

Your **Power** for Health



**HYGIENE 2011**

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**Dr. Martin Thieves**

## **VACUETTE®** **Hygiene Compendium 2011**



**Dr. Martin Thieves**  
Pocket Compendium

# HYGIENE Compendium 2011

## Pocket Compendium

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# I – In General

## 1. Hygiene in Healthcare

### 1.1. Introduction

In order to avoid infections in hospital, the following transmission chain must be broken:

1. **“Focus“ of pathogenic germs**
2. **Transmission way that does not damage germs**
3. **Susceptible recipient**

1. The “Focus“ is usually a patient, occasionally an unknown colonised employee or contaminated object. There are patients in every hospital, and it is not often possible to recognise a member of hospital staff who is unwittingly infected, or a contaminated object.
2. The most easily influenced component is the transmission way, and this is therefore of greatest significance in hygiene.
3. Recipients at increased risk of infection are, amongst others:
  - ↳ Patients with metabolic disorders (e.g. diabetes, liver disease)
  - ↳ Patients with wasting diseases (e.g. cancer patients)
  - ↳ Patients after a serious operation
  - ↳ Patients with a weakened immune system (e.g. transplant patients, HIV patients)
  - ↳ Premature babies, pregnant women
  - ↳ Elderly patients

i.e. -> The majority of all patients in a hospital. It is not always possible to strengthen the defences against micro organisms, certainly not long-term, and in some cases not permitted for therapeutic reasons (e.g. after a transplant, the immune system must be artificially weakened, so that antibodies do not form and cause the new organ to be rejected).

To break the infection chain, the ways of transmission must be understood. The following table should help you to understand hygiene measures and classify them.

## 1.2 Hygienic Relevance

Every employee in the medical branch learns during training and with experience how to appraise the significance of individual micro organisms for treating patients. It will be learnt, which germ causes a disease, how serious the disease is, and how it can be individually treated.

Hygiene in hospitals requires a new viewpoint: The most decisive criteria is not the seriousness of the disease. It is the way of transmission that determines if an individual patient is a danger for other patients and hospital staff, which can lead to an epidemic in the most extreme case.

### Examples:

- ↳ Colonisation with a *Staphylococcus aureus* (regardless of resistance pattern) normally has no criterion, and is therefore not always discovered. However, if the germ finds its way into the blood circulation of a patient with a weakened immune system, sepsis can easily occur. If the germ is multiresistant, a therapy is difficult and even unsuccessful in approx. 50% of cases.
- ↳ Chickenpox is usually a harmless paediatric disease. However, due to the extremely high contagiousness, this can infect all those in a hospital who have not had varicella contact, or those with insufficient immunity due to weakened bodily defence. In particular, if immunodeficient patients contract an additional disease to the existing one, then it is often not possible to cure the patient completely, and a life-threatening condition can develop.
- ↳ In contrast, malaria can be a serious disease for the person affected, without being dangerous for those around. To pass on malaria, the anopheles (mosquito) is necessary. This is not to be found in Northern and Western Europe, and should it be imported unintentionally by air transport, it is not capable of surviving.

For this reason, all protective and isolation measures are derived from the way of transmission. A disregard of hygiene rules, either unincently or due to lack of knowledge, can lead to great suffering (example: multiple resistant *Staphylococcus*), whereby an excessive reaction (typical false conclusion: "Because malaria is subject to registration, the patient must be isolated") can be an excessive burden, which can cause suffering for both staff and patients, as well as causing unnecessary costs.

## 1.3 Infection Risks

### ALL BODY FLUIDS ARE AN INFECTION RISK

**All body fluids are a high infection risk for medical employees, because:**

1. Human body fluids are the ideal culture and transport medium for human pathogens.
2. The recipient is confronted by micro organisms, and is usually defenceless against them.

### Blood, serum and other blood products

Blood and blood components are the best culture medium for almost all human pathogens. The viruses, which cannot remain intact outside of blood, are also transmitted bloodborne. It is these viruses that are usually the trigger for especially serious diseases:

- **HIV**, the AIDS pathogen can be transmitted in the medical sector via a cut wound during an operation, or via a needlestick injury. There is no vaccination available for the foreseeable future.
- **Hepatitis B**, was the most common occupational disease prior to the development of the vaccine. Nowadays, every employee in hospitals, laboratories and doctors' offices should have sufficient hepatitis B vaccination, and have it checked regularly.
- **Hepatitis C**, is less common than hepatitis B. A vaccination is being developed but will not yet be available in the coming years.

- **Hepatitis D**, can occur in addition to hepatitis B but not alone. By vaccinating in good time, the hepatitis B vaccine can also prevent hepatitis D.
- **Hepatitis G**, can occur in addition to hepatitis C. No vaccination is possible.

### Prophylaxis:

Prevention of injuries with sharp contaminated objects:

- No hectic handling with scalpel or needle
- Immediate disposal of all sharp and pointed objects in nonpenetrable disposal boxes by the user herself/himself

Due to the high rate of vaccination amongst hospital staff, infections with hepatitis B have sunk. However, it is of significance for evaluation of the disinfection procedure: if hepatitis viruses are inactivated (incapable of reproduction), the procedure is also HIV effective.

Hepatitis A, E and F are transmitted via drinking water and food. These diseases occur mainly in countries with warmer climates and lower standards of hygiene (e.g. without drinking water processing plants, lack of cold chain). As a rule these are cured without lasting damages. There is also a vaccination available for hepatitis A.

For 10% of infectious hepatitides, there is no pathogen detection (hepatitis X or non A-G). Even if vaccinations for HIV and hepatitis C/G are developed at some point, the risk of a haematogenic infection with serious consequences remains.

## Sputum + Tracheal Secretion

Mouth, nose, throat and trachea are a transition region. Bacteria can be found from:

- Skin
- Respiratory air
- Lungs (in the case of pneumonia)
- Food remains

Saliva rich in protein, food remains and plaque encourages bacterial growth. Amongst others, the following are significant:

- ☞ Staphylococcus (e.g. **MRSA**)
- ☞ Streptococcus (e.g. **scarlet fever**)
- ☞ Mycobacteria (e.g. **tuberculosis**)
- ☞ Legionella

#### Prophylaxis:

Work in such a way as to avoid sputum or cough droplets getting into the mouth:

- ☞ Mouth/nose protection is an effective barrier
- ☞ Wear protective gloves, putting them on early enough
- ☞ It is recommended, that in the laboratory, the samples be processed below the work bench
- ☞ Hygienic disinfection of hands after every possible contact

## Urine

Urine is inherently free of bacteria, or, at least low in bacteria. However, invasive bacteria often find the ideal incubatory conditions. Recurrent infections of the urinary tract, for which treatment has been started, provide favourable conditions for multi resistant germs, which due to the awkward treatment, is not just a problem for the patient. If the handling is not quite hygienic, a nosocomial infection could spread, putting other patients in danger.

Significant examples:

- ☞ E. coli
- ☞ Proteus
- ☞ Klebsiella
- ☞ MRSA
- ☞ Fungus (candida)

#### Prophylaxis:

- ☞ Take care with collection and processing of urine samples
- ☞ **NEVER** disconnect a drainage system
- ☞ Wear protective gloves
- ☞ In addition to wearing protective gloves, disinfect hands hygienically

## Liquor

Normally, liquor is sterile in blood, even where there is bacterial colonisation, as the blood-brain barrier prevents transfer. If liquor collection is indicated, there is often an infection in the cerebral region.

Of particular significance:

- ☞ **Purulent meningitis** (as the blood-brain barrier must be overcome, there is often a highly virulent pathogen – to be on the safe side, the highest isolation level should be applied, until the bacteria has been specified)
- ☞ **HSE** = human spongiforme encephalitis (amongst others Creutzfeldt-Jakob disease. The brain tissue is infectious, to be on the safe side, liquor suspected of HSE should be seen as potentially very infectious. The pathogens are prions and related to BSE amongst cattle).

#### Prophylaxis:

- ☞ Prior to collection, label tubes with the infection
- ☞ Adapt protective measures depending on possible pathogens (see chapter 2 + 14)
- ☞ For destroying prions, the usual disinfection and sterilisation procedures are not effective (see chapter 5)

## Wound Secretion

Thanks to the components, wound secretion is an ideal medium for all contact bacteria, i.e. skin and ambient bacteria. Smear contact, e.g. when changing bandages, or in the case of open wound treatment, can easily lead to further spreading.

Significant examples:

- ☞ Staphylococcus aureus
- ☞ Enterococcus faecium
- ☞ Pseudomonas aeruginosa

Each of these is especially feared in case of multi resistance.

### Prophylaxis:

- Careful and hygienic wound treatment (non-touch technique)
- Wear protective gloves
- Hygienic disinfection of hands in addition to wearing gloves

## Gastric Juice

Gastric juice is not usually infectious. Although all freshly swallowed bacteria can be found there, they do not often lead to transmission of an infectious disease.

Significant example:

- Tbc

### Prophylaxis:

- Wear mouth and nose protection when collecting sample
- Wear protective gloves
- Hygienic disinfection of hands in addition to wearing gloves

## Intestinal Contents and Stool

Intestinal contents and stool are not just unaesthetic; they usually contain a mixture of bacteria. To be on the safe side, it should always be assumed, that the sample is colonised with pathogenic bacteria.

Significant examples:

- Salmonella enteritidis
- Salmonella typhi, paratyphi
- Campylobacter
- Other gastroenteritis pathogens

### Prophylaxis:

- Wear protective gloves
- Hygienic disinfection of hands in addition to wearing gloves

## 1.4 Typical Ways of Transmission

### 1. Aerogen: the airborne infection

|                           |   |
|---------------------------|---|
| Transmission:             | Bound to minute particles, which float in the air before settling: droplets and dust  |
| Examples:                 | Flu/influenzal infection, varicella (chickenpox) = MRSA = <b>m</b> ultiple <b>r</b> esistant <b>S</b> taphylococcus <b>a</b> ureus with nasopharyngeal colonisation |
| General significance:     | Average: everybody has had frequent contact to this in their lifetime, but usually it runs its course without any harm  |
| Significance in hospital: | High: as patients with infections transmitted airborne must be shielded, which is particularly time and cost consuming  |

### 2. Manual: the smear infection

|                           |   |
|---------------------------|---|
| Transmission:             | In 90% of cases: passed on via employees' hands. Otherwise, via contaminated objects (clothing, door handles, food...) or contaminated employees (colonised nasal/pharynx region) or intestines with the bacteria spreading to other body parts, to which patients may have contact |
| Examples:                 | 1. General wound infection regardless of pathogens, 2. Special colonisations or MRSA infections (see above), salmonella, enteritis infection  |
| General                   | Low: These colonisations usually take course asymptotically or are not serious illnesses  |
| Significance in hospital: | High: As wound infections are an unpleasant complication, and unknowingly colonised employees can spread the germs widely, thus endangering many patients   |

### 3. Haematogenic: personal infection typical in hospitals

|                           |   |
|---------------------------|---|
| Transmission:             | From blood to blood or from body fluid to blood   |
| Examples:                 | Hepatitis B, C, HIV   |
| General significance:     | Low: As this way of transmission is unlikely in significance: everyday situations   |
| Significance in hospital: | High: A serious illness can occur, which can often be led back to incorrect working procedure and could have been prevented |

#### 4. Alimentary: Infection or poisoning from food

|                           |   |
|---------------------------|---|
| Transmission:             | Via contaminated drinking water or other food   |
| Examples:                 | Hepatitis A, Staph. aureus poisoning, typical traveller's diarrhoea   |
| General significance:     | High: this includes most non-specific gastrointestinal disturbances and most traveller's sicknesses.  |
| Significance in hospital: | Low: water quality is well checked and hospital kitchens work in accordance with the HACCP* concept and are subject to official inspections<br>*Hazard Analysis and Critical Control Points |

#### 5. Venereal: the infectious sexual disease

|                           |   |
|---------------------------|---|
| Transmission:             | Via sexual intercourse  |
| Examples:                 | HIV, Gonorrhoea   |
| General significance:     | High for those concerned and their partners, as there are consequences for the sex life |
| Significance in hospital: | None  |

#### 6. Parasitic: Animals as intermediate hosts

|                           |   |
|---------------------------|---|
| Transmission:             | Via animal as intermediate host   |
| Examples:                 | Malaria, tape worm, psittacosis, borreliosis and spring-summer meningoencephalitis        |
| General significance:     | In temperate zones low; in the tropics high   |
| Significance in hospital: | Hygienically none, as under normal circumstances transmission is not possible in hospital |

## 2. Protective Measures

### 2.1 General Protective Measures

### Prevention Is Better Than Getting Ill

For protection of medical staff, the following applies:

- Build up active protection with vaccination as much as possible. A titre check should be carried out, to determine if a booster is required. The company doctor is responsible for this, and the following matters, amongst others, should be discussed with him/her: hep. B, hep. A, diphtheria, tetanus, polio, TB, flu'.
- A post-exposition prophylaxis should be kept ready for diseases not protected by vaccination: HIV/AIDS, hep. C
- Avoid any injuries with needles or other sharp objects by careful handling and use of all available sharps disposal systems.
- Do not pipette by mouth.
- Put on protective clothing (gloves, lab coat, apron, mouth protection) before any possibly risky contact takes place.
- Disinfect hands after any contact with material that could potentially contain pathogens.

### Prevention Is Better Than Infecting Others

For protection of all those around, the following applies:

- Disinfect hands before any contact that could lead to infection.
- Put on protective clothing (gloves, lab coat, apron, mouth protection) before any possibly risky contact takes place.
- If suffering from any infectious illnesses, this should be clarified, in order to prevent infecting others, possibly by going on sick leave.
- A ban on contact with food in case of certain illnesses.
- Correct waste disposal (enclosed, non-penetrable containers, decontamination or sterilisation, disposal containers labelled sufficiently as hazardous waste, secure containers for infectious waste). The details should be discussed with the waste officer, and a standard operating procedure should be put in the hygiene plan, and made known.

## 2.2 Protection of Personnel With Practical Hygiene

### Hand Hygiene

#### General

- ☞ Your hands are your most important tools. Keep them in good condition.
- ☞ Moisturise your hands during breaks and after work.
- ☞ Keep fingernails short.
- ☞ Fungal infections in nails can be treated effectively with local antimicrobics.
- ☞ Nail polish cannot withstand repeated disinfection -> *whoever treats a patient with painted fingernails, is "blatantly" not disinfecting their hands correctly!*
- ☞ Due to the material, false fingernails are significantly more contaminated.
- ☞ If there are purulent wounds, they should be covered with germproof dressing before treatment.
- ☞ Rings and watches should be taken off before disinfecting, as the sweat below the metal is a good culture medium for bacteria, just washing around the pieces of jewellery is insufficient.

#### Hygienic, Effective Disinfection of Hands

- ☞ Rub at least 3ml alcoholic hand disinfectant into dry hands for more than 30 seconds. In case of virus or Tb prophylaxis, a longer application time should be allowed, or possibly a repeat application. It may be recommendable to use a disinfectant especially effective against viruses.
- ☞ Following this, hands should only be washed if required, i.e. in case of visible contaminations, e.g. with blood or grease.
- ☞ Washing hands with soap and water removes dirt but not really bacteria. The so-called "medical soaps", available at chemist's shops, have a similar efficiency factor. The term "medical soap" in this case refers just to the pH value, which has an effect on the skin tolerance, but does not kill germs.

| Procedure                  | Product                       | Area of application           | Efficiency factor for bacterial reduction |
|----------------------------|-------------------------------|-------------------------------|---|
| Washing hands              | Soap and water                | Daily life, private sector    | 5–20                                      |
| Hand disinfection          | Disinfection soaps with water | Anglo-American medical sector | 100–200                                   |
| Hygienic hand disinfection | Alcoholic preparations        | The rest of western Europe    | 1.000                                     |

Soap is particularly ineffective where viruses are concerned.

- ☞ The so-called disinfection soaps, e.g. with quaternary ammonium compounds as active substance, reduce the amount of bacteria significantly. However, based on the usual amounts of bacteria found on the hands, which is around 1 – 10 million, there will still remain a higher amount of bacteria on the hands, than the minimum infection dosage. I.e. infection by manual bacterial transport is made more unlikely, but not effectively prevented.
- ☞ Hygienic disinfection of hands with alcoholic preparations (depending on the chemical composition 55-75% alcoholic content) is the most effective for reduction of bacteria. Modern preparations no longer have the disadvantage of drying out the skin, as fatty substances to protect the skin barrier are contained ("lipid replenishing"). This can also be carried out in close proximity to the patient, even if there is no washbasin. Usually it is not necessary then to wash hands. However, if they are very dirty, then they should be washed afterwards so as not to dilute the alcohol and reduce the effectiveness.
- ☞ It is interesting to note, that over the past few years, alcoholic hand disinfection is becoming increasingly more standard in the Anglo-American region, in particular in the USA and as recommended by the WHO.

### Skin Care

The fatty substances for protecting the skin barrier contained mean that alcoholic hand disinfectants work as hand care at the same time. If you would like to see how this "side effect"

works, place the amount of disinfectant required for one disinfection (3 – 5 ml) in a fire-proof dish, and incinerate it. The moisturising substances will be left over, usually a coloured glycerine based fat.

In addition to this, all manufacturers offer moisturising lotions or skin salves / creams, which do not impair the disinfection effect.

Dry skin tends to suffer with lesions, with the resulting wound secretion providing an ideal culture medium for micro organisms. Therefore: preventive skin protection by repeated moisturising is practical hygiene, and thus to the advantage of the employer, which is why he should cover the costs.

## 2.3 Needlestick Injuries From Sharps

### Causes

#### Needlestick Injury Due to Unconfident or Hectic Handling

If you work hectically, unconfidently or without fully concentrating, then you are putting yourself and those around you in danger. In particular, when working together on a patient, all movements should be predictable for everyone concerned. Otherwise, it is possible that the needle tip or scalpel blade comes into contact with the wrong place. It is especially dangerous to place something to the side without looking.

#### Needlestick Injury Due to Replacing the Needle Cover

The protective cover on a needle should protect from contamination and injury right up until the needle is used. Before use, the cover should be removed and not replaced with the hand (sometimes known as bimanual recapping)! Injuries are frequently caused by recapping: to the fingers, to the hand or even to the tongue.

#### Needlestick Injury Due to Needles Lying Around or Not Cleared Away

If needles or other objects that can cause an injury are not cleared away properly, then this is negligent behaviour, endangering both the user and those around. This should be discussed openly, and all those employed in the medical branch should be responsible enough to accept this.

#### Needlestick Injury When Disposing of Problematic Waste Like Winged Needles, Port-Needles, or Bulky Large Parts

As a basic rule: Always dispose of tips in the disposal box. Problems arise when needles have attachments (wings, flexible tubing, leftovers from adhesive plaster) and with large parts (mandrins, central venous systems, stylets with tips – e.g. for suprapubic bladder puncture).

The following is applicable:

- ⚡ Never push back with the fingers – NEVER!
- ⚡ If possible, use a larger disposal box with a sufficient opening.
- ⚡ If necessary, use tweezers or scissors to help.
- ⚡ If necessary, cut off any attachments (tubing, adhesive plaster) that are in the way.

#### Needlestick Injury Due to Insufficient or Defect Sharps Disposal Box

Disposal systems should be:

- ⚡ Non-penetrable
- ⚡ Unbreakable
- ⚡ Leak-proof
- ⚡ Easy to close firmly

The opening should be designed so as to prevent the contents from spilling out if the box falls over.

Should one of these conditions not be fulfilled, continued use and transportation of the box is dangerous: in case of needlestick injury, it is impossible to find out from which patient it is.

## 2.4 Procedure In Case of Needlestick Injury, PEP

#### Preliminary remark:

It is important for every employee to know, that there is a special Post-Exposure-Prophylaxis (= PEP).

- ⚡ PEP against HIV should be administered within 2 hours.
- ⚡ PEP against Hep. C need only be started, when an infection can be seen in the titre conversion. However, the initial position should be checked within a few days. This is carried out with interferons.
- ⚡ PEP reduces the infection risk up to 80% - NOT by 100%!

## 1. Let wounds bleed as far as possible, or remove the fluid containing a virus immediately

**Use disinfectant only if immediately available, otherwise the first measure is to rinse out with running water**

- Needlestick injury: Above / central to needlestick position, stimulate bleeding by massaging in the direction of the needlestick position / periphery
- Cut wound: Spread the edges of the wound and rinse
- Blood contact to broken skin: Rinse thoroughly
- Mucous membrane contact inside the mouth: Spit out and rinse immediately with water, after this, rinse with 80% alcohol if possible
- Mucous membrane contact in eye: Spread out eye, and rinse out with water or isotonic saline solution. Afterwards rinse with isotonic watery PVP-iodine solution, 2.5%

## 2. 10 min. disinfection with quick spreading skin or hand disinfectant, possible alcoholic or PVP-iodine (virus effectiveness is on label)

**Hand disinfectants containing alcohol burn but are very effective**

## 3. Check source of infection in order to appraise risks

- Was the injury made with a hollow needle or with another sharp object, e.g. scalpel?
- Is the needle which caused the injury visibly contaminated by blood, was it applied i.v. / i.a. or just s.c / i.m.?
- Is it known, on which patient the needle was used?
- Does this patient have a haematogenic transmittable disease (either suspicion or confirmed)?
- Which diseases can be excluded on the grounds of available data (e.g. HIV, Hep. A, B, C, Tbc)?

## 4a. On suspicion of HIV exposure: contact could be made with the closest clinic for:

- Competent advice,
- Risk appraisal <--> side effects of a therapy
- Possible initiation of antiviral therapy

### Currently the international recommendation, from both CDC (USA) and RKI (Germany):

|                          |   |
|--------------------------|---|
| <b>No prophylaxis</b>    | For superficial scratches on skin with a noncontaminated sharp / pointed object, with no visible opening of blood vessels.  |
| <b>Offer prophylaxis</b> | For a superficial injury with a surgical needle (does not apply to hollow needles). On contact to mucous membranes or broken skin with blood heavily burdened with a virus. |

|  |  |
|--|--|
| <b>Prophylaxis</b> If certain or highly likely inoculation of infectious material: |  |
| <b>with</b>  |  |
| <b>1.</b>  | Combivir® (2x300/150mg) or Retrovir®<br>+  |
| <b>2.</b>  | Epivir (2x150/1x300mg)<br>+  |
| <b>3.**</b>  | Viracept® (2x1250) or Crixivan,(3x800mg) or Lopinavir/rit® (2x400/100mg) or Sustiva./Stocrin,(1x600mg)   |
|  | Begin: if possible within 2 hours!<br>Length: at least for 2 weeks, if possible 4 weeks!<br>Changes in therapy at short notice should be expected! |

Current recommendations on the general procedure and exact dosaging can change at short notice, in order to conform to newest discoveries.

Please refer to:

CDC = Center for Disease Control: [www.cdc.gov](http://www.cdc.gov) – Search: Term "PEP" = Post-exposure Prophylaxis

RKI = Robert Koch-Institut: [www.rki.de](http://www.rki.de) – Englisch – Search: Term "PEP" = Post-exposure Prophylaxis

**Note:**

If there is a significant risk, this can be reduced by 80% by applying the post-exposure prophylaxis

#### 4b. If exposure to Hepatitis-B-Virus is suspected:

- ☞ If there is already sufficient protection due to Hep.-B-vaccination: no further measures are necessary.
- ☞ If there is insufficient protection or none at all from Hep.-B-vaccination:  
Simultaneous vaccination passively with HBIG and actively with HB vaccination within 48 hours.

#### 4c. If exposure to Hepatitis-C-Virus is suspected:

- ☞ Determine the correct HCV status (take blood sample immediately, request lab results for within a week – no emergency status).
- ☞ Take controls at 6, 12 and 24 weeks.
- ☞ Initiate antiviral therapy if there is seroconversion.

### Important notes on protection/documentation/ cost insurance for employer

If a needlestick occurs, and the blood/serum of the index patient is to be tested for HIV/HBV/HCV as a result, then it is obligatory to obtain prior permission (from practical experience, the best method is with an open chat). The affected member of staff should seek counselling on PEP, and countersign the result (i.e. recommended, offered, not recommended). If costs are not covered, he/she must confirm with signature that costs will be covered personally.

### Screening after HIV-Exposure

Recommended basis and control examinations, current RKI recommendations:

|                          | Index-person <sup>o</sup> | Exposed Person |                |                |          |           |           |            |
|--------------------------|---------------------------|----------------|----------------|----------------|----------|-----------|-----------|------------|
|                          |                           | Initial Exam   | 2nd week       | 4th week       | 6th week | 3rd month | 6th month | 12th month |
| HIV-antibodies           | X                         | X              |                | X              | X        | X         | (X)       |            |
| HBsAG                    | X                         | X              |                |                | X*       | X*        | X*        | X*         |
| HCV-antibodies           | X                         | X              |                |                | X*       | X*        | X*        | X*         |
| Further STDs             | X*                        | X*             | X*             | X*             |          |           |           |            |
| Examination by physician |                           | X              | X              | X              | X        |           |           |            |
| Medication history       | X <sup>1</sup>            | X <sup>2</sup> | X <sup>2</sup> | X <sup>2</sup> |          |           |           |            |
| Blood count              |                           | X              | X              | X              |          |           |           |            |
| Transaminase/A/gamma-GT  |                           | X              | X              | (X)            |          |           |           |            |
| Creatinin/Urea           |                           | X              | X              |                |          | X**       | X**       |            |
| Glucose                  |                           | X              | X              | X              | X        |           |           |            |

<sup>o</sup> If the person is known, but infection status not clear, consent must be given, if applicable a quick test can be used  
<sup>\*</sup> If indicated / if exposure has occurred  
<sup>\*\*</sup> Control in case of hepatitis B or hepatitis C exposure  
<sup>1</sup> Treatment history with anti-retroviral medication (appraisal of resistance situation)  
<sup>2</sup> Has other medication been taken (warning! Interaction!) PEP tolerance?

## 3 Isolation measures

### 3.1 Isolation of Infectious Patients

#### a) Officially recommended measures:

There are official guidelines in every country, on how to deal with infectious patients and which isolation and protective measures are to be taken, for example, via the CDC in the United States. On the website [www.cdc.gov](http://www.cdc.gov), you can download measures and use them as orientation for your own actions. The target of the EU is harmonisation, but this progress is very slow.

#### b) Implementation on own premises: Hygiene plan

The implementation in the own hospital must be documented in written form in the hygiene plan. For orientation, the official guidelines of the regional government agency must be referred to. However, the particular characteristics of each institute must also be taken into account, though which measures are necessary or sensible for which disease, can largely be derived and worked out.

The necessary measures can be derived by answering the following questions:

- ⦿ What is the way of transmission?
- ⦿ Which media occur as subcarrier?
- ⦿ How remanent (resistant) is the pathogen against disinfection measures?
- ⦿ Is there multiresistance?
- ⦿ How great is the infection risk?
- ⦿ How great is the contamination risk?  
I.e.: How great is the risk of triggering an epidemic or endemic?
- ⦿ How great are the morbidity and lethality risks for the transmitter?  
I.e.: Which screening measures are necessary, sensible and feasible?
- ⦿ How great are the morbidity and lethality risks for the recipient?
- ⦿ Which other prophylactic measures (e.g. antibiosis) are possible and sensible?
- ⦿ How is the immune system of those potentially in danger?

#### c) Derived measures

##### Single room or cohort isolation

In case of easy transmission  
If transmission is difficult to detect early on  
If the morbidity or lethality risk is high  
If the therapy possibilities are limited

##### Protective gloves

In case infection possible via an intermediate carrier  
In case of contact with infectious material  
If there is an injury on hand – even minimal: Personnel protection!

##### Hygienic hand disinfection

If there is doubt – again and again!  
After any contact if highly contagious, including after taking off gloves  
Prior to contact, if defences are low.

##### Mouth+Nose protection, Surgical Face Mask

If highly contagious and if transmitted in the air.

##### Protective clothing

If transmission is via an intermediate carrier, if close patient contact is required, and if highly contagious.

##### Disinfection measures

The choice of procedure for inactivating bacteria is dependent on pathogen, transmission way and object.

**Important:**

**Keep a sense of proportion when organising the protective measures. Excessive measures, which cannot be justified, may be ignored. This could have fatal consequences for the next infection patient.**

## 3.2 Reverse Isolation of Immunodeficient Patients

Reverse isolation means that instead of protecting the environment from the patient, the immunosuppressed patient is protected from his/her surroundings.

Thus, all protective measures are necessary prior to contact instead of after.

### Particular responsibility for all staff members:

Carriers of facultative pathogenic bacteria can trigger very serious infections, whilst they are not aware of the risk. Regardless of whether it is just a harmless illness that does not prevent going to work (e.g. a common cold, stool abnormality, common acne) or if there is a known carrier that does not show symptoms (MRSA; salmonella), all necessary protective measures must be individually carried out.

The initiative must come from the employees, as only they themselves can know their colonisation.

### Particular Risk: Legionella:

It is highly unlikely that a person with an intact immune system contract legionella pneumophila. However, for those with immunodeficiency, then just a minimal amount of bacteria in warm water is sufficient.

## 3.3 Isolation During Building Work Generating Dust

Dust from building work often contains large amounts of aspergillus spores (aspergillus niger/arcantis). Even when ripping down walls that are hundreds of years old, these spores can germinate again.

For Asperillogose, only the briefest of exposures between an immunosuppressed patient and building dust is enough (e.g. a few minutes in a waiting area next to building work).

The appropriate protective measures are compulsory, also for asbestos renovation.

## Building Company/Hospital and Responsibility for Maintaining Protective Measures

- All building sections must be completely sealed off
- Dust protection walls, as solid as possible with silicon sealing must be used
- No thin plastic sheets, which rip easily and can loosen at the edges
- Provisional dust protection walls, even for small building jobs
- Minimisation of dust generation during building work, e.g. by using low pressure suction or damp methods to prevent dust flying
- Separated walkways
- Access to building site and building waste disposal is never to be in a patient area, and building site exits should be via "locked entrances" with wet towels covering walkway, between double doors
- Frequent dust removal when there is a small building job being carried out, e.g. clean 5 times a day
- Inform patients in good time to stay away from building dust (curiosity can be dangerous!)

### Important:

**Dust protective measures should be established at the building planning stage! Only a responsible building site manager will be able to sufficiently instruct and keep a check on his/her workers.**

## 3.4 Infection Catastrophe Medicine Preparations: Preliminary Question: Why Prepare and For What?

Nobody can know which infection catastrophe will come next, nor can anybody know, if the danger is real, or if it has "only" been blown up out of proportion by the media. Depending on the patients, advance precautionary preparations can be carried out at

minimal cost, which in an actual disaster situation would be hectic measures at incalculable cost.

## All genuine infection catastrophes have the following in common:

- Extremely contagious
- Infectious before showing symptoms, or with few apparent symptoms, in prodromal stadium
- Course of disease can barely be treated, or only symptomatic therapy possible
- High lethality

As the two final points are too late for active medicine, measures must already be taken at points 1 and 2. It is therefore decisive, to react on the very first suspicion, and protect oneself. Usually, very simple protective measures are sufficient for this.

### For example, SARS:

An analysis afterwards showed, that the majority of those infected had had close patient contact early on without wearing protection. If a simple (cheap) face mask had been worn (costing < EUR 0.20), it would have been more effective than the expensive breathing masks type FFP3 (approx. EUR 5) which were used later. Decisive was the behaviour regarding symptoms of an inconspicuous influenza infection. But who wears a face mask when dealing with patients with a "normal" cold?

## a) Practices and Medical Centres

This preparation applies to:

- Non-specific early contact,
  - Initial care
- Determine in advance, in which room potentially infected patients should wait and be examined.

In the entrance area to this room, an >Emergency Box< should be available containing the following:

- 1 pack of face masks (multi-layer standard surgical masks – FFP1)
  - 1 pack of sterile gloves, in a size suitable for the biggest members of staff (sterile gloves, as the quality is better, and the cuff is longer)
  - 1 pair protective goggles or other form of eye protection for each staff member to prevent droplets from spraying in the eye (a frequent way of transmission for noro-viruses when vomiting)
  - 1 full length white coat for each staff member
  - Hand disinfectant effective against viruses
  - Surface disinfectant effective against viruses (Recommendation: In this case with formaldehyde!)
- The room should have a telephone connection, provided the practice is equipped with a land-line, so that the necessary telephone conversations can be carried out discreetly and without being disturbed by frequent door opening.

## Costs for an emergency box of this kind < 100.– EUR

With these measures, you can assure your employees and patients who may ask that all necessary protective measures are on offer. (If the contracting of an infectious disease must be examined as an occupational illness, this is always examined officially. Even partial blame can cause considerable cost.)

## b) Hospitals WITHOUT Maximum Care Facility

The preparation is valid for:

- Non-specific early contact
  - Initial care
  - Short-term standard therapy until transfer possible
- Determine in advance, in which room potentially infected patients should wait and be examined.

☞ In the entrance area to this room, an >Emergency Box< should be available containing the following:

- 1 pack of face masks (multi-layer standard surgical masks – FFP1)
- 1 pack of face masks (multi-layer standard operating masks – FFP1)
- 1 pack of face masks (type FFP2 for certain pathogens)
- 3 packs of sterile gloves, sizes 6 1/2, 7, 7 1/2 (sterile gloves, as the quality is better, and the cuff is longer)
- 5 – 10 pairs of protective goggles or other eye protection to prevent droplets from spraying in the eye (a frequent way of transmission for noro-viruses when vomiting)
- 10 full length white coats
- Hand disinfectant effective against viruses
- Surface disinfectant effective against viruses (recommendation: In this case with formaldehyde!)

The room should have a telephone connection so that the necessary telephone conversations can be carried out discreetly and without being disturbed by frequent door opening.

☞ Measures should be established in writing in a hygiene plan, and everyone should be made familiar with them (e.g. in training)

## c) Hospitals WITH Maximum Care

The preparation is valid for:

- ☞ Non-specific early contact
- ☞ Initial care
- ☞ Simple standard therapy
- ☞ Emergency treatment if transfer is not possible

☞ Determine in advance, in which room potentially infected patients should wait and be examined.

☞ In the entrance area to this room, an >Emergency Box< should be available containing the following:

- 1 pack of face masks (multi-layer standard surgical masks – FFP1)
- 1 pack of face masks (type FFP3 without valve for patient)
- 1 pack of face masks (type FFP3 with valve for staff)
- 3 packs sterile gloves, in sizes 6 1/2, 7, 7 1/2 (sterile gloves, as the quality is better, and the cuff is longer)
- At least 10 pairs of protective goggles or other eye protection to prevent droplets from spraying in the eye (a frequent way of transmission for noro-viruses when vomiting)
- 20 full length white coats
- Hand disinfectant effective against viruses (DGHM list!)
- Surface disinfectant effective against viruses (recommendation: In this case with formaldehyde!)
- Special disposal containers for infectious waste (so-called C waste containers)
- The group of rooms should not have floor drainage. Alternatively, special gel mats can be acquired, which safely seal up drains. These can be bought in catalogues for chemical facilities at reasonable prices.

The group of rooms should have a telephone connection so that the necessary telephone conversations can be carried out discreetly and without being disturbed by frequent door opening. The group of rooms should have a connection to medical gasses.

☞ The differentiated measures for various cases should be established in writing in a hygiene plan, and everybody should be made familiar with them (e.g. in training).

## d) Special Isolation Units

For the various highly infectious life-threatening diseases, special hospitals or treatment centres can be set up, depending on the country and circumstances. They are specialised in treatment, and for this purpose have special equipment, and above all staff purposefully trained and prepared for dealing with these diseases.

In preparation, all contact addresses, emergency telephone numbers and specialist laboratories should be recorded in a list, so that in case of emergency, the contact can be found without a search being necessary.

# II - Handling Medical Products

## 4. Disinfection

**Definition:**

**Destruction / Inactivation of enough micro organisms to ensure that no infection transmission is possible. Usually, this means a bacterial reduction to a factor of 105.**

**Purpose:**

**To interrupt the infection chain, as well as protect personnel and patients.**

### Hand Disinfection

#### Hygienic hand disinfection (Standard procedure with alcoholic preparations)

Rub at least 3ml alcoholic hand disinfectant for 30 seconds into dry hands. Wash hands after this only if necessary. Allow either a longer application time or a repeat application for virus or TB prophylaxis (see label).

#### Surgical hand disinfection (Standard procedure with alcoholic preparation)

1. Hygienic hand disinfection in the entrance area of the operating theatre.
2. 2½ min.: washing of hands and underarms – whereby the dripping should be in direction of the elbow.
3. 2½ min.: rub in alcoholic hand disinfectant in hands and underarms (limit movement from the elbow to the middle of the underarm).
4. Put on sterile lab coat and gloves –

**Warning:** Latex allergy!

## Disinfecting Skin of Patients

### ☞ Before blood collection or injection of medication

Spray or rub in skin disinfection – application time 15 – 30 sec. Rub off with sterilised swab\*. If traces of dirt come off on swab, repeat the procedure.

### ☞ Before operation, opening of a sterile cavity, application of a central catheter on normal skin

Possibly shave before the procedure (max. 6 hours before). Rub in skin disinfectant 2 or 3 times, starting in the centre and moving outwards, in each case with a sterile swab\*\* and for at least 1 min.

**Warning:** Any liquid that runs off must be dried immediately, in order to avoid burns during intra-operative electro coagulation.

### ☞ On skin with excessive sebaceous glands

Possibly shave before the procedure (max. 6 hours before). Rub in skin disinfectant for 10 min. (!), starting in the centre and moving outwards, always using a sterile swab\*\*.

**Warning:** liquid running off.

\* Sterilised swab can be sterilised on a roll of swabs and torn off as required. It must not remain sterile right up to application.

\*\* Sterile swab must be packaged individually or in small amounts, and may only be opened directly before application.

## Disinfecting Instruments

Treatment of instruments includes pre-wash / ultrasound. If the dirt is dried up, the instruments must be cleaned and disinfected, as only clean instruments with just a small amount of bacteria can be sterilised ( → Sterilisation Chapter 5). Maintenance and control, packaging, sterilisation. The type of preparation decides the order:

### ☞ Manual treatment

1. Soak in a disinfecting solution straight after use (observe application time\*).
2. Clean thoroughly, with a final rinse in sterilised or deionised water.
3. Dry with a lint-free towel, blow through cavities with sterile, filtered air.
4. Inspect and check functioning. Instrument maintenance.  
\* Refer to manufacturers' instructions concerning concentration and application time (usually, this is 5% - 1% for 15 – 60 min.).

### ☞ Automated treatment

Automated:

1. Cleaning (nowadays, usually at a low temperature at the start of the programme, in order to prevent coagulation of blood).
2. Thermal disinfection (e.g. 93°C, 10min.) or chemical-thermal (e.g. 60°C for 5 min. with chemical application).
3. Final rinse with sterilised water or deionised water.
4. Drying.

By hand:

Inspect and check functioning. Instrument maintenance. Principally, automated preparation is preferable:

- To relieve personnel.
- To decrease risk of injury.
- The procedure can be validated, thus guaranteeing that the quality remains the same.
- Less burden for the environment, as less water, energy and chemicals required.

## Disinfection of Surfaces

Disinfect work surfaces, furnishings, walls, flooring using a cloth, mop or similar with a disinfectant solution and wiping or scrubbing (the scrub/wipe method of disinfection). Large areas of contamination should be cleaned away first. Please refer to manufacturers' instructions for concentration and application time.

### Important:

- Do not use cleaning additives, unless the manufacturer specifies them. Many cleaning components cancel out the disinfection effect, providing a culture medium for germs, and occasionally poisonous vapours.
- Basis of the solution: first cold or at the most lukewarm water, then add the concentration.
- Never continue work with a dirty solution. As soon as it is noticeably dirty, replace the solution.

### Warning:

**Avoid the spray disinfection, which used to be popular:**

1. The chemicals that get sprayed into the air can be inhaled and cause an allergy.
2. Germs and impurities are on the surfaces, not in the air. Surfaces are cleaned and disinfected much more effectively via the scrub / wipe method than via the spray and wipe off method.

## Room Disinfection (Gassing/Atomisation)

Disinfection of a room by means of gassing or atomisation should only be carried out as a final disinfection in case of the following illnesses:

- Pulmonary anthrax
- Plague
- Virus related haemorrhagic fever (e.g. Lassa fever, Ebola fever)
- Especially contagious diseases which are difficult to treat, caused by indestructible micro organisms

If a room is disinfected by gassing, the responsible authorities must be informed, approval given, and control measurements must be carried out. The persons responsible for the procedure require a special qualification and extensive protective equipment.

Atomisation is carried out with at least 5g formaldehyde/m<sup>3</sup> of the room capacity. The room can only be used again, when the remaining amount of formaldehyde in the air is below the permissible tolerance range. Depending on the amount of absorbent materials, it can take a lot longer than usual to recede.

## Disinfection of Crockery, Bedding, Mattresses

Crockery is disinfected chemical-thermally on an industrial scale, or purely thermally in a closed dishwasher (e.g. 93°C for 10 min.) for infection wards.

Bedding is disinfected chemical-thermally by washing in the hospital laundry – in contrast to other laundries, this process is subject to microbiological controls.

A certain steam-vacuum process can disinfect mattresses. Nowadays, in many hospitals, mattresses are covered with breathable micro fibre fabrics, and then it is sufficient to disinfect just by scrubbing / wiping.

## 5. Sterilisation

### Definition:

#### Classical: Destruction/Inactivation of all micro organisms

New insights on destruction kinetics say, that micro organisms do not all die off at the same time. Instead, the amount halves itself over a certain period of time, or reduces itself to a tenth. Mathematically, this is an exponential function that asymptotically tends to zero without ever reaching it. Therefore, a new definition is required (Euronorms EN 556, Paragraph 4.1).

**Currently: Destruction / inactivation of enough augmentable micro organisms, so that at the most, every millionth object carries a surviving germ (sterilisation probability  $p \leq 10^{-6}$ )**

Language problem: The word "sterilisation" as used in the Romance languages does not refer to this definition, and must be translated with "disinfection".

### Condition for each sterilisation:

**Clean instruments with low germ count (less than 1000 germs per instrument), i.e. disinfected instruments, without leftover salts (final rinse with fully desalted deionised water or sterilised water).**

### Thermostable instruments in the operating theatre (metal instruments, tubing, cable, cautery, compresses, swabs and other single-use textiles)

Steam steriliser (used to be known as autoclave) after fourfold pre-vacuum sterilisation at 134° C, 3 bar, > 5 minutes sterilisation time, length of procedure approx. 30 minutes. Longer sterilisation times are required after prion diseases.

### Problems:

- Steam quality requires saturated steam with no foreign vapours
- Steam penetration must be guaranteed; it must be able to reach everywhere. This can only be achieved with 3 – 4 fractioned pre-vacuums
- Impurities, blood crusts, salts and residues from disinfectants cannot be sterilised, and must therefore be completely removed to start with, especially contagious diseases which are difficult to treat, caused by indestructible micro organisms
- Disinfection must be carried out so as to guarantee a low germ count

### Thermostable instruments in the operating theatre (metal only) and laboratory (metal and glass)

Hot air at 180° C, > 30 minutes pure sterilisation time, length of process including cooling up to 6 hours.

### Problems:

- This sterilisation method is thought to be unsafe, as only the temperature of the air in the chamber can be measured. The temperature reached on and in the instrument (= compensation time) can only be estimated.
- Textiles, rubber and plastic cannot withstand the heat.
- Warming up, distribution of warmth in the steriliser and amongst the items to be sterilised takes a long time, and the entire sterilisation process takes 2 – 3 hours.

### Textiles (lab coats, sheets) and rubber

Steam steriliser (formerly autoclave) as with the instruments, or at 121°C, 2 bar, 15 – 20 minutes sterilisation time, the process lasting approx. 50 minutes, or an hour for laundry, due to the longer drying time necessary.

### Problems:

- Steam quality requires saturated steam with no foreign vapours.
- Steam penetration must be guaranteed; it must be able to reach everywhere. This can only be achieved with 3 – 4 fractioned pre-vacuums.
- Impurities, blood crusts, salts and residues from disinfectants cannot be sterilised with disinfectants.

## Thermolabile Objects (Plastics)

### 1) Gas: Ethylene oxide

Advantage: good penetration of the plastics, and therefore sterilisation of narrow / enclosed hollow cavities.

**Problem:** extremely toxic

- ☞ 1 – 14 days required for outgassing the ethylene oxide infiltrated in the plastic
- ☞ High standards required of employees (special training, temporary authorisation permits)
- ☞ High demands on company security
- ☞ High demands on environmental protection (control measurements, catalyser, post-combustion)
- ☞ High demands on operator (obligation to obtain permit, disclosure duty, controls)

**Warning:** Before acquiring an instrument – even a “small” one – the operator should clarify all of these requirements.

### 2) Gas: Formaldehyde

Advantage: only toxic during and shortly after sterilisation.

**Problems:**

- ☞ Since the formaldehyde does not always reach the cavities or closed systems in sufficient concentration, it is only suitable for sterilisation of surfaces
- ☞ High demands on operator, employees and instrument due to toxicity

### 3) Physical Plasma: H<sub>2</sub>O<sub>2</sub>

Advantages:

- ☞ Gentle sterilisation of fine instruments and electronic instruments including video camera
- ☞ No heat damage (45°C)
- ☞ No damages from dampness, as the process is dry
- ☞ Quick re-availability

- ☞ Non-toxic
- ☞ No safety requirements
- ☞ Not harmful to the environment

**Problems:**

- ☞ Cannot be used on absorbent materials (fabric, paper)
- ☞ Cannot be used on liquids
- ☞ Since the physical plasma does not reach terminal closed cavities (balloon-tipped catheter) or long channels with very small diameters, only for sterilisation of surfaces
- ☞ Expensive: high acquisition and packaging costs

### 4) Radiation (Gamma) Sterilisation

Industrial process with hard, germ-killing radiation for disposable items.

Infection / Laboratory Waste

Steam steriliser (=autoclave) at 121°C, 2 bar, >15 minutes sterilisation time, length of process 60 - 90 minutes

**Advantages:**

- ☞ Potentially contaminated infection waste, i.e. hazardous waste, is transformed to normal waste (saves on costs)
- ☞ Microbial contamination with pathogens from protective class 3 and 4 in accordance with European protective classification and genetic engineering laboratory work require that there is a waste steriliser on the premises

**Problem:**

- ☞ Due to the considerable amount of dirt caused in the sterilisation chamber, as well as odours, a separate steriliser should be available for waste

## Sterilisation on suspicion of prions

Instrumentation that has been in contact with the brain, spinal cord or liquor on suspicion of a prion disease, should be sterilised in a steam steriliser at 134°C, 3 bar for 60 minutes. This can be achieved by 20-fold sterilisation in a normal 134°-program. Following this, the standard procedure of cleaning, maintenance, packing and normal sterilisation.

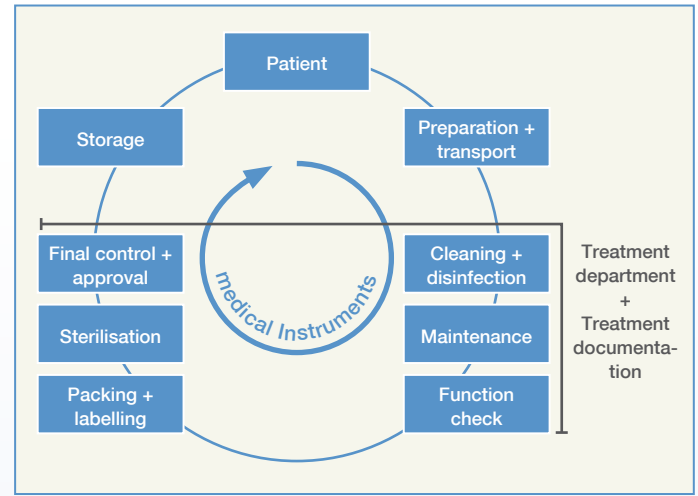
Any objects that cannot withstand this sterilisation process must be destroyed (waste incineration or hazardous waste).

## Obsolete: So-called “Cold sterilisation”

Chemical immersion bath for supposed sterilisation. There is bacterial reduction, but no definite destruction or inactivation of all micro organisms. In spite of the name, this is not a sterilisation procedure, and may only be seen as **disinfection**.

# 6. Instrument Preparation

## 6.1 Medical Product Preparation



### Aim:

It must be possible to apply the instruments safely and without risk:

- Faultless technical functioning
- No infection transmission
- No pyrogen-related reactions
- No allergic reactions
- No toxic reaction

For every medical instrument, a risk evaluation must be carried out, depending on the kind of application and preparation opportunities available. An evaluation determines if or how often and with which procedure the preparation is carried out.

## Risk classes

|                  | Area of application                               | Preparation requirements   | Example                            |
|------------------|---|--|------------------------------------|
| 1) Non-critical  | Contact only with intact skin                     | 1)   | EKG-electrodes                     |
| 2) Semi-critical | Contact with mucous membrane or broken skin       | 2A) normal   | Speculum                           |
|                  |   | 2B) increased  | Flexible endoscope (gastro-scope)  |
| 3) Critical      | Contact to blood, inner tissues or organs, wounds | 3A) normal   | Retractors                         |
|                  |   | 3B) increased  | Minimally invasive surgery trocars |
|                  |   | 3C) especially high (as the preparation can slightly damage materials) | Thermolabile objects               |

For the risk evaluation, and to make sure that preparation is carried out correctly up until the approval, personnel must be fully trained. Management staff must have enough theoretical background knowledge to be able to react correctly in case of a problem, and all other employees must have sufficient practical knowledge.

## Treatment Stages

### 1. Prior to Treatment and Transport

#### **Take care ! Risk of injury !**

*An injury from a used instrument is a high infection risk.*

- Dried up blood and other impurities must be avoided. This should be the basis of the disposal system.
- Superficial dirt can be removed/wiped off straightaway, as long as there is no risk of injury.
- Channels should be flushed out immediately.
- Assembled instruments must be dismantled.
- Take care with transport!  
(Semi-skilled workers are not always aware of how sensitive fine instruments are, and how valuable they are).

- Carry out transport without danger of infection. Closed systems may only be used for transport of sterilised goods after disinfection

### 2. Pre-Treatment

The type of treatment is decisive for the sequence:

- Manual treatment: disinfect at the start
- Automated treatment: disinfect at the end

### 3. Cleaning and Disinfection

The type of treatment is decisive for the sequence:

- Manual treatment: disinfect at the start
- Automated treatment: disinfect at the end

#### ➤ Manual treatment

1. Immediately after use, soak in disinfectant.  
For concentration and application time, see literature.
2. Clean thoroughly, rinse finally with sterilised or deionised water.
3. Dry.

#### ➤ Automated preparation

1. Cleaning (nowadays, usually with a low temperature at the start of the cycle to prevent blood from coagulating)
2. Thermal disinfection (e.g. > 90°C, 10min\*) or chemical thermal (e.g. 60°C 5min. for chemical effect) (nowadays usually at the end of the cycle, so that warmth can be used for drying, whilst saving energy)  
\* Modern machines are no longer adjusted to time/temperature, but rather to the entire effect of the warmth, i.e. the E0-value
3. Finally, rinse with sterilised or deionised water
4. Dry

## Principally, automated treatment is preferable:

- To relieve personnel
- Less risk of injury
- The process can be validated

The European Guidelines, i.e. Robert Koch Institute in Germany, has established the following in hygiene guidelines: as of risk group 2A treatment SHOULD be automated as of risk group 2B, treatment MUST be automated

## 4. Inspection and Control

- Has all dirt been removed without leaving residue?
- Is it completely dry?
- Has all residue from cleaning materials been removed?
- Are there no traces of rust?

## 5. Maintenance and Function Check

- Spray all hinges and joints with maintenance products (oil, silicon, Teflon)
- Check hinges and joints (ease of movement, firm tracks)
- Re-assemble all instruments that have been dismantled, checking for precise fitting, possibly stripping down again partly for sterilisation
- Check function of all instruments

## 6. Packaging and Labelling

### a) Packaging

Depending on type of sterilisation, storage, period of shelf-life

- Container or box
- Sieve in germ-free overpack
- Sterile tubing packaging
- Sterile paper
- Combinations of different packaging

**Note: Fabric is not germ-free packaging, but can be used as additional dust protection.**

### b) Labelling

- Sterilisation date
- Shelf-life of guaranteed sterility
- Steriliser (optional)
- Batch (optional)
- Recipient (optional)
- Contents (optional)

## 7. Sterilisation

As a rule, sterilisation is in a steam steriliser set to the instruments program, although for laundry a program with longer drying time is selected, for rubber a lower temperature is chosen, for prions a longer sterilisation time is necessary.

### 7.1 Control and Documentation System (Example)

#### 7.1.1 Every Day Before Starting Work

##### 1. Vacuum Test

To check that the pumps can draw and maintain sufficient vacuum (grit stuck between sealing and closure or porous rubber sealing let air through).

##### 2. Bowie-Dick

To check the steam penetration through the absorbent sterilisation items in accordance with the EN procedure. Inert gases (foreign gases or residual air) prevent the penetration of the saturated steam, e.g. through laundry parcels. This is also an indirect control of steam quality.

#### 7.1.2 Batch Control

1. Documentation of important process parameters (pressure and temperature curve, chronological sequence). These are usually print-outs on paper. On the newest systems, data can be saved on the main computer, also allowing for uninterrupted transmission to CD-ROM.

**Warning: The steam quality / share of inert gases is not recorded continually.**

2. Chemical-indicator with colour change after reaching the approximate temperature range. If the system is good, it also depends on steam / steam penetration.  
 Note: The time factor is either recorded not at all or only recorded generally.

### 7.1.3 Sieve Control

1. Chemical indicator with colour change after reaching the approximate temperature range, whereby a good system has a range from 121°C to 134°C, and it is possible to have steam with steam penetration. If documentation is not kept on which sieve is sterilised and in which batch, such a system is preferable. The indicators can be filed according to patients.  
 Note: The time factor is either recorded not at all or only recorded generally.
2. Adhesive strips or similar, with a simple chemical indicator which changes colour immediately on temperature increase.  
 Note: This is not a quality control! It serves just to identify which items have already been sterilised, and which have not been sterilised.

### 7.1.4 Validation and Function Control

All the controls listed above can only provide indirect conclusions on germ-killing conditions during the sterilisation process. To be sure of a successful sterilisation process, validation of every steriliser when placed into operation is nowadays a must. Otherwise, a quality management system and annual revalidation must be set up.

## 8. End Control and Release

- ☞ Has the steriliser program cycle been fully completed?
- ☞ Are the sterilised items dry on removal?
- ☞ Is all packaging ok?
- ☞ All labelling ok?

Only when every question can be answered with YES, can APPROVAL be given.

## Examples for company internal storage periods

| Packaging         | Storage  | Max. Storage Period                      |
|-------------------|--|--|
| Paper/single wrap | Open   | 1 day or consumption as soon as possible |
| Paper/single wrap | In cupboard/<br>protected from dust  | 6 weeks                                  |
| Paper/double wrap | Open   | 6 weeks                                  |
| Paper/double wrap | In cupboard/<br>protected from dust  | 6 months                                 |
| Container         | Open   | 1 week                                   |
| Container         | Open in store room<br>where little or no dust<br>(sterile filtered supply air) | 6 weeks                                  |
| Container         | In cupboard/<br>protected from dust  | 6 weeks                                  |

- ☞ The expiry date refers to dry, dust-free storage and undamaged packaging / overpack.
- ☞ The user – not the manufacturer or sterilisation department – is responsible for maintaining sterility by correct storage!
- ☞ Sterilisation items should be sorted from behind, and taken out from the front, in order to prevent overlapping (on the basis of “first in- first out”).

## 6.2 Endoscope Handling

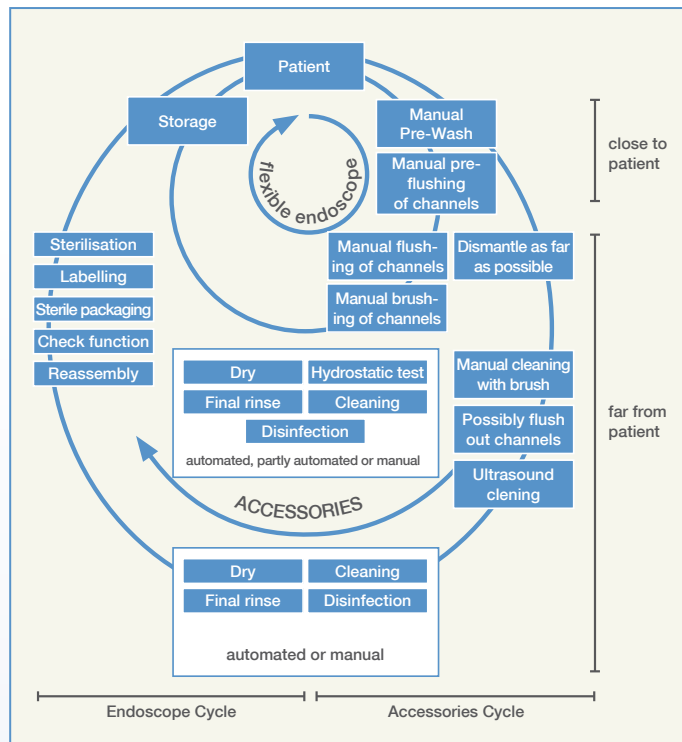
### 6.2.1 Preliminary Notes

- ☞ Treatment of a flexible endoscope is extremely specific, due to the channels which cannot be seen, the complexly joined materials and the delicacy of the increasingly innovative models.
- ☞ Flexible endoscopes are Class 2B medical devices (mucous membrane contact = semi-critical with higher standards required of treatment).
- ☞ Endoscope accessories fall into Class 3B (application in sterile area, critical medical device with higher standards of treatment required) if they can be sterilised by steam, and into Class 3C (application in sterile area, critical medical device with especially higher preparation requirements), if they cannot be sterilised by steam.
- ☞ The treatment must eliminate all contamination, even those in the inaccessible channels, which are partially branched (Caution: sputum-mucopolisaccharide are practically impossible to remove when dry!).
- ☞ The treatment must be virus-free, including polio viruses, in order to be sure of preventing transmission of hepatitis.
- ☞ The treatment must be completely free of worms, including worm eggs, if the area of application is the lower gastrointestinal tract.
- ☞ Treatment of a flexible endoscope so that it is suitable for prions, is practically impossible. If there is sufficient indication, an instrument should be hired, which is only to be used on patients with prion disease. These instruments can be hired from National Reference Centres.
- ! **QM:** All stages of the process must be recorded in writing (SOP) and compliance must be documented.
- ! Investments in personnel educated to high standards pay off in the long run, as well as investments in technical equipment (room interior, preparation machines) due to longer life span and far less repair costs for the endoscope and endoscope accessories.

### Three Handling Procedures

1. Automated treatment  
The pre-washed endoscope and additional instrumentation are placed in an instrument for cleaning and disinfecting endoscopes. This carries out automatically a hydrostatic test, cleaning, disinfection and drying.
  2. Semi-automated treatment  
The pre-washed endoscope and additional instrumentation are placed in a bath filled with solution. All the individually attached channels are flushed out with the solution via a pump for a defined length of time. The rest of the treatment is manual.
  3. Manual treatment  
The pre-washed endoscope and additional instrumentation are placed in a bath filled with solution. The procedure is carried out by hand.
- ☞ According to tests, the first procedure is clearly the best!
  - ☞ Even automated treatment requires first manual preparation, for example cleaning channels with brushes, since it is not possible to check that the channels have all been flushed out sufficiently, but there is a new development that excludes this problem.
- ! Whoever works with endoscopes, will prefer to work with instruments that have been prepared by the automated method.

## 6.2.2 Preparation Cycle for Endoscopy



## 6.2.3 Treatment of Flexible Endoscopes

### 1. Preparatory manual outer cleaning

Wipe the endoscope – still connected – with a lint-free cloth

### 2. Manual pre-flushing of channels

Wipe the distal end in cleaning solution, and flush out all channels several times

### *Disconnect*

*Take endoscope and accessories into a preparation room where there is no risk of environmental contamination (e.g. closed box with lid)*

### 3. Manual flushing out of channels

Soak in disinfectant solution and flush out all channels with disinfectant solution several times.

### 4. Manual brushing of channels

Brush all channels, taking care, that the brushes below the surface exit from the distal end, so that no contaminated aerosols are generated and inhaled. Brushes should always be cleaned immediately and disinfected at least once a day.

### 5. Hydrostatic test

A hydrostatic test, to prevent resulting damages in case of defective outer and inner surfaces. For hydrostatic tests in an endoscope cleaning machine, it should be ensured, that the program stops automatically if the test is not successful.

### 6. Cleaning

According to the manufacturers' instructions and using the solutions recommended (otherwise guarantee will be invalidated). Best results are achieved by using an alkaline cleaner, possibly with enzymes for intensifying effect (based on sufficient application time < 50°C).

### 7. Disinfection

Chemical or chemical thermal (only possible for automated treatment) using listed solutions (see literature). The base of the solution should be according to the manufacturers' information. Both inside and outside should be completely moistened (channels filled and free of blow holes). Observe application time.

### 8. Final rinse

Deionised water with low germ count, in machines via thermal water or water prepared by UV disinfection, sterile water filtered by hand or good quality sterile water.

### 9. Drying

Dry thoroughly inside and out, using an air supplying device for the channels.

### 10. Storage

The dry endoscope must be stored free of dust, and every kind of contamination should be prevented (disinfected hands and gloves!) If possible, store vertically (wall cupboards), and if this is not possible, in drawers. It should be guaranteed, that no water is left behind in any channels, as this would otherwise cause extreme contamination with germs.

## 6.3 Endoscope Accessories Treatment

For accessories, which penetrate or injure the mucous membranes, or accessories which come into close contact with injured mucous membranes, the treatment of sterile items (category 3B of instrument preparation) apply. This leads to additional treatment stages:

### Preparation

1. As soon as the accessories are removed from the endoscope, they should be given an initial clean.
2. Up until actual preparation, accessories should be stored so as to prevent dirt from drying up, by soaking in a solution. The parts should be completely submerged and filled with solution so that there are no bubbles.

### Treatment

1. For treatment, dismantle as far as possible.
2. To prepare the lumen of the endoscope accessory, it must be flushed out constantly. There are special instruments for this purpose. Otherwise, a solution must be injected using a syringe – a physical activity that should not be underestimated. (Tip: every doctor who works with endoscopes should try this at least once).
3. Ultrasound is good for loosening dirt, but usually only on the outside, and is no replacement for flushing out by hand. Exception: special ultrasonic basins connected to each lumen, so that ultrasonic energy is conducted into the lumen.
4. Cleaning and (chemical-) thermal disinfection, as far as possible in machines intended for cleaning / disinfection, always with individual connection to each lumen with the appropriate connector. Where possible, there should be automatic drying.

### After drying

1. Assemble
2. Function check
3. Sterile packaging
4. Labelling (Shelf-life after sterility)
5. Sterilisation
6. Storage like any other sterilisation items

Change the cleaning solution daily (the disinfectant solution according to the manufacturers' instructions), in case of visible contamination or when changing from anally to orally applied instruments.

## 7. Requirements for a Blood Collection System

### Conditions

#### 1. Treatment And Problem Awareness

Although blood collection and handling of needles has become daily routine, great care should always be taken. Only those aware of the problems, can avoid them. Training and familiarisation in blood collection, meaning the whole environment right up to disposal, is important.

#### 2. A Complete, Harmonious System

It is not the individual quality of each needle, syringe, blood collection tube and disposal box that ensure success and safety in blood collection. All components should complement each other; similar to individual building stones that are put together to form the entire concept. All needles and other sharp-edged objects must be disposed of immediately, and in between be stored where no risk is possible, right up to being transported to the rubbish disposal.

#### a. Hygienic Requirements For Point of Collection

- Sufficient free space
- Easy to disinfect materials
- In risk areas, low-germ air with air-gates (Lamina flow workbench, e.g. for mixed infusions in neonatology, or for preparing cytostatics for cancer chemotherapy – whereby there are often special GMP conditions to observe regarding manufacture of drugs)
- Large disposal box for immediate disposal of all possibly risky objects (needles, glass ampoules, transition systems, scalpels)
- Collection containers for recycling glass bottles 50ml – 2000ml)

#### b. Hygienic Requirements for Blood Collection System

- No blood leakage

- No danger of contaminating or polluting the sample during collection
- Easy handling – efficiency without wasting time
- Unbreakable during transport and processing in the laboratory
- Clean collection in the laboratory with no chance of contamination or danger to employees
- Immediate, quick and easy disposal

### c. Requirements for Collection Tray

- Sufficient space for all required utensils
- Firm position for sharps disposal box
- High rim
- Material easy to clean and disinfect

### d. Requirements for disposal box

- Sufficient size
- Non-penetrable
- Opening big enough for bulky needles (winged needles, mandrins, port needles)
- Opening for unthreading conventional needles
- Closure or safety system on opening so that needles do not fall out if box is tipped over
- Firm position - it should be possible to attach the box to the tray

### e. Requirements for Waste Transport

- Non-penetrable!!!
- Firm closure
- Does not break or open after a drop from 5 feet
- Labelling to indicate waste can cause injury, e.g. as “Sharps”
- Classification normally as hospital waste, and where there is particular infection risk (e.g. certain infectious diseases as well as sharps used in infection dialysis), this is hazardous waste, and there are special requirements for transport (e.g. European Guideline “Transport of Dangerous Goods”) and disposal.

If just one of these requirements is not fulfilled, then staff members are put at risk if use is continued, during transport into the laboratory as well as during disposal.



The **VACUETTE®** Blood Collection System, for example, is based on a coherent safety concept. All individual components are matched to each other perfectly.



With the VISIO PLUS Needle, bloodflow into the view window indicates that the the needle is in the correct position in the vein.



Safety Blood Collection Set:  
The winged needle is retracted into the safety shield by pulling back the safety mechanism.



**VACUETTE®**  
QUICKSHIELD Safety  
Tube Holder:

With this safety product for blood collection, the used needle is enclosed securely in the protective cap attached to the holder, with the aid of a solid support. An audible "Click" indicates to the user, that the protective mechanism has been activated.



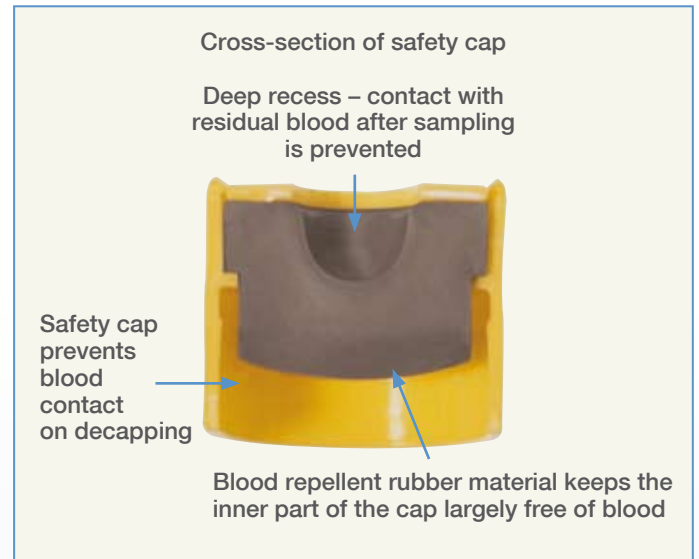
The  
**VACUETTE®** QUICKSHIELD  
is particularly suitable  
for daily blood collection  
routines.



**VACUETTE® TIPGUARD Safety Tube Holder:**

With this product, after blood collection, the two blue activation mechanisms are pressed in to retract the needle automatically into the holder due to spring mechanism. This function means that the contaminated needle is completely and securely encased in the plastic holder and can then be disposed of in a sharps disposal container.

**VACUETTE® PREMIUM Tube with Safety Twist Cap:**  
For safe and easy manual opening



Safety cap, as provided with the **VACUETTE®** Blood Collection Tube



Taking blood for a smear test from a "closed" **VACUETTE®** Blood Collection Tube



Hygienic, no-risk transfer of urine from a urine beaker into a urine centrifugation tube with conical base



Automatic opening of sample tubes demands the highest safety standards

This is a system, which fulfils all requirements optimally:



Safety blood collection systems, thanks to the vacuum, allow tubes to fill quickly and under pre-defined conditions, an important condition for the consistency of evaluations.

It is possible for samples to be taken from the tube for further processing by any number of persons, without blood leaking or the sample becoming contaminated.

## 8. Protective Gloves

### 1. Simple disposable gloves

Purpose

- Protect staff from patients' bacteria.
- Protect patients from receiving bacteria from others via hands of staff.
- Protect staff from contamination.
- Protect staff from aggressive chemicals.

Usually, these are only worn briefly and are disposed of after wearing. They are used in large amounts, are a mass product, and are available in cardboard boxes containing 50 or 100 pairs, in just a few different standard sizes.

- ➔ Check for holes and tears everytime when putting on a pair: micro lesions are rare but possible all the same.
- ➔ Wearing gloves does not mean that hygienic hand disinfection is not necessary! They should remain as free of bacteria and pathogens as possible. This is the case when manufactured, and this should remain the case when being removed from the packaging just prior to use.
- ➔ Do not carry a stock of gloves around in coat pocket!

**Warning: Beware of powdered latex gloves – risk of allergy!**

**Warning: Beware of single (thin) examination gloves – these let most chemicals through!**

### 2. Surgical gloves

Purpose

- Protect patients from bacterial invasion in a sterile area.
- Limited protection for staff.

They must be sterile.  
They must be packed in pairs.  
They must remain non-penetrable for longer periods.  
They must fit perfectly, and are therefore available in all glove sizes.

They cannot be cleaned and used again (the material changes during sterilisation). As a high-quality, sterile product, they are relatively expensive. Warning: Beware of powdered latex gloves – risk of allergy!

### 3. Double layer of operating gloves

Purpose

- Protect staff when the risk is higher (HIV, Hep.C).
- Protect patients from bacterial invasion in a sterile area.

In case of contact with a sharp object, or in order to prevent penetration of pathogens from diseases transmitted by blood, or if a glove is defect, two pairs of gloves worn over one another can be worn to reduce increased risk.

Important: the gloves must be made of different materials, so that the stretch zones of the material when expanded do not lie over one another. This reduces the risk of penetration through both pairs of gloves.

Useful: if the inner glove is in a darker colour, it is easier to see if fluid has penetrated the outer glove due to a defect.

### 4. Chemical gloves

Since most standard gloves for medical purposes can be easily penetrated or even dissolved by many chemicals, special gloves must be worn for handling chemicals. The technical safety consultants can advise on this.

## 9. Allergies and Intolerances

### 1. On disinfectants and cleaning materials

Hand disinfectants usually consist of a small amount (1 – 5) of disinfectant components and lots (to some extent > 50) of ingredients for lipid replenishing, colour, scent, viscosity, stability etc.

Procedure:

Dermatological control, if the allergy is genuine or if there is other damage to skin.

Test with the "raw material" 70% proof isopropyl alcohol.

Note: this is universally tolerated. There are no known allergies across the world. Should symptoms occur similar to an allergic reaction, then a psychosomatic irritation may be assumed, and other causes should be looked for, for example problems at work (e.g. mobbing). Important: This test dries out the skin completely, thus the application of a rich cream is essential. In order to avoid an allergic reaction to the rich cream, a skin cream should be used that has been well tolerated before.

If it is found out, that the allergy is just to an ingredient typical in the product, then as many different alternatives should be tested, each for one whole working week (samples can be obtained from the manufacturer). The person affected should keep a journal, inserting photos of damage to skin if possible (digital photos from cell phone sufficient).

## 2. On latex gloves and powder

***The most frequent allergy in the healthcare sector – up to 10% of employees!***

Latex is a natural product with very high allergisation potential. Mainly loose latex powder that comes into close contact with skin due to sweat or other liquids, can lead to allergisation after thousand-fold application. This effect is increased due to the corn starch as powder in combination with gamma sterilisation.

Powdered gloves are classified as dangerous goods and must be listed in the company dangerous goods index.

*Recommendation 1:* As prophylactic measure, gloves should be as powder-free as possible or latex-free. Allergic persons require latex **and** powder free gloves (expensive!).

*Recommendation 2:* Patients with a latex allergy may not come into contact with latex gloves. Allergy anamnesis prevents processes!

## III – Special Part

# 10. Bacteria

## 10.1. Coccus Bacteria, Gram-positive cocci

### General

Coccus Bacteria play a major and varied roll in humans; they are predominantly valued as being positive. For example: Staphylococcus epidermidis forms a layer on the skin with a pH value of 5.5. Without it, the skin would be chapped, rough and provide no protection against the environment. Individual cocci can be medically challenging due to their resistance; however, this can be controlled with current antibiotics. Nevertheless, to prevent complications, transfer of cocci to third persons must be prevented to break the chain of infection.

### 10.1.1 MRSA and cMRSA (caMRSA)

MRSA are staphylococcus aureus germs with methicillin (or oxacillin) resistance.

The preceding “c” or “ca” refers to the subcategory community-acquired MRSA. This form of MRSA presents very different characteristics, affects other patient groups and has a different disease progression.

Therefore, it must be considered separately – medically and hygienically.

### Measures with MRSA Patients

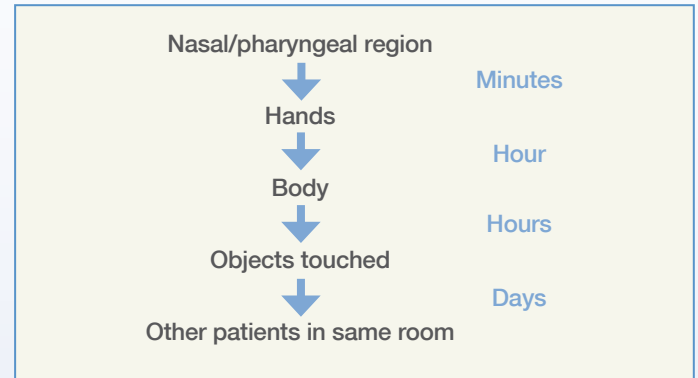
Patients colonised with MRSA, are handled very differently from country to country. USA, UK, Japan and South European Mediterranean neighbouring countries have such a high quota of patients colonised with MRSA (>20% although in some hospitals >50%), that measures to prevent colonisation are not possible. It is consciously accepted, that the carrier spreads the germ, which could then have serious consequences for those with a weak immune system – even fatal consequences.

In the Netherlands and the Scandinavian states, a concept of isolation is strictly adhered to. Every patient admitted to a ward is examined, and kept in isolation until the results are known. This time-consuming procedure means that there are hardly any MRSA patients, and virtually no cases of MRSA sepsis.

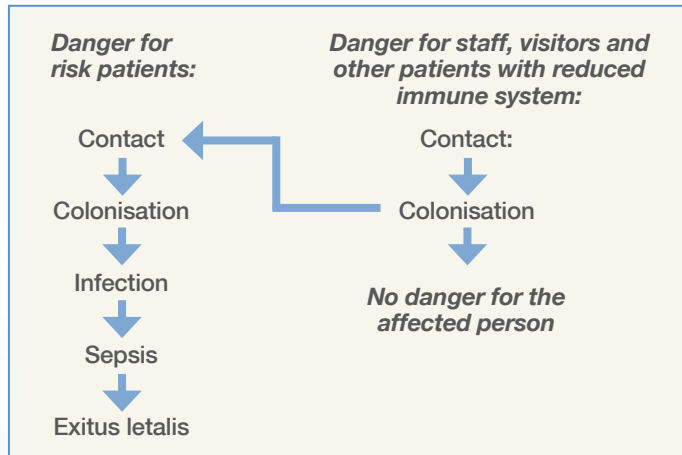
Many other states, e.g. Germany, Austria, Switzerland fall somewhere in between, and make the effort to keep the rate of MRSA incidents low, with the targeted examination of patients likely to contract MRSA. Those with a positive diagnosis are then selectively decontaminated. This concept is effective in keeping the MRSA sepsis and mortality low, but the contamination has been rising steadily for years.

### 1. Way of transmission

The bacterial increase of the multi resistant Staphylococcus aureus mainly occurs in the nasal / pharyngeal region, and can also occur in all damp biotopes on the body surface (sweaty regions, perineal region, damp base of wound).



## 2. Risk estimation



**No danger of becoming ill for staff and non-risk patients**, with intact immune system, as after contact, only colonisation without symptoms can occur.

Due to this, MRSA colonisation is often not noticed, which increases the risk of spreading further to risk patients.

All MRSA measures have the purpose of protecting risk patients. However, the measures should be applied on all those affected, even non-risk persons.

### Procedure with MRSA Patients in USA

The essential points:

- No isolation in health care institutes, including hospitals
- Targeted diagnostics on risk patients
- If antibiotics are given, then only the few effective ones for maximum treatment at high costs
- Acceptance of a small amount of systematic MRSA infections as complication of a serious disease, also of related increased lethality

### Procedure with MRSA Patients in Countries with Moderate Therapy Regime (Example Germany)

The essential points:

- All MRSA patients (even for "Only Colonisation") must be isolated in hospital. Several MRSA patients can be isolated together.
- Hygienic hand disinfection after every contact, even if gloves have been worn.
- Change white coat when entering room, and remove before leaving room. It is possible to re-use the coat several times over a period of a few hours.
- Wear face mask to prevent personal contamination.
- Wear disposable gloves prior to contact with contamination.
- Clearly mark isolation room / area and determine measures **for everybody!**
- Appliances and instruments should be used in a manner as patient oriented as possible, and always be left in the room.
- Reduce transport and transferrals to a minimum; if still necessary, give advance information.
- If possible, carry out minor surgery in room.
- If possible, avoid major surgery in the room; otherwise plan as septic operation and carry out at end of program.
- Patients' surroundings should be disinfected daily, remove used instruments directly after use from the isolation room.
- Collect waste from room daily and dispose of as category B waste.
- Collect laundry from room daily and dispose of as infectious laundry.  
Disinfect crockery in dishwasher (65°C).
- **Screening:**  
Not necessary as routine for patients or staff!  
**For patients** from **risk areas** or with a high **MRSA risk**: smears from nose, throat, perineal regions, possibly wounds  
**For staff**, if there has been an **accumulation** of **MRSA** in one area (≥3 identical MRSA): smears from nose, throat.

- ☞ **Disinfection** (on at least 3 days in a row):  
**Vestibules of the nose:** with antiseptic ointment (e.g. Mupirocin, Bacitracin, Octenidin).  
**Body including hair:** with decontaminating soap.  
**Surroundings:** (all objects in close proximity to the body, e.g. glasses, artificial replacements, personal hygiene items like toothbrush, contaminated objects like bed) are to be completely disinfected by wiping or replaced.
- ☞ **Disinfection control:**  
 3 days after the disinfection, smears should be taken from positions that previously came up positive. Repeat for 2 days in a row. If all results turn out negative, the isolation measures can be abandoned.
- ☞ Staff contaminated with MRSA may not have direct patient contact until disinfection has been effectively carried out and successfully controlled.
- ☞ Patient can be released, as soon as clinically possibly, even if there is still MRSA colonisation, but with advance information!
- ☞ Transport or transferral only with advance information and subsequent disinfection of trolley. Decontaminate patient as soon as possible (see disinfection). If nasal/pharyngeal region is colonised, the patient should wear face protection. Wounds should be covered with sterile material.
- ☞ Advance information to doctor, hospital or institute where treatment will be continued.

### Procedure with MRSA Patients in North European States

The essential points:

- ☞ Every patient is examined on admission via MRSA screening.
- ☞ The patient is isolated in a single room, or assigned to cohort ward until the results are available.
- ☞ If the result is negative, the isolation measure can be withdrawn.
- ☞ If the result is positive, the patient remains in isolation, with the aim of eradication and decontamination. The patient may only be removed from isolation after several controls have given a negative result. Otherwise, the isolation is maintained for the entire stay in hospital.

- ☞ As soon as there are 2 (!) MRSA patients on one ward, a weaknesses analysis is carried out as well as staff screening.
- ☞ If there are 3 (!) MRSA patients on one ward, the ward is closed.
- ☞ Close information network with healthcare outpatient clinics.

**As a result of this high expenditure, the MRSA incidence rate is extremely low.**

### c-MRSA or ca-MRSA for Community-acquired

Outside of health facilities, a new type of MRSA has developed, referred to as community-acquired or ca-MRSA / c-MRSA. Characteristics:

- ☞ Often occurs in younger patients and frequently teenagers.
- ☞ Local infectious recurrent boils or abscesses.
- ☞ Poor healing tendencies, particularly in difficult regressive diseases.
- ☞ High recidivism.
- ☞ Treatment via large surgical excision is often necessary.
- ☞ **Also acquired by verifiably absent hospital contact.**
- ☞ Often acquired through sporting activities involving sweat and bodily contact.
- ☞ Other resistance patterns, but by definition, Staph. aureus with Methicillin / Oxacillin resistance.

### 10.1.2 VRE = Vancomycin-resistant enterococcus

VRE are gram-positive coccus mainly located in the intestine, which, depending on the clinical characteristics, can occur in wounds, the lung or other sterile areas of the human body.

It is important to determine pathogen localization throughout the whole body to decide on specific protective measures which can be implemented to break the infection cycle.

Any transmission to a third person is to be prevented, particularly patients with decreased immunity, such as patients undergoing immunosuppressive therapy e.g. to prevent rejection in transplant patients, oncological cancer therapy. Premature babies and HIV patients are also at high risk.

## Hygienic Measures:

- Maintain strict basic hygiene
- Hygienic hand disinfection following EVERY contact
- Protection (Gown/Gloves...) when handling material containing pathogens
- Protect immunosuppressive fellow patients by transferring to another room

## 10.2. Highly Resistant Gram-Negative Rod Shaped Bacteria

### General

Hygienic significance of the bacteria group:

1. There are still no new antibiotics against gram-negative rod-shaped bacteria – at least 10 years away!
2. The resistance can be genetically determined within two different cell components:
  - Localised in the nucleus => chromosomal inheritance => transfer within species
  - Localised in the plasmid => plasmid inheritance => cross transfer between species

The plasmid resistance species can move between the total gram-negative bacteria group to pass on their gene sequence and form new resistance. E.g. Klebsiella bacteria can be transferred to Escherichia coli bacteria.

So far this phenomenon has not only been postulated theoretically and experimentally in the laboratory, but also been implemented by nature with ESBL and with Carbapenem resistance on NDM-1.

The spread of common resistance in previously unaffected bacteria travels quickly around the world with the aid of medical tourism. Question medical history and specifically in case of fresh operation scars, ask about operation location and if in doubt, use an internet search to assist with determining resistance risks.

### 10.2.1 ESBL = Extended Spectrum Beta-Lactamase

ESBL are gram-negative bacteria with plasmid resistance, which can render a wide spectrum of Beta-lactam antibiotics ineffective. It now affects all E. coli and Klebsiella as well as increasingly Pseudomonas.

*Hygienic Considerations:*

- Maintain strict basic hygiene
- Hygienic hand disinfection following EVERY contact
- Protection (Gown/Gloves...) for contact with contaminated material
- Protect immunosuppressive fellow patients by transferring to another room

*Antibiosis Considerations:*

- Resistant against penicillins, cephalosporin (generation 1 – 4), monobactams
- Beta-lactam antibiotics must be given together with a beta-lactamase inhibitor (clavulanic acid, sulbactam, tazobactam)
- For serious infections, carbapenem are the antibiotics of choice (excluding NDM-1)

### 10.2.2 Carbapenem Resistance - NDM-1

New Delhi metallo-beta-lactamase describes a new resistant bacteria that originated in India and is spreading – refer to previous chapter – Carbapenem resistance via plasmid encoding. Due to the therapeutic limitations of this bacterium, patients must be treated so that further distribution of this resistant bacterium is prevented.

*Hygienic Considerations:*

- Maintain strict basic hygiene
- Hygienic hand disinfection following EVERY contact
- Protection (Gown/Gloves...) for contact with contaminated material
- Strict isolation when suspected, no communal sanitation

*Antibiosis Considerations:*

Reserve antibiotics are still an effective second choice:

- Tigecycline
- Colistin

## 10.3. Clostridium Difficile Including Ribotype 027

Clostridium difficile is a gram-positive spore-forming bacteria located within the human intestine. It is frequently the cause of pseudomembranous Ulcerative Colitis following broad-spectrum antibiotics use.

The frequent almost ubiquitous occurrence in healthy intestinal flora plays no role as other bacteria grow around Clostridium difficile. However, following disruption of the normal intestinal flora, spores and uninhibited spore replication occurs resulting in the generation of the dynamic yet mainly toxic building bacteria (Toxins A and/or B).

The toxins cause the macroscopic separation of the pseudomembrane and the ileus through atony of the muscularis.

-> *Differential diagnostic importance:*

Clostridium difficile exists in many sub-groups/ribotypes, which differ in toxicology. In recent years, new ribotypes have developed with more aggressive toxins. As a result, mortality rates are well above 50%. The most prominent of this malignant subtype is ribotype 027, toxin type III, PFGE NAP 1, which forms toxin A, B or A + B.

-> *Hygienic importance:*

The spores are ubiquitous and are not killed by normal disinfectants! This also applies to most hand and skin disinfectants. The main active ingredient, alcohol, leads to preservation of the spores.

**Therefore, a two-part process for hand preparation is essential:**

- **30 second alcohol based hand disinfection to kill the dynamic bacteria**
- **Thorough washing of hands with plenty of running water to wash away the spores**

Furthermore:

- Convert to surface disinfectant that is effective against spores
- Consider transmission methods and initiate use of protective equipment (gown, gloves...)
- Be aware that the spores are persistent and can drift in the air for days

**Additionally** - with malignant subtype e.g. Ribotype 027:

- Strict isolation in single or cohort rooms and specific sanitary room/ward cover bed pans immediately following use, no bedside commodes in rooms
- Full face (nose and mouth) mask when dealing with faeces
- Always keep doors closed and locked if possible (prevent airborne spores)

-> *Laboratory diagnostic importance:*

The standard method for Clostridium detection provides no indication as to Ribotype 027 or other malignant subtypes. Here, close coordination with the clinician is necessary and sometimes life-saving: if the medical history is unfavourable or unexpected and there is no explanation for the clinical course of intestinal atony, a subtype of malignant MUST be considered more likely than Ribotype 027. The suspected diagnosis must come from a clinician, who suddenly forms a suspicion on the ward – they should then immediately request a hygienist!

The laboratory diagnostic limitations of non displayable ribotypes are currently handled by a number of routine PCR procedures. Although considerably more expensive, they assist the clinician in the diagnosis and can detect or rule out outbreaks. The diagnostic cost is quickly justified when evidence of a non-malignancy is present and the above mentioned special hygiene measures need not be implemented.

# 11 Viruses

Viruses are a challenge for hospital hygiene: They cannot be prevented with routine procedures. They can only be dealt with indirectly by logic: On the one hand, means of transfer are known and can be prevented, on the other hand, closely constrained surveillance through ward layout can detect viral diseases via comparison of possible nosocomial genesis.

## 11.1. Noro Viruses: The Explosive Intestinal Disease

- Viruses similar to Norwalk
- Norwalk like Viruses
- Norwalk viruses
- Noro viruses

A group of calici viruses with currently 15 sub-groups, was first isolated 30 years ago in Norwalk as a epidemic pathogen for gastro-enteritis infections.

The more frequently an epidemic could be led back to them, the shorter the name became.

- Occurs:**
- Worldwide
  - Most frequently in the winter months
  - For adults, 50% of all non-bacterial gastro-enterides
- Incubation:**
- 1 – 3 days
- Infectiousness:**
- > 2 days after the symptoms have subsided

- Ways of infection:**
- Faecal-oral
  - Aerogen in an acute stadium (!)**, when vomiting, presumedly when talking (casuistic evaluations in 2006).  
By contaminated food.  
By a smear infection, e.g. contaminated crockery.

**Contagiousness:** Extremely high, 10 – 100 virus particles are enough

**Effectiveness of disinfectants (resistance, remanance):**

- Low
- Many standard disinfectants (e.g. alcoholic hand disinfectants with <75% alcohol, surface disinfectants bases on Quats, do not achieve sufficient reduction of bacteria, others require 2 – 4 times application time (e.g. 120 seconds for hand disinfection)

- Current recommendation:
  - Peracetic acid, undiluted, 10 minutes
  - Quats 240 min. application time
  - Glutaraldehyde 1% 1 minute
  - Alcoholic hand disinfectant with high alcoholic content or in combination with biphenylol for 2 min. or according to manufacturers' instructions

The disinfectants market is currently open towards noro-viruses and will make changes depending on new test results. Always ask about the virus-effectiveness with specific reference to noro or rota viruses.

**Clinic:**

- Gastro-enteritis which begins highly acutely with extreme sickness, explosively occurring vomiting and diarrhoea (classic description: "I couldn't get to the toilet in time", pronounced feeling of illness with headache, aching muscles. Only slightly increased temperature.

**Course of illness:**

- For a patient of normal constitution, usually harmless, i.e. with no lasting damages

**Length of illness:**

- 1/2 – 3 days






**Therapy:**

- Symptomatic, substitution of fluids and electrolytes

**Diagnostics:**       Examination of stool with specific questioning

**Important!!**

**Due to the high contagiousness and the spreading via almost all ways of infection (including aërogen), and that infectiousness remains even after all symptoms have subsided, as well as the insufficient effectiveness of all standard disinfectants, all communal institutes are at particular risk. The bigger, the more pronounced.**

-  Measures must be taken immediately, in any case, the confirmation of diagnosis from the lab should not be awaited.
-  Significant for the diagnosis, is an anamnesis with “explosive begin”.
-  Isolation and protective measures should begin immediately, and be continued up to 48 hours after end of the illness.
-  Protective measures: protective gloves, face mask, care of lab coat and change of disinfectants.
-  Staff ill with gastro-enteritis should stay on sick leave until 2 days after the symptoms have ended.

## 11.2 Influenza – The Real Flu

**Influenza NEVER (!) confuse with >Common cold infection< or other winter illnesses**

Common colds are light winter colds with runny nose, cough, hoarseness, slightly elevated body temperature and are caused by thousands of different pathogens.

They last for about a week (Vernacular: >with the doctor 8 days, without, one week<) and cure themselves harmlessly.

Antibiotics are only able to help with bacterial pathogens, a vaccination is not available and due to the varying pathogens it is not possible to develop one.

### Real Flu = Seasonal Influenza

Influenza is caused by the influenza virus type A or B.

With type A, a further determination is haemagglutinin = Hx and neuraminidase factor = Ny, e.g. Influenza type A7H5N1 was widespread in 2006/2007 and was universally known as Bird Flu; In 2009/2010, H1N1 was discovered in Mexico and referred to as Swine Flu.

Influenza viruses are genetically extremely variable and can easily mutate between mammals and birds.

Seasonal Influenza is a serious illness with symptoms lasting for weeks. Symptoms include a temperature above 38.5°C, dry cough, severe headaches, severe migratory muscle and joint pain. These symptoms are usually followed by months of difficulty concentrating and a general feeling of weakness.

Influenza affects many older people and in combination with other illnesses and old age can lead to death.

### Annual Vaccinations

Seasonal Influenza occurs frequently in winter. The rampant strains are usually very predictable as they have spread from Asia where they were prevalent during the previous spring.



Each year, the WHO predicts the expected influenza strains, so that a suitable combination vaccine can be produced in time. This method is very reliable: In 9 out of 10 years, the pool contained vaccines against three influenza strains; 97 – 98% of all influenza strains that appeared in Europe were covered.

The antiserum usually consists of inactive viruses which following vaccination results in antibodies being produced. The vaccination for the Mexican group was developed within a short three month time. Following initial controversy due to the accelerated development the vaccination was well tolerated by the population.

The annual vaccine only needs to be administered once and has few side effects. It is recommended by the CDC for:

1. All people over 60 years
2. All patients with underlying illnesses which affect the immune system
3. All medical personnel
4. All people who are particularly susceptible to infection, including medical staff, teachers, bus drivers etc.

The vaccination should not be given to:

-  People with a protein allergy
-  People who have experienced a previous allergic reaction to an influenza vaccination

## Protective Measures

1. All medical personnel should be vaccinated against influenza to prevent medical services failing during the winter influenza peak.
2. Protection against known infections is simple: mouth and nose protection, additionally disposable gloves and long sleeve gowns for close contact care. When working with patients presenting a cold and fever, for example in an outpatient clinic, mouth and nose protections should be used as a precaution.
3. Hygienic hand disinfection - 30 second alcoholic hand sanitizer rubbed into the hands - effective protection against infection and transmission to third parties.
  - ☞ This is for any influenza type, regardless of the type.
  - ☞ This applies to any alcoholic hand sanitizer regardless of the brand, whether limited antiviral or antiviral.
  - ☞ Note: antiviral with limits is only suitable for an unchanged stable virus, influenza does not fall in this category.

## 11.3 Forms of Hepatitis and Relevant Hygiene

**Hepatitis A** is transmitted via contaminated food or water. The infection leaves no clinical signs and is often undetected, leading to lifelong immunity. In regions where there are higher environmental temperatures and poorer hygiene, almost 100% of the population is infected; otherwise, thanks to well established vaccinations, depending on vaccinations, is almost up to 100%.

**Hepatitis B** is transmitted haematogenously. Protection through vaccination is the best means of prevention. Previously, hepatitis B was the most common occupational disease in medical fields. Since vaccination and consistent serological testing of medical employees in the last 40 years, the incidence as an occupational disease has decreased to virtually zero. Even so-called non-responders (after 5 times no increase in antibodies) have relatively good protection and as a rule their risk of contracting Hepatitis B is slim at the most.

Today, hepatitis B is most often transmitted through unprotected sexual intercourse. The WHO has recommended since 2000, that young people worldwide are vaccinated before puberty. Adult re-vaccination is suggested in some countries, but is not the standard. In population groups with increased promiscuity, it is highly recommended.

**Hepatitis C** is transmitted via contaminated food or water. The infection leaves no clinical signs and is often undetected, leading to lifelong immunity. In regions where there are higher environmental temperatures and poorer hygiene, almost 100% of the population is infected; otherwise, thanks to well established vaccinations, depending on vaccinations, is almost up to 100%.

**The procedure for a needlestick injury is described in Chapter 2.4, with titer control in paragraph 4.c.**

**The best prophylactic protection is via the use of needles with integrated safety system.**

Daily use and practice with safety systems reduce the risk of injury from contaminated needles and infection by up to 99%!

**Hepatitis D** is an additional condition to hepatitis B. Timely vaccination against hepatitis B will not only impede an outbreak of hepatitis B, but also prevent the subviral satellite hepatitis D virus.

| Preventative Measures |   |
|-----------------------|---|
| Hepatitis A           | Vaccination   |
| Hepatitis B           | Vaccination   |
| Hepatitis C           | <b>Prophylaxis: Use of Safety Products</b><br><b>Post exposure: Titer control, in case of increased titer then interferon therapy</b> |
| Hepatitis D           | Vaccination against hepatitis B   |

## 11.4 HIV/AIDS

**HIV/AIDS** is a venereal disease with a huge social impact. It has led to protective measures against blood-borne transmissions in medical fields being given a huge boost: Since HIV, safety systems have been developed to prevent injuries from contaminated needles or sharps. In the meantime, these systems have been included in laws and safety laws with varying time delays. As a result, the transmission rates within medical fields have been significantly reduced. Infection rates for both HIV and hepatitis C - which is the more contagious of the two - have been minimized amongst medical personnel.

The procedure for a needlestick injury is described in detail in Chapter 2.4.

It is important to know the initial primary response:

1. Let it bleed
2. Disinfect the site
3. Start post-exposure prophylaxis drugs within 2 hours!

A delayed start of up to 48 hours will reduce the effectiveness from an initial 80% to almost zero. This emphasises the fact that post-exposure prophylaxis is not a substitute for unprotected sexual intercourse.

| Preventative Measures |   |
|-----------------------|---|
| HIV/AIDS              | <b>Prophylaxis: Use of Safety Products</b><br><b>Post exposure: Begin prophylaxis drug within 2 hours</b> |

## 11.5 Highly Contagious Life-Threatening Diseases

### 1. Viral haemorrhagic fever, e.g.:

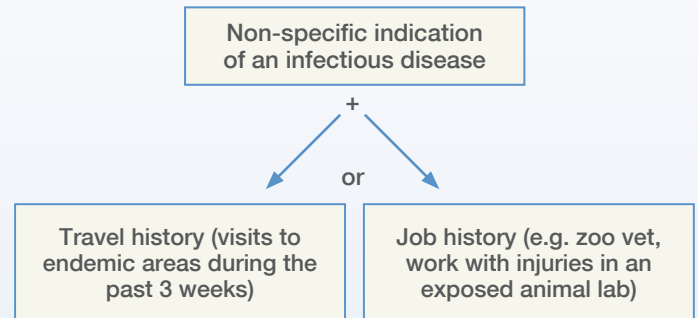
- ↳ Lassa fever
- ↳ Marburg fever
- ↳ Ebola fever
- ↳ Crimean Congo fever
- ↳ Rift Valley fever

### 2. Pneumonic plague

### 3. Pox viruses

In Western Europe, this life-threatening infectious disease occurs very rarely, but is highly contagious.

**Differential diagnostic:**

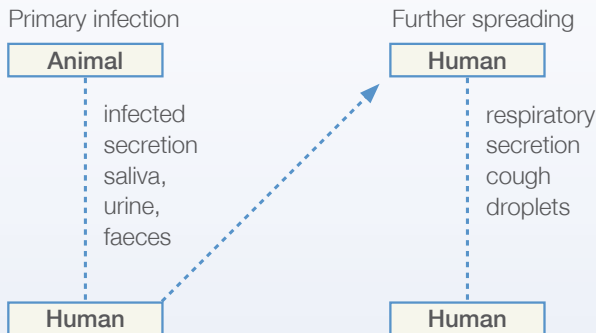


**Even if there is a mere suspicion in the differential diagnostic, crisis management is called for.** For this reason you must be prepared for this case. It is a good idea to have an emergency plan, even if it will probably never be needed.

Differentiate between 3 patient groups:

| 1. Manifest sufferer   | 2. Non-specific sufferer   | 3. Contact persons                                  |
|--|--|---|
| e.g. Infected in the tropics, return flight due to serious illness | Non-specific infectious indicator leading to hospital admission  | Primarily no signs of infection                     |
| Diagnosis (almost) definite  | Diagnosis suspicion after exclusion of flu, malaria, or similar, based on exposure followed up on in anamnesis | Diagnosis unlikely, but can occur after observation |

### Ways of transmission



**Due to high contagiousness and mortality, comprehensive protective measures are absolutely compulsory! Due to infectiousness, the problem can only be solved after the first clinical symptoms have occurred, and the transmission way has been narrowed down to droplets.**

### 1. Manifest sufferer is admitted

Anybody manifestly suffering from a highly contagious life-threatening disease is seriously ill and requires intensive medical care. If the diagnosis has already been made, and provided that there is transport available, the patient should be transferred if possible to a special isolation unit (see chapter 3.4). If transport is not possible, the patient must be admitted and treated. Every hospital should be prepared for this situation.

#### 1. Measures on admission:

- Patient must remain in transport vehicle until admission in intended isolation unit is possible
- Keep the number of contact persons to a minimum
- Record all contact persons with surnames, forenames, addresses and telephone numbers
- Shield from the public, onlookers prevent work and put themselves at danger! An onlooker who gets in the way of work must face legal proceedings! Make this well known!

#### 2. Call up a crisis board.

The crisis board should be made up of the following:

- Medical director
- Head physician of the medical clinic or department for infection
- Hygienist
- Microbiologist / lab manager
- Responsible nursing team leader
- Possibly responsible employee from logistics / transport
- Possible responsible employee for public information

#### 3. Inform the supervisory body by telephone

- All cases of haemorrhagic fever must be registered.
- The supervisory body / health authority must take measures, if the disease occurs frequently.

#### 4. Prepare intended isolation unit

- ☞ Ensure that access is limited
- ☞ Clear rooms of all objects apart from those required
- ☞ Switch off air conditioning and extractor fans!
- ☞ Close and block off drains in the floor and sinks / basins

**Warning: Contaminated liquids are not to get into wastewater!**

- ☞ Place collection containers for infectious waste in sufficient amounts ready

**Warning: Contaminated waste is not to be disposed of as normal hospital waste!**

#### 5. Protective clothing

- ☞ Liquid-repellent disposable protective suits with hood, CE category III type 4 (At a push, an operating overall + head protection “astronaut helmet” can be used until correct protective clothing is available)
- ☞ Protective goggles with side protection
- ☞ Face mask type FFP3 (with valve)
- ☞ Double gloves
- ☞ Liquid-proof disposable booties or rubber boots
- ☞ If working closely with a patient, or if there is a risk of cough secretion from patient getting to the mucous membranes of the employee, respirator masks can be borrowed from the fire brigade with protection covering whole head

#### 6. Admitting patient

- ☞ Adhere to protective measures during treatment
- ☞ Prepare for respiration in time
- ☞ Prepare for dialysis in time

#### 7. Verify diagnosis

- ☞ A special anamnesis sheet should be prepared containing the following:
  - Patient data, current location, abode
  - Responsible health authority

- Hospital where first admitted
- Travel history with exact times (if possible day and time!) spent in which countries and individual regions, type of accommodation and contact to sufferers, persons who have died in the meantime, animals, animal bites, insect bites
- Supposed location where infection contracted
- Current symptoms/results with day/hour of begin
- Previous treatment
- Vaccinations (must be checked in vaccination pass)
- Malaria prophylaxis
- For infection suspected in lab: name/address of laboratory, suspected course of infection

#### 8. Diagnostics by responsible laboratory

- ☞ Sample transport according to regulations for infectious samples at the highest risk classification
- ☞ Sample containers are to be conform to the packaging instruction P650 (according to ADR 2005) and suitable for safe transport of diagnostic/clinical samples (UN 3373). The system must consist of 3 parts: primary, secondary and outer (third) packaging. All components must be precisely labelled as biologically infectious substance and with address
- ☞ The transport route is to be clarified in advance
- ☞ Direct consultation with laboratory on sample, arrival and expected results

#### 9. Regulate public information

- ☞ In past experience, the press is usually informed earlier than expected
- ☞ Public information should be well coordinated. Press conferences given by the health authority have always worked well
- ☞ Information should be given to the public comprehensively and early enough, if the media is to be used for giving out details on contact persons. Otherwise, a press conference should be organised once a day
- ☞ Warning: Do not let yourself be put under pressure, and possibly end up giving contradictory statements or interviews. Bear in mind your medical obligation to confidentiality!

## 10. Closing procedures

- All rooms in which the patient has been treated must be steamed out with formaldehyde – this includes the transport vehicle.
- If the patient has died, the corpse must be cremated in a special body bag in a combustible coffin under medical supervision in a crematorium.
- Autopsies should only be carried out if absolutely necessary, and under special safety conditions.

## 2. Non-specific sufferer is admitted, diagnosis is made during stay on ward

Patient with non-specific signs of an infectious disease with no particular suspicion is admitted. Within the scope of a differential diagnosis, e.g. after excluding malaria, the suspicion is of a highly contagious life-threatening disease.

### Procedure:

- The on-duty head physician must be involved from the start.
- If the suspicion is substantiated, the above procedure from points 2-10 is to be followed.
- An additional 2 employees for recording all previous contact persons are to be taken on:  
The first employee finds out all hospital staff and patients who have had contact.  
The second employee finds out all visitors who have had contact (by questioning patients and appealing via local press/radio).

It is important to record day, time and intensity of the contact in order to be able to appraise the risk.

## 3. Contact persons

### Preliminary remarks

There is only a risk of infection, if the affected person (the “index patient”) is manifestly ill. I.e. with fever, chills, extreme headache etc. Contact prior to showing these symptoms is usually of no consequence.

All contact persons should check their temperature twice a day. If there is an increase > 38.5° C then there is a possibility of becoming ill.

An antibiotic exposure prophylaxis is only indicated after close contact and not for all cases of haemorrhagic fever.

## Classification of contact persons depending on risk

(according to Fock et.al.,2000 or “Competence Centre” Frankfurt/Main)

| Cat. | Exposure  |
|------|---|
| Ia   | <b>Contact person at high risk</b> <ul style="list-style-type: none"> <li>• Persons who have had direct mucous membrane contact or invasive skin contact with blood, other body fluids or tissues from patients (e.g. via needlestick injury, by invasive surgery, reanimation or autopsy)</li> </ul>   |
| Ib   | <b>Contact persons at increased risk</b> <ul style="list-style-type: none"> <li>• Persons who have had contact to blood, other body fluids or tissues from a patient to intact skin or as aerosol (e.g. nursing or medical staff, laboratory staff, cleaning personnel in pre-treatment zones, or staff from external examination labs if applicable)</li> <li>• Persons who have had contact to blood, excretion, tissues or animal corpses, which is proven to have been infected with viral haemorrhagic fever</li> </ul>  |
| II   | <b>Contact persons at moderate risk</b> <ul style="list-style-type: none"> <li>• Persons who have nursed the patients, or processed examination samples (e.g. members of family or persons living with patient, friends or neighbours, if applicable doctors consulted prior to hospital admission, hospital transport staff, hospital nursing staff, hospital doctors, cleaning personnel etc.)</li> <li>• Persons who have had indirect contact with the corpse of a patient dead due to haemorrhagic fever, or if this was the suspected cause of death</li> <li>• Persons who have had contact to an animal infected with viral haemorrhagic fever</li> <li>• Persons who have had longer exposure to the index patient, if the patient had already shown symptoms (e.g. on the next seat on a flight)</li> <li>• Persons who have had direct contact to clothing, bed linen or other objects which could have been contaminated with blood, urine or other body fluids of the patient</li> </ul> |
| III  | <b>Contact persons at low risk</b> <ul style="list-style-type: none"> <li>• Any other type of contact to the index patient (e.g. staying in the same room, use of the same public transport, general social contact)</li> <li>• Medical staff wearing provisional protective clothing</li> </ul>  |

# 12 Prions

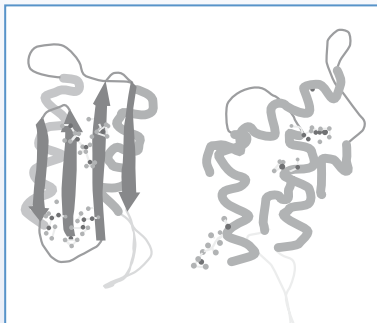
Prions are complex protein molecules whose protein tertiary structure have undergone spatial configuration changes and are therefore destructive to the central nervous system and nerve cells.

Protein molecules with identical primary and secondary structures and with the same atomic chain formation have no disease causing effect on mammalian brains. Only changes within the protein tertiary structure can:

1. Attach to a nerve cell
- > 2. Excite the adjacent protein molecules (to modify)
- > 3. Cause a chain reaction - ring-shaped clasp of the nerves cells
- > 4. Strangle and destroy nerve cells

Many dead nerve cells leave holes which under microscopic examination have the appearance of a sponge. Therefore, the term "spongiform" in the title (BSE = Bovine Spongiform Encephalopathy).

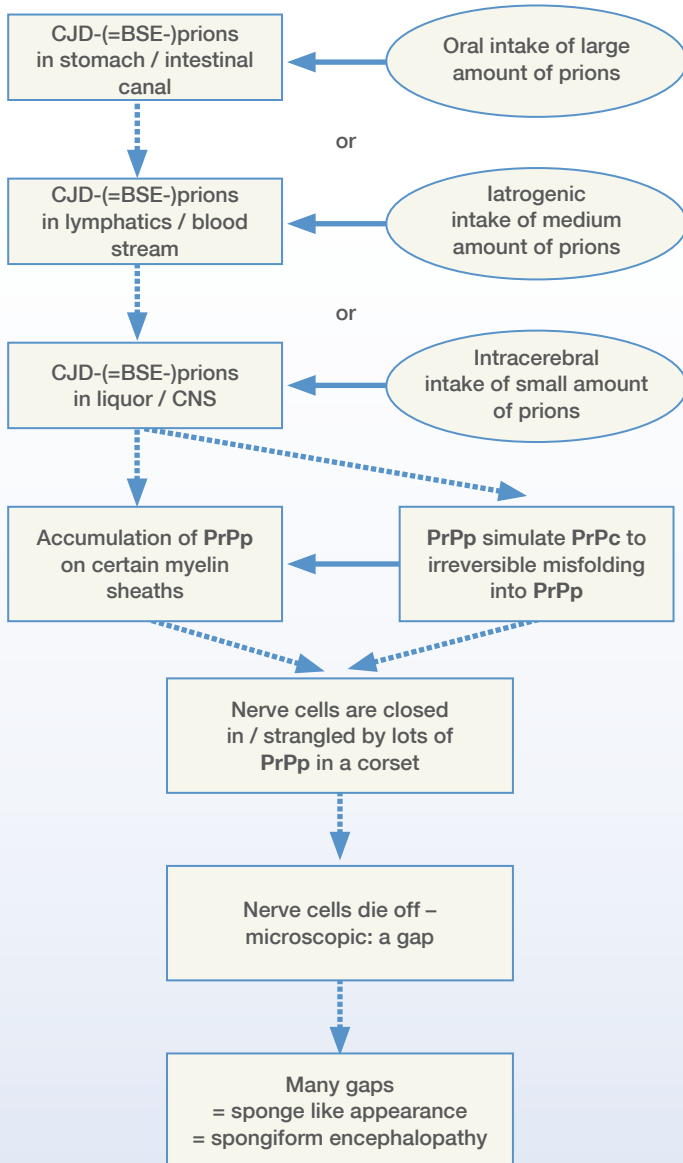
## 12.1 Human Prion Infections, BSE / vCJK



Drawing of a prion PrPp (left) and the matching endogenous protein PrPc without pathogenic characteristics (according to D. Ellison and S. Love)

| Prion Characteristics  |
|--|
| Prion (originally Proin/Proinp)<br>= Abbreviation for "Proteinaceous infectious particle"  |
| Prions contain neither DNA nor RNA, which is the difference to a virus   |
| Prions consist only of protein   |
| Prions consist of a protein which is very similar to the body's own protein: <ul style="list-style-type: none"> <li>• The primary structure is identical</li> <li>• The secondary/tertiary structure is only different in the spatial make-up</li> </ul> |
| Usual description in literature:<br>PrPp = prion = pathogenic protein foreign to body<br>PrPc = endogenic non-pathogenic (correct) protein   |
| PrPp – prion is described as "misfolded"<br>PrPc – endogenic protein is described as "correctly folded"  |
| PrPp – prion is very stable and cannot be broken down<br>→ there is no cure for prion diseases<br>(at the most, the advance of the disease can be slowed down)<br>PrPc – endogenic protein is slightly stable and broken down by proteinase-k            |
| PrPp – encourage the surrounding PrPc to misfold, in order to form new PrPp (=infection)   |
| Due to the similarity between PrPp and PrPc, antibodies are not formed => there is no antibody detection procedure   |

## CJD-Infection



## CJD-Infection

- Frequent and plentiful consumption of beef from BSE infected cattle. This risk is reduced due to the compulsory BSE test when slaughtering. However, the risk is not completely eliminated due to a big diagnostic gap. Detection is only successful in animals older than 30-36 months. However, contagiousness occurs soon after contracting the illness (the Committee for Biological Working Materials grades nerve tissue, eyes and tonsils from 12-month old cattle as risk material).

Incorporation in medical devices, e.g.:

- Dura mater
- Hypophyseal hormone
- Catgut from bovine intestines is forbidden since 2001

Intraoperative:

- Insufficiently prepared reusable instruments in experimental laboratory:
- Experimental use of in vivo detection of prions
- Experimental use of fundamental research

## Risk Analysis

Prion compatible preparation is so damaging to materials and time-consuming, that it cannot be applied as standard procedure.


## Risk Estimation of Patient

|             |   |
|-------------|---|
| High risk   | <ul style="list-style-type: none"> <li>• Patients with confirmation of CJD</li> <li>• Patients with clinical risk of CJD</li> <li>• Carriers of pathogenic mutations in prionprotein gene</li> </ul>  |
| Medium risk | <ul style="list-style-type: none"> <li>• Patients with inexplicable, advanced central nervous system illnesses, with or without dementia</li> <li>• Members of families, in which this type of illness frequently occurs</li> <li>• Recipients of human hypophyseal hormones (growth hormones, gonadotropin)</li> <li>• Recipients of dura mater between 1974 and 1987</li> </ul> |
| Low risk    | All others  |

## Risk Estimation of Body Organs

|                       |  |
|-----------------------|--|
| Highly infectious     | <ul style="list-style-type: none"> <li>• Brain</li> <li>• Spinal cord</li> <li>• Eye</li> </ul>  |
| Moderately infectious | <ul style="list-style-type: none"> <li>• Hypophysis, epiphysis (=pineal gland), Dura mater, liquor, peripheral nervous system</li> <li>• Spleen, tonsils, lymphatic nodes</li> <li>• Ileum, prox. and dist. colon</li> <li>• Suprarenal gland</li> <li>• Placenta</li> </ul> |
| Barely infectious     | <ul style="list-style-type: none"> <li>• Nasal mucosa</li> <li>• Bone marrow</li> <li>• Liver, pancreas, thymus</li> <li>• Lungs</li> </ul>  |

After taking these risks into consideration, this is the result:

|  |  |
|--|--|
| high risk<br> | <ul style="list-style-type: none"> <li>• Do not operate</li> <li>• Use single-use instruments</li> <li>• Prion compatible preparation of instruments (see following sections)</li> </ul> |
| low risk   | <ul style="list-style-type: none"> <li>• Normal preparation of instruments</li> </ul>  |

## Preparation of Instruments If Prion Contact Is Suspected

### Preliminary remark

In Great Britain, a great deal of experience has been gained regarding tonsillectomies. It turned out, that the use of disposable instruments was not worthwhile – for cost reasons, these instruments are lower quality, and lead to significantly higher risk. An increase in postoperative haemorrhaging has caused death in several cases. As a result of this, use of disposable instruments has been discontinued. The theoretical risk of transmitting prions via surgical instruments has been compared to the actual risk of higher complication rates. This day in age, throughout the world, more attention is paid to better cleaning procedures, which are modified to the specific characteristics of prions. The prion load is reduced by mechanical cleaning procedures; by using cleaning agents with a pH > 11, the prions cannot adhere to metal, and the prion inactivation is improved due to longer sterilisation times.

## The Author

After studying physics and medicine, Martin Thieves worked in several German hospitals in the urology and surgery departments, before specialising in Hospital Hygiene. He completed his training as hygiene and environmental medicine specialist at the Westphalian Wilhelm University in Münster.



He has been head of the department for hospital and environmental hygiene at the Darmstadt clinic since 1994, and nursing institutes. Furthermore, Dr. Thieves cooperates with expert panels and working parties on the future of medical hygiene.