

HARPS Insights



Do Disinfectants Present a Risk for the Safety of Medical Gloves?

Numerous institutions and authors have investigated the "possibility to disinfect medical gloves" and urgently warn against this practice as a general practice in clinical routine – HARPS informs about the risks, recommendations and regulations.

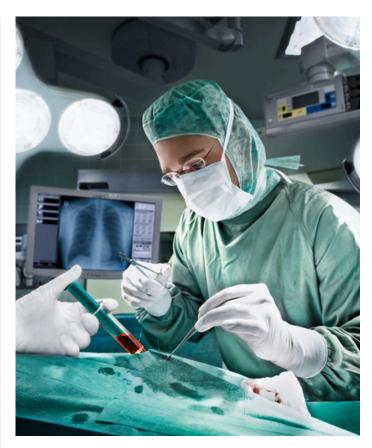
In times of increasing nosocomial infections (infections acquired in hospital), resistance to antibiotics, mechanization and lawsuits by patients, measures to break the chain of infection are more important than ever before. The safest passive infection protection is to create a distance (non-contamination) with barrier measures, i.e. use of gloves or instruments (non-touch technique). The most effective active infection protection is hand disinfection, with which about 30% of nosocomial infections can be prevented if it is done properly. In hectic clinical routine, however, hand hygiene is frequently neglected - the compliance rate is 30-59%. In order to save time with hand disinfection when changing gloves or patients, it has become a common habit to keep the disposable medical gloves on and spray them with disinfectant, or to perform hygienic hand disinfection without taking off the gloves. Such practices can have disastrous results that most people are not aware of. - The following information should provide enlightenment.

Questions asked by glove users:

- Can medical gloves be disinfected and used again without their protective function (microbial barrier) being impaired?
- How do medical glove materials react to disinfectants?
- What happens if the disinfectant penetrates the glove and gets onto the skin?

Disinfectants = Hazardous Substances

In the health professions, disinfectants are part of everyday routine. Chemical substances regulated by laws on hazardous substances are used. Disinfectants are substances or preparations that kill off or inactivate micro-organisms on surfaces, including skin and mucous, in liquids or in gases.



Whilst sterilization aims at destroying all microbes completely, disinfection aims to kill off pathogens or reduce their numbers by damaging them irreversibly, so that they can no longer cause infections. In the Ordinance on Disinfection and Disinfestation, disinfection is defined as "rendering certain pathogenic microorganisms innocuous by interfering with their structure or metabolism". Thereby, the microbial count should be reduced by a factor of at least 105, i.e. only 1 in 100,000 viable microbes may survive.





Active Substances & Applications

The effect of disinfection depends on the microbial count and species, active substance, concentration, action time, temperature, penetration capacity of the disinfectant, and penetration capacity and contamination of the object to be disinfected.

The choice of disinfectant is usually based on the microbiological spectrum of action (e.g. bactericide, virucide, fungicide, sporicide) and the area of application – in the health sector mainly:

- hand, skin and mucous disinfection
- instrument disinfection (immersion method)
- surface disinfection (scouring/wiping disinfection of surfaces and floors)

The agent of choice for hand disinfection is alcohol (ethanol, propanol, isopropanol). Usually, alcohols or PVP iodine are used for skin disinfection. To disinfect surfaces and instruments, aldehydes, phenols or quaternary ammonium compounds are commonly used. Lists of disinfectants from independent institutions, in which the tested preparations are classified according to their field of action (including information on concentration and action time), offer support in the choice of product. Disinfectants that are applied to the human body are regulated by the Austrian Drugs Act, disinfectants for instruments by the Medical Devices Act, and surface disinfectants by the Biocides Act.

Hand Disinfection

Hands are the most common vehicle for pathogens – about 80% of infections are transmitted by the hands. Fingerprint cultures have shown that the same pathogen is still detectable after 5 hand contacts. In order to protect yourself and others from infection,

routine hand disinfection before and after every patient contact, after (potential) microbial contamination, and immediately before and after using gloves is required. Because of the significantly lower effectiveness and greater skin stress, washing your hands is not an alternative and indicated only in case of visible soiling. Up to 75% of the hands can be colonized with transient micro-organisms (air-borne microbes). Hygienic hand disinfection decimates the transient skin flora and is an imperative especially on the wards and in outpatient areas. Surgical (pre-operative) hand disinfection, on the other hand, aims at eliminating virtually all microbes on the skin, including the resident skin flora, in order to prevent any skin bacteria from penetrating the surgical wound with sweat in the

case of glove lesions.

Implementation & Errors

The EN standard rubbing methods are recommended for disinfection. They provide for application to the dry hands for 30 sec (hygienic hand disinfection) or 3 min (surgical hand disinfection) until the alcoholic preparation has dried completely. The most common deficits in hand disinfection are too short, too rare and incomplete disinfection, as well as inadequate ventilation of the hands before putting on gloves. On average, 5.3 areas per hand are missed, especially on the thumb (57%) and the fingertips (35%). Alcohol residues on the hands cannot evaporate in the occlusion of the gloves, and they can cause skin damage and damage to the inner glove material.

Effectiveness of Hand Disinfectants

Alcoholic preparations to rub in act very quickly and strongly, they are easy and fast to use, and they have a wide range of action. The disinfection effect depends on the agent and the user – it correlates strongly with the alcohol concentration and type, and with the duration and thoroughness of application.

The test for effectiveness is based on determining the microbial count reduction, which is specified in standards (EN 1499: disinfecting hand wash, EN 1500: hygienic hand disinfection). These tests are performed on the bare hand, not on hands wearing gloves, of course.

Protective Gloves

In the health sector, gloves of different materials are used depending on the activity. They all have one thing in common: They protect the hands from contamination, injury and pollutants. Depending on the type of glove and material, different standards must be met:

- The three-part standard EN 455, which covers the specifications and tests for impermeability, physical properties and biocompatibility, applies to disposable, singleuse medical gloves.
- EN ISO 21420 standardizes the general requirements for gloves (personal protective equipment).
- The three-part standard EN 374, which defines the performance specifications and the testing of penetration and permeation resistance, applies to protective gloves for chemicals and micro-organisms.
- Protective gloves for mechanical risks are regulated in EN







Correct Use & Selection Criteria

All the required tests are oriented towards the intended use – if the tested gloves are used for the intended purpose, their protective function is guaranteed to the wearer. The user in turn must observe the relevant rules of application and regulations for use of the gloves. These are also set out in laws and therefore relevant with regard to liability. The accident prevention regulation, for example, states that "protective gloves must not be exposed to any influences that could impair their safe condition (e.g. chemicals, or even extreme temperatures, for which they are not suited)."

In addition to the purpose, the choice of glove is also based on the type and level of risks, exposure and skin compatibility. In gloves that are exposed to mechanical stress, properties such as tear resistance, elasticity and abrasion are important. When handling sharp and pointed objects, perforation resistance is important. Where gloves come into contact with chemicals, impermeability and resistance are essential. Where there is a risk of infection, tactile properties and tear resistance are important in addition to impermeability.

Contamination Protection & Impairment

The protective integrity of gloves is closely linked to material, wall thickness and conditions of use. Even the best gloves cannot offer absolute protection from hand contamination, since microbes can reach the skin when the gloves are taken off or through small glove defects. Therefore, the hands must be disinfected properly before and after using gloves. EN ISO 21420 requires glove manufacturers to ensure proper donning and doffing of gloves, by mentioning how to do so to prevent the user for contamination. Gloves can be damaged e.g. by high stress, instruments, chemicals, long wearing time, sweat, grease or water - often without even being noticed. Therefore, a regular change of gloves, as also recommended by the WHO and the CDC, is very important in order to prevent infection.

Gloves & Disinfectants

Thin-walled disposable medical gloves are designed neither for repeated use, nor for disinfection tasks. Nor are there any normative regulations for this. Practice has shown; however, that depending on their material gloves can withstand many disinfectants for some time, or at least offer protection from splashes.

Disinfection Resistance of Gloves

To evaluate the resistance of gloves, you have to distinguish between degradation, penetration and permeation first.

Degradation is a physical impairment of the glove material due to the effect of chemicals. **Penetration** is the passage of substances through macroscopic holes. Permeation is the passage of substances in the molecular range (i.e. the molecules are absorbed by the outer surface, diffuse, and are then released onto

the skin on the inside). EN 374-1 for protective gloves against chemicals requires testing for permeation resistance against numerous chemicals that decreases in proportion to the wall thickness of the gloves.

The protection index is classified according to the time until breakthrough (highest class: > 480min., lowest class: > 10 min.) -1-11 min. offer protection only from splashes, i.e. the gloves must be changed after contact. HARPS has this permeation test (as set out in method EN 16523-1) performed with the relevant chemicals by independent institutes, even for medical gloves.

Glove Behavior

Degradation makes the gloves useless -they become sticky, stiff, wider or brittle, form creases on the fingers, or tear - the user notices the damage and can change gloves. Permeation, on the other hand, is unnoticeable, the glove becomes leaky gradually. Disinfectants weaken the glove material and thus the resistance properties and protective effect of the glove. Asa result, contamination is possible.

How a glove reacts to disinfectant depends on a number of

- · Handling of the disinfectant
- · Quantity and concentration used
- Active ingredients and additives in the disinfectant
- Glove material, wall thickness and type
- Glove exposure (mechanical, thermal, stretching?)
- Area and time of use of the glove
- Intensity and duration of contact with chemicals (splashes, spraying, immersion?)
- Solvent medium of the chemical (solid, liquid, gas?)

Glove Disinfection & Re-use

A number of studies can be found in literature, in which the impermeability and the disinfection performance (microbial count reduction) of various disinfectants were tested. Whilst some investigators found an adequate microbial count reduction and no leaks after repeated glove disinfection, others reported an increase in micro-perforations and structural changes in the glove material, as well as a decrease in disinfection effect. Mostly gloves made of natural latex or synthetic materials were tested in combination with isopropanol or ethanol. Thereby, significant differences were found. Even with the same material - depending on the type of alcohol, some gloves could be disinfected 5-10 times, whilst others were useless after just 1-2 disinfections (stickiness, tears, etc.).

This means that it is basically possible to disinfect gloves while wearing them, but due to the strongly differing disinfectant formulas and glove properties it is not possible to make a generally valid assessment. All the authors agree that the disinfection of hands wearing gloves is acceptable only in exceptional cases and





under certain conditions (see recommendations). The disinfection must be effective (it decreases e.g. on blood exposure) and must not impair the integrity of the glove (e.g. due to microperforations).

Guidelines & Recommendations

It is the opinion of numerous health organizations are of the opinion that the

disinfection of disposable medical gloves while wearing them, as well as their re-use, is a safety risk and cannot be recommended.

- WHO Guidelines 2003: "The re-use of disposable gloves is not recommended."
- CDC Guidelines 2002 (Centers for Disease Control and Prevention): "Medical gloves must not be disinfected or reused." The CDC has basically issued this recommendation for developing countries as well, but with the moderation that in case of a glove shortage hands wearing two pairs of gloves can be disinfected between patients, and that the gloves must be replaced when sticky.
- AWMF Guideline 2004 (Association of the Scientific Medical Societies in Germany, D): "The disinfection of protective gloves in the clinical area is obsolete as a general principle to reduce costs. Although it has been shown that some glove makes can be disinfected repeatedly and remain impermeable, this cannot be said generally for every glove. Naturally, glove disinfection must be rejected in cases of virus infection, direct blood contact or visible perforation."
- BGW 2004 (Institution for statutory accident insurance and prevention in the health and welfare sector, D): "Use disposable gloves only once. If they are re-used, they become permeable for harmful substances that are deposited and migrate through the material unnoticeably."
- RKI Guideline 2000 (Robert Koch Institute, D): "Hygienic hand disinfection of hands wearing gloves is not generally recommended, but maybe considered in exceptional cases (e.g. i.v. blood collection). Prerequisites: disinfection capacity is proven (frequency, material compatibility between glove make and disinfectant), no perforation, no contamination (blood, secretions, excretions), no risk of infection (esp. viruses and multi-resistant pathogens)."
- **Health Department** of the Land Baden-Württemberg: "Disinfection of gloves while wearing them is not permissible."

HARPS Opinion

Disposable gloves are not intended for (repeated) disinfection and re-use (MDR, EN 455); therefore, this lies beyond the scope of risk assessment by the manufacturer. Re-use without quality testing means a health risk for the patient and the healthcare providers (risk of infection, skin damage), since microfine glove lesions and the result of disinfection are both invisible. In legal terms, any person who changes the intended application becomes a manufacturer and thus accepts liability in the case of infections (damages). There are also practical reasons not to do it (e.g. stickiness, poorer fit and tactile properties).

Therefore, it is 'opinion that in times of increasing nosocomial infections any discussion on the re-use of disposable medical gloves – with or without disinfection – must be rejected in the interest of safety, and that its propagation is irresponsible. This would lower the standard of hygiene that we have reached today and would foster infections. Safety should not be put at stake for the sake of (supposed) time and cost savings. For HARPS it is important to build the user's awareness for his own safety, and not to endanger his and other people's health by providing untrustworthy information.

HARPS Glove Tips:

- Use the type of glove (unsterile/sterile) and material suited to the task
- Check gloves for defects before use(visually/inflation)
- · Wear gloves that fit properly
- Use powder-free, low-allergen gloves
- Disinfect and ventilate hands properly before and after using gloves
- Always put gloves on with clean and dry hands immediately before contact with the patient
- · Adjust wearing time to stress and activity
- Change gloves after every patient
- Change damaged, soiled or wet gloves immediately
- Use disposable gloves only once
- Do not disinfect hands while wearing gloves
- Intra-operative change of gloves: at the slightest suspicion of micro-perforations, if the glove "wanders" (slips), after the septic part of the operation
- Treat gloves carefully, where possible (e.g. non-touch technique, blunt needles, endoscopy)
- Wear 2 pairs of gloves: when the risk of perforation is high, during hour-long operations, and if there is special risk of infection (HIV, hepatitis)
- Apply hand care consistently, but do not use care products before wearing gloves



