Recommendations by the Quality Task Group (62): Manual Reprocessing of Medical Devices (wish-wash workshop, DGSV Cogress, Fulda)

This recommendation describes the results of Workshop 1, conducted at the 13th Congress of the German Society of Sterile Supply (DGSV) in Fulda from 15 to 17 October 2009. The complete text of the presentation is available on the DGSV website at www.dgsv-ev.de. This text is not structured exactly as a recommendation, but entails an overview of the current state of the activities being carried out by the working group comprising members of the German Society of Hospital Hygiene (DGKH,) DGSV and Working Group Instrument Preparation (AKI). Publication of concrete recommendations is planned for next year.

The use of validated processes to reprocess medical devices is a legal requirement. In Germany this is stipulated in the Medical Devices Operator Ordinance (MPBetreibV).

Even when using automated cleaning and disinfection, certain types of special instruments are often subjected to manual pretreatment. Sometimes subsequent manual cleaning is also needed. Some medical devices can, for various reasons, only be cleaned and disinfected manually. That was the reason why the members of the DGKH, DGSV and AKI Working Group, after having drawn up a guideline for automated cleaning and thermal disinfection in washer-disinfectors, wanted to at least formulate recommendations for the manual procedures involved here.

Initially, the term "validation" was the subject of much controversial debate in the Working Group since there were different perceptions of the extent to which manual processes could be validated. Following an in-depth search of the literature, it was noted that there is no clear evidence suggesting that validation can be conducted only for automated processes. The Working Group believes that the definition proposed by the US Food and Drug Administration (FDA) in 1986 for validation to be the most appropriate one:

"A documented procedure for furnishing, recording and interpreting the requisite results, in order to demonstrate that a process continually meets the given specifications".

Is it at all possible to meet the target "validation" of manual cleaning and disinfection processes? First of all, the DGKH, DGSV and AKI Working Group involved in drafting a guideline on standardisation/validation of manual cleaning and disinfection processes focused on issues related to the ACTUAL situation:

1. ***Does immersion of an MD in a detergent/disinfectant solution assure adequate disinfectant action (i.e. reduction of the microbial count by 5 log_{10} levels) (using a disinfectant on the approved List of Disinfectants of the Association for Applied Hygiene (VAH)?***

Following preliminary tests, a study was carried out at the hygiene institute (department of infection control) at Bonn University Hospital with anatomical/surgical tweezers (critical A) and Crile clamps (critical B), which had been contaminated with 50 µg sheep blood + protamine. Some of the process steps were altered (brushing, rinsing, ultrasound, etc.; Fig. 1 and 2).

Reduction of the microbial count by 5 log_{10} levels was assured for the tweezers only if they were brushed for 2 min, thus bringing the microorganisms into contact with the disinfectant. Alone the exposure to the detergent components in the immersion basin was not enough to bring about the required reduction.

For the Crile clamps reduction of the microbial count by 5 log_{10} levels was assured only by additional ultrasonic treatment (pursuant to the recommendation by the Robert Koch Institute (RKI) and the German Federal Institute for Drugs and Medical De-

Testdesigns III, IV, VI:

Test design		Reprocessing	Product	Contamination: *E. faecium* with	Contamination volume	MV RF (log_{10} levels) – with US	MV RF (log_{10} levels) – after enzymatic cleaning and 2nd rinse	MV RF (log_{10} levels) – after 1st rinse
III	a	Wet transportation B (15 min RT) Disinfection (15 min) with brushing (2 min) Rinse with water (30 sec)	C	Sheep blood + protamine	50 µl	6,45		
			D		50 µl	6,75		
	b	Wet transportation B (15 min RT) Disinfection (15 min) – Rinse with water (30 sec)/brushing (2 min)	C	Sheep blood + protamine	50 µl	4,58		
			D		50 µl	6,75		
IV		Dry transportation B (60 min, 20 °C) Rinse with water (30 sec) Enzymatic det. (10 min) with brushing (2 min) Rinse with water (30 sec) Disinfection (15 min) Rinse aid	J + C	Sheep blood + protamine	50 µl	5,45	3,11	0,15
			J + C	0.3% sheep erythrocytes + 0.3% albumin	50 µl	6,74	3,67	3,05
			J + D	Sheep blood + protamine	50 µl	6,77	2,42	0,64
			J + D	0.3% sheep erythrocytes + 0.3% albumin	50 µl	6,71	3,77	2,65
VI		Dry transportation B (60 min, 20 °C) Disinfection (15 min) with brushing (2 min) Rinse with water (30 sec) Disinfection (15 min) – Rinse aid	D	Sheep blood + protamine	50 µl	6,18	4,14	

Fig. 1: Manual disinfection of tweezers

Results: Crile clamps

Testdesign IV:

Test design		Reprocessing	Product	Contamination: *E. faecium* with	Contamination volume	MV RF (log_{10} levels) – with US
IV		Dry transportation B (60 min, 20 °C) Rinse with water (30 sec) Enzymatic det. (10 min) with brushing (2 min) Rinse with water (30 sec) Disinfection (15 min) Rinse aid	J + C	Sheep blood + protamine	100 µl	4,62
			J + C	0.3% sheep erythrocytes + 0.3% albumin	100 µl	4,27
			J + D	Sheep blood + protamine	100 µl	5,59
			J + D	0.3% sheep erythrocytes + 0.3% albumin	100 µl	5,50

Fig. 2: Manual disinfection of Crile clamps

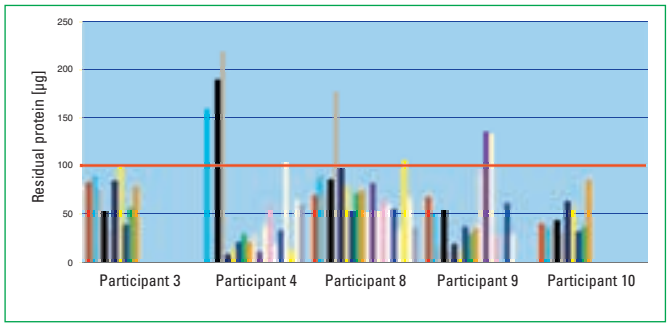

Fig. 3: Manual cleaning of Crile clamps without ultrasound

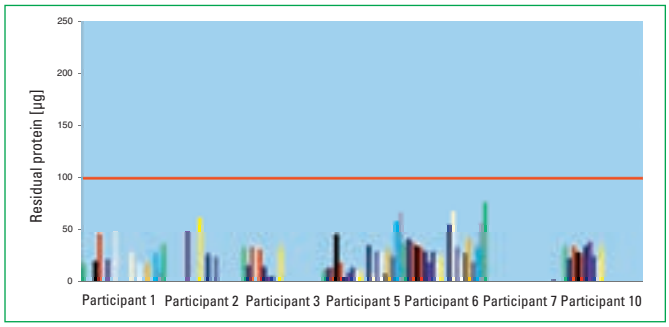

Fig. 4: Manual cleaning of Crile clamps with ultrasound

vices (BfArM), critical B MDs must in principle be subjected to automated cleaning and thermal disinfection. In the tests, the clamps were used to simulate testing of WD processes).

2. Does immersion in a disinfectant/detergent solution or detergent solution assure adequate protein removal?

To investigate that, two other laboratories conducted a multicentre trial together with 10 hospitals. Manual cleaning and disinfection of the Crile clamps was conducted in each of the 10 Central Sterile Supply Departments (CSSDs) taking part in the study. Cleaning and disinfection were performed in strict conformance with the standard operating procedures (SOPs) of the respective CSSD. The clamps were returned to the laboratory where the o-phthaldehyde (OPA) method was used to investigate them for any residual proteins. The results obtained clearly show that only on using ultrasound could protein residues be removed to values of 100 µg protein/clamp or less (Fig. 3 and 4).

3. What results can be obtained for wipe disinfection with a surface disinfectant?

To explore this, in Workshop 1, conducted during DGSV Congress 2009 in Fulda, volunteers wiped two aluminium containers, from different manufacturers with a solution as prescribed by the respective SOP. The solution contained a fluorescent additive. This workshop was repeated five times. Wipe disinfection took between 1.1 and 3.0 minutes. Under UV light it could be clearly demonstrated that several locations, in particular in the filter and in grooves as well as the sealing nuts were not accessed when wiping (Photos 1 and 2).

Despite having carried out meticulous wipe disinfection, it was clearly shown that wetting of all surfaces was incomplete even though the containers had mainly smooth surfaces. Moreover, the wiping process was time consuming and uneconomical since the disinfectant residues had to be rinsed or wiped off after expiry of the exposure time.

Outlook

The Guideline Group intends drafting standard operating procedures for non-critical, semi-critical and critical A medical devices. When properly observed, these instructions should permit reproducible results. Following that, control methods are to be devised for everyday practice because for any validation of the methods it must be possible to verify and document the test results.

The Working Group has still much to accomplish. The next results will be presented at the DGKH Congress in April 2010 in Berlin. Since, as mentioned above, validated processes must be used for reprocessing medical devices, it is absolutely necessary that, in addition to validation of partial steps of automated reprocessing, evidence be produced that manual processes, too, can be carried out in line with the dictates of quality assurance and thus validated. ✦

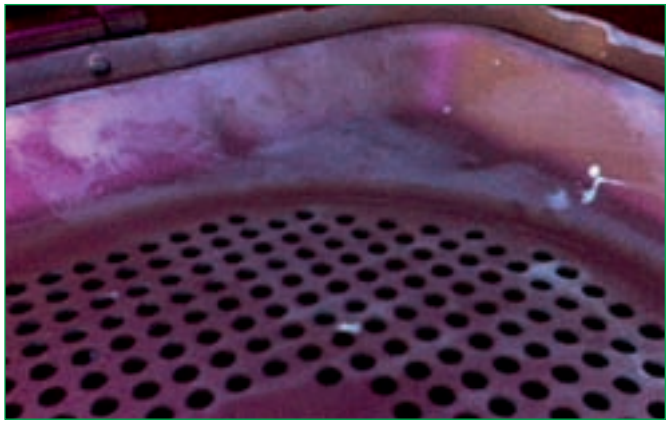

Photo 1 and 2: Visualisation of the wetted and unwetted surfaces using UV light