CORRESPONDENCE

Infection Risk in Sterile Operative Procedures—A Systematic Review and Meta-analysis

by Prof. Evelina Tacconelli, Dr. Niklas F. Müller, Prof. Sebastian Lemmen, Dr. Nico T. Mutters, MPH, Dr. Stefan Hagel, M.Sc., and PD Dr. Elisabeth Meyer
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Maintenance of Sterility: A Base of Aseptic Procedures

Poor hygiene is not only found in clinical practice but also in the manufacture and distribution of medical materials (1). The most frequently occurring errors include failure to observe well-known rules of hygiene, e.g., removal of jewellery from hands and arms before starting work or full covering of the hair on the head and face throughout the operation (category IB of the Robert Koch Institute guidelines).

For sterile medical devices the norm is the sterility assurance level of 10^{-6}, i.e., the probability of non-sterility should be equal to or less than 1:1 000 000. To monitor the maintenance of sterility during storage, information is needed on the filtration capacity of the air permeable components of the packaging material, in order to estimate the risk of recontamination by airborne microorganisms (see ISO 11607–1) (2, 3). Unfortunately, this information is currently rarely supplied by the manufacturer. The airborne microbial challenge (N_0) of terminally sterilized products is dependent on the airborne microbial concentration (particle size ≤ 3 µm) and the volume of air that enters the packaging during storage, which depends in turn on fluctuations in air pressure and temperature (see the Boyle-Mariotte and Gay-Lussac laws). According to the calculation $N_0 \times$ (100 – filtration capacity in %): $100 \times n \leq 10^{-6}$, commercial paper-based packaging material, with a relatively high filtration capacity of 99 %, guarantees sterility for only a few days at the required level, even in optimal storage conditions (20 colony-forming units per m3 of air, changes in temperature and air pressure not exceeding 2 °C and 15 hPa, packaging volume 100 cm³, n = frequency of changes in temperature and air pressure).

Millions or even billions of terminally sterilized products are used every day around the world. Therefore, even a low rate of non-sterility increases the risk of nosocomial infections that could be avoided by paying greater attention to the filtration capacity of the packaging material in relation to storage conditions. Not every requirement—as Tacconelli et al. (4) themselves write—has to be based on evidence.

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REFERENCES

1. Sinclair CS, Tallentire A: Definition of a correlation between microbiological and physical particulate barrier performance for porous medical packaging materials. PDA J Pharm Sci and Tech 2002; 56: 11–9.
2. Dunkelberg H, Schmelz U: Determination of the efficacy of sterile barrier systems against microbial challenge during transport and storage. Infect Control Hosp Epidemiol 2009; 30: 179–83.
3. Dunkelberg H: Sterile supply of medical devices and pharmaceutical products—quality standards and applied risk management. PharmInd, in press.
4. Tacconelli E, Müller NF, Lemmen S, Mutters NT, Hagel S, Meyer E: Infection risk in sterile operative procedures—a systematic review and meta-analysis. Dtsch Arztebl Int 2016; 113: 271–8.

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Conflict of interest statement
Prof. Dunkelberg has received payments from Kimberly-Clark. He holds a patent related to the topic of the article discussed.

Progressively Reduce the Number of Infections

The authors refer to the demand of the German Society for Hospital Hygiene (*Deutsche Gesellschaft für Krankenhaushygiene*, DGKH) for a "Zero Infections" campaign in Germany. They come to the conclusion that even now reductions in the rate of nosocomial infections much higher than the usually quoted 20 to 30% could be achieved for certain interventions (1).

However, the implementation of the DGKH demand is not as close as the authors seem to believe. The goal of the Zero Infections campaign is to establish awareness of hospital-acquired infection in society in the long term and to progressively reduce the number of these infections. The vision of eliminating nosocomial infections is primarily a political demand and cannot be tested with clinical evidence. Nosocomial infections are never a matter of "fate", as some expert witnesses presume to claim.

Lowering the rate of nosocomial infections will require not only measures to enhance hygiene but also improvements in building design (e.g., more single rooms) and in staffing levels (e.g., 1:2 or 1:1 care in intensive care units), new medical devices, or new treatments. We all need to get involved and contribute original ideas.

Other segments of our society have long adopted "Vision Zero": examples are road traffic (reduction of annual road deaths from more than 20 000 in the 1970s to well under 4000 today), occupational safety, and aviation. The German Traffic Safety Council (*Deutscher Verkehrssicherheitsrat*) has been committed to Vision Zero since 2007: "Life is not

negotiable." The German Social Accident Insurance (*Deutsche gesetzliche Unfallversicherung*, DGUV) says: "We align our prevention strategy clearly with Vision Zero." And Lufthansa follows the maxim: "Imagine your child is on board!" If we healthcare workers were to base our decisions on this principle, we would not go within a mile of some hospitals—often including our own.

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REFERENCES

1. Tacconelli E, Müller NF, Lemmen S, Mutters NT, Hagel S, Meyer E: Infection risk in sterile operative procedures—a systematic review and meta-analysis. Dtsch Arztebl Int 2016; 113: 271–8.

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Prof. Popp is medical director of HyKoMed GmbH.

In Reply:

As Prof. Popp explains, the Zero Infection campaign has the long-term goal of anchoring awareness of hospital-acquired infections in our society in order to progressively reduce the number of infections. The campaign does not, however, actually have reduction to zero as an endpoint. Prof. Popp therefore voices the criticism that elimination of nosocomial infections is a political demand and not amenable to substantiation or testing with evidence. In point of fact, we are also of the opinion that such a demand is inevitably primarily political in nature.

Nevertheless, we fear that without supportive evidence there may be negative consequences. For example, creation of exaggerated expectations (infection-free surgery) on the part of the general public may lead to prosecutions based on the "zero infections maxim". This, in turn, could have a negative impact on medical practice—e.g., increased or prolonged prophylactic administration of antibiotics to avoid postoperative infections because of the fear of legal consequences. Resistance rates could increase, resulting in nosocomial infections with bacteria significantly more difficult to treat.

Another alarming scenario—one that has already arisen in the USA as the result of a zero infection policy with penalties if nosocomial infections occur—is the reduction or complete discontinuation of microbiological diagnostics. In this way nosocomial infections are no longer diagnosed and penalties are avoided. The patients, however, suffer, because the nosocomial infections they actually have go undiagnosed and thus cannot be properly treated.

We share the opinion of Prof. Popp and the DGKH that discussion in the political arena is long overdue and are grateful to our colleagues for raising this demand and opening the discussion. Our publication (1) contributes to the scientific debate and provides, for the first time, data on the realistic potential for reduction of postoperative wound infections. We therefore believe that politically motivated demands and visions should stay within the boundaries of what can realistically be achieved by the medical profession and not arouse expectations among the general public that cannot be fulfilled.

As Prof. Dunkelberg rightly says, a sterility rating of $\leq$ 1:1 000 000 is assumed for sterile medical devices and sterile products. This means that "zero infections" can never be achieved when such devices are, for example, used in surgery (e.g., total hip replacement). Prof. Dunkelberg also lucidly explains how other factors (storage conditions and transport) can have a negative impact on sterility and thus increase the risk that medical devices are no longer sterile at the point of use.

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REFERENCES

1. Tacconelli E, Müller NF, Lemmen S, Mutters NT, Hagel S, Meyer E: Infection risk in sterile operative procedures—a systematic review and meta-analysis. Dtsch Arztebl Int 2016; 113: 271–8.

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The authors declare that no conflict of interest exists.