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Importance of cleaning for reprocessing endoscopes and thermolabile sterile medical devices: French use and regulations

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Summary In France, endoscope maintenance regulations present some particularities in terms of the definitions and texts referring to the disinfection and sterilization of medical devices, with respect to the prion risk. The main measures specified are a double cleaning prior to disinfection, with some stipulations concerning the procedure itself, such as time limits, duration and rinsing. The use of aldehydes in cleaning products is prohibited and it is recommended that peracetic acid, or any chlorinated product, be used at the disinfection phase. For machines, the recycling of detergents or disinfectants is prohibited, and traceability procedures are mandatory. The French Agency for Safety of Health Products (AFSSAPS) is committed to providing standards that prevent any undesirable consequences for the patient, the operator or the equipment. All these measures will be described in a 'user's guide' intended for medical care units, to be released by the National Technical Committee on Nosocomial Infections (CTIN).

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Introduction

According to French regulations, disinfection should be carried out and applied to flexible endoscopes as well as to all sterile medical devices, which need to be reused and cannot undergo heat processing. A somewhat different nomenclature from that of other countries is used to designate those procedures: thus, the term 'liquid cold sterilant' is never used to designate those procedures or products. Two situations are considered:

Those where the medical device is introduced into the vascular system or any body cavity or sterile tissue, regardless of the route of entry. It

should be demonstrated that it is impossible to use a normal sterilization method, and the alternative processing used is then called 'high-level disinfection' (e.g. coelioscopes, arthroscopes, choledochoscopes). Such high-level disinfection is always completed by a sterile water rinse using injection-grade water as per the European Pharmacopoeia.

Those where the medical device is in contact with the mucosa or superficially-injured skin. In France, disinfection in this case is said to be 'simple' and can be carried out by soaking in a non-sporicidal disinfectant liquid or in a machine (e.g. for gastroscopes, colonoscopes, bronchial fiberscopes). The final rinse may be done simply

using microbiologically-controlled water, within the limits described.

Regulation

In either case, the desired result, i.e. post-processing non-infectivity, is strongly related to the quality and performance of the cleaning procedures applied prior to the disinfection step *per se*. However, the cleaning procedures, as evaluated by the detergent effect, are extremely difficult to validate. Moreover, French official requirements have evolved too rapidly in recent years in consideration of the 'prion' risk, which was added to the precautions already taken to reduce the risk of dissemination of conventional identified agents, such as those linked to the risk of hepatitis. Initially, in 1995, the French health authorities published a regulation¹ taking into account the particular epidemiological situation created by the use of extracted growth hormone, and the identification of classical CJD, the incidence of which was higher in France than in neighbouring European countries. In 2001, following identification of the nv-CJD transmission risk via lymphoid tissue, more restrictive regulations² endeavoured to consider any patient as liable to transmit the infectious agent. The reason for this is that it was not possible to determine for any given person, whether or not the particular precautions needed to be taken since the entire population had been exposed to the same food-related risk. The overlapping of the forms of

CJD identified led one therefore, to consider four different types of patient (Table I).

Specifically regarding the reprocessing of flexible endoscopes, a new regulation will replace the current reference document.³ The studies carried out by the National Technical Committee on Nosocomial Infection describe the hand processing methods together with joint protocols using accessory workbench equipment (pumps, equipped vats), and the automated methods using a washing and disinfecting machine either at some stage of the processing or for the whole cycle. The French Agency for Safety of Health Products (AFSSAPS) is in charge of the survey of chemical products recommended by the CTIN.

General principle applying to the imposed procedures

No chemical product used for the processing of endoscopes is capable of inactivating in any validated manner, the infectiousness in connection with prions. Furthermore, aldehydes have been shown^{4,5} to be protein-sticking agents. Their use can lead to increased risks linked to biofilm.^{6,7} In view of this, it was decided that reinforced cleaning would be routinely required,⁷⁻⁹ usually in addition to the former procedure, and that a policy encouraging use of peracetic acid or chloride-based products instead of glutaraldehyde at the disinfection phase should be put in place. The latter has not yet quite undergone implementation in

Table I Patient type according to CJD and nv-CJD transmission risk

Patient	Type	Characteristics	Number/year (number)
(A)	Presenting no special characteristics	Any patient likely to transmit nv-CJD via lymphoid materials, the central nervous system or the eye, due to exposure of the general population to contaminated food	All the French population
(B)	At risk	Any patient presenting individual risk factors: history of extracted growth hormone therapy, or with a genetic case of CJD in the family. Past neurosurgery is no longer included	1200
(C)	Suspected patients	Occurrence of at least one clinically apparent neurological sign of recent onset and progressively evolving, when all other causes have been eliminated	950
(D)	Affected	Suspected case confirmed by neuropathological tests	80

France, since a complete AFSSAPS study of the formulations available on the market is still under-way. Thus, only the cleaning and pre-processing phases now well-defined will be described below.

Recommended protocols

Hand processing methods

The current use of the varying cleaning procedures according to the type of patient and the investigation concerned, are described in Table II.

In all cases, the treatment of the device is carried out as promptly as possible, as soon as it has been used, so as to avoid the drying off of organic soils. This is a paramount requirement for the effectiveness of any further treatment. Thus, as soon as the endoscopy is terminated, following the wiping and aspiration of all irrigation channels, the device must be immersed in an aldehyde-free detergent solution. The necessary dismantling and cleaning are then carried out, and the swab as well as the detergent solution used are obligatorily for single-use and must be discarded afterwards.

The overall duration of the primary cleaning procedure should not be less than 10 min. This is a formal requirement.

As regards endoscopes used in the alimentary tract, no accompanying biopsy forceps may be reutilized, so these must be solely single-use.

The cleaning procedure must be repeated using fresh reagents. The total duration of the second cleaning should not be less than 5 min. This is a second formal requirement for the soaking time. An intermediate rinse between each cleaning, as well as another prior to disinfection are mandatory. This measure is essential owing to the use of peracetic acid, which is incompatible with nearly all alkaline detergents.

The regulations also include indications concerning repeat processing consecutive to a period of non-use, specifications concerning carrying conditions within services (on-site processing), traceability, training of staff and requirements in terms of premises.

Procedure for the use of endoscope-washing machines

These machines will shortly be described in accordance with pr EN-ISO 15883-1 and pr EN-ISO 15883-4 specifications. They are exclusively adapted for the processing of heat-sensitive endoscopes, exclusive of any heat-resistant parts thereof, which must be sterilized in another way. The specifications to be met may further indicate special procedures pertaining to each country, as is already the case for France where specific regulations have been implemented since 1998.⁹ This should be shortly completed by the AFSSAPS. The principle retained for the national recommendations is to try and ensure the same safety of use as that provided by manual processing when automated devices are used. The overall efficacy of these machines is not doubted, however, manual processing remains the reference treatment. The contamination of channels and filters by pathogenic agents, both conventional and prions constitutes the main function failure to be feared. The specification already takes into account a certain number of precautions and validations to avoid the recirculation of microorganisms, although the French authorities have decided to introduce some supplementary features. These measures concern:

Recirculating the disinfectant in a machine from one cycle to another. This is prohibited as recirculation of water (flushing water, rinsing water, detergent);

A double cleaning must be performed as in the case of manual processing. If the machine is not

Table II Hand processing of heat-sensitive endoscopes according to type of patients and investigational procedures

Patients at no particular risk (A)	Patients at risk (B)	Suspected patients (C)	Affected patients (D)
Soaking	Soaking	Soaking	Destruction by incineration
Cleaning I (10 min)	Cleaning I (10 min)	Cleaning	
Rinse	Rinse	Rinse	
Cleaning II (5 min)	Cleaning II (5 min)	Sequestration awaiting diagnosis	
Disinfection	Prion inactivation (minimum 0.5% chlorinated water—15 min)	Procedure (A) if final diagnosis is negative	
	Disinfection (preferably with paracetic acid)	Procedure (D) if final diagnosis is positive	

designed for this type of performance, machine-processing of the endoscope must be preceded by a primary hand cleaning step (soaking, first cleaning, first rinse);

The same mandatory intermediate rinsing procedures as those applying to manual processing are applicable;

In case the endoscope is used in a CJD or nv-CJD suspected patient, manual processing is mandatory, followed by sequestration while awaiting diagnosis; if the suspicion of the diagnosis arose after disinfection of an endoscope carried out in a machine, the machine should be treated by a special cycle with 2% sodium hypochlorite at 20 °C. This prion-specific procedure must be carried out in addition to the standard auto-disinfection cycles;

Manual processing is necessary prior to any lending out of equipment or dispatching for after-sales service.

Discussion and conclusion

All the procedures described relative to the cleaning and disinfection of flexible endoscopes, especially those applying in France, have been developed primarily in response to the threat from increasing CJD and nv-CJD. The difficulty encountered in identifying the suspected patients, as well as the impossibility of totally avoiding contact with lymphoid materials, particularly during endoscopy of the alimentary tract or during bronchoscopy, have led the authorities to extend the so-called 'double cleaning' procedure to all types of investigations and subjects. This measure can be criticized because of its cost, and its actual efficacy is hard to assess. It involves an important increase in the time taken by reprocessing, which might reduce the range of endoscopic applications. In fact, at the end of 2002 and the beginning of 2003, the number of identified nv-CJD cases greatly declined, and markedly so in Great Britain. No new cases have been reported in France where there were five cases in 1996-2002. Although the

above measures are still in force, as the requirements for proper cleaning, they will soon be replaced by stronger incentives toward non-use of glutaraldehyde where peracetic-acid compatible devices are concerned. This will have the beneficial effect of reintroducing former procedures and certainly of improving their efficacy, including with respect to conventional infectious agents. This has concurrently led the manufacturers of detergent agents as well as research laboratories, to carry out scientific studies on detergent activity and soil removal,^{1,3} which in the long-run will prove useful in the necessary development of endoscopic investigations toward the prevention and treatment of many diseases.

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