partly covered or not addressed at all as part of the education or training, this knowledge has to be supplemented or updated through adequate training.

A specialist training is necessary if there is **no evidence of education or training** in a relevant medical profession - this could be based on the specialist training courses according to the qualification frameworks of the German Society for Sterile Supply or covered through training by associations of medical professions or public institutions.

Furthermore, public bodies and scientific societies, such as the German Society for Sterile Supply, provide information about the requirements regarding subject knowledge.

Annex 7 Measure for minimising the risk of a transmission of CJD/vCJD through medical devices

Applicable annex to the Recommendation from the Commission on Hospital Hygiene and Infection Protection at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene requirements for the reprocessing of medical devices".

Introduction

The sporadic Creutzfeldt-Jakob Disease (CJD) occurs at a prevalence rate of 1-2 cases per one million population per year, making it a rare disease in humans. Nevertheless, the transmission of CJD through contaminated medical devices has been reported in individual cases. Furthermore, the disease is usually fatal. The occurrence of a new, BSE-linked variant of CJD (vCJD) in humans also means that this topic has to be specifically addressed because the pathogens show a high tolerance against usual reprocessing procedures for medical devices [1-3].

Information about the epidemiological and pathogenetic background can be found in Beekes 2010 [1] and up-to-date data about the prevalence of CJD/vCJD can be accessed under www.rki.de> Infektionsschutz > Infektions- und Krankenhaushygiene > Themen von A-Z > CJK/vCJK (in German only).

CJD has a long incubation period which is not known for each individual case. Patients in the asymptomatic stage of a progressing CJD, i.e. who have continuously multiplying pathological prion proteins (PrP^{TSE}) [4] in their body while not yet showing any clinical symptoms can present a currently neither identifiable nor quantifiable risk for iatrogenic transmission of TSE pathogens. Another factor are cases where invasive surgery is being performed and where the disease pattern or the genetic or other risk (see 1.1) has not been recognised as such.

The aim of the measures described hereafter is to minimise the risk of human-to-human transmission for all forms of transmissible spongiform encephalopathies (TSEs), including the variant CJD (vCJD) through contaminated medical devices.

According to what has been established above, the measures can be divided into

1) measures in case of an identifiable (or presumed) risk (i.e. diagnosis of potential or clinically probable CJD/vCJD or a rapidly progressing dementia) (procedure I) or
2) measures in the case of no identifiable risk (procedure II).

(also see table I)

The risk of transmission through appropriately reprocessed medical devices which have been used on asymptomatic or unidentified carriers is currently not objectively quantifiable but considered low by all estimations [1] and generally depends on:

a) the prevalence of the illness in the general population and
b) the co-occurrence of

- a previous contamination of a medical device (intervention on pathogen-infected tissues of an asymptomatic or unidentified carrier of CJD/vCJD),
- the incomplete removal (decontamination) or inactivation of the CJD/vCJD pathogen through cleaning/disinfection and, if applicable, sterilisation of the instruments used during the intervention and
- the use of a medical device that is still contaminated (contagious) on the next patient, resulting in transmission, whereby the probability of an infection not only depends on the residual pathogen load on the medical device but also on the susceptibility of the tissue into which the TSE pathogens are being inserted.

Main parameters of the risk analysis and risk evaluation also include knowledge of

- the pathogen load of different tissues [5],
- the effectiveness of different decontamination and inactivation procedures (also see table 2)

and

- the initial protein burden on the used surgical or endoscopic instruments (see table 3).

The deduction of risk minimisation measures is also based on these considerations.

For risk management purposes, it is essential to identify

a) people at risk (risk groups 1.1) and
b) high-risk interventions (high-risk surgery 1.2).

1.1 Risk groups

People at risk of CJD/vCJD can be divided into the following risk groups:

risk groups (I-V):

I. Patients suffering from vCJD or suspected to suffer from the disease (possible or clinically probable vCJD).

II*. Patients suffering from CJD or suspected to suffer from the disease (possible or clinically probable CJD).

III. Relatives of a CJD patient (in risk group II or who has died of CJD) (unless a genetic form of the disease has been ruled out for the relatives concerned).

IV. Recipients of (non-recombinant) human growth hormone and cornea or dura mater transplants.

V. Patient with a rapidly progressing disease of the central nervous system of unknown origin, with or without dementia and without concrete suspicion of CJD.

VI. Any other person

(* This includes sporadic, genetic and iatrogenic CJD as well as other human forms of TSE such as Gerstmann-Sträussler-Scheinker syndrome and sporadic fatal/fatal familial insomnia).

1.2 High-risk tissues or high-risk surgery

Due to the distribution pattern of the pathological prion protein in the human system, interventions have to be classified into the following high-risk interventions [5]):

high-risk interventions (a-e; differentiated by the pathogen load of the affected tissue and the presence of CJD or vCJD):

a) Neurosurgery involving the central nervous system (brain, spinal cord, optic nerve) as well as interventions involving the dorsal root or trigeminal ganglia, inner ear, pituitary gland or the olfactory region of the nasal mucosa;

b) Eye surgery (posterior segment of the eye: retina and optic nerve); (as well as cornea transplants and surgery using cornea transplants[1])

c) other surgical interventions contact to high-risk tissue (ENT, olfactory epithelium)

d) lumbar puncture for taking samples of cerebrospinal fluid (usually irrelevant as disposable products are generally used)

e) in the case of vCJD: also surgery on lymphatic tissues, such as for example tonsillectomy, splenectomy, appendectomy, surgery of the terminal ileum, lymphadenectomy, lymph gland biopsy, bone marrow surgery (for example in orthopaedic or trauma surgery).
Blood is only to be considered a specified risk material in cases of vCJD.

1.3 Risk management

► *Before each invasive procedure, the patient should be checked for signs of possible or clinically probable CJD/vCJD in order to be able to take specific preventive measures if necessary. These measures become necessary if the pathogen load on the medical devices to be used exceeds the cleaning/decontamination/inactivation performance of the routine reprocessing procedures in place. This should be particularly kept in mind for neuro- and eye surgery as well as ENT- or oral surgery (see 1.2) because of the pathogen distribution in the body.*

► A *case is considered as suspected CJD if the patient shows symptoms of a neurological multi-systemic disease that is quickly progressing. A recent history of cortical visual impairment can for example be a concrete reason for suspicion. Ophthalmological symptoms are the most common neurological initial manifestations of CJD [6]!*

Typical scenario:
a) At the onset, the patient is suddenly no longer able to read the newspaper; in this case, signs of cortical visual impairment should be checked: Pictures appear no longer to be square/rectangular, tile joints in bathroom/kitchen do not seem straight, colours changed,

[1] It is not the cadaveric-donor cornea which presents a risk but the cross-contamination of the cornea from retinal tissue when extracting the graft.

distances cannot be gauged anymore (mostly men report that they can suddenly no longer drive a car).

b) An initially mild dementia rapidly worsens, so that within days/the previous month the patient's forgetfulness considerably worsens or he or she has additionally developed disorientation, apraxia, lessened ability to speak or ataxia.

In the case of patients with clinically suspected CJD/vCJD, it might prove useful to delay the intervention/endoscopy by approx. 5 days to allow a more precise risk assessment. If the patient's neurological condition has noticeably worsened within a short period of time and without any other apparent cause this is suggestive of CJD.

► *Every physician involved - that is to say both the referring physician as well as the physician carrying out the intervention - is obliged to verify with each patient whether the current clinical picture is suggestive of suspected human TSE. For elective interventions on patients with suspected CJD, a neurologist should be consulted before the examination and the execution of the intervention planned accordingly. If a consultation is not possible beforehand due to the urgency of the examination, it should be carried out under the conditions of procedure I (identifiable risk, see below). If necessary, the medical devices (for example endoscope) can be stored/quarantined after the examination until the suspicion of CJD has been confirmed/ruled out (see 1.3.2.1).*

1.3.1 Procedure in case of no identifiable risk (procedure II), general measures for the reprocessing of medical devices to avoid the transmission of pathological prion protein (best practice)

► For interventions on high-risk tissues (see 1.2 a) -d)) **single-use medical devices** should be used, if possible. This includes

- *scalpels,*
- *biopsy needles and cannulae, medical devices for spinal anaesthesia and nerve conduction blocks,*
- *bone drills and bone screws that might be exposed to the central nervous system or cerebrospinal fluid.*

► ***Reprocessable medical devices** fall into thermostable and thermolabile medical devices (for example flexible endoscopes).*

General measures for avoiding a transmission of pathological prion proteins through medical devices will be described hereafter. Specific aspects of the reprocessing of flexible endoscopes will be discussed further below. The reprocessing recommendations for

thermostable surgical instruments also apply to rigid endoscopes which can be steam-sterilised.

► *The reprocessing of medical devices should always be undertaken in compliance with the common recommendation of the Commission for Hospital Hygiene and Infectious Disease Prevention and the Federal Institute for Drugs and Medical Devices "Hygiene Requirements for Reprocessing Medical Devices" in the latest applicable version and combine at least two procedures which are also (at least partially) suitable for the decontamination or inactivation of prions (see table 2 [7]).*

These procedures include for example:

- pre-cleaning and cleaning
- appropriate (chemo-thermal, if applicable) disinfection
- sterilisation with proven effectiveness against prions (also see table 2 and the ANSM list (*www.ansm.sante.fr*)).

1.3.1.1 Pre-cleaning and cleaning

► *Appropriate measures have to be taken to prevent excessive drying of residual tissue and blood on the inner and outer surfaces of medical devices. This can for example be achieved by optimising the disposal times and by avoiding influences that lead to protein fixation (for example the presence of high temperatures or certain disinfectants) as well as through pre-cleaning of the medical devices immediately after use on the patient.*

► *The cleaning performance proven in each case (also see the specifications concerning the validation of cleaning and disinfecting procedures) is decisive when assessing the suitability of a cleaning process (also see table 3).*

► *Based on current knowledge, reprocessing in an alkaline environment is preferable in terms of cleaning performance (the proven cleaning performance is always decisive). The capacity of a detergent to inactivate prions is most likely with pH-values > 10 and a soaking time of more than 10 minutes under elevated, but not protein-fixing temperatures (for example55 °C). However, claims that a product can inactivate prions must be evidence-based (see for example list of the ANSM [7,8]).*

► *Generally, no problems are to be expected when using alkaline cleaning processes on medical devices made of stainless steel. In the case of medical devices containing other materials, information on the material compatibility of the detergent should be obtained from the manufacturer and an appropriate procedure with a high cleaning performance chosen.*

► *In the case of eye surgeries, complications at the patient's eye (for example ocular burns) due to alkaline detergent residues must be excluded. Therefore, a standardised and appropriate pre-rinsing with suitable water between uses is of major importance when reprocessing medical devices used in ophthalmology. When washing and disinfecting ophthalmologic devices in a washer-disinfector, a suitable programme should be used to ensure the success of the rinsing process and to prevent potential ocular burns of the patient's eye due to alkaline detergent residues . The removal of alkalinity has to be proven in the course of the process validation.*

1.3.1.2 (Chemo-thermal) disinfection

► *It is recalled that chemical (for example aldehydes, alcohols, peracetic acid) or thermal processes during the reprocessing in the washer-disinfector (for example thermal disinfection, drying) can affect the anti-prion effectiveness of the following process steps (for example sterilisation). Pre-cleaning and cleaning ahead of potential chemical or thermal protein fixation is therefore of utmost importance. This is another reason why the use of appropriate detergents constitutes an advantage.*

1.3.1.3 Sterilisation

a) Steam sterilisation

► *Steam sterilisation at a temperature of 134 °C with a hold time of at least 5 minutes is recommended for sterilisation, as long as a pre-treatment (pre-cleaning, cleaning, disinfection) has been carried out as described above [9].*

► *Medical devices which cannot be reliably or safely reprocessed (for example because of the danger of ocular burns when performing surgery on the eye) in a washer-disinfector using a cleaning stage with an at least partially prion-inactivating or prion-decontaminating effect and which are intended to come into contact with high-risk (prion) tissue (for example high-risk surgery a,b,c) can, if possible, undergo a different standardised and documented cleaning procedure, followed by steam sterilisation at 134 °C with a hold time of 18 minutes. If this is not possible either, a suitable reprocessing procedure has to be developed and laid down in detail or , if necessary, reprocessing be dispensed with [6].*

b) Alternative reprocessing procedures for thermolabile medical devices

► *The development of more and more complex medical devices for invasive procedures using different materials requires the development of new reprocessing procedures (particularly in the sectors of ophthalmology, ENT, dental, oral and maxillo-facial surgery as well as surgery on the central nervous system and the spine). Over the last years, various partially prion-decontaminating reprocessing procedures have been developed (see for example the ANSM list [10-17]). Certain H_2O_2-based sterilisation procedures for example can - at least partially - inactivate the TSE infectivity on those outer and inner surfaces of medical devices which can be reached by the sterilising agent [10-17]. The effectiveness of this procedure depends, inter alia, on the pre-treatment of the medical devices, the type and nature of the potentially contaminated surfaces, the concentration of H_2O_2 on the surfaces to be treated as well as on the type of load (partial load/full load). Before application, it has to be verified if reliable data are available, according to which the effectiveness of the procedure has been successfully tested under real-life or comparable conditions (goods to be sterilised, bioburden, pre-treatment, sterilising parameters relevant to the effectiveness) (see for example ANSM list, [10-17]).*

1.3.2 Procedure in case of an identifiable risk (procedure I) (prion-specific safety measures)

► *If the suspicion of a possible or clinically probable CJD/vCJD (see 1.3) has been raised **prior** to an invasive procedure of if a procedure (including endoscopic interventions) has to be performed on a patient with suspected possible or clinically probable CJD/vCJD, the indication should be carefully reassessed and a risk-mitigating approach identified accordingly. If the indication for a surgery persists, the following measures might be taken:*

► *Prion precautions have to be taken for the following combinations of risk groups and high-risk interventions:*

- *For risk group I (suspected vCJD, see 1.1) the measures listed below are required for all invasive procedures (see 1.2).*

- *For risk group II (suspected CJD, see 1.1) and III - V, the measures listed below are required for high-risk procedures a-d (see 1.2 procedures on the central nervous system, eye, olofactory epitheum, cerebrospinal fluid).*

The following prion precautions are advisable in this context:

► *Whenever possible and justifiable under surgical considerations, **disposables** should be used for invasive surgery on patients with definite, clinically probable or possible (v)CJD. These are to be discarded and incinerated after use in line with EWC code 18 01 03.*

► *If the use of disposables is not possible, the surgery should be planned in advance to enable identification, after careful consideration, of the medical devices that can be safely reprocessed after use. All other medical devices must be discarded and incinerated after use in line with EWC code 18 01 03.*

► *The medical devices that can be safely reprocessed thanks to their design and material characteristics (for example thermostable medical devices "critical A"), have to undergo **appropriate pre-cleaning** observing occupational health and safety regulations (see1.3.1.1). According to WHO guidelines, NaOH, NaOCl and guanidinium thiocyanate can be considered for initial prion decontamination. For practical reasons, the pre-cleaning has to be done in a suitable basin, which has to be suitably disinfected or discarded after use. The instruments used for pre-cleaning (for example brushes) have to be discarded and incinerated in line with EWC code 18 01 03.*

► ***After pre-cleaning** and rinsing in water, the instruments are separately and mechanically cleaned in a validated, prion-effective cleaning process and, if necessary, disinfected in a suitable, non-fixating, chemo-thermal disinfection process. Thermal drying should not be carried out since it might*

affect the following sterilisation process. Afterwards, the washer disinfector should run on an empty cycle.

► *Alternatively (for example in the case of unclear neurological diagnosis, for example risk groups III-V), the medical device can be stored under suitable conditions after separate pre-cleaning and rinsing until the diagnosis has been established. If* ***CJD/vCJD has been ruled out****, a common reprocessing procedure (procedure II) can take place.*

► *In cases of* ***suspected vCJD****, all invasive medical devices (critical medical devices and semi-critical instruments contaminated with tissue (for example biopsy channel)) are to be regarded as potentially contaminated with* Prp^{TSE}*. If these medical devices are not discarded, they can be stored until the diagnosis has been established (see table 1).*

1.3.2.1 Storage of medical devices

► *The storage of medical devices until the confirmation or exclusion of the diagnosis should be carefully planned and centralised (for example in the central sterile services department (CSSD)). The suspected diagnosis has to be documented on a form (accompanying certificate for medical devices) by the physician in charge. One copy has to accompany the stored instruments, a second copy has to be filed in the patient record and a third copy should be sent to the hospital hygienist/the person in charge of hygiene. The dry instruments are put onto mesh trays in an alkali-resistant container (for example V4A steel, DIN material number: 1.4401) with a tightly closing lid or a suitable disposable container which can be steam sterilised. To this end, the container has to be permanently and clearly labelled (for example: medical device with suspected prion contamination, do not use).*

The following rules apply when storing devices:

- *Disposables should be screened out beforehand and put in a safe container for incineration as waste (EWC code 18 01 03.),*
- *gross debris has to be removed from the medical devices that might be reprocessed later on, strictly observing occupational health and safety regulations (also see suitable pre-cleaning),*
- *avoid injuries at all costs,*
- *do not overload containers and sieves,*
- *sort instruments and place with open joints or hinges,*
- *make sure containers are securely closed (for example sealed on both sides) and*
- *confirm the handing over of the container to the CSSD/the reprocessor*

on the accompanying certificate.

► *Pending the establishment of the diagnosis (CJD/vCJD confirmed, inconclusive or safely ruled out), the instrumentation has to remain at a designated location under the responsibility of a designated person. The diagnosis has to be communicated in writing by the physician in charge and has to be documented on the accompanying certificate. Because of the complexity of the problem to be solved, it is recommended to inform the responsible hospital hygienist about the process. In the case of a confirmed or definitely inconclusive diagnosis (CJD/vCJD), the semi-critical or critical medical devices used (see "Hygiene Requirements for the Reprocessing Medical Devices") are safely discarded through incineration (EWC 18 01 03) (or reprocessed using prion precautions (if justifiable in the context of CJD).*

► *If CJD/vCJD has been safely ruled out, the instruments can be reprocessed as usual in accordance with the "Hygiene Requirements for the Reprocessing Medical Devices" (also see annex Hygiene Requirements for Reprocessing Flexible Endoscopes and Additional Endoscopic Instrumentation).*

1.4 Use of flexible endoscopes in relation to CJD/vCJD

a) Procedure in case of no identifiable risk (procedure II)

Flexible endoscopes are frequently used in modern medicine, for example when a PEG is placed. Precisely patients for whom this procedure is indicated also include some who suffer from dementia. If careful history-taking (see 1.3) cannot clarify the issue further, it has to be ensured nevertheless that patients who are examined afterwards are not exposed to any risk and that no other medical devices are cross-contaminated as a result of (invasive) medical devices being used on those patients. This is the purpose of the Recommendations to the "Hygiene Requirements for Reprocessing Flexible Endoscopes and Additional Endoscopic Instrumentation".

Some important aspects have to be reiterated here:

► *In the interest of traceability, a documentation of the endoscope used should be done for every patient.*

► *The pre-cleaning is an essential step in the reprocessing of medical devices and of flexible endoscopes, in particular. Inappropriate pre-cleaning or brushing of the channels in a cleaning solution which is used for several endoscopes without replacing it, can pose the risk of cross-contamination of other medical devices. From this point of view, the following procedure is always recommended after the completion of endoscopy:*

► *Immediately after the end of the examination, the instrument channel as well as all other channels of the instrument have to be thoroughly flushed with water and the inserted part of the endoscope has to be cleaned with a disposable cloth from the outside in order to wipe off gross debris.*

► *Without allowing the debris to dry, the device has to be placed in an immersion tray/a basin for pre-cleaning with a suitable and effective detergent and the channels need to be thoroughly flushed whilst paying attention to staff protection (see table 2; 1.3.1.1). Cleaning brushes used (flexible brushes, hand brushes and toothbrushes) have to be cleaned in an ultrasonic bath and subsequently disinfected after each use. After cleaning and disinfecting, the brushes have to be stored in a dry place that is safe from contamination at the end of each working day. The cleaning solution is contaminated with organic matter and chemical residues and a new solution has to be prepared at least each new working day while paying attention to occupational health and safety. In the case of visible debris or contamination by faecal matter on an endoscope, the cleaning solution must be changed immediately. The cleaning basin must undergo thorough mechanical cleaning and disinfection at the end of each working day.*

► *The pre-cleaning tray should also undergo wipe cleaning with an appropriate detergent.*

► *After a thorough pre-cleaning, the endoscope is further reprocessed according to the general recommendations for the reprocessing of flexible endoscopes.*

A current risk assessment by a commission of experts from the United Kingdom (UK) concludes that endoscopes used in the upper or lower gastrointestinal tract presented only a low risk of relevant contamination with pathological prion proteins, as long as they were not used invasively (for example as long as no biopsies were being performed) or used on patients with vCJD. Endoscopes used in ENT or in neurosurgery (high-risk surgery a, b, c and e) are assumed to have a higher potential pathogen load (MDA DB 2002(05) with Annex A1 and F) [18, 19].

A risk-adjusted use of flexible endoscopes will therefore be based on the following considerations:

b) Patients with confirmed CJD/vCJD and patients with suspected or an elevated risk of CJD/vCJD (risk groups I-V), (procedure in case of an identifiable risk, procedure I)

► *Flexible endoscopes in neurosurgery, oral surgery and otorhinolaryngology*

- *For neurological-neurosurgical interventions as well as ENT or oral interventions with possible exposure to the olfactory epithelium, flexible endoscopes should not be used on patients with CJD/vCJD or suspected CJD/vCJD if medically acceptable. If it has to be used, it should be withdrawn from circulation after use (see 1.3.2.1). Further steps have to be assessed individually for each case.*

► *Flexible endoscopes in gastroenterology, pulmonology, intensive care and urology*

- *Endoscopes which are have been used in areas other than otorhinolaryngology, oral or neurosurgery on patients with suspected CJD/vCJD should be withdrawn from circulation (quarantined) until further notice (see 1.3.2.1) after having been pre-cleaned (see 1.3.1.1). The decision whether or not they can be reprocessed will be made at a later stage.*
- *The endoscope or the endoscope channel might be contaminated when extracting biopsies or during other invasive procedures (for example through lymphatic tissue when performing polypectomy in the terminal ileum).*
- *If the suspicion of CJD persists, reprocessing should not be undertaken.*
- *In case of suspected CJD (risk group II), endoscopes may be reprocessed after endoscopic procedures in the fields of gastroenterology, pulmonology, intensive care and urology if extra care is taken and if the additional precautions listed above concerning additional instrumentation and cleaning brushes are observed.*
- *Aldehyde disinfectants with fixating properties (such as glutaraldehyde or OPA) can stabilise and fixate prions. Disinfectants with fixating properties should not be used when reprocessing flexible endoscopes that have been used on patients with suspected CJD.*

► *Additional Endoscopic Instrumentation*

- *Brushes that have been used to clean the endoscope channels should be discarded after use and disposed of (EWC code 18 01 03)*
- *When undertaking a biopsy, disposable biopsy forceps have to be used which have to be discarded and disposed of after use (EWC code 18 01 03).*
- *After a biopsy, the biopsy port cap must be discarded and disposed of before reprocessing the endoscope (EWC code 18 01 03).*

1.5 Staff protection

Concerning staff protection, explicit reference is made to the Technical Regulation for Biological Agents, TRBA 250 and the Committee for Biological Agents (ABAS) decision 603.

In order to render this recommendation more practicable, some measures are only briefly mentioned, such as wearing a liquid tight apron or coat, an appropriate protection of the mucosa from splashes (for example a mouth and nose cover/safety goggles) and double layer gloves as well as using liquid tight surgical drapes when performing invasive procedures.

In the daily (basic) care of patients with (v)CJD, no special measures that go beyond standard hygiene are necessary, unless they are required because of other (different) diagnoses. The precautions put in place against HIV, hepatitis B and C can be considered effective.

1.5.1 Measures after unprotected exposure to pathogenic material

According to ABAS decision No 603:
In the event of cuts or needlesticks involving exposure to pathogenic material, free bleeding should be encouraged, the wound region rinsed under running water and the treated wound region treated with 1M NaOH (if necessary with a mull or cotton pad soaked in the solution in order to protect uncontaminated areas of skin) for 5-10 minutes. Afterwards, the area should be thoroughly rinsed under running water for a second time.
In case of skin contamination (no visible wounds), the respective area has to be thoroughly rinsed under cold water first,
then treated with 1M NaOH as described above and then again thoroughly rinsed with water.
Mechanical irritation of bruised or contaminated areas of skin (for example scrubbing with a brush)
should be avoided.
Solutions for wound treatment have to be stored separately and replaced every three months (stability of NaOH).
A physician might be consulted for further treatment after the emergency measures have been taken. In case of invasive contamination, mucosal contamination (i.e. eyes) or peroral contamination with materials which contain human TSE agents, the decision of whether an immunosuppressive therapy or other measures could be advisable as further prophylactic steps
has to be made after a comprehensive consultation with an experienced physician and a careful risk-benefit
assessment.
PLEASE NOTE: NaOH solutions should be kept in closed containers.

1.6 Disposal of waste that has been contaminated with pathogenic tissue (see 1.2)

This waste has to be collected and incinerated according to EWC code 18 01 03.

All other waste resulting from caring for patients with CJD/vCJD has to be collected and disposed of according to EWC code 18 01 04.

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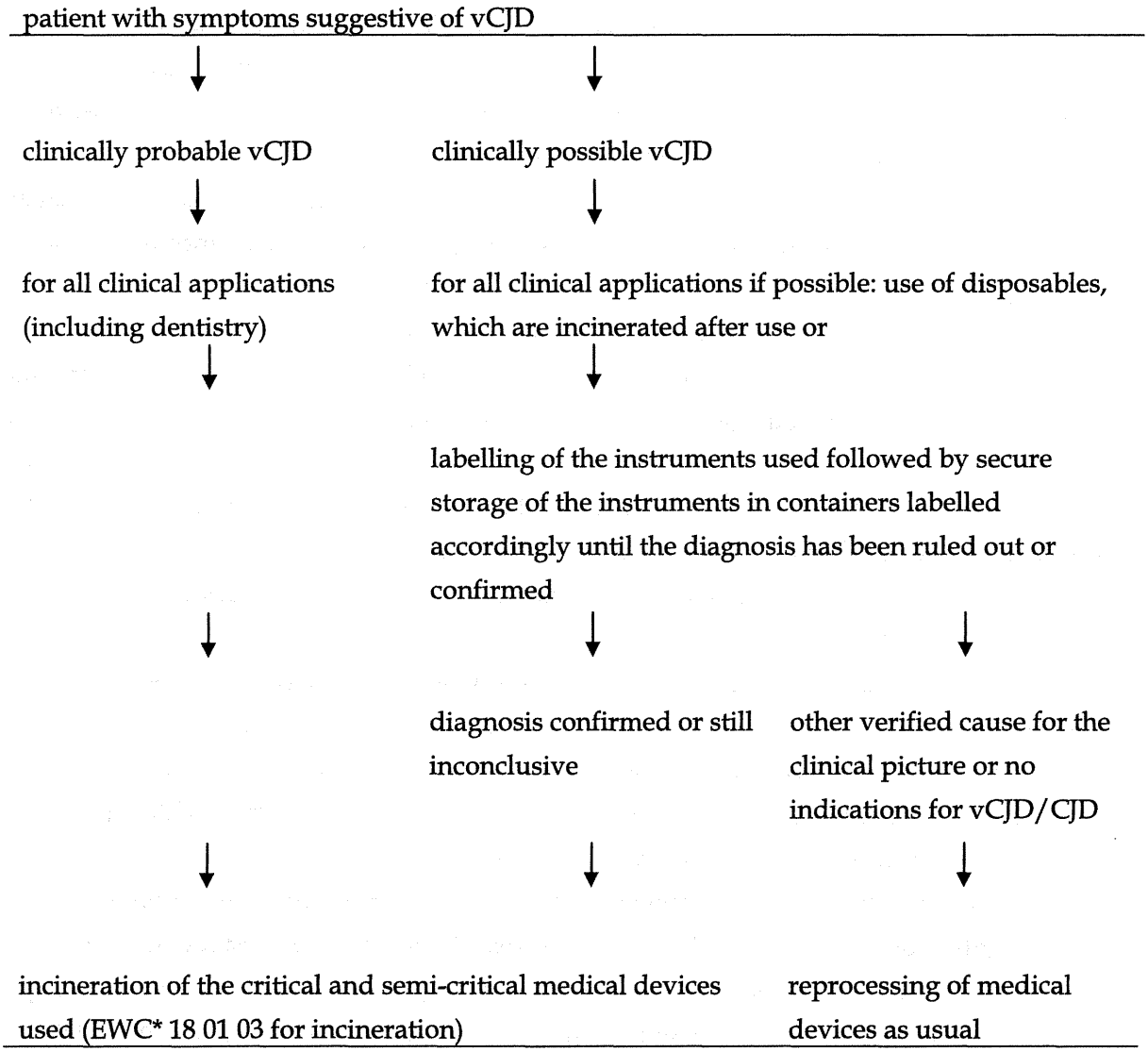
Table 1

Recommendation for the handling of medical devices used in elective surgery on patients with clinically probable or possible vCJD in accordance with the generally accepted criteria for differential diagnosis of CJD, vCJD, Alzheimer's and depression with cortical visual impairment, peripheral dysaesthesias or myoclonic seizures



* Waste code according to the European Waste Catalogue

Table 2

Effectiveness of different procedures to decontaminate instruments or inactivate prions when reprocessing medical devices

At least partially effective procedures/agents	**ineffective or fixating procedures/agents**
- carefully validated (particularly alkaline) cleaning* (see also 1.3.1.1) - 1 M NaOH* (40 g / l minimum 1 h at 20 °C) - 2.5 - 5 % NaOCl* (minimum 1 h at 20 °C; minimum 20 000 ppm chlorine content) - ≥ 4 M GITC* (minimum 30 min at 20 °C) - steam sterilisation (minimum 5 min at 134°C) - H_2O_2 (certain procedures, see also 1.3.1.3)	- alcohol - aldehydes, formaldehyde gas - ethylene oxide gas - iodophors - HCl - dry heat - UV radiation - ionising radiation - peracetic acid

* It is recalled that the devices must be thoroughly rinsed in order to remove harmful residues.

Table 3

Important parameters and assumptions, as used for risk assessment [20]

parameter	**comment**		**(CJD) central nervous system/eye**	**(vCJD) tonsils**
		ID_{50}	**ID_{50}**	**ID_{50}**
average initial load of organic material on an instrument	10 mg	10^{7}	10^{6}	
decontamination (cleaning/disinfection)	decimating factor (or remaining infectivity)		(100 to 10 µg)	
	first cleaning	$10^{-2 \text{ bis } -3}$		
	further cleaning cycles	$10^{0 \text{ bis } -2}$	10^{5} to 10^{4}	10^{4} to 10^{3}
inactivation (sterilisation)	decimating factor (or remaining infectivity)			
	first-time sterilisation	$10^{-3 \text{bis } -6}$	0 to 10^{2}	0 to 10^{1}
	further sterilisation	$10^{0 \text{ bis } -3}$		
percentage of material transmitted during a single procedure	time-dependent? if applicable completely in the case of implants	$10^{0 \text{ bis } -1}$	0 to 10^{2}	0 to 10^{1}
average number used during an intervention	on average for all surgeries	20	0 to 10^{3}	0 to 10^{2}
	tonsillectomies	12		

According to these theoretical considerations, a protein load of < 100 µg / instrument after cleaning and an inactivation performance of at least 10^{-4} ID_{50} for sterilisation should be aimed for.