Use of disinfectants in the health care sector: Chemical hazards and preventive measures

Factsheet 6: Instrument disinfection

Foreword

The Chemical Risks workgroup of the Health Services Section of the International Social Security Association (ISSA) has studied the risks linked to disinfection activities in the health care sector and the preventive measures that should be applied. This workgroup has defined a position shared by all the occupational health and safety organisations represented within the group: BGW (Germany), INRS (France) and Suva (Switzerland).

This project included a collaboration with the Infectious Risks workgroup of the Section, to summarise the general principles of disinfection (Factsheet 1) for the audience targeted by the current series (see below).

For practical reasons, the results of this work will be presented as a series of technical Factsheets:

- Factsheet 1: Principles of disinfection
- Factsheet 2: General principles of prevention
- Factsheet 3: Hazards of chemical disinfectants
- Factsheet 4: Selecting safe disinfectants
- Factsheet 5: Surface disinfection
- Factsheet 6: Instrument disinfection
- Factsheet 7: Skin and hand disinfection
- Factsheet 8: Specific procedures (disinfecting premises, medical equipment, linen and clothing)

Each factsheet contains the essential information relating to the theme covered, and can therefore be read separately. These factsheets are destined for use by those responsible for organising and performing disinfection tasks in the health care sector, by occupational physicians and by all those involved in preventing occupational risks – in particular occupational hygienists and safety officers – as well as interested personnel and their representatives.

For questions on hospital hygiene and environmental protection, the reader is invited to consult the specialised literature.

1. Definition/field of application

Instrument disinfection involves the treatments applied after use to instruments and parts of medical devices to eliminate infectious agents. Instruments may be surgical instruments, material for anaesthesia or devices such as endoscopes, for example. As most instruments will be sterilised after disinfection, disinfection is mainly used to reduce exposure to microorganisms, thus protecting workers from infectious risks. It also helps avoid material drying on instruments, and may reduce corrosion.

2. General

Disinfection of medical instruments or, more generally, of "medical devices", must meet very strict rules of hygiene as these devices are used to keep blood or other biological fluids circulating, or are used to perfuse liquids, insufflate gases or introduce products into the human body, and thus often come into direct contact with the bodies of patients, or are placed inside their bodies. Because of this, in various European countries precise instructions have been published on how to check the efficacy of disinfectants and how to perform disinfection effectively (see Factsheet 1).

Pre-treatment of instruments generally includes the following steps:

- Pre-cleaning in disinfectant solution
- Cleaning/disinfection, rinsing and drying
- Verifying that instruments are clean and in a good working state
- Maintenance and repair
- Verifying the functionality and, as appropriate,
- Labelling
- Packaging and sterilisation.

Each of these steps should be performed taking the nature of the device, the previous step, and the past and future use of the device into account. Validated methods should be used to guarantee the traceability and reproducibility of results (see Factsheet 1).

The requirements relating to the pre-treatment process indicate that the various steps of use and treatment of medical instruments should be the object of close consultation, to ensure a reproducible degree of disinfection without damaging the instruments. However, the prevention of occupational risks should not be neglected. Thus, it is important that occupational risk prevention representatives be consulted during the development of procedures, along with all the relevant specialists.

3. Main methods used

Disinfectants can be used in many ways to treat instruments. We will list three particularly frequently used methods here:

a) Soaking instruments in disinfectant solutions

As part of medical examinations or surgical interventions, instruments are often disinfected by soaking in a disinfectant solution, this reduces the infectious risk for workers while also avoiding drying of biological fluids or tissues on the instruments. Instruments placed in disinfection basins generally do not undergo any other treatment in these basins.

During soaking, workers can come into contact with the disinfectant in the following ways:

- During dilution of the concentrated product the skin can come into contact with the product for a short time, or the concentrated active ingredients may be inhaled.
- Short-duration contact with the diluted solution is possible when placing instruments or baskets in or removing them from the basin, and during elimination of the used solution.
- When the basins are uncovered, all the personnel present in the room are exposed to a permanent risk of inhaling the volatile compounds present in the disinfectants.

b) Manual instrument disinfection

Small instruments, and sometimes larger ones (e.g. endoscopes), must be cleaned and disinfected mechanically before any other pre-treatment step. This operation can include some manual steps. Therefore, in addition to the modes of exposure mentioned in a), this mechanical treatment can lead to contact with splashes of the disinfectant solution, and aerosol formation.

c) Instrument disinfection in automated systems

The use of automated machines allows the disinfection procedure to be performed according to a standardised programme, in a closed system, and thus in a practically isolated volume. Automated disinfection systems are commonly used to treat endoscopes or tubes for anaesthesia. Under normal conditions, it is practically impossible for personnel to be exposed when using this type of system. Dermal and inhalation contact can only occur during a short time-frame, when a concentrated supply of disinfectant is attached, or during dilution of the disinfectant. Given the substances that may be contained in the vapours extracted from the automated system, it is important to ensure that they are rejected outside the work area, after treatment if necessary.

Please note: Automated disinfection systems are not infallible, and faults should be planned for when devising the disinfection procedure. As a preventive measure, it is important to establish a safe replacement procedure and to make the materials necessary for performing it available.

4. Main disinfectants/active substances and groups of active substances

The ingredients in products used to disinfect instruments vary depending on the cleaning and disinfection tasks to be performed. The most commonly used groups of active substances are as follows:

- Alcohols (ethanol, 1-propanol, 2-propanol)
- Aldehydes (formaldehyde, glutaraldehyde)
- Quaternary ammonium compounds
- Guanidines/Biguanides
- Alkylamines
- Acids and bases

A systematic search for the products available on the German market made it possible to analyse the compositions indicated by manufacturers in detail. The most frequently used substances are indicated in **Table 1**.

Table 1: The twenty most frequently used substances in the 182 instrument disinfection products studied (according to the information supplied by manufacturers, search performed in 2010, see [1])

Substance name	CAS No.	Group of active substances	Number of disinfectants containing this substance
N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine	2372-82-9	alkylamines	51
2-Propanol	67-63-0	alcohols	47
Glutaraldehyde	111-30-8	aldehydes	28
Butyldiglycol	112-34-5	glycols and derivatives	27
Cocospropylenediamine guanidium acetate	85681-60-3	guanidines/ biguanides	22
Potassium hydroxide	1310-58-3	bases	21
1-Decanaminium, N-decyl-N-(2-hydroxyethyl)-N-methyl-, propanoate (salt)	107879-22-1	quaternary ammonium compounds	20
Didecyl dimethyl ammonium chloride	7173-51-5	quaternary ammonium compounds	16
Branched tridecylalcohol, ethoxylated	69011-36-5		16
Didecylmethylpoly(oxethyl) ammonium propionate	94667-33-1	quaternary ammonium compounds	15
Ethanol	64-17-5	alcohols	14
Alkyl(benzyl) dimethyl ammonium chloride	68391-01-5	quaternary ammonium compounds	13
N-dodecylpropane-1,3-diamine	5538-95-4	alkylamines	12
Formaldehyde	50-00-0	aldehydes	11
1-Propanol	71-23-8	alcohols	10
1,4-Butanediol	110-63-4	glycols and derivatives	9
Piperazine	110-85-0		8
Polyhexamethenebiguanide-hydrochloride	27083-27-8	guanidines/ biguanides	7
Ethylene diamine tetracetic acid, tetrasodium salt	64-02-8		7
Alcohols, C9-11, ethoxylated	68439-46-3		7

Of the 182 disinfectants studied (products specifically destined for instrument disinfection), many presented dangerous properties requiring labelling with a hazard symbol. The proportions were as follows:

- irritant (Xi) = 22.5%
- corrosive (C) = 52.8%
- harmful (Xn) = 12.1%
- highly flammable (F) = 1.1%
- dangerous for the environment (N) = 17.6%

In addition, 44 instrument disinfection products (= 24.2%) were classed as skin or respiratory sensitizers: 9 (= 4.9%) were skin sensitizers (risk phrase R43), 7 (= 3.8%) were respiratory pathway sensitizers (R42), and 28 (= 15.4%) were both skin and respiratory pathway sensitizers (R42/43). Ten products (= 5.5%) were suspected of having a carcinogenic effect (R40).

Only 23 products (= 12.6%) were not labelled with any hazard.

5. Assessing inhalation and dermal exposure

In the context of common tasks performed during instrument disinfection, concentrated disinfectants may be manipulated in open systems in volumes ranging from a few millilitres to a few hundred millilitres. Diluted products are more generally measured in litres (up to around 30 litres).

According to the usage indications, the working solutions correspond to a 50- to 200-fold dilution of the concentrated product. Acute hazards - those indicated by a hazard symbol - are therefore only likely to be a danger when manipulating the concentrated solution. When using diluted solutions, the risk of sensitisation is probably greater, as are potential effects related to repeated exposure to very low concentrations.

The level of **inhalation exposure** during instrument disinfection depends on the following factors:

- Procedure used
  During pre-disinfection and manual disinfection of instruments, splashes can be produced due to mechanical effects. Similarly, filling operations (e.g. on automated systems) can result in splashes and aerosol formation. Outside these scenarios, exposure to the concentrated or the dilute product by inhalation is only a risk when some of the ingredients in the disinfectant have a sufficiently high vapour pressure to cause them to be released into the atmosphere (N.B.: vapour pressure increases with temperature).
- Physical properties of the ingredients
  Among the compounds mentioned, the aldehydes (e.g. formaldehyde, glutaraldehyde) and alcohols (e.g. ethanol, propanol) are the main substances with a vapour pressure potentially leading to inhalation exposure. The actual level of exposure also depends on other parameters.
- Concentration of the ingredients
  In many cases, the working solution is a highly diluted (sometimes less than 1%) form of the concentrated product. The concentration of the working solution should be considered when assessing exposure.
- Dimensions of the area to disinfect, and amount of solution used
  When a substance evaporates into the atmosphere, the emission rate for the product is proportional to the dimensions of the wet or damp surfaces. This is mainly an issue when manually disinfecting instruments. The amount of solution used also determines the surface of the disinfectant bath in contact with the air, from which a constant flux of disinfectant is released into the atmosphere.
- Size of the area
  In principle, dangerous products are released into the air of the work area throughout the whole of the available volume. If ven-

tilation is poor or non-existent, the concentration in the air [mg/m^3] corresponds to the evaporated mass [mg] divided by the volume of the workplace [m^3].

- Ventilation of the work area
  If ventilation, λ, is not negligible (i.e., if $\lambda \geq$ 0.1 work area volumes/hour), the dangerous substances emitted are extracted from the area by the ventilation system and a steady state is reached, in which the airborne concentration [mg/m^3] in the zone corresponds to the substance emission [mg/h] divided by the flow of fresh air introduced into the zone [m^3/h].
- Duration of worker exposure
  Worker exposure not only depends on the time over which a substance is released into the air, but also the time that workers spend in a polluted environment.
- Position of workers relative to the instruments during disinfection
  As the emission of dangerous substances is often brief during instrument disinfection, workers whose workstation is closest to the source of emission may be more exposed than other workers in the same area, but who move about or whose workstation is at a greater distance from the source.

During instrument disinfection, the level of **dermal exposure** depends mainly on the following factors:

- Concentration of the ingredients
  The concentration affects both localised dermal effects and systemic effects (e.g. effects on some organs).
- Surface of skin in contact with the product
  Whether for local effects (irritation, corrosion, sensitisation reactions) or for dermal penetration, the skin surface affected plays an important role. Thus, it is important to distinguish between contact due to splashes of product and contact of an entire body-part with the product (e.g. when the operators plunges their hand into a bucket or basin of disinfectant).
- Duration of contact
  While contact due to splashes is generally rapidly eliminated, the skin is much more exposed during tasks of long-duration, such as manual disinfection of an endoscope. The German Technical Rules for Hazardous Substances (TRGS 401 [2]) clearly distinguish between short-term skin contact (< 15 min) and prolonged contact (≥ 15 min) when determining the appropriate protective measures.

Individual factors should be added to these various parameters. Operators' experience and their behaviour (e.g. tolerance towards splashes and spills of products) can have a positive or negative influence on exposure by inhalation and dermal exposure.

6. Risk assessment

The risks for workers can be assessed as follows:

Dermal risks:

In the absence of protective measures, manual disinfection of instruments can result in prolonged contact with the chemicals making up the disinfection and cleaning solutions. Given the irritant and corrosive properties of many concentrated disinfectants, an acute risk of dermal irritation is encountered when handling concentrated products. The working solutions are generally diluted with water 20- to 200-fold, and therefore present a lower risk of acute effects. However, their use is often regular and prolonged, resulting in a risk of chronic dermatitis (“wear-and-tear-dermatitis”).

The active substances may also penetrate through the skin; however, given the conditions in which the products are used (intensity and duration of exposure) during instrument disinfection, systemic effects such as organ damage or neurological effects are unlikely, and there is no mention of them in the literature.

Due to the sensitising power of many products used to disinfect instruments, allergic contact eczema can develop. This risk should be taken seriously. It is encountered both with concentrated and diluted products. In addition, some compounds can favour the absorption of allergens. However, the different groups of active substances found in disinfectants have different sensitisation potentials: aldehydes or quaternary ammonium compounds are often classed as sensitizers.

Risks associated with inhalation: Among the substances used to disinfect instruments, only a small number have an occupational limit value (see **Table 2**). Thus, data relating to exposure to a product can only be qualitatively interpreted.

Inhalation exposure can lead to acute or chronic irritation of the airways and conjunctival membrane, and a risk of respiratory allergy linked to specific sensitisation. Due to their high vapour pressure, aldehydes used in disinfectants (formaldehyde and glutaraldehyde) can have effects on the respiratory tract. On the other hand, inhalation of biguanides and quaternary ammonium compounds, for which the vapour pressure is lower, is only a risk when the procedures used produce aerosols. The risk is particularly high during tasks such as manual instrument disinfection, or manipulation of concentrated disinfectants.

Systemic effects could, in theory, be observed (e.g. with intensive manipulation of products containing aldehydes or alcohols, in particular if aerosols are formed). However, given the conditions in which the products are used (see “Assessing specific risk” below, these effects are unlikely.

Table 2: Substances found in products used to disinfect instruments which have an occupational exposure limit in France, Switzerland and Germany, and for some in Sweden (source Liste Internationaler Grenzwerte of the Gefahrstoffinformationssystem GESTIS of the German DGUV, as of August 2013). The limit values [in mg/m^3] are applicable for the duration of a shift at a workstation/for short-term exposure.

CAS No.	Compound	Germany	France	Switzerland	Other
50-00-0	Formaldehyde	-/-	0.5/1 ppm	0.37/0.74	
59-50-7	4-Chloro-3-methylphenol	-/-	-/-	-/-	3/6 Sweden
64-17-5	Ethanol	960/1920	1900/9500	960/1920	
67-63-0	2-Propanol	500/1000	-/980	500/1000	
71-23-8	1-Propanol	-/-	500/-	500/-	
111-30-8	Glutaraldehyde	0.2/0.4	0.4/0.8	0.21/0.42	
112-34-5	Butyldiglycol	67/100	67.5/101.2	67/101.2	

Physical risks:
Alcohol-based disinfectants are often classed as highly flammable (F) or extremely flammable (F+). The risk of fire and explosion, although rarely observed, must therefore be taken into account when disinfectants with a high alcohol content are used.

Products containing peroxides (e.g. hydrogen peroxide, peroxyacetic acid) release oxygen, and can thus have an oxidising effect.

These physical properties must be taken into account not only during use, but also when storing these products.

Other risks:
Employers are required to assess the risks at workstations; to do this they should adhere to the national regulations. Occupational physicians and other occupational health specialists should be involved in the assessment, as necessary.

We will briefly list the other risks to which workers may be exposed during instrument disinfection:

- **Infectious risks** when handling instruments which have not yet been (or are incompletely) disinfected
- **Risks of needle sticks or cuts** linked to handling sharp instruments
- **Musculoskeletal disorders** linked to handling heavy loads and postural constraints during loading of automated disinfection and sterilisation systems, for example
- **Risks of burns** when handling materials disinfected by heat
- **Wet work**, linked in particular to constantly wearing gloves

Assessing specific risks (according to data from the literature):
Factsheet 3 of this series supplies precise data on the potential hazards linked to chemical disinfectants.

The risks most commonly described in the literature with regard to the use of disinfectants are the following: direct dermal or conjunctival irritation, irritation of the upper and lower airways, allergic reactions due to immediate or delayed-type sensitisation.

The disorders linked to occupational use of **glutaraldehyde**, especially for instrument disinfection, and particularly for the preparation of endoscopes, have been the subject of research in recent years, and preventive measures have been recommended.

United States: Cohen and Patton [3] studied the use of glutaraldehyde in a 486-bed institution. Workers presented diffuse respiratory disorders for a number of years, with headaches and manifestations of dermal irritation. These symptoms were considerably reduced by re-housing the department in a well-ventilated modern building, and by improving organisational preventive measures. Collins et al.[4] analysed incidences of cancer in workers exposed to glutaraldehyde but did not identify an increased risk of cancer of the airways, for either low-grade (0 - 100 ppb-yr) or high-grade (100+ppb-yr) exposure; nor was there an indication of increased risk of leukaemia.

United Kingdom: a working group from the British Society of Gastroenterology - Endoscopy Committee published recommendations on safety when using glutaraldehyde (Cowan, Manning et al. [5]), which takes the toxic, irritant and allergenic properties of this active substance into account. They emphasise the need to take action given the high prevalence of disorders linked to the use of glutaraldehyde (dermal and respiratory disorders, but also headaches, etc.) in gastroenterology departments. A more recent study of exposure levels and symptoms in personnel assisting at endoscopies confirms the high frequency of symptoms [6].

Italy: exposure to glutaraldehyde was also found to be a significant cause of occupational asthma in health care workers in Italy. Di Stefano et al. [7] described 24 cases of workers in the health care sector presenting glutaraldehyde-related asthma.

The airborne glutaraldehyde concentrations found at workstations were 0.208 mg/m^3 (mean), 0.14 mg/m^3 (median) and ranged between 0.06 and 0.84 mg/m^3 for short-duration samples. For long-duration samples, the values were between 0.003 and 0.28 mg/m^3, with a mean of 0.071 mg/m^3 and a median of 0.07 mg/m^3.

In poorly-ventilated work areas (i.e., in many cases, naturally ventilated), a study of 27 endoscopy setups showed higher levels of exposure (0.015 - 2.32 mg/m³) [8].

More recent metrological data (n = 52) from an endoscopy unit in an Italian hospital, where the rate of air renewal was 6.3/h, revealed concentrations between 0.0037 ± 0.0074 mg/m³ [9].

In **Australia**, **Japan**, **Kenya** and **Singapore,** a relationship was established between the symptoms of exposure to glutaraldehyde reported and performing disinfection operations [10,11,12,13,14].

A series of **potential substitutes for glutaraldehyde** have been tested in recent years by hygienists and manufacturers of disinfection products. Unfortunately, these products have their own negative effects on workers in the health care sector:

Ortho-phthalaldehyde (CAS No. 643-79-8), or OPA, has irritant and allergenic properties [15,16,17,18] (Anderson, Umbright et al. (2010); Fujita, Ogawa et al. (2006); Purohit, Kopferschmitt-Kubler et al. (2000); Rideout, Teschke et al. (2005)).

Asthma can also be triggered by a mixture of **peroxyacetic acid** and **hydrogen peroxide**, which was also tested as a substitute for glutaraldehyde [18,19]. These effects can also be caused by peroxyacetic acid alone.

7. Preventive measures (STOP)

The following types of exposure should be avoided during instrument disinfection:

- Any contact, of short or long duration, between the skin/mucous membranes and the concentrated disinfectant, to prevent acute effects.
- Any contact between the skin/mucous membranes and the working solution, particularly when the concentrated product is labelled R40 (Suspected carcinogenic effect), R41 (Risk of serious ocular lesions), R42 (May lead to sensitisation by inhalation) or R43 (May lead to sensitisation by skin contact).
- Inhalation of vapours or aerosols.
- Inhalation of splashes.

Therefore, preventive measures should be applied in all cases. These should be adapted to the risk. The list of measures below can help with decision-making.

*Substitution (**S**TOP)*

Among appropriate disinfectants for use to maintain hospital hygiene, the prevailing principle is to choose products presenting the fewest potential risks for patients and personnel. If health problems occur when using a disinfectant, the first step to take would be to look for a product presenting fewer health risks (see Factsheet 4, Selecting safe disinfectants).

It may also be possible to choose a different disinfection method (e.g. thermal disinfection).

*Technical measures (S**T**OP)*

Among the technical preventive measures, the following have been selected as particularly relevant:

- Disinfection procedure using a machine (automated disinfection system, etc.)
- Evacuation of vapours or active substances emitted by automated systems or by basins of disinfectants from the work area
- Method excluding aerosol formation as far as possible
- Use of technical assistance (tongs to remove instruments from basins, baskets for soaking, localised capture devices, etc.)

- Dispense the concentrated disinfectant automatically, or using dosing aides
- Ventilate the work zone
    - sufficient fresh air (according to the national regulations) should be supplied
    - or a mechanical ventilation system (in line with national norms) should be fitted

*Organisational aspects (ST**O**P)*

The technical measures should in most cases be complemented by organisational measures and changes to behaviour:

- Employ only appropriately qualified personnel, who have been informed of the risks and receive regular in-service training
- Do not stop or open automated systems during the disinfection process
- To avoid continuous exposure of workers, do not place basins of disinfectants in an examination room or near to a source of heat
- Always cover recipients containing disinfectant solutions. Never allow disinfectant recipients to remain open, except for immediate use
- Do not dilute products using hot water
- Avoid all contact between the disinfectant (solution and concentrated product) and hot surfaces
- When planning tasks, determine safe replacement procedures in case automated disinfection systems fail
- Repair and check instruments only after disinfection
- Transport and eliminate sharp instruments only in sharps-resistant containers

*Personal protective measures (STO**P**)*

Wearing personal protective equipment is a constraint for workers, and should only be used when other (reasonably applicable) protective measures do not offer sufficient protection.

- Eye protection
  During handling of the concentrated product (e.g. dilution or transfer of the concentrated product), if there is a risk of aerosol formation, eye protection (mask-type goggles) should be worn.
- Hand protection:
  If skin contact with the disinfectants is unavoidable, it is essential to wear appropriate protective gloves. To improve comfort when worn for long periods, cotton lining gloves may be. These should be washed regularly. The protective gloves should be chosen based on the risk of contact with the disinfectants used, and should be changed as necessary.
- Skin protection
  The means to protect, clean and care for the skin should be conform to the skin protection plan.
- Protective clothing
  If work clothes are likely to become soaked with product during instrument disinfection, waterproof protective clothing (e.g. waterproof apron) should be worn.
- Respiratory protection
  If there is a risk of exceeding the occupational exposure limit values for some compounds (e.g. aldehydes), appropriate respiratory protection should be used. Exceeding the occupational limit value is, however, unlikely if the preventive measures described in this factsheet are applied.

8. Medical surveillance

Medical surveillance of workers is regulated differently in different countries. In the case of occupational medical consultations or preventive medical surveillance, the attention of workers should be drawn to the risks linked to the use of products to disinfect instruments and the applicable measures, in particular:

- Risks linked to wearing gloves for prolonged periods
- Methods to clean, dry and care for the skin
- Early symptoms of skin, eye and respiratory disorders
- Individual risk factors
- History of allergy.

9. Monitoring preventive measures

When national limit values for substances contained in disinfectants exist, the employer must prove that the preventive measures implemented allow these values to be respected. For this, they can measure concentrations (in the air), compare data with published data, or apply validated calculation and assessment methods.

Once it has been established that the task in question can be performed without risks, it is sufficient, in the follow-up, to periodically check the efficacy of the steps taken and ensure that the task has not changed significantly (e.g. extent of the task, how the chemical products are used).

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