"Main principles in sterilization at Hospitals"

Good midday ladies and gentlemen,

First and foremost I would like to thank the organisers for offering me the opportunity to talk about sterilization at the prestigious ICCAID congress. It is a great honour for me to be invited to participate and at the same time to be able to discover the beauty and mystery of Kazakstan.

Allow me to introduce myself. I am Wim Renders and I work as a pharmacist in the General Hospital Saint John in Bruges, Belgium. Amongst others I am responsible there for the central sterilization department. I am also the chairperson of the Flemish society for sterilization and of the World Forum for Hospital Sterile Supply (WFHSS). The World Forum consists at the present moment of 48 members: sterilization societies from all over the world. It dedicates itself, as our mission statement says "to the promotion of the worldwide harmonization of sterilization departments and of decontamination practices especially by providing:

- a meeting place for national and regional sterilization societies, thus stimulating cooperation and the exchange of information and best practices;
- information via our website to all our stakeholders and interested parties.

In this way we make a contribution to ensure that the quality of reprocessing is of the highest possible level across the globe".

On our website you can find a lot of useful information, at least we hope so.

Each year at our annual congress our aim is to be the meeting place for the sterilization world. At this congress we bring together more and more colleagues from all ever more countries. This is not unimportant as research has shown that the drive in an organisation to learn and to innovate is amongst others influenced by its contacts with foreign and domestic innovative organisations. Our next congress will take place in Milan, Italy, in the first week of June. I look forward to meeting some of you there.

Innovation in our departments is necessary in order to make progress. In our case progress means that the sterilization department provides a device of an ever better quality.

The basis for innovation is knowledge. Josy Holdener has summarised this very well in the following slide which you can also find on our website: “The probability that your processed devices reached sterility is directly proportioned to how much you know about sterility”.

The World Wide Web has made information available just by touching a few keys on a computer keyboard or even on a mobile phone. However it is essential that this information is transformed into knowledge and that this knowledge is disseminated and put into good practice.

This is, according to me, the “core” business of a national sterilization society. And that is why I am a fervent supporter of national societies and, where they do not yet exist, for their establishment.
On quite a number of occasions we have already experienced that such a society can bring about a complete turnaround in the sterilization practice in a particular country.

Undoubtedly the representatives of “DAS” will agree with me. They themselves have proven this point. By organizing study days and congresses, by setting up training programmes and by drafting, in collaboration with the authorities, recommendations for good sterilization practice they have given an enormous boost to sterilization in Turkey.
I hope that a number of you will follow the example of “DAS”: it is an excellent role model which can stimulate and inspire you.

Excuse me for devoting so much time to my introduction while you are all eagerly expecting practical information about sterilization. But to me the transfer of knowledge through a national society is the “main principle”, the lever to good sterilization practice. This principle will in the end be the most successful one in providing a state-of-the-art device to the patient.

What I have discussed in my introduction encompasses the subject I am supposed to be talking about:
“Main principles in sterilization at Hospitals”.

What are these main principles?

Let’s start with some definitions.

1. What is a principle: principles are like laws of nature; they are timeless and universal; they transcend individual persons and specific cultures. They were valid in the past and will remain valid in the future (Jan Bommerez: Flow). This is also the case for the principles which govern sterilization. By the way: in the Anglo-Saxon world the term sterilization, which only refers to a specific, limited activity, is being replaced more and more by the concept “decontamination”, which is more active and incorporates the totality of actions which lead to sterility.
2. Sterility: State of being free from viable micro-organisms.
3. What is sterilisation: “Destruction of all living organisms by exposure to physical or chemical agents”. “The” problem is that we will never be able to reach this goal because sterility is not an absolute state but a statistical concept.
   The killing curve of a population of micro-organisms has exactly the same pattern as the curve of a chemical reaction of the first order. Herein the zero point is also never reached.

Numbers smaller than 1 express the survival rate. For example 0,01 means that 1 instrument out of 100 can be contaminated.
No matter to whatever extent this possibility can be reduced, it can never be excluded altogether. There will always be a risk that a micro-organism survives.
That is why in the EN 551 – 1; 2001 “Sterilization of medical devices - Requirements for medical devices to

be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices”
a product is labelled as “sterile” when the theoretical probability of there being a viable organism present on the device shall be equal or less than one in 1 x 10 to the 6^{TH}. This is the sterility assurance level of SAL.

The logical follow-up question is: when is or does sterility become a necessity? The answer is provided by Dr. Spaulding in the classification which is named after him:

Low risk (noncritical items)
Noncritical items are items that come into contact with normal and intact skin as stethoscopes or with the inanimate environment (e.g. walls, floors, ceilings,furniture, sinks, etc.). Cleaning with a detergent and drying is usually adequate. Stethoscopes are usually cleaned and in rare cases they should be disinfected if used on infectious patient or highly susceptible patient.
Intermediate risk (semi-critical items)
Semi-critical items are items that do not penetrate the skin or enter sterile areas of the body but that are in close contact with mucous membranes or with non-intact skin. Cleaning followed by HLD is usually adequate. Examples include respiratory equipment, flexible endoscopes, laryngoscopes, specula, endotracheal tubes, thermometers, and other similar instruments.
High risk (critical items)
High risk items are items that penetrate sterile tissues such as body cavities and the vascular system. These items are called critical items because of the

high risk of infection if such an item is contaminated with any microorganism before penetrating the tissue. Cleaning followed by sterilization is required.
High-level disinfection may sometimes be appropriate if sterilization is not possible, e.g., flexible endoscopes. Examples of high-risk items include surgical instruments, intra-uterine devices, vascular catheters, implants, etc.

So now we know when devices have to be sterile. It is not acceptable, certainly not to the patient, that in this regard compromises are allowed and that a lower level of sterility is opted for due to a lack of instruments and/ or bad planning of surgical interventions. Typical examples here are arthroscopies and re-use of single use items.

The only remaining question is how to sterilize these devices?

Principle: the end result: a sterile medical device is the sum total of a number of actions of which the sterilization process itself is just one part.

Decontamination circle

Sterility is the result of an integral process.

It is imperative that in order to be in a position to guarantee sterility and the quality of the end product the different steps in the total process should be geared for one another and that these steps should be controlled. Obviously this can only be done in an effective manner if the different actions are co-ordinated in a central department. Moreover, this

creates the possibility of standardizing the processes with the result that the number of mistakes is reduced and reproducibility increased.
Appointing a person who is in charge of the decontamination activities and who takes final responsibility is to my mind a must. This person should be someone with academic training and a scientific background such as a pharmacist or a microbiologist.

Furthermore there is a second important reason for centralization: cost control as a result of the more efficient use of means and manpower. Prof. Weekers of the University of Louvain in Belgium last year carried out an extensive research project. He came to the conclusion that centralization of the different satellite sterilization departments in his hospital is significantly cheaper amongst others through the more efficient use of the available means.

Moreover, employing motivated and specifically trained members of staff will make a big contribution to the delivery of a device with the highest possible quality. An additional indirect advantage is that theatre nurses can concentrate optimally on their own task, namely the care for the patient. They often lack the necessary motivation to take care of the instruments in between surgical interventions.

By the way: in some Western European countries there is a trend to centralize on an even larger scale by combining the sterilization departments of different hospitals in 1 central department outside the hospital. This is for example the case in England and France where a number of real “super centres” are set up.

There is thus a distinct trend towards the "industrialization" of sterilization activities, in other words the treatment of the CSSD as an industrial production unit. This approach is, as I have already indicated, based on economic and quality concerns. The CSSD can only benefit from this rational approach.

This way of doing things is, in Europe, also the position taken by the Medical Device Directive (MDD). It regulates the bringing onto the market of medical devices. The important paragraph 2 posits that the health and the safety of the patient have to be guaranteed. Although the MDD was originally meant for the company world the basic safety principle has also been extrapolated to the production of Medical Devices in the hospital.
This is of great significance as the CSSD is thus obliged to adhere to the essential requirements of the MDD.

Because the EN are the technical translation of these essential requirements, applying the norms automatically means conformity to the MDD.
That is why it is self-evident in Europe that a CSSD only buys products which meet the EN or ISO norms even if purchasing them is more expensive.
Products meeting the norm offer conformity to the regulations, safety to the patient and confidence to the user!

Principle: purchase products which meet the norms and ask the supplier for the conformity certificates.
This should also be getting easier outside Europe now that CEN and ISO have started collaborating closely together with the aim of arriving at a worldwide harmonisation of norms.

Let’s take a closer look at a CSSD.

Principle: the separation of the different areas of activity is necessary in order to avoid cross contamination and errors.

The collection of devices and their transport are done in dry and covered conditions. Ideally instruments should be treated as soon as possible in order to prevent the proteins from drying on the instruments and corrosion resulting from blood, bodily fluids, disinfectants and rinsing fluids.

Without doubt the unclean area, has in recent years become the most important compartment in a CSSD. The importance of thorough cleaning can best be illustrated with a statement made by David Hurrell at our London congress. He said: “A perfectly cleaned device should not need sterilization anymore.”
Cleaning and disinfecting should as far as possible be carried out by machine for two reasons. Firstly the quality is better and secondly machine cleaning reduces the risk of infection to the members of staff. The guidelines of the German Robert Koch Institute can be used a benchmarks in this regard.
An alcaline detergent with a pH value higher than 10, a disinfection with an Ao minimally of 3000 and a sterilization time of 5 min at 134°.
In manual procedures the baths have to be regularly drained and refilled.

Clean area: This is where the checking and the packaging are taking place.

The selection of packaging materials is of the utmost importance. The packaging should guarantee sterility until the moment of use.
In a modern sterilization department linen is no longer used as a packaging material. There is a growing trend to make use of non woven packaging material.
Containers have advantages and disadvantages. The most important problem is that after each use the container has to be cleaned.

As far as sterilization is concerned steam sterilization should be used whenever possible!
Pre vacuum autoclaves make it perfectly possible, depending on the programme, to remove air and to ensure complete steam penetration even in instruments with long, narrow lumina.
The sterilization plateau is 134° 5 min.

Flash sterilisation should not be used, neither should sterilization methods based on immersion. The material is not packaged, as a result there is no guarantee of sterility.

Low temperature sterilization remains a difficult topic. The available methods EO, gas plasma and LTSF have their specific advantages but also their peculiar disadvantages.

The first question, which should be asked is whether we really need low temperature sterilization in our hospital? This is not unimportant as more and more instruments are steam sterilizable. If the answer to this question is positive a choice will have to be made.

Validation of the sterilization processes is inscribed in any normative system. Validation proves that the sterilization process is adequate and reproducible. It is in fact an essential procedure and should be carried out once a year.

As far as routine checks of steam sterilization are concerned the emphasis has shifted to controlling the physical parameters. On this basis the loads are released instead of on the basis of the use of as many as possible chemical and biological indicators.

To guarantee sterility a good logistical system is necessary. It is expressed in the time related - event related sterility concept. This supposes that sterility is more event than time related. The storage life depends for example on the number of manipulations, the way of storing etc. In other words the way the sterile medical devices are handled.

Re-use of sud’s should be restricted as much as possible. It is an insidious threat to public health. This can be achieved relatively easily by not doing it for too cheap or too complex medical devices and by opting as much as possible for re-usable instruments.

Conclusion:

Sterilization or decontamination, if you wish, has to be based on principles and carried out knowledgeably. The definition of sterility leaves no other choice and each and every compromise will sooner or later be detrimental to the patient.

That is why, even if the circumstances are not optimal at the present moment, there is no excuse to stick to the business as usual model. Even with limited means a lot can be achieved. These are e.g. the thorough cleaning of the work stations, the implementation of zoning, the drafting of standard operating procedures, the training of personnel etc..
Step by step we have to take the road to the ultimate goal: to put at the disposal of the caretaker and of the patient a medical device of the highest quality.

In sterilization too times are a changing!

Wim Renders
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