

# "The importance of Logistics in the CSSD"

**Wim Renders**  
**WFHSS Honorary-President**

























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World Federation for  
Hospital Sterilisation Sciences

## Welcome!

Dear Colleagues, dear Friends,

The primary mission of WFHSS is to contribute ensuring that patients all around the world are treated with high-quality medical devices. A necessary condition for this is that infrastructure, materials, consumables, working methods and training of staff meet essential requirements. The indirect effect is the recognition of the CSSD as a fully-fledged, supportive and constructive department of the hospital.

Cooperation between national sterilization associations with emphasis on exchange of information and sharing of knowledge must foster harmonization. Knowledge hereby is the most important instrument to base practice on evidence from research and to finally get rid of tradition and (bad) habits.

Theoretical knowledge can nowadays everywhere be found and acquired. It is, for example readily available on our website. However, the transposition in practice sometimes is lacking although this is an essential step in the whole process. To eliminate this shortcoming WFHSS launches therefore a practical training

## NEWS



### [WFHSS Congress 2017!](#)

Bonn, Germany

4th – 7th October

**Abstract Submission is Open**

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**Programme Brief**  
**(as at 10 February 2017)**

**Workshop on Sterilization and Infection Control related to Operating Theatre**

**Organised by Infectious Disease Control Training Centre, Hospital Authority/  
Infection Control Branch, Centre for Health Protection;  
Chief Infection Control Officer's Office, Hospital Authority**

**Date: 1 March and 2 March 2017**

**Venue: Lecture Theatre, G/F, Centre for Health Protection, 147C Argyle Street, Kowloon**

**Objectives:**

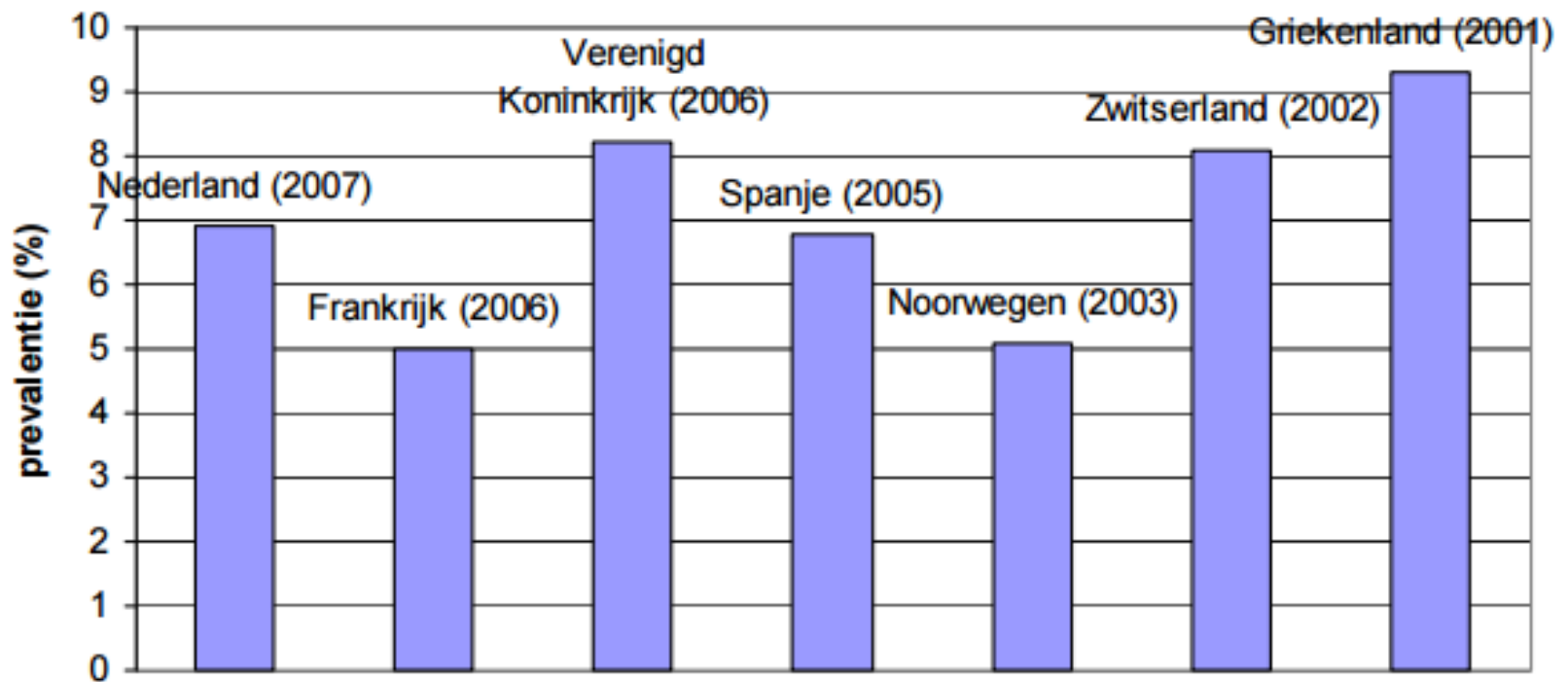
The workshop would focus on the following aspects:

1. Disinfection and sterilization process in healthcare facilities
2. Infection control related to Operating Theatre
3. Experience sharing on the latest development in countries abroad.
4. Explore the best practices and recommendations
5. Review the local practice and protocols



# CSSD - Infection Prevention <sup>(1)</sup>

Resultaten van de recente prevalentie studies in Europa



Sterility Assurance Level in sterilization:  $10^{-6}$

## 10 FACTS ON PATIENT SAFETY

- Hospital infections affect 14 out of every 100 patients admitted
- Of every 100 hospitalized patients at any given time, 7 in developed and 10 in developing countries will acquire health care-associated infections (HAIs). Hundreds of millions of patients are affected worldwide each year. Simple and low-cost infection prevention and control measures, such as appropriate hand hygiene, can reduce the frequency of HAIs by more than 50%.

# CSSD - Infection Prevention <sup>(2)</sup>

- Decontamination" is an industrial process
- Reprocessing then becomes measurable and hence an objective, rational process of which the result is mathematically guaranteed. In other words: if we validate and control the production processes in the sterilization department patient safety is no longer a gamble





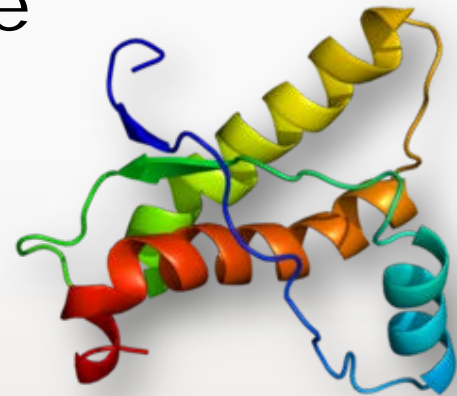








- In the past: focus on the sterilization process because of the conviction that a device which was sterilized would be and remain sterile
- Due to new insights, new diseases and triggers of diseases, from the 90's, the accent shifted to cleaning and disinfection
- A marginal phenomenon in and around sterilization still is the logistical process although it is an integral part of the decontamination cycle





Transport



Sterile Storage



Sterilization



Packaging

Use



Transport



Cleaning/  
Disinfection



Inspection &  
Tray Assembly



Quality Assurance



# **Purpose of the logistical process:**

- Delivery on time
- To maintain the sterility of the sterile medical devices until they are used!

Our responsibility does not stop at the exit doors of the CSSD







# Room for improvement

1. Stacking of sterile medical devices in the OR















# Room for improvement

1. Stacking of sterile medical devices in the OR

2. Sets are opened and set out in advance









## **Time-dependent contamination of opened sterile operating-room trays.**

Dalstrom DJ, Venkatarayappa I, Manternach AL, Palcic MS, Heyse BA, Prayson MJ.

Orthopaedic Surgery Residency Program, Miami Valley Hospital, 128 East Apple Street, Suite 2830, Dayton, OH 45409, USA. orthodjd@yahoo.com

### **Abstract**

**BACKGROUND:** There are no clear guidelines for how long a sterile operating-room tray can be exposed to the open environment before the contamination risk becomes unacceptable. The purpose of this study was to determine the time until first contamination and the rate of time-dependent contamination of sterile trays that had been opened in a controlled operating-room environment. We also examined the effect of operating-room traffic on the contamination rate.

**METHODS:** Forty-five sterile trays were opened in a positive-air-flow operating room. The trays were randomly assigned to three groups. All trays were opened with use of sterile technique and were exposed for four hours. Culture specimens were obtained immediately after opening and every thirty minutes thereafter during the study period. Group 1 consisted of fifteen trays that were opened and left uncovered in a locked operating room (i.e., one with no traffic). Group 2 was identical to Group 1 with the addition of single-person traffic flowing in and out of the operating room from a nonsterile corridor every ten minutes. Group 3 included fifteen trays that were opened, immediately covered with a sterile surgical towel, and then left uncovered in a locked operating room (i.e., one with no traffic).

**RESULTS:** Three of the thirty uncovered trays (one left in the operating room with traffic and two left in the room with no traffic) were found to be contaminated immediately after opening. After those three trays were eliminated, the contamination rates recorded for the twenty-seven uncovered trays were 4% (one tray) at thirty minutes, 15% (four) at one hour, 22% (six) at two hours, 26% (seven) at three hours, and 30% (eight) at four hours. There was no difference in survival time ( $p = 0.47$ ) or contamination rate ( $p = 0.69$ ) between the uncovered trays in the room with traffic and those in the room without traffic. The covered trays were not contaminated during the testing period. The survival time for those trays was significantly longer ( $p = 0.03$ ) and the contamination rate was significantly lower ( $p = 0.02$ ) than those for the uncovered trays.

**CONCLUSIONS:** Culture positivity correlated directly with the duration of open exposure of the uncovered operating-room trays. Light traffic in the operating room appeared to have no impact on the contamination risk. Coverage of surgical trays with a sterile towel significantly reduced the contamination risk.

Problems are not only situated outside the CSSD. The department too has to pay more attention to the correct handling of medical devices



### Cartoon 15 - Logistics in Sterile Storage



Logistics in Sterile Storage



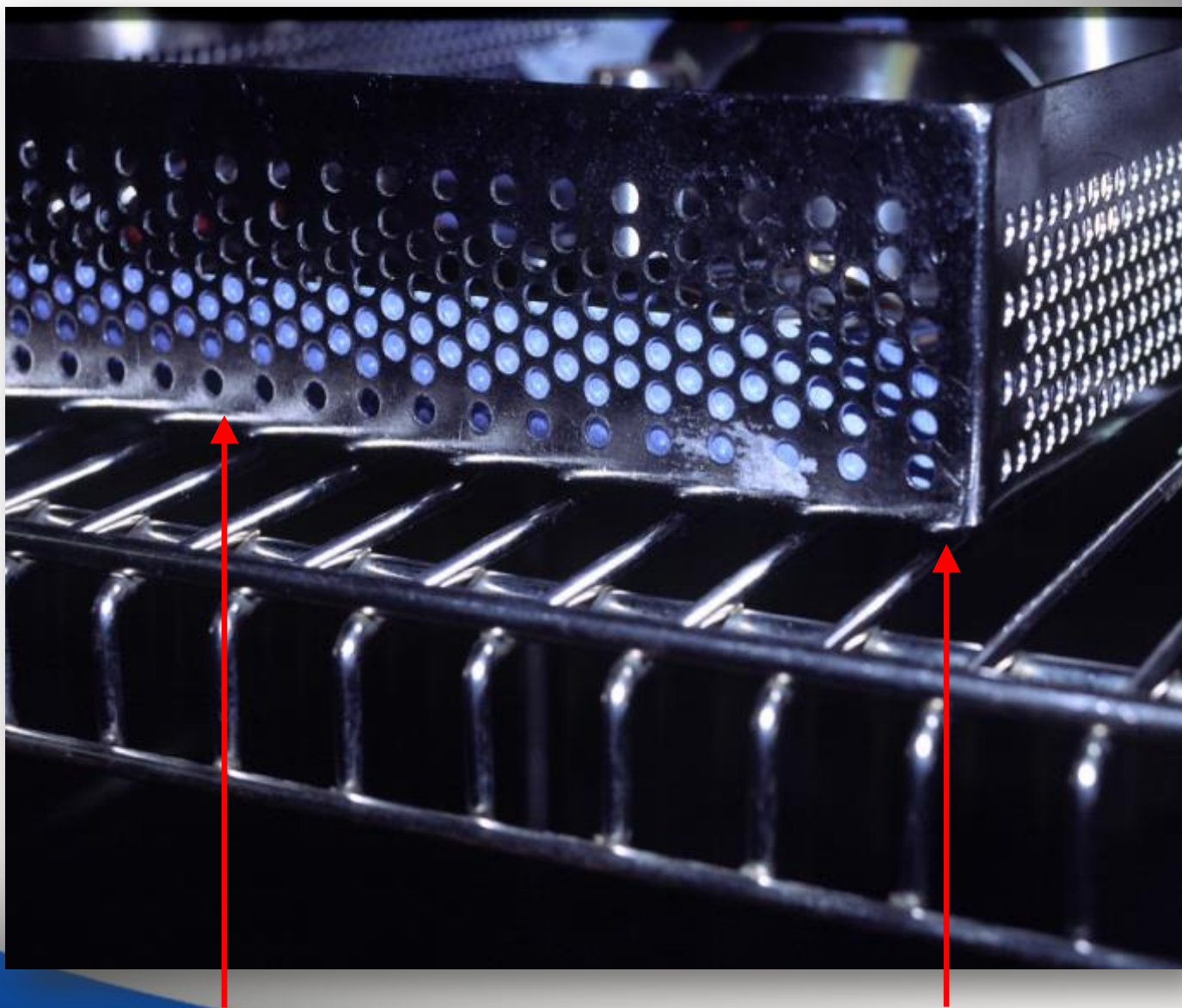












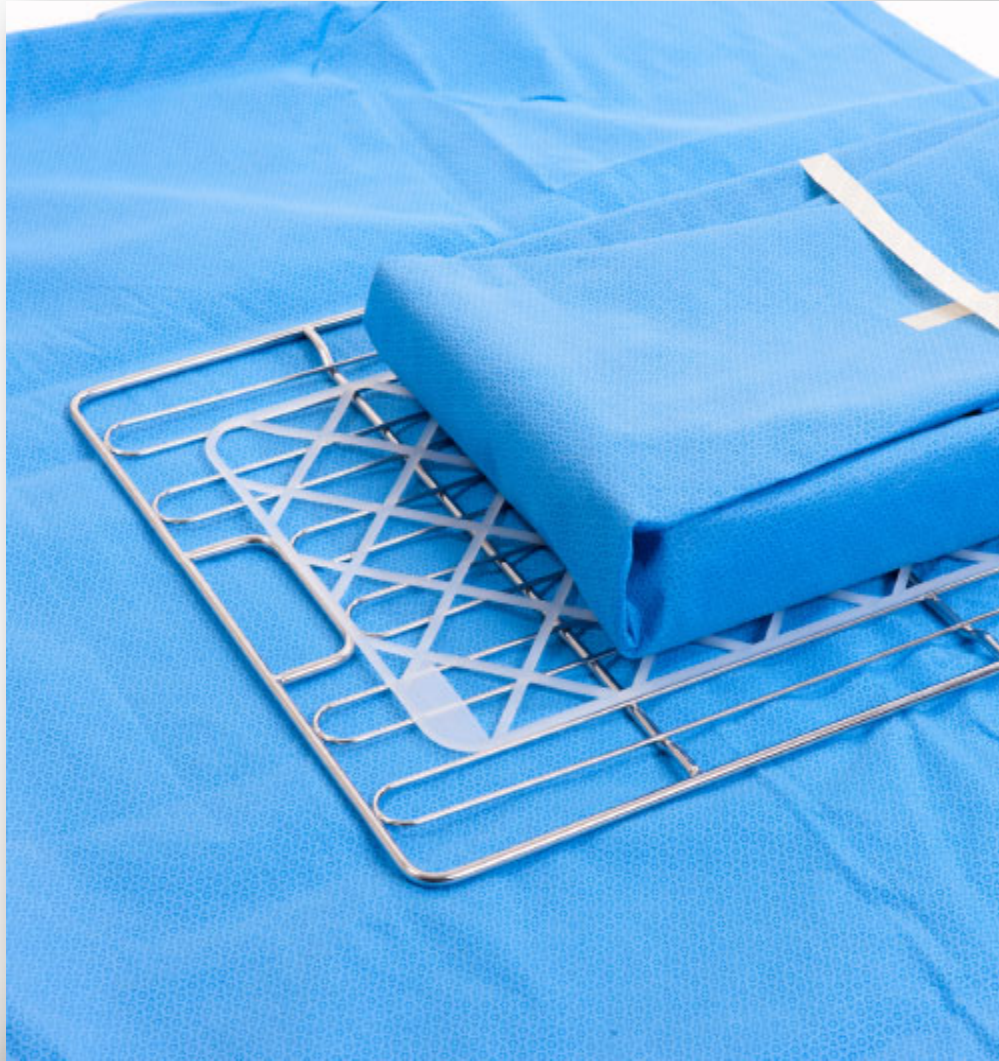
























- Our packaging problem under control: 20 used sets checked: no damaged packaging found
- In 2 other Belgian hospitals by checks in the OR: 15% damaged packaging found

# An integrated logistical concept

- Which encompasses the whole hospital is often lacking
- Logistics has to be based on a general concept which is rolled out throughout the whole hospital
- Integration of all logistical activities



# General problems with logistics

- Staff with low qualifications what makes their training necessary
- Means are not sufficient
- Storage rooms do not meet the requirements
- At the end of the cycle people are too careless: nets on top of each other, pushing the products on the shelves etc.









Ladies,

Please lift the sets well when placing!!!

Thank you.

# Basic rules:

1. Sterile material has to be manipulated as little as possible. Baskets are manipulated not the sets
2. One way traffic from storage to the patient

# Central sterile warehousing <sup>(1)</sup>

- In a sterile warehouse (only for sterile products)
- Dutch building norms: Class 100.000 (ISO 8)



# Bouwmaatstaven voor de sterilisatie-afdeling

- in de ruimten voor inpakken, ontladen en opslaan moet de kwaliteit van het eindfilter overeenkomen met minimaal 95% DOP-test (klasse 100.000). De eindfilters worden zo dicht mogelijk bij de uitblaasroosters aangebracht. De filterspecificatie ten behoeve van de mechanische ventilatie van de overige ruimten moet zijn volgens 80% Dustspot;

## RECOMMENDATIONS

### Keywords

- sterilisation
- CSSD
- architecture

# Architecture and Sterilisation Premises

*AFS Working Group\**

# Central sterile warehousing <sup>(2)</sup>

- Access for authorized persons only
- Delivery and return via a goods sluice
- No direct contact with outside air
- No direct exposure to sunlight
- Dust- and draft free, dry, constant temperature, no condensation



# Central sterile warehousing (3)

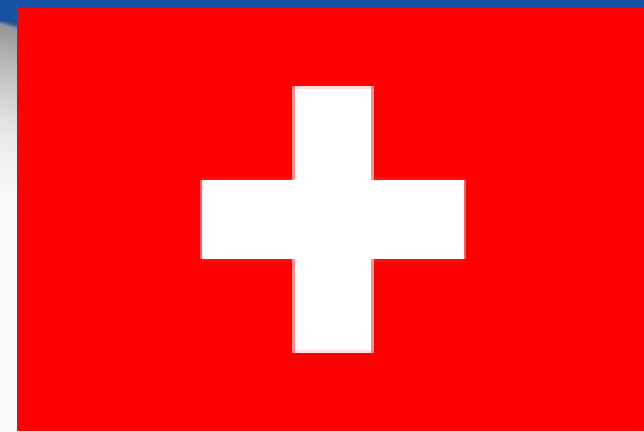
- The level of the germ load on the packaging constantly increases until, between week 6 and 12, equilibrium is reached between the number of sedimenting and the number of dying micro-organisms
- Sterile material stored in closed cupboards remains sterile for much longer than on open shelves.
- Big changes in temperature and humidity levels result in faster contamination than in conditions in which the environmental factors are constant.
- Medical materials contain a certain amount of water. This is linked to hygroscopic materials such as cotton and paper. This leads to a certain level of humidity in the packaging. The porosity of the packaging material allows for an exchange of this humidity with the environmental air. The material constantly absorbs humidity and releases it in the environment.

# Central sterile warehousing <sup>(4)</sup>

- The packaging breathes. So make sure that a package is not substantially warmer or colder than the ambient air; If it is put in a colder location or gets colder the humidity condensates with all foreseeable consequences. A constant temperature is a must.
- Micro-organisms can more easily penetrate wet packaging. When a calamity occurs in the storage room the supply has to be carefully checked.
- Air has to keep on circulating around the packaging. Big air movements result in an increased exchange of air with the risk that micro-organisms will penetrate the packaging.



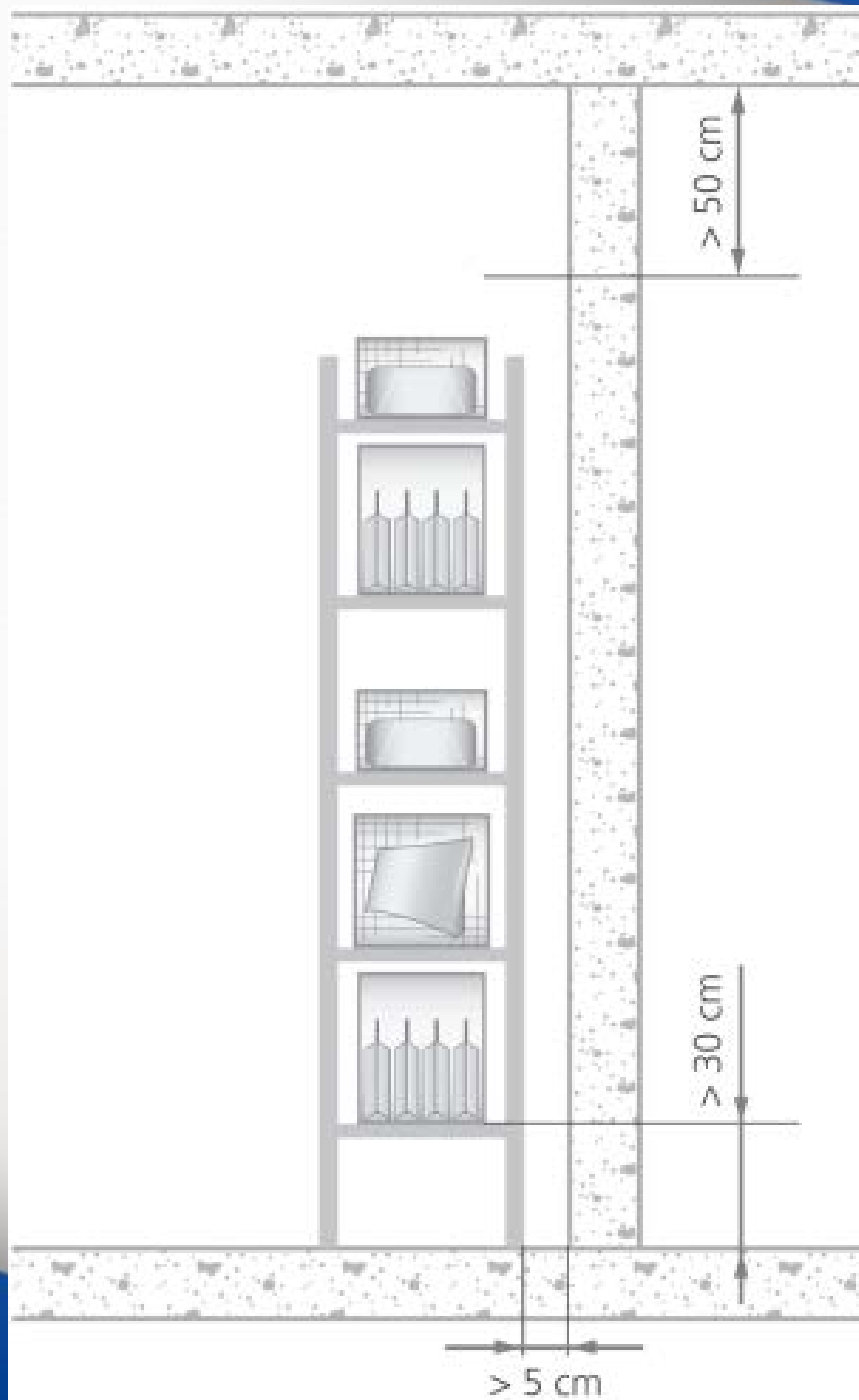




- Frédy Cavin – expert en stérilisation CHUV  
**Analyse de risque suite aux  
contrôles d'étanchéité des joints  
des conteneurs dans plusieurs  
établissements suisses**

16<sup>èmes</sup> congrès WFHSS  
Lille 2015





Dennhofer

# Central sterile warehousing <sup>(5)</sup>

- No open drains and water tap points
- Floors smooth and impermeable
- Walls, floors and ceilings: prevent dust accumulation
- Shelves, cupboards and means of transportation have to be made of material which is easy to clean and have to be clean and dry
- Transport packaging removal in goods sluice
- Relative humidity between 50 and 75% (between 40 and 75% AFS)
- Temperature around 20° C, + 5° , – 2°

# Determination of the efficacy of sterile barrier systems against microbial challenges during transport and storage

Hartmut Dunkelberg and Ulrich Schmelz  
Medical Institute of General Hygiene and Environmental Health,  
University of Goettingen, Germany

11<sup>th</sup> World Sterilization Congress and the 7th International  
Symposium of Sterilization and Hospital Infection Control,  
July 30 – August 01, 2010  
Sao Paulo, Brazil



## Determination of the efficacy of the sterile barrier system

$N_0$  = Number of bacteria in the air volume passing the porous packaging material during the test (= microbial challenge)

$N_1$  = Number of bacteria registered on the plates in the packaging

$$\text{Filtration efficiency (\%)} = \left[ 1 - \frac{N_1}{N_0} \right] \times 100$$

Microbial barrier effectiveness in terms of the Logarithmic Reduction Value (LRV):

$$\text{LRV} = \log \frac{N_0}{N_1}$$



# Confirmation of the maintenance of sterility

1. Sterility assurance level  $\leq 10^{-6}$
2.  $N_0$  = Microbial challenge during transport and storage
3. LRV = Microbial barrier efficiency of the packaging

$$\text{Log } N_0 - \text{LRV} \leq -6$$



# Sterile supply of medical devices and pharmaceutical products

Quality standards and applied risk management<sup>\*)</sup>

Hartmut Dunkelberg

Universitätsmedizin Göttingen, Georg-August-Universität Göttingen, Germany

**Correspondence:** Prof. Dr. med. Hartmut Dunkelberg, In der Lember 4, 37242 Bad Sooden-Allendorf, Germany; e-mail: hdunkel1@gwdg.de

## ■ Table 1

Risk management of the maintenance of the sterility of pouches (15 x 18 cm) by calculation of the compatibility of the filtration efficiency with the airborne microbial challenge during the storage period.

wrapping method	number of events (n)	1 event per week (scenario A)	7 events per week (scenario B)
		shelf life	shelf life
single wrapping	1.95	2 weeks	2 days
double wrapping	162	3.1 years	0.4 years

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The question is whether it is Cost  
Benefit to control all these event  
conditions?

And are we able to procure all  
relevant information?



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[/ Education / Articles / European Expert Condemns the Re-use of Sterilization Packaging](#)

## European Expert Condemns the Re-use of Sterilization Packaging

Tim Galekop, who is employed by [Ahlstrom FiberComposites](#) as a Director of Global Business Development, Medical Fabrics responsible to present a paper at the SATS Congress in Cape Town. He also did a series of joint presentations with René Vis on sterilization matters at the VU University Medical Centre in Amsterdam, the Netherlands and his visit was sponsored by Ahlstrom FiberComposites. He was asked the following questions:

**SV**

You have been a member of the Dutch Norm Standards Group from the day of its foundation and serve as an expert to the CEN. What are you involved with standards and why are they important to hospitals?

**TIM**

Individual technical experts are appointed by the CEN parent body or by National members, to serve in a personal capacity.

The Working groups may also include experts from organizations, which have only observer status in the parent body.

To answer the second part of your question, it really started years ago. The Netherlands was the first country to publish a law regulating sterilization. It was certainly a case of "locking the stable door after the horse had bolted". The Dutch National Institute of Public Health and Environment (RIVM) and the Dutch Sterilisation Association (NF Steriliseren Steriliteit) were established as a result of the devotion of Jack van Asten, who worked for the RIVM for 17 years. Jack sadly passed away in 2005. His goal was to improve the quality and image of the sterilization departments in the Netherlands and the British and the Germans had published some standards.

The reason why I got involved was mainly due to the fact that the management of the company I was working for in the Netherlands at the time was not aware of the importance of sterilization. The first department they will investigate, if there is an infection problem in the operating room is the CSSD "the heart of the hospital" if you will. My travels is: "Where is the published information and how can I convince to my management that we have to follow correct procedures? Standards are written for patient and staff safety.

Today, I am the last and only person left from the day of foundation of the Dutch Norm group, in other words "the last of the Mohicans"

**SV**

Why do you think that linen should not be used as a sterile barrier material in hospitals?

**TIM**

















# Storage on nursing and treatment units

- In storage cupboards
- Or on dressing trolleys



# Cupboards

- Dedicated cupboard, preferably closed
- Replenishing once a week minimally
- Easy to clean (1 x every 3 months)
- Only for sterile material
- FIFO
- Internal distribution packaging should be replaced
- Clean, dry and dust free



Re-stocking of secondary bin



# Dressing trolleys

- Stock: no more than 24h-48h
- Do not take into the room of the patient
- Not in use: in area without increased contamination risk, closed or covered
- Weekly cleaning
- FIFO
- In principle: Never from trolley to storage cupboard









# Treatment trolleys

- For 1 patient
- For 1 treatment
- Cleaning/disinfection after use







# Storage of medical devices in the patient room

- In closed box
- For 24-48 h
- Never put back in the supply of the ward
- Don't use for another patient
- Unused = discarded
- Cleaning: 1 x week

# Transport of medical devices within the institution

- Clean: closed vehicles or containers exclusively for sterile medical devices (cleaning 1/week)
- Dirty: separate closed transport (cleaning after use or at least 1/day)











# Trends in logistics

1. Case cart with most of the products used for 1 surgical intervention
2. Procedure packs: the industry provides both the draping material and the single use devices, sterile, in 1 pack
3. Outsourcing of logistics: the warehouse is outside of the hospital



# Case carts

- Readyng the so called “Case cart” per procedure
- On the cart:
  - non- sterile and sterile medical devices
  - instrument sets are readied per surgical procedure
  - “Just in time” concept
  - facilitates the task of the nurses in the operating theatre and gives responsibility to where it belongs:
    - the logistics department
- In the case cart preparation the CSSD plays a big role



# Procedure packs

- Procedure packs or the industry which provides sterile delivery of both the draping material and the single use medical devices in a pack
- 10% more expensive than the addition of the individual components.
- The intention is to save time for the nurses so that they can concentrate on their core task: to look after the wellbeing of the patient.

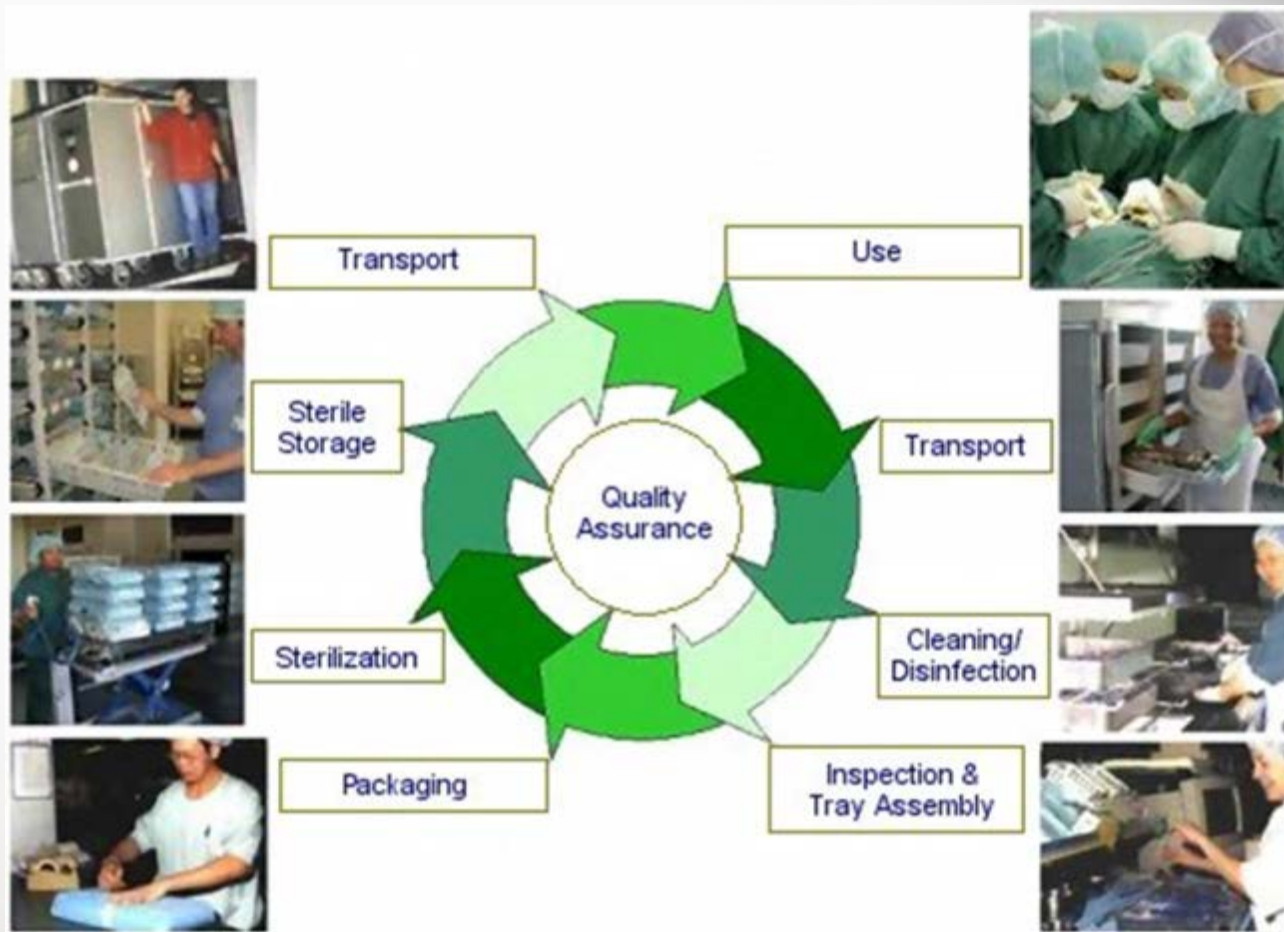




# Outsourcing of logistics

- Hospital space is very expensive
  - In Belgium the going price is 2000 Euro/m<sup>2</sup> for a technical service
- Hence the idea of outsourcing the storage space of the hospital
- The storage room is no longer in the hospital but outside of it
- The space which is gained can be used for the expansion of patient care
- The departments are directly supplied from the warehouse via a 2 bin system





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Knowledge and motivation

**Thank you!**