

# Ethical aspects on hygiene, infection prevention and infection control

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**Introduction** In many aspects healthcare, dentistry included, can be regarded as a high-risk activity. It would be impossible to have laws, regulations or other demands on healthcare providers to avoid all known or theoretical risks when treating patients. A risk-prevention approach would make modern healthcare almost impossible to carry out. Dental, medical and surgical procedures will always involve minor or larger risks as well as known and unexpected side-effects.

## **Infectious diseases – one of the major threats to mankind**

The global burden of infectious diseases has a major impact on all healthcare systems as well as international prosperity and welfare. Throughout the history of mankind, infectious diseases have been one of the largest killers. As recently as the 19th century, the likelihood of dying prematurely from infectious diseases was as high as 40%.

Not until the late 1930s did humanity find a way to counterattack bacterial infections through penicillin and antibiotics. For more than half a century, antibiotics have been – and still are – important lifesavers. By the mid-1960s, confidence in the ability to fight infectious diseases had become so high that some professionals were even regarding infectious microbes as largely conquered. However, with the ever-increasing development of antimicrobial resistance, the world population faces a serious threat to major achievements in healthcare, which is in turn a challenge for the development of modern society and global economy.

## **Discovery of micro-organisms – important turning point in history**

Giralamo Fracastoro (1483–1553, Italian physician, poet, mathematician and astronomer) is generally given credit for being the first to recognize the existence of tiny living particles that cause disease by direct contact with humans and animals and by indirect contact with objects. He proposed that infectious diseases spread through very small particles—too small to be seen—which he called “seminaria”. Fracastoro anticipated, by nearly 350 years, one of the most important turning points in biological and medical history: the discovery of micro-organisms by Louis Pasteur and Robert Koch in the late 1870s.

The idea that infection is spread by air was described already in the second century A.D. The Roman Marcus Varro advised against building houses near bogs and marshes *“because there are certain minute creatures, which cannot be seen by the eyes, which float in the air and enter the body through mouth and nose, and there cause serious disease.”*

## **Women died because doctors didn't wash their hands!**

In the early 1800s, outbreaks of puerperal sepsis, a streptococcal infection, were responsible for the deaths of up to 70% of new mothers. Already in 1846, the Hungarian surgeon/doctor Joseph Ignaz Semmelweis (1818–1865) discovered the importance of hand hygiene, thirty years before the works of Koch and Pasteur.

Semmelweis was the head of one of the two birth clinics in Vienna. The number of women who died of puerperal fever at one of the clinics was as high as 13%, and at the other one

only 2%. The only difference between the two clinics was that at the first clinic, doctors and students of medicine attended the deliveries, often coming directly from an autopsy, but at the second clinic the deliveries were done by midwives. This difference between the two clinics was generally known, and it was supposed to be caused by the association with the hospital and by some unknown factor, depending on bad atmospheric conditions.

During an autopsy, Semmelweis' colleague Jakob Kolletschka cut himself and rapidly developed a high fever and blood poisoning – the same symptoms as the women at the first clinic showed.

Semmelweis deduced that “corpse particles” were transmitted from the department of autopsy to the maternity ward. He then introduced the procedure that all doctors and students had to wash their hands before entering the maternity ward to get rid of the “corpse particles.”

These precautions eventually resulted in the death rates at the two clinics becoming almost equally low: 1.27% and 1.34%, respectively. In spite of the good results, the head of the hospital, professor Joseph Klein, was decidedly against Semmelweis' ideas, and prohibited them from being used at the hospital.

Semmelweis was met with opposition from fellow scientists, which resulted in his being more and more frustrated and eccentric, and he made enemies among almost the whole of the academic hierarchy. The death rate at several European maternity wards was as high as 26%, and Semmelweis' studies were a dangerous proof that it was the doctors themselves who caused the high death rates, and that precautions were so easy and simple: many women could still have been alive if only their doctors had washed their hands!

Semmelweis was eventually admitted to a mental hospital. He was discovered to have an infected wound on one of his fingers, acquired during a gynaecological operation. In spite of all efforts to stop the infection, Semmelweis developed serious blood poisoning which led to his death at the age of 47. It is a tragic irony that Semmelweis died from the disease he had devoted his life to fight.

It was not until 14 years after Semmelweis' death, in 1879, that his ideas started to be acknowledged when the works of scientists like Louis Pasteur and Robert Koch supported Semmelweis' finds with their own reports.

### **Primum non nocere est – the primary goal is to cause no harm**

The most fundamental issue in all forms of healthcare must be to cause no harm or to cause as little harm as possible. All individual daily activities are associated with certain risks, such as accidents, damage, diseases etc. We all know that driving a car will include certain hazards which can be reduced by our own individual choice of precautions, such as keeping speed limits, the use of safety belts, never drive under the influence of alcohol or other drugs etc. There is also a responsibility among car manufacturers to develop vehicles that are as safe as possible based on the analysis of actual or supposed accidents or risks. In aviation security, all incidents and crashes are analysed in order to make flying and airplane construction as safe as possible. However, as passengers, we know that there are risks even if they are very low.

## **The importance of trust and confidence**

In the car, we can take individual responsibility and, as in many other individual daily activities, to a high degree reduce the risks. In the case of airplane transportation, the flight crew shares the risk of hazards with the passengers. These facts give us comfort and confidence.

All healthcare personnel must recognize that providing health care is very different from all other societal functions and services in the sense that the patient will actually take the whole risk, while the healthcare providers will make the risk analysis, inform the patient about the alternatives and give suggestions and advice for proper methods of care. Patients should be in no doubt that the healthcare they receive is safe.

Most daily activities are performed on the basis of free and individual choices, but healthcare is based on personal needs when well-being, health or life is threatened.

## **Micro-organisms know no borders**

The European Union has enforced strong Medical Devices Directives as well as recommendations, standards and norms to reduce risks and improve quality in healthcare. In spite of this mutual European legislation, the issue of infection control in dentistry varies greatly throughout Europe as does the understanding of the risks. Every member state still seems to believe that things are different within its own borders. But since micro-organisms are universal and know no borders, both national and professional protectionism are counter-productive.

Despite national, regional and professional differences, the most basic fundamental principle that must be shared by all healthcare personnel is ethics. In a human rights perspective, cross-infection control must be recognized as today's most important task in all healthcare systems. Everyone has the right to benefit from any measures enabling him or her to enjoy the highest possible standard of health attainable. It is part of the healthcare profession to prevent (as far as possible) epidemic, endemic and other diseases as well as accidents.

## **Respect for autonomy, non-maleficence, beneficence, and justice**

The book "Principles of Biomedical Ethics" by the authors Beauchamp and Childress is a classic in the field of medical ethics. The first edition was published in 1979 and 'unleashed' the four principles of respect for autonomy, non-maleficence, beneficence, and justice:

- **Respect for autonomy:** respecting the decision-making capacities of autonomous persons; enabling individuals to make reasoned informed choices.
- **Beneficence:** this considers the balancing of benefits of treatment against the risks and costs; the healthcare professional should act in a way that benefits the patient.
- **Non-maleficence:** avoiding the causation of harm; the healthcare professional should not harm the patient. All treatment involves some harm, even if minimal, but the harm should not be disproportionate to the benefits of treatment.
- **Justice:** distributing benefits, risks and costs fairly; the notion that patients in similar positions should be treated in a similar manner.

## **Obvious principles can sometimes be difficult to fulfil**

The suggested principles of respect for autonomy, beneficence, and justice are rather easy to identify, recognize and pursue. At a quick glance, the most obvious principle will actually be the most difficult to achieve for all healthcare providers – the principle of ‘non-maleficence.’

Having the theoretical knowledge that proper hand hygiene will substantially reduce the number of Health Care Associated Infections (HCAI’s) and then not performing the procedure properly when treating patients will actually mean to neglect one of the four most basic principles in the field of medical ethics. The risk for an individual patient within dental care might be low, but it is still there as a disturbing fact for the healthcare provider.

The same principle applies to the use of modern medical devices. If anybody uses yesterday’s technology and techniques in daily practice—knowing that there are more modern, more efficient, safer equipment and still not replacing it with up-to-date devices and procedures—they will inevitably, at a certain stage, violate the principle of ‘non-maleficency.’

The paragraph above should not be understood as if only modern devices and processes are valid. There are of course many established procedures and devices that can still be deemed best practice, but they must be continually validated and re-evaluated.

## **Professional responsibility**

In modern health and medical care facilities, a lot of sophisticated medical devices are used in the daily care of patients. The standard of equipment, technologies and processes available today was in some cases science fiction not many years ago. Globalization, rapid international transport possibilities, the increased number of international arrivals, health tourism, transfer of micro-organisms and the development of antimicrobial resistance place high demands on all healthcare providers. Professional responsibility and regulations must keep up with the pace of change in order to reduce the global burden of infectious diseases.

## **Medical devices must be safe during their entire lifespan**

The requirements in the European Medical Devices Directives are not only very high for the manufacturer, but also for the users. The newest amendment to the Medical Devices Directives (2007/47) clearly states that *“All medical devices must be produced in a safe environment and all products must be safe for patients, personnel, technicians and others. These legal requirements must be fulfilled by manufacturers and must be maintained and monitored by the end-user during the entire lifespan of the medical device.”*

In the case with disinfectors and sterilizers, to ‘be safe’ means that instruments must be clean, decontaminated, disinfected and sterilized after the process in such devices. This puts a lot of responsibility into the hands of the dental personnel—not only at the time of acquiring specific equipment, but also during the entire lifespan of the device. They have to ensure that the medical device is safe as a result of the process of the purchased equipment’s intended purpose as stated by the manufacturer in the Declaration of Conformity.

In the Declaration of Conformity, the manufacturer must describe the intended purpose in detail, as well as how this purpose is validated and verified, and according to which laws and regulations, norms and standards.

## **The role of harmonized standards**

Most norms and standards are recommendations to simplify the common European market, but some of the European standards are so-called harmonized standards. In accordance with the so-called method of presumption the producer, by fulfilling a harmonized standard, will also fulfil legal and regulatory demands within the European market. The EN standard for washer-disinfectors and the EN standard for sterilizers are harmonized standards.

## **European Standard for steam sterilizers**

Steam sterilization is more effective than other forms of sterilization because brief exposure to steam destroys most resistant bacterial species. Heat is rapidly achieved because of mass heat transfer as the steam condenses.

Steam sterilization requires exposure of each item to direct steam contact at the required temperature and pressure for the specific time. The major problems during the process are air evacuation, superheating and load moisture. Virtually all air must be evacuated during pre-treatment so that the saturated steam can come into contact with all surfaces of the goods during the sterilizing phase.

Homogeneous instruments require only the surfaces of the instrument to be sterilized. Hollow instruments with internal lumen have both inner and outer surfaces and the inner surfaces are difficult to access with steam. For energy to be released and to ensure that all items intended to be sterilized are accessible to the saturated steam in the sterilizer, it is important that the air first be removed from the sterilizer chamber and from all parts of the goods intended to be sterilized. Instruments and items located where there are pockets of air never come in contact with saturated steam and will therefore not be sterilized. The same thing goes for internal surfaces in hollow instruments, where air pockets can easily be trapped.

The European Standard EN 13060:2004 specifies the performance requirements and test methods for small steam sterilizers and sterilization cycles which are used for medical purposes or for materials that are likely to come into contact with blood or body fluids. All CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

## **Different sterilization cycles for different types of loads**

EN 13060:2004 specifies the general requirements for small steam sterilizers and the type of sterilization cycle. The different sterilization processes are defined as Class B, Class S or Class N cycles.

Class B – B refers to 'Big,' (a small sterilizer performing a similar cycle as large/big hospital sterilizers). Class B performs the sterilization of all wrapped or non-wrapped, solid, hollow load products and porous products. It is important to note that packaging material itself (paper, textiles) is a porous load and should be handled as such. All packaged/wrapped goods require sterilizing in steam-sterilizer processes with pre-vacuum and post-vacuum cycles. Sterile wrapping (packaging) is a prerequisite if sterile goods are to be transported and stored at different locations.

Class N – N refers to ‘Naked,’ indicating that the sterilization cycle is intended only for naked, non-wrapped solid products. Non-wrapped, sterilized instruments are intended either for immediate use or for non-sterile storage, transport and application. Sterilizers with only class N cycles are still widely used. However, these are increasingly being superseded by steam sterilizers with pre-vacuum and post-vacuum processes. Preconditioning with several pre-vacuum phases is essential for sterilization of wrapped, hollow or porous items.

Class S – S refers to ‘Specified.’ The sterilization of products as specified by the manufacturer of the sterilizer including non-wrapped solid products and at least one of the following: porous products, small porous items, hollow load products, single-wrapped products, multiple-layer wrapped products. Medical devices constructed only for the purpose of sterilizing hollow dental rotary instruments will be a class S cycle or rather a class B cycle only intended for a specified type of instruments. In accordance with the European Medical Devices Directives, the manufacturer must prove through verification and validation tests that the device process is safe, and in turn undoubtedly will result in sterile goods.

The responsibility of the user will be to ensure that the device will continue to be safe and that the process will result in sterile goods during the device’s entire lifespan – this should be tested and validated at the site of use, and at regular intervals.

### **The quality of steam will be essential for the result of the sterilization process**

The result of a sterilization process is greatly influenced by the quality of the steam, and the water quality influences the quality of the steam produced. Certain standards are therefore required for the quality of the steam as well as for the water being used. Solid particles such as welding parts, graphite, rust flakes, sand etc. must not be present. Nor can other liquids than the water itself or chemicals be present. The salt content should not exceed 1 mg/kg of steam. The ion concentration and pH-level will affect the sterilization results. For example, a single calcium carbonate crystal can harbour up to 100 viable bacterial endospores. Spores can have a 900-fold increase in resistance to steam when embedded in calcium carbonate crystals. Therefore deionized and clean water should always be used for steam sterilization.

Checking the so-called conductivity of the water gives a measurement of the salt (ion) content. The conductivity is the capability to transfer electricity which in turn is dependent on the amount of ions in the water. Higher levels of ions (salts) in the water will result in higher conductivity. The conductivity is also related to the risk of corrosion of instruments, e.g. rust, calcification, mineral deposits, discolorations, etc.

### **The end result will never be safer than the weakest link**

The result of all steps included in the reprocessing of instruments from usage through transport, decontamination, cleaning, disinfection, sterilization, storage and delivery is greatly influenced by the handling itself. Proper instrument handling directly influences the lifespan of the instruments and also to a great extent the quality as well as the final result of treatments carried out with these instruments.

To ensure proper and complete elimination of all biological materials prior to sterilization, it is crucial to control and handle the whole process of decontamination—cleaning and disinfection—correctly. The cleaning of instruments and articles is the all-important issue in decontamination, disinfection and sterilizing. It is not only the micro-organisms (i.e. bacteria,

virus, fungi etc.) that have to be removed during the cleaning process, but also organic substances. These substances consist of carbohydrates, fat and protein and if they are not removed from the instruments before sterilization, the sterilization process itself will prove inefficient.

### **The patient in focus**

Quality procedures, regulations and requirements aim at putting the individual patient in focus. It is the responsibility of the producer to make sure that medical devices fulfil essential requirements—which also must be proven. Safety and performance must be validated and verified—side-effects and risks must be described and risk analysis shall prove that the advantages are superior to possible side-effects and hazards.

### **Patient safety, professional pride and job satisfaction**

Modern healthcare has every possibility to provide patients good care with high safety and quality. Cross-infection control and prevention, hygiene and sterilization must be recognized as today's most important tasks in all healthcare systems. Healthcare-associated infections (HCAI) cause tremendous additional costs, increase antibiotic resistance, jeopardize treatment outcomes, prolong patient suffering, decrease treatment capacity and create 'bad-will' for healthcare providers. The care provider must make sure that all patients should be able to get dental care with the best possible quality, the greatest possible safety, and with as few side effects as possible.

Healthcare providers have very delicate professional responsibilities in deciding when and if new technologies and processes should be included in regular clinical procedures—the benefits for the patients must always be in focus. This must include, not only the regular patients of the care provider in question, but all actual and coming patients at any care provider's.

### **Conclusions**

- The first approach to preventing disease transmission is to keep micro-organisms in their proper place by preventing contamination. If they should accidentally appear where they should not be anyway, they should be removed, killed or kept from growing to harmful numbers. Intervening should be carried out with the following priorities: cleaning, growth inhibition, disinfection, sterilization, surveillance, isolation, immunization and, if these measures are not successful, by antimicrobial therapy.
- With increased antimicrobial resistance and even bacteria that are able to destroy antibiotics, we must—to be able to succeed—go back to the basic principles described so many times in history: the importance of cleaning, decontamination, disinfection and sterilization as well as limiting outbreaks of disease through surveillance, isolation and destruction of infected material by heat. Such precautions are therefore some of the most important functions in all healthcare contexts.
- With increasing knowledge about the risk of transmission of infection and about hygiene, all types of care can be provided under safe, hygienic conditions that minimize the risk of transmission of infection.

- A decrease in the incidences of infectious disease also leads to a reduction in the use of antibiotics. This will save lives, reduce additional suffering and contribute to minimizing further development of antibiotic resistance.
- A decrease in the incidences of infectious disease also leads to lower incidences of patients with healthcare-associated infections, which will have a great impact on the care provider's reputation and economy.

A universal approach towards safety and quality in healthcare is necessary if progression and development are important. It is very easy to end up in a similar situation as in the Semmelweis case: due to professional protectionism, important initiatives and improvements can be at stake. True professionalism comprises fulfilment of the basic ethical principles of respect for autonomy, non-maleficence, beneficence, and justice. Practicing these principles will not only add patient value and safety but also professional pride and job satisfaction.

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