Role of disinfection in the Infection Prevention MultibARRIER System

Abstract

The role of disinfection in infection prevention has been analyzed over the past 50 years both in the form of benefit-risk evaluations as well as in an epidemiological sense. This has served as the basis for not only national and international guidelines and recommendations, but has also created the legal and normative framework for regulation of infection control (and hence of disinfection) in numerous acts and ordinances. Likewise, today the efficacy of disinfection measures, user safety and environmental compatibility in line with the state of the art are assured. Compliance as regards the conductance of disinfection measures has increased accordingly. The user is able to select and correctly employ the disinfectant most suited to the intended disinfection procedure. The quality of the apparatus used has vastly improved since the coming into force of the German Medical Devices Act (MPG). And finally the preconditions for conductance of disinfection have become so matter of fact that it is easy to forget just what progress has been made here. This applies e.g. to the facilities now available for hand hygiene, for decontamination of instruments, laundry and bedpans with washer-disinfectors as well as for surface disinfection and drinking water disinfection.

But it is the human being who continues to pose the greatest risk. Risk awareness does not always result in proper action being taken: it is hard to really grasp something that one cannot experience. As such, hand disinfection is often dispensed with, and without any sense of having done something wrong, the debate about the evidence of the usefulness of floor disinfection continues, and often medical practitioners fail to resort to exclusive automated decontamination of medical devices because of the costs incurred.

Hospitals, nursing homes and rehabilitation establishments are obliged to set up a quality management system, and to continue developing this. This calls for a quality assurance system regulating organizational procedures, responsibilities, workflow patterns for the entire domain of infection control within the hospital or medical practitioner’s premises and outcome evaluation (microbiological monitoring, surveillance of nosocomial infections). An indispensable component of primary prevention is assurance of structural and process quality. In turn, disinfection is indispensable for assurance of process quality.

Zusammenfassung

Die Bedeutung der Desinfektion für die Infektionsprävention wurde in den letzten 50 Jahren sowohl in Form einer Nutzen-Risiko-Bewertung als auch epidemiologisch analysiert. Auf dieser Basis sind nicht nur nationale und internationale Richtlinien und Empfehlungen entstanden, der Infektionsschutz (und damit auch die Desinfektion) sind gesetzlich und normativ in zahlreichen Gesetzen und Verordnungen verankert. Ebenso wird heute die Wirksamkeit der Desinfektionsmaßnahmen, die Sicherheit für den Anwender und die Umweltverträglichkeit entsprechend
dem Stand der Technik gewährleistet. Die Compliance zur Durchführung von Desinfektionsmaßnahmen ist entsprechend angestiegen. Dem Anwender ist es möglich, das für die vorgesehene Desinfektionsmaßnahme am besten geeignete Mittel auszuwählen und richtig einzusetzen. Apparative Verfahren haben seit dem Medizin-Produkte-Gesetz einen Qualitätssprung hinter sich. Und schließlich sind die Voraussetzungen zur Durchführung der Desinfektion so selbstverständlich geworden, dass darüber leicht ihr Fortschritt vergessen wird. So z.B. die Ausstattung zur Händehygiene, zur Aufbereitung von Instrumenten, Wäsche und Steckbecken mit Reinigungs-Desinfektions-Geräten, zur Flächen- und zur Trinkwasserdésinfektion. 

Der Mensch aber ist nach wie vor das größte Risiko; Einsicht schafft nicht immer Verhalten, es scheint so schwer zu verinnerlichen, was man nicht erleben kann. So verzichtet man zu oft und ohne Unrechtsbewusstsein auf die Händedesinfektion, streitet nach wie vor über die Evidenz der Fußbodendésinfektion, nicht selten fällt beim niedergelassenen Arzt den Kosten die geforderte ausschließlich apparative Aufbe-reitung von Medizinprodukten zum Opfer. Krankenhäuser, Vorsorge- und Rehabilitationseinrichtungen sind verpflichtet, ein Qualitätsmanagement einzuführen und ständig weiter zu entwickeln. Vorraussetzung dafür ist ein Qualitätssicherungssystem mit Regelung der Aufbauorganisation, der Verantwortlichkeiten, der Abläufe für den Gesamtbereich der Krankenhaus- bzw. Praxishygiene und der Ergebnisbewertung (mikrobiologische Überwachung, Surveillance nosokomialer Infektionen). Unentbehrlicher Bestandteil der Primärprävention ist die Sicherung der Struktur- und Prozessqualität. Zur Gewährleistung der Prozessqualität sind Desinfektionsmaßnahmen unentbehrlich.

**Risk-benefit evaluation and evidence**

In general, collecting evidence-corroborated data for infection control measures is an onerous task. One reason for this is that any strategy devised to obtain proof of correct hygienic practices compared with incorrect hygienic practices would be forbidden for ethical reasons. This situation is further obscured by the interval elapsing between any violation of hygiene principles and the occurrence of subsequent infection. Depending on the respective scenario, often several thousand cases are needed, something that for cost reasons is difficult to achieve especially in a prevention setting. The following conclusion can be drawn: if an infection control recommendation is justified on the basis of a scientifically corroborated risk-benefit evaluation, and if possible additionally by laboratory experiments, epidemiological justification is not then necessarily needed.

**Task definition**

Disinfection is effected with the intention of killing pathogens or putrefactive microbes by means of chemical and/or physical inactivation, so that under the given circumstances they can no longer give rise to infection or putrefaction, respectively. In the case of a microbially colonized indoor area, this entails eradicating the pathogens themselves as well as avoidance of the release of microbial volatile organic compounds (MVOC), in order
to counteract health disorders or sick building syndrome (SBS).

With the development of hand disinfection, a distinction was made at the same time between it and the measures used for skin, mucosal and wound antisepsis; the former is used to interrupt infection chains, while the latter measures serve to protect the patient against his/her own microflora, transient flora as well as against undesirable colonization or are used to treat local infections.

In medical establishments, patient and personnel protection against infection is the rationale that determines the indications for hand disinfection, surface disinfection (elimination of microbial reservoirs within the patient's immediate environment), decontamination of medical devices and laundry, disinfection of critical waste and in exceptional cases also of excretions. Special tasks include disinfection of drinking water in the event of critical microbial contamination and disinfection following bioterrorist attacks.

What has been accomplished?

1. In a legal and normative sense, since 2001 German hospitals, day clinics, etc. are obliged pursuant to the Protection against Infection Act to formulate an infection control policy for the internal procedures used for infection prophylaxis. This also entails regulation of disinfection. The Biological Substances Regulation, accident prevention regulations and BG regulations governing infection prevention among employees advocate task-specific disinfection measures, with definition of time, approach, product, adjuncts, personnel and responsibilities. The German Medical Devices Act (MPG) aims to assure the protection of patients, users and third parties by stipulating quality requirements in respect of hygienic safety when medical devices are placed on the market or decontaminated. Validated disinfection constitutes an indispensable component of every decontamination process. To assure reliable infection control practices, a written standard operating procedure (SOP) must be compiled for each medical device, specifying how it is to be decontaminated, including inspection and documentation. The state of scientific knowledge is furthermore defined in the recommendation formulated by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI), in medical/nursing guidelines compiled for specialist societies as well as in German (DIN), European (EN) and international (ISO) standards. There is virtually no RKI recommendation that does not address task-specific indications for disinfection. The guidelines of the German Society for Hospital Hygiene and of the Working Group for Hygiene in Hospital & Practice (AWMF) give disinfection the importance it deserves.

2. The role of disinfection in infection prevention has been analyzed over the past 50 years both in the form of scientifically corroborated benefit-risk evaluations as well as in an epidemiological sense, hence this has served as the basis for national and international guidelines and recommendations.

3. The scientific principles underlying physical and chemical disinfection have been reviewed in greater depth, hence the efficacy of disinfection measures, user safety (pose no harm to health, material compatibility) and environmental compatibility in line with the state of the art are assured. This also entails compliance as regards conduct of disinfection measures, something that is particularly obvious when managing outbreaks of nosocomial infection and in risk areas.

4. The properties of chemical disinfectants have been experimentally elucidated bearing in mind the spectrum of action and compatibility with established, and mainly standardized, test methods. On that basis, the user is able to select and correctly employ the disinfectant most suited to the intended disinfection procedure, while bearing in mind economic feasibility. One of the most important outcomes of more in-depth investigation of surgical hand disinfection is the, skin-protective, changes made to the entire procedure, dispensing with the 1 min. washing with soap which traditionally constituted the first step in surgical hand disinfection as well as the shorter exposure time of 1.5 min. depending on the product. Proof of efficacy as dictated by the European test hierarchy (quantitative suspension test with and without a load, practice-related test methods) is a precondition for inclusion in the Disinfectants List of the Association for Applied Hygiene (VAH). The Protection against Infection Act is the basis for the RKI Disinfectants List. Products are listed in accordance with test requirements specified by the RKI, entailing in-house tests as well as a study of submitted expert opinions. This list gives the user a sense of confidence when it comes to selecting a product. Within the framework of implementation of the Medical Devices Act (MPG), thanks to validation and ongoing verification a quantum leap has been seen in the quality of automated decontamination processes, as reflected in the increasing popularity of such processes.

5. The preconditions for conductance of disinfection have become so matter of fact that it is easy to forget just what progress has been made here. This applies e.g. to the facilities now available for hand hygiene (washbasin with dispensers for disinfectant, soap, skin care lotion and towel, in risk areas with terminal sterile filters and thermal siphon disinfection), for decontamination of instruments, laundry and bedpans with washer-disinfectors, for surface disinfection and cleaning (systems with automated dosage, change of utensils, etc.) and for drinking water disinfection (e.g. automated dosage facilities and computerized automatic monitoring of thermal disinfection measures).

What has not been accomplished?

- 100% compliance for conductance of disinfection – this fails, inter alia, because of human nature and of-
ten because measures that in principle are very easy to implement are deemed less effective by many people than e.g. technically cumbersome and complicated interventions.

- A sense of not having done anything wrong when disinfection is forgotten – to date there is failure to appreciate the necessity of this measure.
- The intellectual appraisal of the distinction between hand washing and hand disinfection, with its myriad implications in respect of efficacy, compatibility and necessity – this hurdle can be surmounted relatively easily through training and continuing education.
- Epidemiological evidence, provided hitherto only for outbreak situations and in relation to hand disinfection and distancing measures but not in the context of the microbes that are constantly shed as a normal course, of the efficacy of floor disinfection in patient areas – it is here that the viewpoints diverge between the advocates of primary prevention and the supporters of epidemiological evidence.
- Exclusive use of automated decontamination of medical devices with validated processes – to solve this problem, in particular in medical practitioners’ premises, cost-effective organizational forms e.g. access to central processing facilities or manufacturer-organized decontamination (one example is the cost-effective decontamination of reprocessable terminal sterile filters for water outlets).
- Decontamination of medical devices exclusively on the basis of differentiated SOPs – responsible cooperation between infection control departments, the public health service, appointed bodies and the manufacturer of the respective product is needed to overcome this hurdle.

Quality assurance in infection prevention

Successful infection prevention calls for a balanced interaction between the measures used for primary, secondary and tertiary prevention (Figure 1). Hospitals, nursing homes and rehabilitation establishments are obliged to employ uniform quality assurance measures aimed at enhanced outcome quality. To that effect, each establishment must set up and continue to develop a quality management system (Section 70 of Book V of the German Code of Social Law - SGB V). This calls for a quality assurance system regulating organizational procedures, responsibilities, workflow patterns for the entire domain of infection control within the hospital or medical practitioner’s premises and outcome evaluation (microbiological monitoring, surveillance of nosocomial infections).

Figure 1: Points to ponder

An indispensable component of primary prevention is assurance of structural and process quality. In turn, disinfection is indispensable for assurance of process quality.

Curriculum Vitae

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Axel Kramer studied medicine in Greifswald with study visits to all East-European countries. He habilitated in the subject of Hygiene in 1986, he was appointed as professor for Hygiene and Environmental Medicine at the Ernst-Moritz-Arndt University, Greifswald in 1990. He became head of the institute in 1992 and at the same time Hospital Hygienist of the University Clinic of Greifswald.
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His special interest is in the research for anti-microbicidal agents, the medicinal relevance of the vitaminoid thiocyanate, internal and allergic diseases, documented in more than 300 original lectures, about 200 contribution for monographs, school books and manuals as well as 49 patents.

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