Reprocessing of medical devices (MD) in Germany with analysis of reprocessing quality in 170 German Central Sterilization Service Centers and in 18 dermatological medical practices

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Structure of my presentation

1. Status of reprocessing within the infection control measures
2. Published results on contamination of reprocessed MDs and caused infections
3. Historical development of Central Sterilization Service Centers (CSSCs) and present status in Germany
4. International status of reprocessing of single-use MDs
5. Basic principles of the RKI / BfArM Guideline for reprocessing in Germany
6. Analysis of reprocessing - a representative sample
7. Conclusion

Ethical requirement of reprocessing of medical devices

Reprocessing of surgical instruments is a major element of the quality management to ensure patient safety. A nosocomial infection may have a legal consequence for the responsible sterilization personal.

Study groups of the 2nd Global Patient Safety Challenge (WHO 2006)

- **Surgical site infection prevention**
  - **antibiotic prophylaxis within the hour prior to incision**
  - **effective sterilization of instruments**
- **Safe anaesthesia**
- **Safe surgical teams**

  Teamwork is the core of an effectively functioning system.
- **Measurement of surgical services**

  Efforts to reduce maternal and neonatal mortality during childbirth have been reliant on routine **surveillance** of mortality rates and systems of obstetric care to monitor successes and failures. Similar surveillance has generally not been undertaken for surgical care.

Position of reprocessing within the multibarrier strategy for prevention of SSI

Time point of intervention	Realisation in Germany
Pre-, perioperatively	
Reprocessing of medical devices	standard (eE)
short preoperative hospital stay	standard (eE)
MRSA screening	growing importance (eE)
Timely PAP	standard (eE)
clipping or no shaving	standard (eE)
surgical hand disinfection	standard (RA)
skin protection	neglected (RA)
skin antisepsis	standard (eE), but most effective technique is unclear
microbial impermeable OP drape	standard (eE)
OP-gloves / double gloving	growing importance (RA)
skin sealant	growing importance (eE)
antiseptic incision foil	not widely spread (RA + eE)
renouncement of bowel cleaning	growing importance (eE)

eE = epidemiological evidence RA = risk assessment

Position of reprocessing within the multibarrier strategy for prevention of SSI

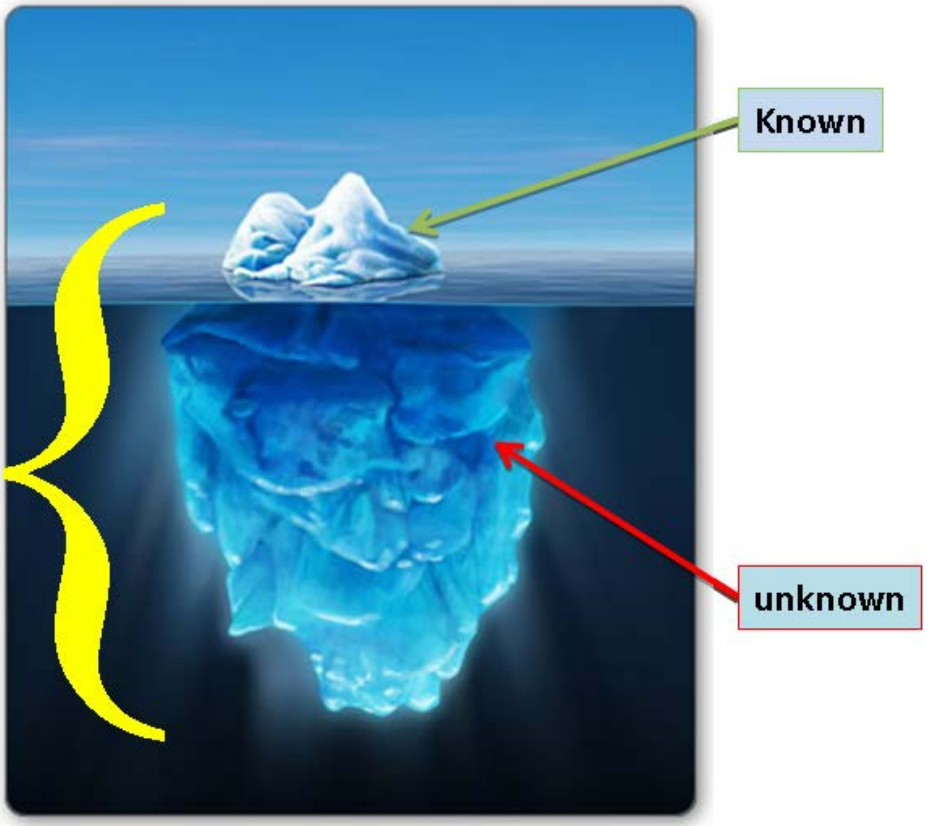
Time point of intervention	Realisation in Germany
Intraoperatively	
normothermia	growing importance (eE)
antiseptic sutures	growing importance (eE)
surgical gloves / intraop. standardised changing	introduction (RA)
laminar airflow with storage of MDs inside the airflow	standard: benefit only for implant. of hip+knee (RA + eE)
sterile package until implantation	growing importance (RA)
Postoperatively	
aseptic wound treatment	standard (RA)
restricted usage of drains	growing importance (eE)
surveillance	standard (eE)
Framework	
QM of hygiene	standard (eE)
adaequat number of personal	growing importance (eE)
introduction of bundles	growing importance (eE)
evaluation of hygiene by patients	growing importance (RA)

eE = epidemiological evidence RA = risk assessment

Published lacks of reprocessing

are generally not published because of possibly legal consequences

Infection resp. contamination



Sterility after reprocessing

Steam sterilization

- **57 endoscopic instruments (products from Germany, Japan, U.S.)**

42 non-sterile

- **25 reusable biopsy forceps**

20 < 100 cfu / instrument,
7 of them were contaminated with streptococci, enterococci or *P. aeruginosa*

EO sterilization

10 disposable biopsy forceps (sterilized with EO)

9 up to 50 cfu / instrument

Roth et al. ZentrSteril 1999;7(2):84-96

Risk of infection associated with endoscopy

- In the period of 1966-1992, 281 infections caused by gastroscopes and 96 infections caused by bronchoscopes were documented

  Spach DH, Silverstein FE, Stamm WE. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. Ann Intern Med 1993: 118(2) 117-28.

- Transfers are described for *M. tuberculosis* and HCV

  Bryce EA, Walker M, Bevan C, et al. Contamination of bronchoscopes with Mycobacterium Can J Infect Control 1993: 8(2) 35-6.

  Bronowicki JP, Venard V, Botte C, et al. Patient to patient transmission of hepatitis C virus during colonoscopy. New Engl J Med 1997; 337: 237 –40.

- Risk of transmission of *H. pylori* is about 1 %

  Langenberg W, Rauws EAJ, OudbierJH et al. Patient-to-patient transmission of Campylobacter pylori infection by fiberoptic gastroduodenoscopy and biopsy. J Inf Dis 1990; 161: 507-11.

- A review for the period of 1966-2004 revealed 140 outbreaks of infectious transfers under endoscopic examinations

  Seoane-Vazquez E, Rodriguez-Monguio R, Visaria J, Carlson A. Endoscopy-related infections and toxic reactions: an international comparison. Endoscopy 2007; 39: 742 – 6.

- Infection during endotracheal intubation for one-lung ventilation with identical strain, the detergent tank was contaminated, the washing machine had been remodeled – thereafter no contamination

  Shimono N, Takuma T, Tsuchimochi N, et al. An outbreak of Pseudomonas aeruginosa infections following thoracic surgeries occurring via the contamination of bronchoscopes and an automatic endoscope reprocessor.
  J Infect Chemother 2008; 14(6): 418-23.

Contamination of flexible endoscopes before and after reprocessing

- Samples from internal channels of endoscopes were collected after patient examination and again after cleaning/disinfection procedures
- after patient examination → contamination >3 log10 by gram-negative bacilli (n = 142, 56%), gram-positive cocci (n = 43, 17%), yeast cells (n = 43, 17%), and gram-positive bacilli (n = 26, 10%)
- after cleaning and disinfection procedures → 72 out of 149 samples were positively (48.3%) gram-negative bacilli (n = 55, 61%), gram-positive cocci (n = 21, 23%), gram-positive bacilli (n = 8, 9%) and yeast cells (n = 6, 7%). *Pseudomonas aeruginosa, Klebsiella pneumoniae, Escherichia coli, Enterobacter spp, Serratia marcescens, Proteus mirabilis, Citrobacter freundii, Staphylococcus aureus, Staphylococcus coagulase negative, Micrococcus luteus, Candida albicans, C. tropicalis, C. glabrata, C. guilliermondii, Bacillus spp and Corynebacterium spp* were predominantly identified.
- Esophagogastroduodenoscopes and colonoscopes were the most frequently contaminated devices.
- Inappropriate cleaning and low times of disinfection were the major factors associated with the contamination.

Machado AP et al. Microbiologic profile of flexible endoscope disinfection in two Brazilian hospitals. Arq Gastroenterol 2006; 43(4): 255-8

Contamination of the air/water channels of gastrointestinal endoscopes

- **Contamination was detected in 71.8% (28/39) of the samples of colonoscopes, and in 70% (42/60) of gastroscopes.**
- **The median microbial load was 1.800 CFU/mL in the colonoscopes and 750 CFU/mL in the gastroscopes.**
- **The main microorganisms isolated were *P. aeruginosa* (26.4%), *E. coli* (18.9%), and *A. baumannii* (9.4%); from the colonoscopes *P. aeruginosa* (46.4%), *A. baumannii* (14.3%), and *K. pneumoniae* (10.7%), among others.**
- **The possible causes of the contamination included the failure to fill these channels with cleansing solution, lack of friction during cleaning, and inadequate rinsing.**

Ribeiro MM, de Oliveira AC. Analysis of the air/water channels of gastrointestinal endoscopies as a risk factor for the transmission of microorganisms among patients. Am J Infect Control 2012.

Contamination of the Endowasher

- 24 endowashers were sampled. Sterile rinse-water was pumped through the endowasher and tested microbiologically.
- Sampling was performed in 18 hospitals, including 2 university teaching hospitals in Northern Germany.
- Of 44 samples, 6 (14%) were contaminated with pathogens of up to >20.000 cfu/ml. *P. aeruginosa* and other Gram-negative non-fermenters such as *Stenotrophomonas spp.* (18x) and *Acinetobacter spp.* (2x), *S. aureus* (1x), *E. cloacae* (1x), *C. albicans* (1x), *Serratia spp.* (1x), *Streptococcus spp*. (1x) and others (2x).
- If endowashers were contaminated, devices were reprocessed and re-tested.

Endowashers can be a potential source of infection. Endowashers should be clearly mentioned in guidelines and routine quality control. Sampling of endowashers should be part of such recommendations.

Hübner NO, Assadian O, Kramer A. Endowashers: an overlooked risk for possible post-endoscopic infections. GMS Krankenhaushyg Interdiszip 2011; 6(1):Doc13 (20111215)

Infection risk by endoscopy

- endoscopic biopsy in HCV-Antibody-positive patients was identified as an independent risk factor for a HCV infection

  Andrieu J, Barny S, Colardelle P, et al. Prevalence and risk factors of hepatits C virus infection in a hospitalized population in a gastroenterology unit. Role of endoscopic biopsies. Gastroenterol Clin Biol 1995; 19: 340-5.

Therefore endoscopy with biopsy in the previous 4 months is an exclusion criterion for blood donation in Germany since 2010

Infection risk by endoscopy

Since undetected defects were the cause of infections in and on the endoscopes, a risk of infection even exist with the correct treatment, hence the regular periodic check of the endoscopes after processing is essential

Corne P, Godreuil S, Jean-Pierre H, et al. . Unusual implication of biopsy forceps in outbreak of Pseudomonas aeruginosa infections and pseudo-infections related to brochoscopy. J Hosp Inf 2005: 61: 20-6

DiazGranados CA, Jones MY, Kongphet-Tran T, et al. Outbreak of Pseudomonas aeruginosa infection associated with contamination of a flexible bronchoscope. Inf Control Hosp Epidemiol 2009; 30: 550-5.

Also after arthroscopy septic arthritis and gas gangrene occurred by improper treatment.

Armstrong RW, Bolding F. Septic arthritis after arthroscopy: The contributing roles of intraarticular steroids and environmental factors. Am J Infect Contr 1994; 22:16-8.

Herzberg W. Problems with the sterilisation and the maintenance of sterility of arthroscopic instruments: a comparison of different types of camera drapes. Knee Surg Sports Traumatol Arthrosc 1993;1(3-4): 223-5.

Manually vs. mechanically reprocessing

Manual methods combined with sonication were totally ineffective compared to mechanically methods for cleaning of single-use biopsy forceps.

Even the use of retroflush cleaning was not totally effective.

Alfa MJ, et al. Infect Control Hosp Epidemiol 2006, 27(8): p841-6

Rigid laryngoscopes for multiple use

P. aeruginosa **outbreak in neonatal ICU with 2 deaths is described due to a deficient treatment of the rigid laryngoscopes.**

Muscarella LF. Reassessment of the risk of healthcare-acquired infection during rigid laryngoscopy. J Hosp Infect 2008; 68(2): 101-7

Reprocessing of single use shaver blades

Microscopic detection of abrasions on the surface of the inner blade and fractures of the inner tube after 1st reprocessing and increased after 3rd reprocessing + chemical deposits (calcium, hydroxyapatite, proteins) were shown. Clinical significance was left open.

Kobayashi M et al. Structural damage and chemical contaminants on reprocessed arthroscopic shaver blades. Am J Sports Med 2009; 37(2): 266-73.

Reusable sharp containers

They were returned to medical facilities with bacterial and viral contamination.

- 27 containers (90%) were positive for bacteria, 10% of the recovered isolates were gram-negative rods

- 9 out of 30 (30%) cultures were positive for viruses: HIV (10%), HAV (6.7%), HBV (6.7%), and HCV (13.3%),

- several containers were positively tested and diverse viruses and bacteria were detected

Runner JC. Bacterial and viral contamination of reusable sharps containers in a community hospital setting. Am J Infect Control 2007; 35(8): 527-30

Historical development of Central Sterilization Service Centers (CSSC)

- Cause for formation: Increasing demand of higher hygiene quality and the advance of reprocessing technique
- In **1890**, the first sterilisation department but with decentralised cleaning and disinfection in adjacent to an operation room was built in the Charité Hospital in Berlin, **Germany**
- In **1920**, the first CSSC with complete reprocessing process was build in Standford Hospital, Connecticut, **US**. 4 years later, the next CSSC was opened in Misericordia Hospital, Philadelphia.
- In **1958**, the first CSSC in Europa was established in **UK**, in Musgrove Hospital, and only in the 1980s in Germany.

A legal basis of the obligation to reprocess medical products in Europe was established through the released EU law 1993/42/EWG, which is harmonized in all European countries and embodied within the national law.

The Joint Guideline of the Robert Koch Institute (RKI) Berlin and the Federal Institute for Drugs and Medical Devices (BfArM) on reprocessing of Medical Devices was published 2001 and revised 2012.

Current situation of reprocessing in Germany

- **Hospitals for maximum care were usually fully served by an outsourced CSSC provider at the site**
- **Smaller hospitals are served by an independent regional CSSC, which in the same time also supplies several other hospitals.**
- **Most of the private practices are taking self-responsibility to reprocess their medical devices. However, some physicians rely upon a CSSC service.**

Education

For **personnel of CSSCs** the training for "**sterilization assistant**" in Germany have been started since 1993 and is classified into three qualification levels

- Level 1 „Technical sterilization assistant“ (120 h)
- Level 2 „Technical sterilization assistant with a broader scope of responsibilities“ (80 h)
- Level 3 for „Management“ (200 h).

For **medical practices** a **Competence Course for Reprocessing of Medical Devices** (CCRMD) has been established since 2003 (40 h).

International situation of reprocessing of single-use MDs

- **The reprocessing is legally allowed under strict conditions in Germany**

Kramer A, Assadian O. Ethical and hygiene aspects of the reprocessing of medical devices in Germany. GMS Krankenhhyg Interdiszip 2008, 3(3); Doc25.

Großkopf V, JÄkel C. Legal framework conditions for the reprocessing of medical devices. GMS Krankenhhyg Interdiszip 2008, 3(3); Doc24

- **Even in the U.S. (FDA), Canada (National Scientific Advisory Panel on Reprocessing of Medical Devices) and other European countries the reprocessing is allowed**

NN. Medical devices; reprocessed single-use devices; requirement for submission of validation data. Direct fi nal rule. Fed Reg 2006;71 (185):55.729–37.

Lee RC, Berzins S, Alfieri N. Single-use device reuse risks. Can J Infect Control Fall 2007, 22(3): 142-6.

Popp W, Rasslan O, Unahalekhaka A, et al. What is the use? An international look at reuse of single-use medical devices. Int J Hyg Environ Health 2010; 213(4): 302-7.

O'Brien V. Controlling the process: legislation and guidance regulating the decontamination of medical devices. J Perioper Pract 2009;19 (12):428–32.

Regulation for reprocessing of single-use MDs in Germany

- **In Germany medical devices may only be reprocessed and reused if a product-specific validation process exists and the processor holds to EU law and the joint guideline 93/42/EEC of RKI/ BfArM.**

- **The quality management system for the reprocessing of single-use medical devices has to be certified by an agency accordance with DIN EN 13485/2003 which is accredited by the Central German Federal Agency for Health Protection in Pharmaceuticals and Medical Products (ZLG)**

  → Currently there are only 4 accredited certification agencies

Requirements for a specialized professional reprocessing of single use MD

1. **Proofing of the feasibility** for reprocessing

2. **Risk assessment** of the reprocessed MD (safety, biocompatibility)

3. **Development of validated reprocessing procedure** with exemplary check of the material properties + codification of the number of allowed reprocessing cycles

Hazard analysis

1. **Risks that may result from the application of processed MD**
2. **Risks by unsuitable cleaning and disinfection (methods, devices, media)**
3. **Risks by unsuitable sterilization (method, device, media)**
4. **Risks by unsuitable product design (as well as technical and functional tests)**
5. **Risks by unsuitable other processing steps (packaging, transportation, storage, labeling, etc.)**

No siginificant differences between new and reprocessed ablatio cardiac catheters

Marker	New catheters (n = 100) median, sd	Reprocessed catheters (n = 101) median, sd
X-Ray duration time	34 ± 32	31 ± 28
Duration of procedure	111 ± 76	95 ± 60
HF power input	13 ± 15	10 ± 8,5
Arrhythmia recidive	7	6
Complications	1	1

Under the precondition of patient safety every opportunity of a controlled reprocessing based on a validated procedure contributes to cost containment

The economic effects of reprocessing based on a controlled procedure are significantly convincing.

Only one single ablation catheter

Germany: 16 to 23 Mio. €
England (UK): 4,9 to 7,0 Mio. €
France: 9,4 to 13,5 Mio. €
Italy: 8,4 to 12,0 Mio. €
Spain: 3,0 to 4,25 Mio. €
Netherlands: 1,9 to 3,1 Mio. €
Austria: 0,5 to 0,75 Mio. €
Switzerland: 1,5 to 2,1 Mio. €
Poland: 3,0 to 4,3 Mio. €
Portugal: 0,4 to 0,6 Mio. €

Basic principles of the RKI/ BfArM Guideline for reprocessing in Germany

The reprocessing is legally considered as "full manageable risk“ with the following requirements:

- **Qualified and trained personnel within a defined organisation structure**
- **Establishment of quality management with defined responsibilities, clear description of all reprocessing steps in a Standard Operating Procedure (SOP), starting with containment, handling, collection and transportation, preparation, disassembling, actions according to the manufacturer´s instructions of use, cleaning, drying, disinfection, inspection, function testing, assembling, packaging, sterilization, storage, quality control, maintenance, service, performance test and labelling**
- **validation and documentation of the whole reprocessing process**
- **risk classification of MDs**
- **development of routine evaluation concept**

Risk classification of MD`s for the processing

- **uncritical MD**

  contact only with **intact skin, or no contact**, e.g. scissors for cutting the band-aid, ECG electrodes
- **semi-critical MD**

  Contact with **mucosa or pathologically altered skin**

  (A) no special requirements = **visual inspection of cleanliness possible**, e.g. speculum

  (B) with increased requirements (e.g. **narrow lumens**) = limited visual inspection, e.g. lumina in endoscopes, immediately after

  pre-cleaning, lumen-covering machine reprocessing
- **critical MD** → **sterile** application e.g., MDs for surgical intervention

  (A) – **visual inspection possible**, e.g. retractors

  (B) – **limited visual inspection**, e.g. MIC-Trokar

  (C) – limited visual inspection and **no steam sterilization** (thermolabile)

If there are doubts about the classification of the MD, the next higher risk level should be assigned.

Requirements for reprocessing derived from the risk assessment

- **not critical** → cleaning (C) → disinfection (D) spectrum of efficacy A*, optionally A+B**

- **semi-critical** → **(A)** C → D (A+B)
  → **(B)** precleaning (P) immediately after application
  ⇓
  C → D, preferably mechanically inclusive lumen

- **critical** → **(A)** optionally P → C → D → steam sterilization
  → **(B)** P → generally mechanically C → D → steam sterilization
  ⇓
  technical sterilization assistant or expertise in instrument processing of MD in ambulance is acquired
  → **(C)** P → mechanically C → D → not-thermal process (EO)
  ⇓
  externally certified QM-System

*A = Bacteria, **B = Virus

Additional classification by risk of vCJD or CJD (risk groups)

I. Disease or suspected vCJD

II. Disease or suspected CJD

III. Related with CJD-patients (except it was a familial genetic unbiassed detected)

IV. Receiver of human Growth hormone (non-recombinant) and of corneal or dura mater transplants

V. Patients with unexplained, rapidly progressive disease of the CNS (with and without dementia), without suspected CJD

VI. All other patients

Risk materials or risk interventions of CJD or vCJD

a) neurosurgical procedures with contact to the CNS (brain, spinal cord, optic nerve), as well as spinal and trigeminal ganglia, inner ear, pituitary or olfactory area of the nasal mucosa

b) eye surgery (posterior segments of the eye: retina and nervus opticus and corneal transplant surgery and corneal transplants using)

c) other surgical procedures involving contact with risk materials (ENT, olfactory epithelium)

d) lumbar puncture (usually not relevant, because basically disposable products are used)

e) additionally in vCJD operations on lymphatic tissue such as tonsillectomy, splenectomy, appendectomy, interventions at the terminal ileum, lymph node resections, biopsy, surgery on the bone marrow (e.g. in orthopedics and trauma surgery). Blood must be considered only as risk material in case of vCJD.

Approach to recognizable risk

- **at risk group I (**disease or suspected vCJD) **after all interventions**
- **at risk group II-V only after use on risk tissues a)-d)**

- **Disposable products dispose and burn**
- **Reusable products - central processing allowed only at a central location in Göttingen**

Approach to risk group VI = no identifiable risk of CJD or vCJD

When possible, whenever acting on risk tissues (a - d) **medical devices are used for single-use**, e.g.

- scalpels
- biopsy needles and cannulas, MD for neuraxial anesthesia and nerve conduction block
- bone drill and -screws with possible contact with CNS or CSF

At **each reprocessing** at least **two effective methods** for the decontamination or inactivation of **prions** have to be combined**.** These methods include e.g.

- **Pre-cleaning, thereafter not fixing alkaline cleaning** (pH> 10 for 10 min)
- **mechanical chemo-thermal disinfection**
- sterilization with (partially) documented prions activity, **134 ° C for 5 min**, if not possible, alkaline cleaning, **134 ° C 18 min** (during interventions at risk tissues a-d)

Analysis of reprocessing - a representative sample

We have analyzed 156 German Central Sterilization Service Centers (CSSCs) supplying hospitals with 250 to > 1.000 beds in a German-wide hospital network, further 14 CSSCS supplying regional general hospitals and finally decentralized reprocessing in 18 dermatological medical practices.

- **For the CSSCs we submitted an questionnaire that contains the following components:**
  - **organization, physical infrastructure, and personnel requirements**
  - **product-related performance test**
  - **reprocessing of endoscopes.**

  The quality of responses in the collected questionnaires was verified with a structured interview from a random sampling of 10% of all collected questionnaires.

- **In dermatological practices the governmental authority has taken a structured review after returning a preliminary questionnaire.**

Status in the 156 CSSC which served the hospital network

Proportion of qualified sterilization personal

There was only a small difference in the various sizes of the CSSC units.

Total number of staff in the CSSC	**Percentage (%)** [the sum is > 100% due to multiple qualifications]				
	Qualification level			**Competence Course for Reprocessing of Medical Devices**	**without qualifica-tion**
	Level 1	**Level 2**	**Level 3** (highest)		
2-5	**76**	**39**	**28**	**5**	**12**
6-10	**69**	**28**	**12**	**5**	**8**
11-15	**70**	**21**	**12**	**3**	**13**
16-20	**72**	**21**	**12**	**4**	**13**
21-30	**88**	**19**	**7**	**1**	**10**
31-50	**81**	**22**	**7**	**2**	**14**

Basis of comparison between the CSSDs

Number of beds of the hospital, which is supplied by the CSSC:

- **small hospital (n=32) with ≤ 250 beds**
- **middle-size hospital (n=50) with 251-400 beds**
- **larger hospital (n=49) with 401-800 beds**
- **very large hospital (n=25) with >801 beds.**

Certification for reprocessing of thermolabile MDs (critical C)

Although the certification is mandatory, some hospitals do reprocess MDs critical C without certification to DIN EN ISO 13485: 2003 and C 2009.

Deficiencies in the regulation of the reprocessing processes

Supplied beds by the CSSC	No complete reproces-sing SOPs	No validation of all steps of reprocessing in washer sterilizers	Defined number of reproces-sing cycles	Documen-tation of cycle number
≤ 250 (n=32)	2 (6%)	1 (3%)	18 (56%)	23 (72%)
251-400 beds (n=50)	2 (4%)	6 (12%)	29 (58%)	38 (76%)
401-800 beds (n=49)	1 (2%)	9 (18%)	26 (53%)	33 (67%)
> 800 (n=25)	1 (4%)	0	12 (48%)	21 (84%)

Deficiencies in quality management

Criterion	< 250		251 – 400		401 – 800		>800	
	n	%	n	%	n	%	n	%
Current reprocessing standards are available	22	**69**	42	**84**	36	**74**	22	**88**
Quality management have been revised according to the current standard	11	**34**	27	**54**	19	**39**	15	**60**
A recall procedure is available	19	**59**	34	**68**	29	**59**	20	**80**
Person to approve sterile materials is authorized	30	**94**	43	**86**	38	**78**	23	**92**
SOP for performance test for MDs is available	27	**84**	34	**68**	33	**67**	20	**80**
Complaint management system is available	9	**28**	19	**38**	18	**37**	18	**72**
Criteria for non-approval (charge blocking) of reprocessed MDs	30	**94**	42	**84**	42	**86**	23	**92**
annual training of personal	28	**88**	41	**82**	35	**71**	24	**96**

Reprocessing of single-use MDs without accreditation

Supplied beds by the CSSC	N	%
≤ 250 (n=32)	2	6
251-400 beds (n=50)	4	8
401-800 beds (n=49)	1	2
> 800 (n=25)	3	12

Control frequencies by the hospital hygiene department

Rhythm	< 250		251 – 400		401 – 800		>800	
	n	%	n	%	n	%	n	%
six-monthly	18	**56**	26	**52**	18	**37**	12	**48**
Anually	10	**31**	17	**34**	23	**47**	9	**36**
Never	2	**6**	1	**2**		**0**		**0**

Microbiological environmental monitoring

Hospital size	< 250 n	%	251 – 400 n	%	401 – 800 n	%	>800 n	%
drying air	25	**78**	37	**74**	26	**53**	21	**84**
protection gown	8	**25**	8	**16**	7	**14**	6	**24**
work place	17	**53**	31	**62**	21	**43**	16	**64**

Complete vaccination of personnel

Hospital size	< 250		251 – 400		401 – 800		>800	
	n	%	n	%	n	%	n	%
Hepatitis B	29	**91**	48	**96**	41	**84**	22	**88**
Hepatitis A	23	**72**	32	**64**	32	**65**	19	**76**
Rubella, varicella, measles, mumps	4	**13**	8	**16**	6	**12**	1	**4**

Situation in 14 regional general hospitals

Method

- **For quantitative analysis of deficiencies, the poorest quality was defined with a score of 6 and the best quality was defined with a score of 0 in each of the following categories:**
  - **quality assurance**
  - **reprocessing process**
  - **spatial conditions**
  - **personal conditions.**

Results of quality assessment in CSSC of 14 regional general hospitals CSSC of 14 regional general hospitals

Indicator	CSSC established for >10 years (n=5)	CSSC established for <10 years (n=9)
Quality assurance	3.4	1.6
Reprocessing process	3.2	1.8
Room conditions	3.2	2.2
Personnel conditions	3.1	1.4

- 2 CSSCs were immediately closed by the governmental authority because of much too narrow rooms and not acceptable disinfection or sterilization devices
- in 4 CSSC not acceptable technical delay on necessary architectural workflow
- in 7 CSSC allocation from the regional ministry was necessary to perform an essential reconstruction in several settings. In average, the reparation process for these hospitals took usually about one year

Selected deficiencies in CSSCs of the regional hospitals

No training for level 1 of sterilisation assistant	57 %
No training for level 2 and 3 of sterilisation assistant	71 %
No validation of the complete reprocessing cycle	100 %
Sterilizers and washer disinfectors not validatable	each 50 %
No SOPs	64 %
Lack of packaging of sterilized MDs	21 %
Insufficient optical control of cleaning	79 %
No indicator control of sterilizing batches	7 %
No defined approval	7 %

Results of quality assessment in dermatological doctor's offices

Indicator	Duration of practice >10 years (n=5)	Duration of practice <10 years (n=9)
Quality assurance	4.2	2.9
Reprocessing process	1.9	1.4
Room conditions	2.6	1.7
Personal qualifications	3.9	3.4

- 2 medical practices were excluded because they utilize only single-use MDs
- In the other 18 practices the number of deficiencies was higher compared to the 14 regional CSSCs. Similar to the situation in the CSSCs, the quality of reprocessing decreased with a longer duration of practice than 10 years

Selected deficiencies in dermatological doctor's offices

No competence course for Reprocessing of Medical Devices	94 %
No validation	100 %
No SOPs	100 %
Outdated sterilizer	22 %
Lack of packaging of sterilized MDs	72 %
Reprocessing of single-use punchs	22 %
Deficiencis in cleaning and disinfection (i.e. only cleaning, dirty brushs)	33 %
No indicator control of sterilizing batches	39 %
No defined approval	89 %
No skin protection plan	44 %

Analogous situation in 7 offices of gynaecology, surgery and traumatology

Consequences for dermatological doctor's offices

- **For non validatable sterilizers the utilisation of reprocessed MDs was stopped by the governmental authority.**

- **The doctor's offices get a deadline of 3 months to substitute the obsolet reprocessing technique.**

Conclusion

The real situation in CSSCs are rarely published and perhaps in some countries not well known.

For Germany and other European countries like UK and Austria questionnaires for the competent authority to supervise the CSSC were developed. But neither national or international official supervision procedures for CSSC units were established. Our proposal is one step to develop a standardized questionnaire.

To our knowledge, the questionnaires of CSSCs sent out by the Germany-wide hospital network, were the first effort to assess the situation in CSSCs.

Conclusion

The analysis of the obtained data have shown surprisingly poor results.

For the quality of reprocessing the following ranking results: the best quality was found in the CSSDs which supplies the hospital network, followed by the CSSCs for regional hospitals. The most frequently deficiencies was analyzed in the doctor's offices.

An another conclusion seems to be obvious: the 4 certified industrial reprocessing centers for single-use as well as resuable MDs in Germany have the highest quality and safety , which is an important argument to set up such special reprocessing centers with high professional control of the complete reprocessing process.

To evaluate the progress it is planned to repeat similar analysis every two years.

Many thanks for your attention!