The importance of logistics in the CSSD

1. Introduction

Slide 1

First and foremost I would like to thank the organizers for the invitation to me to participate in this workshop. It is my pleasure being here with you.

Allow me to introduce myself a little bit more. I am pharmacist and I worked, almost my whole career, in the general hospital St John in Bruges, Belgium. St John is a regional, general hospital with 1000 beds. The foundation of the hospital goes back to the middle Ages. The oldest known document with the hospital rules dates from 1188.

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Amongst others I was responsible there for the central sterilization department.

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I am also the honorary president of the World Federation for Hospital Sterilisation Sciences. (I was president from '99 to 2014).

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1.1 Patient safety

The umbrella under which this workshop resides is: "Sterilization and infection control related to the operating theatre”.

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An appropriate choice becauseit is the purpose of health careto make a patient better or at least less suffering. Unfortunately, the reality for some patients is different.

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In Western Europe, 5 to 9% of hospital admissions acquire an infection (HAI). This is a dramatic high figure certainly knowing that a number of them could have been avoided if for example standard precautionary measures, treatment protocols and bundles of care would have been applied carefully and consistently.

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WHO states firmly on its website that: 'Simple and low-cost infection prevention and control measures, such as appropriate hand hygiene, can reduce the frequency of HAI's by more than 50%'.

In my view, these days CSSD is, wrongly, more and more linked to 'Infection Prevention'. Do not misunderstand me: by providing a medical device of a high quality the CSSD can undoubtedly make a substantial contribution to safeguarding the health and the safety of the patient. But because the chance that a patient develops a hospital-acquired infection is much higher than the 1 out of a million sterility assurance level (SAL) which is applied in sterilisation it cannot be treated in the same way.

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"Decontamination"in fact is an industrial process. The outcome thereof can be perfectly predicted if the essential requirements of process control are met. To create the conditions to make this possible is the primordial task of the CSSD. 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.

1.2 Change

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The world has never changed as quickly and dramatically as during the last four, five decades. The homogeneous protective environment, in which I was born, has gone lost, no longer exists. This change pushes as a uniformly accelerated motion further through in our society, impossible to slow down.

Also for sterilization, the last 40 years have been a significant period of time. Also sterilization profoundly changed in recent decades. The department, in which I took my first hesitant steps at the end of the 70's, was a traditional department where more compresses and linen were packed then instruments treated.

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In this department the focus was on the sterilization process itself. The conviction reigned then that a device which was sterilized would be and would remain sterile.

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Due to new insights, new diseases and new triggers of diseases, which are not necessarily completely destroyed during the sterilization process, it was necessary to change this approach. In the 90's the accent was shifted to cleaning and disinfecting in an attempt, amongst others, to reduce the bioburden with the aim of guaranteeing the outcome of the sterilization process.

2. Logistics

A marginal phenomenon in and around sterilization still is the logistical process and more in particular that of the sterilized and sterile medical devices. To my mind logistics has been and still is undervalued. Nevertheless it forms an integral part of the decontamination cycle.

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2.1 Purpose of the logistical process

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The logistical process has, apart from a correct and timely delivery, a crucial purpose namely to maintain the sterility of the sterile and sterilized medical devices until they are used.

To create these ideal conditions and to sustain them is one of the most important challenges we are facing day in and day out both in the CSSD itself and outside of it. Because our responsibility does not end at the exit doors of the CSSD

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but is extended to the bed of the patient, to the treatment room of the polyclinic, to the operating theatres.

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I must admit that some time ago I was of the opinion that the responsibility of the CSSD stopped at the exit doors of our department. But while discussing this issue with a friend he made me reconsider my point of view. He was of the opinion that I took the easy way out and that it is the duty of the sterilization department to guarantee the quality of the products until they are used. After some

reflection I had to agree with him. He is right because each patient, wherever in the world has the basic right to be treated with a medical device which is of the highest possible quality. Therefore, we should not turn a blind eye to obvious malpractices also outside the CSSD. It is our duty to intervene and to try and put things right whenever we come across 'malpractices'.

2.2 Room for improvement

And let us not make the mistake of becoming complacent. Often there still is a lot of room for improvement, not only in the sterilization departments but also and perhaps even more so outside the department where supervision of the sterile and sterilized medical devices is much more difficult.

Despite all our efforts our hospital does not always has everything neatly under control.

Sometimes things even seem to be completely out of control.
I give you 2 examples related to logistics to illustrate this point:

2.2.1 Stacking if devices

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The first problem area is the stacking of sterile medical devices in the operating theatres.

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Of course stacking nets on top of each other is asking for trouble. A friend sent me this photo! It speaks for itself

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Stacking can for example be done as follows:

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2.2.2 Opening in advance

Often sets are set out in advance, in other words, they are already opened outside the operating room to allow the surgeon to start the next procedure without delay.

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But the risk of recontamination of unwrapped instruments will be a lot higher than for wrapped instruments and can be directly correlated to the length of the exposure as Dalstrom et al proved.

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2.3 Autobiographical example

Of course we have to take a critical look at what is going on in our own departments too because the problems are not only situated outside the CSSD. The department too has to pay more attention to the correct handling of medical devices.

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2.3.1 Non-woven

Let me give you an autobiographical example: When we changed over to non-woven packaging material- in the 90's -contrary to our expectations not everything went according to plan. During the test phase we noticed something odd: a number of packages already had pinholes in them even before they were put into the sterilizer.

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The use of baskets,

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normally a foolproof method, did not solve our problem. After quite some time we discovered the reason for the holes.

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Handling the already packaged, sometimes heavy nets in a rough manner or simply the shocks when loading the steam sterilizer were sufficient to cause pinholes;

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This by the contact between metal and metal, the metal of the net and the metal of the basket or of the trolley.

It was very hard preventing the packaging from being punctured and to find a good solution.

In our case the use of pads

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and especially a silicone tube under every set, is necessary to keep our packaging system intact.

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An alternative - to avoid production of dust - for a protective cotton packaging for heavy trays can be a third layer of non-woven. Condition is that this system is also validated separately!

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In order to substantially reduce handling, because that’s a crucial factor, we opted, when we moved to new facilities,apart from the generalized use of baskets to put the nets into and the use of silicone

tubing, for floor loader steam sterilizers and the use of the same trolleys for the loading of the sterilizer and for transporting the instrument nets to the OR (4 floors up).

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At present our packaging problem is under control. I checked the packaging of 20 used sets and found no damaged packaging material anymore.

In 2 other Belgian hospitals the soft packaging was checked also in the operating theatre. Remarkably in both hospitals the same percentage of damaged packaging was found namely 15 %, a surprisingly high number.This indicates that it is advisable, even necessary to check the integrity of the packaging on a regular basis!

2.4 Integrated logistical system

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In the light of the above mentioned facts and remarks it is a pity that when I visit hospitals and sterilization departments I very often see that an integrated logistical concept which encompasses the whole hospital is often lacking. Logistics is not considered to be a factor, let alone an important one,determining the quality of the care provided. But to me logistics is fundamental in order to ensure not only the quality but also the efficiency of the different hospital services.

Logistics has to be based on a general concept which is rolled out throughout the whole hospital. As a result the pieces of the jigsaw can be fitted because the departments concerned can no longer behave as autonomous, independent entities. They have to integrate their logistical activities. The result is an optimization and more

participation and commitment to the way in which the hospital functions.

2.5 General logistic problems

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But there are a number of issues in regard to logistics requiring attention:

1. It often is carried out by members of staff with low qualifications who sometimes do not understand the need to treat sterilemedical devices carefully. But this remark actually applies to everyone: also to the personnel with higher qualification and even to the members of staff of the CSSD. Training in how to deal with sterile medical devices will have to provide an answer to this problem.

2.Storage rooms do not meet the requirements. Moreover there often are too many supplieson every level.

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3. Very often the means are not sufficient. Transport trolleys are not in good condition and not closed, sterile and non-sterile transport is mixed.

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4.At the end of the cycle people are often too careless: they put nets on top of one another, they push the products on the shelves, etc.

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All these factors affect sterility. Solutions are not easy because they require a change in mentality, a different way of thinking and especially a different way of doing.

2.6 Basic rules

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There are 2 basic rules regarding the treatment of sterile medical devices –in the meantime we have extended our scope to all sterile medical devices in the hospital - :

1. Sterile material has to be manipulated as little as possible. Baskets are manipulated not the sets. Because the packaging gets deformed through manipulation as air is pressed through the packaging.With this air micro-organisms can migrate as well. Moreover dry packaging sucks in sweat that is loaded with micro-organisms.
2. If possible one way traffic from storage to the patient is organized. Sterile devices which have been in the patient's room cannot be put back in the departmental supply!

3. Storage places

Let's have a closer look at the different storage places in the hospital.

3.1 Central sterile warehouse

Centrally the storage of sterile medical devices is done in a "sterile warehouse" in direct enclosing packaging or distribution packaging.

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- The central sterile warehouse is only for sterile products. If the warehouse is part of the operating theatre, the same guidelines apply as to the operating theatre. According to the Dutch building norms for central sterilization departments the storage spaces minimally have to meet 95% DOP test (Class 100.000/ISO 8). This recommendation is not included in the architectural norm of Association Francaise de Sterilisation.

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- Only accessible to authorized personnel.
- Delivery and return via a goods sluice.
- No direct contact with outside air.
- Medical devices are not directly exposed to sun light.
- Dust free, dry, with a constant temperature, no condensation, draft free. Dust is a vehicle for micro-organisms; especially when opening the packaging this can lead to problems.

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The level of the germ loadon 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. This level and the composition of the population of micro-organisms are dependent of the individual storing conditions and differ strongly. It is thus evident that sterile material stored in closed cupboards remains sterile for much longer than on open shelves.

- It has also been demonstrated that 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.

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The material constantly absorbs humidity and releases it in the environment.

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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. Packaging can get wet as a result of handling, bad storing conditions and also during transport. 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 (drafts, doors opening and closing) have to be avoided. They result in an increased exchange of air with the risk that micro-organisms will penetrate the packaging.

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In a very interesting presentation he gave at the WFHSS conference in Lille Fredy Cavin calculated the possible influx of micro-organisms in containers in different environmental circumstances.

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Experiments have shown that first the inside of the packaging gets contaminated, and only then the device itself. Germs migrate from the outside to the inside!

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Racks should be freestanding: no contact with floor, walls and ceiling. Sterile supplies should be stored far enough from the floor (30 cm),

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the ceiling (50 cm) and the outside walls (5 cm) to allow for adequate air circulation and ease of cleaning.

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- No open drains and water tap points.

- Floors smooth, impermeable and undamaged so that cleaning is straightforward. Walls and floors prevent the gathering and release of dust and micro-organisms.

- 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 has to be removed in the goods sluice.

- Relative humidity between 50 and 75 % (between 40 and 75 % AFS), temperature around 20°C +5°C, -2°C.

- Recontamination depends on the bacterial load in the storage room, the humidity and the temperature of the product, the packaging, the ambient air, but also the resistance to penetration of the packaging. Dunkelberg has, to calculate the efficiency of the packaging, developed the following formulas:

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- Filtration efficiency (%) = [1 – N1 /N0] x 100

- The logarithmic reduction value is calculated as follows:
LRV = log NO /N1

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Confirmation of sterility maintenance is given by: log N0 - LRV < - 6

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In a recent article Dunkelberg has attempted to define expiry dates evidence based. He comes, for peel packs, in a realistic assumption of seven events per week (An event = a temperature variation of 2 °C and a weather dependent atmospheric air pressure change of 15 hPa) to a shelf life in case of single wrapping of two days, in case of double wrapping of nearly five months. He concludes that data of filtration efficiency against airborne microbes is a necessary condition for risk management of porous packaging material, but it is normally not shown in the instruction sheets of the packaging. When tests with airborne microbial challenge are not performed or this data is not given, a data based risk management and shelf life calculations are impossible!

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Pia Hillsberg came already to the same conclusion. In an interesting paper she gave at one of our latest congresses about event related sterility she wondered whether it was possible to implement the concept in sterilization departments. She doubted whether this was possible and whether it was cost efficient to thoroughly analyze all the elements, which contribute to event related sterility and whether it would ever be possible to procure all relevant information to put it into practice. She wondered whether the expense to keep all factors under control would not be too high.

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In our sterilization department we have decided to put 'use-by' dates based on the Dutch point system on our packs. (WFHSS website: article Tim).

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3.2 Storage on nursing units

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- In storage cupboards or for direct use on dressing trolleys

3.2.1 Storage cupboards

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- In a dedicated cupboard, closing should be preferably possible.

- Replenishing once a week minimally.

- Easy to clean material (1 x every 3 months cleaningat least).

- Only for sterile devices.

- First in First out (FIFO) principle should be implemented, supply on the basis of real use (half /full(2 bin))system is ideal.

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The supply is divided over 2 compartments. When one compartment is empty the logistical service replenishes it while the user makes use of the supply available in the other compartment.

- In internal distribution packaging: not replenishing but replacing.

- Cupboard clean, dry and as dust free as possible.

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3.2.2 Storage on dressing trolleys

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- Supply preferably not for more than 24h-48h, with separate compartments for sterile and non-sterile material.

- Do not take the dressing trolley into the room of the patient.

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- When not in use: in service areas without increased contamination risk and covered or closed between rounds.

- Trolleys should be cleaned weekly.

- FIFO!

- In principle: never put anything from dressing trolleyback into storage cupboard!

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3.2.3 Treatment trolleys

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- For 1 patient.

- For 1 treatment.

- Cleaning/disinfection after use.

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3.2.4 Storage in patient room

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Storage of sterile dressings in the room of the patient:

- In a closed box to prevent the packaging from being contaminated by micro-organisms or from getting wet.
- Put the box with dressings in a clean dry place.
- Keep enough supply for 24-48h.
- Never put the dressings from the dressing's box back into the departmental supply.
- Do not use these dressings for another patient.
- Unused sterile material which was in the room of the patient should be discarded as household waste.

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- Clean 1 x per week.

3.3 Transport in hospital

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Transport of medical devices within the hospital

- Sterile: Closed transport trolleys or containers exclusively for sterile medical devices. Cleaning 1/week.

- Used: separate but also closed transport. Cleaning and disinfection: after use or at least 1/day.

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4. Trends in logistics

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4.1 Case cart

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- Readying the so called “Case cart” per procedure. On the cart all the products, including non- sterile and sterile medical devices and instrument nets are readied per surgical procedure. It is a “just in time” concept which 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 can play a big role.

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4.2 Procedure packs

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- Procedure packs or the industry which provides sterile delivery of both the draping material and the single use medical devices in a pack (once again per surgical procedure). It is about 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.

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4.3 Outsourcing of logistics

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- Outsourcing of logistics: hospital space is very expensive. In Belgium 2000 Euro/m2 for a technical service. Hence the idea of outsourcing the storage space of the hospital. In other words 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 half /full system.

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5. Conclusion:

My paper is a plea for both a clear internal vision (in the CSSD) and an external one (encompassing the hospital) on logistics. By participating in a hospital wide logistical process the CSSD will become more integrated in the hospital and thus fully realize its role as a facilitating department.

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Video on youtube:
https://www.youtube.com/watch?v=714NZUymjBs

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Sterility is the result of this integral process + knowledge + motivation of the people.

Wim Renders

Bruges, 13/02/2017