Sterilization – is it useful?

Good morning,

First and foremost I would like to thank the organizers for their invitation to address this congress. It is an honour to participate in the 30th Journées Nationales d'etudes sur la sterilisation of the CEFH.

Allow me to introduce myself. I am Wim Renders and work as a pharmacist in the General Hospital St Jan in Bruges, Belgium. I am amongst others responsible for the central sterilization department. I am also the chairman of the Flemish Society for Sterilization and of the World Forum for Hospital Sterile Supply (WFHSS). At present the World Forum has 48 members: sterilization societies from all over the world.

The Forum dedicates itself, as our mission statement expresses "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 of best practices;
- information via its 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 find, at least we hope so, useful information in connection with sterilization and at our annual world congresses we provide an opportunity for colleagues from ever more countries to meet and exchange views. The next congress takes place in Milan, Italy in the first week of June. I look forward to seeing a number of you there.

Some time ago Mr. Certain asked me to talk today about the question whether sterilization is indeed useful? The brief answer can of course only be 'yes'. I suppose that none of you, numerous as you are, would give the opposite answer if only out of a legitimate concern for your own employment prospects.

By thanking you for your attention I could now end my speech and regain my seat. Mission accomplished! If we are all in full agreement about the answer to the question what more is there to be said? But I doubt whether the organizers would be happy with my short acte de présence. And actually there are a few important reflections regarding Mr Certain's question I would like to share with you.

1. A first point is that the question whether sterilization is useful is a fully justified academic question, but is a question one would expect from an outsider. It is evident that when we put ourselves in the position of the patient, sterilization, in the broadest sense of the word, daily proves its usefulness. I do not think that anybody wants to be operated on with a set of instruments which were

not sterilized let alone not cleaned. In terms of risk management the risk would be unacceptably high because the damage could be severe.
The first risk, an instrument which is not sterilized, could still be an acceptable one. Indeed David Hurrell, an expert in sterilization, made the point at our European congress in London, that a perfectly clean instrument did not need to be sterilized. I hasten to add that he meant it as a bon mot. With this overstatement he wanted to stress the importance of good cleaning.
The necessity of sterilization is proven by the fact that in the past in a number of European countries the authorities intervened after the occurrence of infectious incidents. Often these incidents had resulted in the death of the patient. Despite the fact that these tragic cases were not necessarily linked to inadequate sterilization, the authorities nevertheless imposed measures to improve sterilization practice.

The big leap forward in sterilization in the Netherlands, for years upheld as the shining example in sterilization practice, only took place in the ‘70s after a number of patients had died after the use of badly sterilized infuses. These infuses had been prepared in the pharmacy of the hospital. The authorities took draconian measures, evidently also in the sterilization departments, to prevent a re-occurrence of such a tragedy.

In Great Britain the plan by the NHS to build so called “super centres”, was hatched after it had transpired that a number of central sterilization

departments delivered insufficient quality. This posed a threat to public health during the vCJD crisis.

Here in France strict measures were introduced, also in sterilization departments, amongst others in reaction to the contaminated blood scandal. The intention was firstly to avoid a repetition of this calamity and secondly to prevent the spreading of vCJD.

The relevant question is not whether sterilization is useful, that is beyond any doubt, but what kind of sterilization we want? This question is rightfully at the top of the agenda both of hospital management and of public health authorities.

2. The second related point is that “sterilization” has grown up. In the course of the years - I have been working in a central sterilization department for 22 years - I have seen this department develop from an shoddily and chaotically managed subsection of the operating theatre into a professional, well structured unit. Because the saying goes that history repeats itself, it is sometimes instructive to revisit the past in order to learn how to best prepare the future. That is why I would like to provide a bird’s eye overview of the elements which have contributed to the coming into the existence of the CS as we know it now.

A. Centralization of the sterilization activities within the hospital was undoubtedly the most important turning point towards good practice. In America this trend started 70 years ago.

The reasons for this striving towards better quality were cost reductions through standardisation and a more efficient use of personnel and means.
As far as the first reason is concerned Prof. Weekers of the University Hospital of Louvain which has a number of different satellite sterilization departments, prove only last year in an extensive economic report that centralizing these departments would lead to a substantial reduction in costs.
Regarding the second point, the members of staff, it was the intention to employ low skilled personnel to reprocess the instruments which meant that nurses could concentrate on the more highly skilled caring duties (Perkins).

Nobody could doubt the correctness of the arguments mentioned just now because there is nothing new under the sun. Today the same trend leads to even more centralization but now outside the hospital. It is still based on the same argumentation:
-firstly cost reduction through economies of scale. For example: just to follow and meet the present European norms means a heavy financial burden especially for smaller units,
- and also the personnel policy proposed by Perkins has still got its merits. It should not be swept underneath the carpet, not even in a modern CSA. I share his standpoint and realise that in doing so I take a deviating maybe even a controversial position which is not necessarily shared by my colleagues.

For me too in a period when degree requirements cannot be high enough for members of staff – I am referring to ordinary members of staff – a minimum educational level, corresponding with their duties in the sterilization department, is an absolute requirement. Of course this has to complemented with specific training because the motivation of the individual member of staff will determine his commitment and the quality of the work done. Having good and highly motivated members of staff is the best quality guarantee. A hospital in Courtray (Belgium) has understood this. The new human resources manager, who in his previous life was responsible for personnel selection at the Volvo car assembly plant is using the old selection criteria in his new job. Not the degree is important but the way in which the work is done. The personnel of the CSSD is selected on the basis of their ability to work in a structured fashion. The results are remarkable. The quality of the department has improved enormously. This example provides food for thought. Perhaps we should, in our personnel selection, try out new ways and put more emphasis on specific training and skills than on the formal degrees needed for particular jobs. Such a strategy will undoubtedly contribute to better reproduceability because (too) highly qualified members of staff will very often provide a personal, individual interpretation of procedures and ways of working with the attendant undesired consequences. Now and again I would like to work with somebody who simply does what is expected of him/her.

B. A second element that has had a big impact on the CS is the Medical Device Directive because it has to a large extent contributed to bringing about a change in mentality in the world of sterilization. As you all know the MDD is aimed at the bringing onto the market of safe medical devices within the open European space.
But the extrapolation of the essential requirements to the central sterilization department, because the CS is just another producer of medical devices, has gradually led to the insight that the CS is just another production department which is subjected to the same rules as an industrial production facility. Quality management with documentation and traceability as corner stones, validation of processes and preventive maintenance of machines, risk management etc. have become household concepts in a CS.
Quality, in other words meeting the needs of the customer, was, in earlier, more innocent times just an ethical requirement because the patient had a right to it. But all that has changed.
The competition with third parties forces the sterilization department also for economic reasons to be vigilant.
In this way the MDD has in any case greatly contributed to turning the sterilization department into a professional unit.

C. A third element in this Darwinian evolution is the appointment of a person who is ultimately responsible for the department, similar to the pharmacist in France and in Belgium, the expert

sterile medical devices in the Netherlands, the microbiologist in Turkey. This has resulted in more autonomy for the departments which are now managed by specialists. They have demanded and been granted their own slot in the organigram of the hospital. They were finally recognized and accepted as full, competent discussion partners.
Because the department has its own responsibility it has become a lot easier to fend for the rights of the patient when these are threatened for example as a result of the irresponsible re-use of devices meant for single use or when shortcuts in procedures are taken as a result of a lack of time and/or bad planning.

3. As a result of centralization, the MDD, the appointment of a manager but mainly through the commitment of its members of staff sterilization has made a lot of progress on the road to its ultimate goal: the delivery of a medical device of the highest quality. In the meantime sterilization finds itself on a roundabout. It will have to choose which turnoff to take in order to reach the goal, the state-of-the-art device. The criteria informing the choice of turnoff are bewildering and mutually exclusive:

A. The shortest route is to me: sterilization within the hospital in a department run and controlled by the hospital. This is still the most logical model because not only does one remain in control of one's own department, independent from third parties but one also retains knowledge and know how. By the way: the loss of knowledge is irreversible. This route

makes it possible to react flexibly in a fast developing environment to the ever changing questions of the customer. Moreover it is probably cheaper than insourcing. Conditions which have to be met are sufficient size and the willingness by management to make the necessary investments and to keep on making them in order to keep the department up-to-date. The CS will only be able to defend its position it has had sufficient means put at its disposal.
It is unacceptable that hospital management allows things to slip out of control and afterwards uses the lack of quality as an argument for in- or outsourcing. Nevertheless this is what happens in certain countries.
Insourcing or allowing the use of road charges have to be followed very critically.

2. The fastest route: Outsourcing or external centralization. This model is driven by the rationalizing of the scarce financial means in the health sector, the ever increasing demands being made and the personnel problems. The sterilization department is becoming a sterilization business, a business model.
The world is keenly following the French experiments in which hospitals are collaborating in the setting up of central departments. I am convinced that if they succeed they will be copied everywhere. In this scenario one should beware of the fact that hospitals do not set up small, illegal sterilization departments or that in the operating theatre once again sterilization through immersion is opted for. This

would not be progress but regress because quality could no longer be guaranteed.

These are the challenging choices sterilization is faced with today on a macro level.

4. A fourth is that
a. in the department the motto will be “back to the future”!
The ever more complex instruments will mean that on the shop floor there will be a partial return to more manual work. This is e.g. already the case with instruments used for brain endoscopy and robot surgery.
You can rightfully ask yourself the question what progress means for the sterilization department in a time of more and more automation.
In the same context it is elucidating to take a closer look at the evolution in the NOTES (Natural Orifices Transluminal Endoscopic surgery) surgery technique. These are surgical procedures which are carried out with endoscopic techniques via a normal body opening. They raise a number of important questions about the need for sterility of certain instruments and additional parts.

b. As far as the controls are concerned the replacement of chemical and biological indicators by measuring physical parameters will undoubtedly continue. Whether the “goubane” too will become a compulsory test remains an open question. In this case too sterilization simply follows what is

happening in our homes: wireless connections are becoming the norm.

c. In a broader framework the sterilization world certainly has to make a greater effort to get a real voice in the debate about the norms. At the moment the drafting process favours industry too much. Taking part in the deliberations is essential because the norms will determine the present and future outlook of the department. The European National Sterilization Societies should become much more active in this area and there should be a greater willingness to mutually exchange information.

d. Sterilization urgently needs more independent research. It makes innovation possible and means that processes and techniques can be evaluated on their real merits. France can play a leading role in this area because already quite a lot is happening in France in terms of research e.g. in the framework of the training of pharmacists, responsible for sterilization. But it is essential that knowledge is shared with the rest of the world. This is where the linguistic shoe still pinches.
In this way the foundations can be laid for a real evidence based practice. That this is not always the case is a fact. For example the practice of compulsory pre-desinfection and steam sterilization times of 18 minutes raise a lot of eyebrows amongst experts. I would like to warn you against a false sense of security because even after 18 min. prion proteins can remain infectious. Moreover pre-desinfection is not always carried out diligently.

Conclusion:
It has often been claimed that the sterilization department is the heart of the hospital. We are now at a historic moment at which some would like to transplant this heart. You can rightfully ask whether sterilization in the hospital is really useful or has been useful. And this time the question is no longer academic but it is about the future of the department, our future. By the way, I find it disconcerting that now that we have sterilization more or less under control, we hear more and more about in- and outsourcing. But we should not be guided by our emotions. Reason forces us to remain objective and to wait until the new experimental tracks can be evaluated. Only then the appropriate conclusions can be drawn.

We should not overestimate the importance of sterilization. Sterilization is really not all that difficult. And if it were complex that my motto would still be “Keep it as simple as possible”. That is why I doubt whether the introduction of more and more management concepts will ultimately contribute to a better practice in sterilization departments.

We should not lose sight of the fact that the CS provides a facilitating service. Which does not mean that sterilization is not important, on the contrary. But we should not forget that we can only be as important as the service we provide. Our product should have the highest possible quality. We can and have to be big in something small.

This requires permanent alertness and empathy with the patient.

Finally I would like to congratulate the CEFH on the 30th anniversary of its study days. They have been of seminal importance in the development of the CS in France. They have to a large extent contributed to the transformation of information into knowledge and in the dissemination of this knowledge. And knowledge is still the best medical device.

I would like to extend my congratulations to all members of staff of the CS because you are responsible day after day for putting theory into practice and therefore you are the ones who have made it possible that French sterilization is of such a high quality level.

Lot’s of success in the CS and in your private lives.

Wim Renders,
Lanquais, 08/02/2008