STERILIZATION PRACTICES AND HOSPITAL INFECTIONS: IS THERE A RELATIONSHIP

S1:

S2: With this presentation I want to define the relationship between bad sterilization practices and hospital infections, to identify and criticize the bad practices and propose solutions, to give samples of how to integrate norms, SOPs and guidelines to our daily routine to achieve good practices, and to review the literature reporting the importance of good and bad sterilization practices.

S3: Everyday a lot of surgical procedures have been being performed at hospitals all around the world which means that a lot of patients have been contacting with reprocessed medical instruments every day. The major risk for those patients is the risk of infection if the instruments are not reprocessed in the way they should be. Otherwise THERE IS NO RELATION BETWEEN HOSPITAL INFECTIONS AND GOOD STERILIZATION PRACTICES!

S4: I say this strongly, because of the exciting changes and increased focus on safety and quality. Some of these changes may be short-lived, but some will truly revolutionize the way healthcare is provided. Today, Quality defines both success and failure for physicians, hospitals, and the executives who lead in the healthcare industry.

S5: Before 1995, no one was talking about patient safety and “To err is human” mentality was still accepted. In 2000, a small number in a few pioneering places had developed a strong commitment but, Its impact was limited and Most of health care was unaffected. Since 2005, the majority of health care institutions are involved to some extent and public awareness has soared.

S6. Medical Device Directive also guarantees all medical devices used at hospitals in member countries. According to this directive, member countries have to take all necessary steps to ensure that devices may be placed on the market and put into service only if they do not compromise the safety and health of patients, users and, where applicable, other persons when properly installed, maintained and used in accordance with their intended purpose.
S7: So, according to these regulations and quality management systems we are supposed to use safe medical devices.

S8: But, in 2011, The BBC broadcast a documentary entitled "surgery's dirty secrets".

S9 - 10: It was about problems and infections which occurred in NHS hospitals in UK due to badly manufactured surgical instruments.

S11: Tom Brophy who is the lead technologist in NHS to evaluate instruments before they are accepted, have reported that these instruments having no quality assurance may affect decontamination procedures. They examined 4800 new surgical instruments which were ordered by several hospitals in United Kingdom.

S12: They reported that 15% of the instruments had potential problems like machining burrs and debris in the teeth of the tissue-holding regions, ratcheted instruments, deficient cutting action, protruding guide pins, and corrosion. This study demonstrates the value of quality control for new surgical instruments as blood and tissue debris may collect in the imperfect surface which is impossible to clean.

S13: This brought more concerns as prion disease may survive routine sterilization processes. The Massachusetts Department of Public Health announced in 2013 that five patients treated at Cape Cod Hospital between June and August were at low risk of infection for Creutzfeldt-Jakob disease (CJD). Afterwards, New Hampshire announced eight patients treated at a hospital in New Hampshire may also have been exposed. Surgical instruments used on the patients may have become infected with the microscopic prion protein after they were initially used on someone now suspected of having carried the disease. Normal sterilization procedures at hospitals reduce, but do not eradicate, the protein that causes CJD.
S14: More interestingly, John Collinge, director of the Medical Research Council Prion Unit at University College London, warned that fragments of sticky proteins found in the brains of people with Alzheimer’s disease could potentially be spread to others via contaminated surgical instruments and other medical procedures.

S15: In fact these problems are more related to the standard operating procedures in CSSDs than the quality of instruments. SOPs create more structure in the activities. Well-written SOPs explained visually through a flowchart or annotated illustrations, if needed, make it easier for the members of staff to do their jobs.

S16: Reprocessing of medical instruments is a series of steps involving transfer, pre-cleaning and decontamination, preparation and maintenance, packaging, sterilization, and storage until the moment of use.

S17: In each of these steps it is essential to be adhered to the defined rules of national and / or international guidelines from respected working groups such as RKI, CDC.

S18: and WFHSS. Deviating from the best practices in the sterilization process or failure to comply with basic rules will lead infection. Moreover, bad sterilization practices which are not compatible with any of national or international guidelines increase this risk.

S19: All the surgical instruments are contaminated with blood and microorganisms in different levels after each operation depending on the operation site. The elimination of micro-organisms from a device during a sterilization process is time-dependent, influenced by the intensity of the sterilization process and of the level of the initial microbial contamination.

S20: Besides that, holding time before reprocessing is also important for effective cleaning and also to achieve sterility assurance level.
**S21:** We have reported that the cleaning of the surgical instruments in the first 6 h after use is essential in order to ensure effective disinfection and sterilization by proving that the bacterial count on a used instrument starts to increase logarithmically after 6 h at room temperature and reaches up to $3 \log_{10}$ CFU/cm² after 12 h.

**S22:** Inadequate cleaning of reusable surgical instruments is a common error. One of the most important reasons for inadequate cleaning is lack of enough instruments in the hospital. The staff is forced to shorten the reprocessing time because of the large numbers of patients, which pushes the members of staff to seek short cuts.............

In particular, special attention is required to clean lumened and complex instruments such as arthroscopy. In a case-control study being done following a surgical site infection due to *Pseudomonas aeruginosa* on a patient who underwent arthroscopic surgery in 2009 in Texas, it has been proven that the lumens of the complex structured instruments used during arthroscopy had not been cleaned well.

**S23:** The scandal in dental clinic in Oklahoma which occurred because of dental instruments used without being sterilized in March 2013 is another example of cases sourcing from bad sterilization practice. 7000 patients were screened for HBV, HCV, and HIV due to this scandal

**S24 - 25:** And other scandals from Europe...

**S26:** Despite the fact that the size and the weight for packs to sterilize are clearly defined in all sterilization guidelines and norms, sometimes these guidelines are not followed as they should be as in the case we had in beginning of 2000 at my hospital. It was an outbreak of *Serratia marcescens* mediastinitis in the intensive care unit of cardiovascular surgery. 17 patients were infected and 5 of them died.
S27: The microbiological results of the epidemiological survey that was focused on the central sterilization unit proved that the cause of the outbreak was the use of inadequately sterilized theatre linen. Because we found out that the bacteria isolated from the patients and from the so called sterile drapes were exactly the same genetically. Besides the lack of control and monitorization of sterilization processes the most important problem was reported as the excessive weight of the theatre linen packs. The packs were almost 15kg.

S28: It should also be kept in mind that classical cotton textile drapes have no efficient microbial barrier according to ISO 13795. Besides its inefficient bacterial barrier, folding and packaging textile drapes increase the number of particles in clean area of CSSD which required complying with ISO 8 clean room standards.

S29: A group of American plastic surgeons performed a study to determine if a disposable draping system is superior to reusable draping materials in the prevention of implant-based breast reconstruction infection. From March 2010 through January 2012, 107 women were randomized and 102 completed the study. In the Reusable Group, there were 5 infections (12%) within 30 days compared to 0 (0%) infections in the Disposable Group which is statistically different. There was a trend for positive wound cultures (11% vs. 3%) and positive drape cultures (17% vs.4%) in patients with clinical infection. They concluded that Disposable draping material is superior to a reusable draping system in the prevention of clinical infection within the immediate postoperative period.

S30. In fact it has been already proven 30 years ago that single use drapes decrease the infection rate up to 43% in clean operations and the cost up to 7.5% at the end of a year. So, it is a big question mark for me that although it is more expensive and unsafe why do we insist on using textile drapes. Wrong cost calculation? Bad management? Traditional surgeons? Or what?
**S31.** Misuse of immediate-use sterilization (flash) is another example of bad practice. This process is complex and requires a facility to consistently follow all the necessary steps each time to ensure the sterility of the instruments to the point of use. Improper technique can result in the use of contaminated instruments in surgery resulting in serious consequences including surgical site infections.

**S32.** Here is a very bad experience from Spain. A retrospective analysis was carried out on 328 eyes of 220 patients who underwent LASIK over 9 months. Forty-six (24.5%) of 188 cases of DLK were diagnosed. Sphingomonas paucimobilis and Burkholderia pickettii were isolated in the reservoir of the steam sterilizer. Electron microscopy revealed gram-negative microbes on the tubing walls. After changing the reservoir of the steam sterilizer and implementing a new cleaning and sterilization protocol based on air-drying the instruments and draining and drying the reservoir of the sterilizer, the occurrence of DLK stopped. The authors concluded that the short-cycle steam sterilization, could be responsible for an outbreak of DLK.

**S33:** Lorraine Hutzler designed a program to reduce the use of immediate-use sterilization at their hospital. They instituted a policy whereby nursing leaders are required to approve immediate-use sterilization before it can be used and developed guidelines, and monitored compliance daily. These efforts decreased the use of immediate-use sterilization from 79% in 2010 to 7.5% in 2012. They simultaneously saw an improvement in surgical site infection from 5.4% in 2010 to 1.4% in 2012. Facilities should take action and increase their surgical instrument inventory, employ a scheduling conflict mechanism, improve communications between the operating room and sterile processing personnel, and educate all those involved with immediate-use steam sterilization.
Another problem is reuse of single use devices. In the revision of the Medical Device Directive that was approved in 2017, the reprocessing and further use of single-use devices (SUDs) may only take place where permitted by national law, and in respect of the requirements laid down in this Regulation. By reprocessing a single-use device with the view to make it suitable for further use within the Union the reprocessor should be considered the manufacturer of the reprocessed device. No CSSD can fulfill this requirement.

So we are supposed not to reuse SUD....

BUT in many hospitals around the world, SUD are still being reused.

Here is one of the end results. Endophtalmitis following catarct surgery. In 1994 at my hospital, six patients who were operated upon during the same day developed bacterial endophthalmitis on the following day. Seven eyes were affected. Vitreous cultures taken from six eyes were positive for an Enterobacter sp. Despite antibiotic treatment systemically, subconjunctivally and intravitreally, four eyes had to be eviscerated.

If you think that these cases were over with 21st century, you are wrong. Because in 2010, in another hospital, 7 old patients having cataract surgery on the same day, lost eyesight.

Only a year ago we heard another similar scandal...

What is wrong in the kingdom of ophtalmology. In fact, almost everything is wrong. They still use formalin tablets for the microscope, clean and disinfect the instruments with inappropriate detergents and disinfectants such as sodium hypochloride, use hot air oven with inappropriate exposure time.

No centralization No adaptation No standardization No education

Besides these, they reuse single use phaco cassettes and tubings. This is proven as the most common reason for infections following cataract surgeries.
Another group of instruments which are commonly reused are laparoscopic instruments. Surgeons prefer SULI in stead of reusable ones as they are much cheaper.

But SULI are impossible to clean and impossible to sterilize. You can see the blood coming out of the instrument lumen after vacuum process of hydrogen peroxide sterilizer.

The OR technicians try to sterilize these instruments in high level disinfectants. This method was accepted as appropriate method for laparoscopic instruments by CDC until today. But, recent epidemics pushed CDC also to the point of Europe. In Europe laparoscopic instruments are critical instruments and have to be sterilized like all other critical instruments. Liquid sterilization is not acceptable any longer.

One of the biggest epidemics due to high level disinfection of laparoscopic instruments is reported from Brazil.

An epidemic of infections after video-assisted surgery caused by rapidly growing mycobacteria (RGM) and involving 63 hospitals in the state of Rio de Janeiro, Brazil, occurred between 2006 and 2007. High level disinfected instrument with 2% glutaraldehyde were used instead of sterilization. 1051 possible cases were reported due to inappropriate decontamination method.

Another bad example from India. A series of 145 laparoscopy port site infections due to Mycobacterium chelonae were found in 35 patients following laparoscopy at a single hospital over a six-week period. The contaminating source was ultimately identified as the rinsing water used for washing chemically disinfected instruments. The organism survived and grew within the biofilm at the bottom of disinfectant trays and within the outer sleeves of reusable laparoscopic instruments. Remedial control measures included changing to ethylene oxide gas sterilization of laparoscopic equipment instead of chemical sterilization, thorough dismantling and manual precleaning of instruments, drying prior to gas sterilization, and random checks of environmental samples within the operating room complex for acid-fast bacilli.
No further atypical mycobacterial infective episodes have occurred in the three years since the study.

S49: Making gauzes at hospitals is another important problem for patient safety.

S50: As gauzes are medical devices, according to MDD they have to be produced and sterilized under environmentally controlled and validated conditions. But in hospital environment it is impossible to provide these conditions. In this photo you see how much residues remains on the panths of the staff.

S51: These residues stays in the surgical site as well and may cause foreign body reaction and infection.

S52. Sometimes sterilization may fail due to really stupid reasons. If we have no monitorization, to release control or quality control w emay easily miss these failures. Here is an example from a dental clinic in Hong Kong. Dental surgery assistant on duty on autoclaving cycle: did not press the ‘Start’ button of the autoclave; did not check if the autoclave signaled ‘Ready’, an indicator of the completion of the autoclaving cycle, when taking the instruments out from the autoclave; did not check the printout from the autoclave; unloaded the unsterilized instrument packages from the autoclave and put them on the storage shelf. As a result of this stupid fault, A total 250 exposed patients were identified for risk assessment and testing for blood-borne viruses, HBV, HCV, HIV. Immunization and hyperimmune globulin for hepatitis B, and tetanus toxoids were given to the exposed patients where indicated. Exposed patients were followed-up for 6 months.

S53. Another example is from Australia. They were lucky as they had a manual batch control. Southern Health operating suite staff discovered an unchanged internal integrator and external chemical indicator of an instrument. It appeared that the item had been dispensed incompletely processed. A recall was initiated and 5 unsterile items were found. Seven patients was received an item from the implicated batch. When compliance with the release policy from CSSD was reviewed, documentation was found to be incomplete, including no releasing signature.
The operating room staff routinely entered the sterile processing area to retrieve stock. That is unacceptable. The manual batch tracking system provided a risk management advantage as only seven patients (out of 1000) required follow-up after detection of the breach.

S54: These two sterilization breach prove us the importance of documentation and traceability. Without a documentation system it is very likely to miss these kinds of failures. CSSD is responsible of the sterility of all reprocessed items until it is used on the patient. That is why, Reprocessed items may not be released without the approval of CSSD staff. All the reprocessed sterile medical items and especially the implants should be traced to the patient.

S55. Of course there are a lot more cases of sterilization failure published or unpublished. We can only reach the published ones. As you can see from this table made by Dr. Southworth there a lot reports from all around the world not only developing countries but also so called developed ones. This article reviews reported outbreaks and incidents associated with inappropriate, inadequate, or unsuccessful decontamination of surgical instruments, indicating potential pitfalls of decontamination practices worldwide.

S56. But in summary, the only reason for sterilization failure in all these cases is non-standard and poor sterilization practices. Poor sterilization practices that do not comply with the norms and guidelines directly lead hospital infections.

S57: In conclusion, attention should be paid to the best sterilization practices at hospitals. For best practice, it is required to have good team leader, written standard operational procedures, to comply with national and international guidelines and norms, to employ trained staff and to continue education, not to reprocess single use devices, to monitor and validate the reprocessing cycles, to record all steps that are performed during the process and to sustain a successful quality management. The last but not the least is to learn lessons from previous errors. As long as the good sterilization practices are followed, sterilization has nothing to do with infections.

S58: Thank you!