and can be applied when needed or desired [315]. If the hands are visibly soiled, the skin should be cleaned prior to applying skin protection or care products to counteract the penetration of any irritants remaining on the skin [316].

The protective effect of skin protection products has been demonstrated in skin irritation models [299, 305, 317] and in the operating area [318]. The skin condition of members of a surgical team was significantly improved after they used skin protection and care products (3 times/day each) without impairing the effectiveness of hand disinfection [319]. Since there is evidence that some skin care products can compromise the effect of alcoholic HDs, they should preferably be used during breaks and also at the end of work – unless their impact on the effectiveness of hand disinfection is being studied.

The regular, frequent and proper use of external refatting products and, to a lesser extent, the ratio between time and exposure to water and disinfectants proved to be critical to the measures’ effectiveness, i.e. it was less important whether the skin had been treated with a protectant before exposure or with a care product afterwards [318]. The risk of microbial contamination should be taken into consideration when using skin protection and care products [320, 321], i.e. they should not be taken from ointment jars, and back suction of the extruded product should be avoided when using tubes.

The expert confirmation of effectiveness and/or the results of studies [314] should be a precondition for choosing skin protection and care products. Products with no fragrance or preservative additives should be chosen due to the risk of sensitivity [294, 322]. Skin protection products not containing urea are to be preferred due to their enhanced penetration [312].

9. Quality Assurance

KRINKO’s hand hygiene recommendation should be available to all staff at any time (e.g. as an electronic file that can be accessed via the Intranet). Additional relevant clinical materials can be uploaded to the same location (facility-binding SOPs, training films, videos, handouts, posters, brochures, etc.). Likewise, codifying hand hygiene measures in the form of a standard operating procedure and making it accessible to all staff has proven to be effective.

The hygiene plan should specify the indications, the procedure for hand disinfection, and the HD chosen. The plan should also specify the selection and handling of sterile and non-sterile disposable gloves. At the same time, relevant provisions of the statutory accident prevention regulations should also be incorporated. A skin protection plan usually specifies skin protection and care. New staff must be instructed in hand hygiene before starting employment and the instruction documented. In addition, clearly visible hand disinfection plans, with pictograms if necessary, should be displayed in all relevant workplaces.
Interventions with an emphasis on multimodal programs, with regular evaluation and subsequent feedback, should be implemented at every facility to improve hand hygiene compliance. Direct observation of staff and distance electronic systems are the most accurate measuring systems available; determination of HD use can be a secondary parameter. An interdisciplinary discussion, both in the organization unit and hygiene committee, should be conducted for purposes of evaluation.

It should be ensured that all staff receive training at least annually, as well as promptly if problems are detected.

Direct observation of compliance is recommended if there is an increase in nosocomial infections and increased proliferation of multi-resistant pathogens, in order to see if there is any necessity to improve hand hygiene.

Skin protection and care should be appropriately considered in continuing education and training programs for hand disinfection.

**Justification**

There must be a high level of compliance with hand disinfection for it to have an effect of the rate of nosocomial infections [323]. Areas where no hand disinfection interventions are performed sometimes had considerable deficits in compliance rates, between 5-81 (the average was 40%) [7, 323, 324]. Data collected at 109 German hospitals as part of the 2014 National Hand Disinfection Campaign clearly showed that, with an average compliance rate of 72% before an intervention, there were still deficits in daily implementation [325] especially since the Hawthorne effect can be over 200% [326, 327]. The main reasons for inadequate compliance are an absence of interventions, human weaknesses (lack of discipline, indifference, anonymous misconduct, forgetfulness), colleagues or superiors not being role models, actual or suspected skin allergies to products used, unclear instructions, lack of behavioral control by superiors, insufficient provision of dispensers, doubts about the value of hand hygiene, staff attitudes, lack of information about infection acquisition, and a lack of personnel [6, 323, 324, 320-337].

Increasing awareness and staff responsibility regarding the importance of hand disinfection for patient protection is at the heart of improving compliance. The WHO began national awareness campaigns with the “Clean care is safer care” initiative [51] to increase hand hygiene compliance. The first step depends on facilities confronting the reasons for non-compliance. However, advanced training programs only have a short-term effect if they are the sole interventional measures [330-340], whereas multimodal intervention programs emphasizing regular staff development (training programs) to implement SOPs, awareness of superiors’ role model effect, measurement of HD use with feedback of the results, improvement in the availability of HDs, use of memory and advertising material, parallel evaluation of the incidence of nosocomial infections and visible support from the administrative level have been demonstrated to be sustainable [6, 341-355]. Attention must also be given to the correct performance of hand disinfection during training measures [332]. Staff should be trained in hand hygiene at regular intervals (at least annually). The online campaign program, “Clinical Hand Hygiene,” was inaugurated by the Professional Association of German Surgeons and the German Society of Hospital Hygiene as a testing and teaching program to support the “Clean Hands” campaign [356]. Microbiological testing, e.g. by impressing cultures on the hands, can be performed for specific epidemiological
issues, but, however, is not suitable for routine review of the effectiveness of hand disinfection.

When including an HD in the hygiene plan, acceptance by the majority of the staff should be taken into consideration. A pilot test is recommended to establish this [357]. Depending on the size of the facility, organizational units should have the opportunity to decide between several HDs.

Since both the nursing staff and doctors were obviously lacking information about skin protection and care [358-359], providing this type of information is important when establishing a skin protection plan and contributes to improving skin irritated in the course of the job [360-362].

The hygiene plan should also specify exceptional rules for disinfecting gloves and provide employees with information as part of regular training. Attention should also be given to training employees in these matters, specifically regarding perforations before and after wearing gloves.

### 10. Legal Aspects

The object of decisions in medical malpractice law involving the neglect of hygienic and surgical hand disinfection and the failure to use sterile gloves was gross malpractice. Likewise, refilling the disinfectant in the container may be relevant to liability law.

#### Justification

Compliance with current medical knowledge is assumed if the recommendations of the Committee for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute have been observed [109]. If patients’ complaints are the result of violations that relate to not observing the KRINKO recommendations, this could have legal consequences. Improper hand hygiene accounts for about 10% of medical malpractice cases [363]. Since neglecting hand disinfection is not a misdemeanor but could endanger patients' lives, the ethical dimension of misconduct regarding hand hygiene is more serious than the consequences for legal liability.

In the event of an infection, even filling the HD can be relevant under liability law. In this respect, an HD was filled at a facility, and two filled bottles of the HD tested proved to be contaminated. This was associated with additional improper hygiene behavior, and resulted in a judicial verdict [363].
11. Literature


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Consensus procedure:

Interdisciplinary expert consensus at Working Group “Hospital & Practice Hygiene” of AWMF
www.hygieneklinik-praxis.de/mitglieder.htm

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