Evaluation of disinfectants – the past begets the future

Die Beurteilung von Desinfektionsmitteln – aus Vergangenheit entsteht Zukunft

Abstract

The efficacy of disinfectants is verified on the basis of the results of test methods that have undergone continuous change in line with new scientific insights. To begin with, the prime focus was on the relevance of practical measures: germ carriers were contaminated with, for example, the sputum of patients suffering from tuberculosis or with stools, while the data provided on the recoverable bacteria following exposure were very imprecise since they were based on subjective evaluation – using different methods for the various countries. With the development of the quantitative suspension test various factors of influence were analyzed for the first time and the concept of reduction factors with logarithmic units was introduced. Today, such insights are viewed as something to be taken for granted in all European and international standards. European standardization orchestrated by the European Commission received important impetus from one scientist: H. Reber. An important aspect here was that the European standards introduced and recognized in principle a separation of the methods into “in-vitro tests” and “tests conducted under everyday practice conditions”. The increasingly more precise test methods have, on the other hand, soon revealed shortcomings in the disinfectant performance of even commonly used and hitherto accepted products. This gave rise to tests with a lower margin of error and with quantitative requirements. It is only by having a uniform overview that it is possible to detect and eliminate such shortcomings. The closure of several Hygiene Institutes at German and Austrian universities and the ongoing confinement of this discipline (infection control) to microbiology have additionally meant that already today there is a shortage of infection control experts who have a holistic view of matters and are able to spearhead further development of test methods. Without experts capable of taking a holistic view of matters, it will not be possible to create an atmosphere conducive to the development, and evaluation, of test methods, as needed for quality assurance. The less often disinfectants are evaluated by competent specialists, the greater is the risk that dangers are not recognized and countered.

Zusammenfassung

Die Beurteilung der Wirksamkeit von Desinfektionsmitteln basiert auf den Resultaten von Prüfmethoden, die sich permanent geändert haben mit dem sich ändernden Wissens- und Erkenntnisstand. Zu Beginn stand die Relevanz der Praxis im Vordergrund: Keimträger wurden z.B. mit dem Sputum von Tuberkulotikern oder mit Stuhl kontaminiert, die Angaben über die rückgewinnbaren Keime nach der Exposition erfolgten reichlich unpräzise auf Grund subjektiver Bewertung – nach pro Land unterschiedlicher Art und Weise. Mit der Entwicklung des quantitativen Suspensionstest wurden erstmalig unterschiedliche Einflussgrößen analysiert und der Grundgedanken von Reduktionsfaktoren mit logarithmischen Einheiten vorgestellt. Diese sind heute ganz selbstverständlich in allen europäischen und internationalen Normen zu finden. Die europäische Normierung im Rahmen der europäischen Kommission wurde
Text

The efficacy of disinfectants is verified on the basis of the results of test methods and on the conclusions drawn from these. While this appears to be a simple approach, for many decades it has been subjected to change – or, expressed more correctly, to progress. Since there is increasingly more reason to believe that many people entrusted with decision-making duties are not familiar with these historic developments, this paper gives a brief overview in the hope that a better understanding of matters will produce responsible decisions.

When efficacy testing of disinfectants was first introduced 50 – 60 years ago, this was done in an exclusively practice-oriented manner: disinfectants had the prime function of containing the risk of an epidemic, and it was exactly this that was to be verified. The germ carriers were contaminated with the sputum of patients suffering from tuberculosis or with stools. From our present-day vantage point, the data provided on the recoverable bacteria following exposure to the disinfectant were very imprecise, involving a subjective evaluation ranging from “+” to “+++”.

But these relatively inexact approaches made important contributions to the development of disinfectants – and hence to the prevention of microbial transmission. The specialist discussions were led by specially trained experts. Hence regulations were formulated predominantly by professors of clinical infection control (hygiene).

At the initiation of M. Deutsch and H.-J. Molitor (at that time at Schülke & Mayr) within the framework of the “International Colloquiums” specialists from various European countries were invited to joint scientific colloquia. This provided the first forum for discussion among the representatives of different countries, signaling their desire to understand the views of experts from other countries. Noteworthy here is that the initiative was launched by industry without any input from opinion shapers, nor was there any attempt made to link this to research.

From this International Colloquium was born a European working group composed of infection control experts who took upon themselves the task of defining joint standards for the evaluation of disinfectants. The quantitative suspension test was devised following myriad experimental studies conducted by G. Reybrouck and H.-P. Werner. The aim here was to analyze the various influence factors and to acquaint the specialists with the basic concept of Reduction factors with logarithmic units. Today, such insights are viewed as something to be taken for granted in all European and international standards. If one bears in mind that our previous understanding of the interpretation of results ranging from “+” to “+++”, it is not surprising that at that time it was postulated in many discussions that a 99% reduction in the microbial count in any case would mean the same as a 99.999% reduction. This quantification of the results of such tests was gradually introduced into all areas and consequently gave rise to enormous re-adjustment problems. This will, no doubt, have laid the foundation stone for exact test methods and for qualified assessment of the effects of disinfectants.

Conversely, laying further foundations at European level proved to be relatively easy. European standardization orchestrated by the European Commission received important impetus from one scientist: H. Reber. An important aspect here was that the European standards intro-
duced and recognized in principle a separation of the methods into “in-vitro tests” and “tests conducted under everyday practice conditions”.

Traditionally, European standardization was promoted by representatives of industry. It therefore caused some surprise that the convener of the “Human Medicine” working group at the European Commission did not come from industry, but rather was a professor of infection control. However, this convener supported all developments leading to rapid implementation of European endeavors into national test methods. Accordingly, at least in the field of human medicine it has been possible up till now to assure similar developments in the German-speaking countries and in other European countries.

The increasingly more precise test methods have, on the other hand, revealed shortcomings in the area of disinfection, even of commonly used and hitherto accepted products. This gave rise to tests with a lower margin of error and with quantitative requirements. Since all manufacturers have not shown equal commitment to towing this line, in Germany commercially available disinfectants are now divided into 2 categories: those disinfectants that already meet the requirements of the new test methods and those that do not furnish proof of doing so (see Section 3a and 3b of the List of Disinfectants for Surface Disinfectants and Section 4a and 4b for Instrument Disinfectants).

The same discrepancies between science and industry have also resulted from the European Medical Device Directive as well as from the Medical Devices Act, which is based on the former, stating that disinfection measures for decontamination of medical devices are legally regulated, and as such must meet the already harmonized, mandated European standards.

Whereas formerly scientific activities were promoted, but not influenced, by specialists from industry, it is understandable in principle that changes to the economic parameters mean that by now industry wants to exert an important influence on specialist development. The closure of several Hygiene Institutes at German and Austrian universities and the ongoing confinement of this discipline (infection control) to microbiology have additionally meant that even today there is a shortage of infection control experts who have a holistic view of matters and are able to spearhead further development of test methods. Under these circumstances the likelihood of experts (as e.g. in the USA) being sponsored by certain firms is becoming an increasingly more realistic scenario. There is already evidence that scientific journals and congresses are being influenced by industry.

In Germany, it has been attempted time and again to counter the trend whereby certain strategies are used to influence the development of test methods. Influence factors that merely promote formulation of such methods without expert substantiation must be strictly rejected. It is ironic that, on the one hand, in the interest of quality optimization major efforts have to be made to achieve accreditation of laboratories while, on the other hand, in more or less competent circles, purely formal “approvals” are being defined.

Without experts capable of taking a holistic view of matters, it will not be possible to create an atmosphere conducive to the development, and evaluation, of test methods, as needed for quality assurance. The less often disinfectants are evaluated by competent specialists, the greater is the risk that dangers are not recognized and countered.

Curriculum Vitae

Univ. Prof. Dr. med. habil Heinz-Peter Werner

Figure 1

Specialist for Hygiene and Microbiology – tropical specialist (diploma).

Head of accredited test laboratories HygCen.

Convener of WG1 in CEN/ TC 216 for “Disinfectants and antiseptics in human medicine” and Convener of WG 14 in CEN/ TC205 for „OP cover materials, OP-coats and Clean Air clothing“.

Heinz-Peter Werner studied medicine at the University of Vienna and after obtaining his doctorate he started his career as assistant doctor at the Institute for Hygiene at the Vienna University. Very quickly he took a special interest in the subject “Hospital Hygiene”, which was new at that time and became first head of the Laboratory for Hospital Hygiene in Vienna (1970-1973).

1973 he moved to the Institute for Hygiene of the Johannes-Gutenberg University Mainz, Germany. There he received the venia legendi for the subject “Hospital Hygiene”, which was new at that time and became first head of the Laboratory for Hospital Hygiene in Vienna (1970-1973).

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Figure 1: Heinz-Peter Werner

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After the fall of the Berlin Wall Heinz-Peter Werner left the University and became Director of the Federal Hygiene Institute in Mecklenburg-Western Pomerania in order to help rebuild the health system in Eastern part of Germany. He finally left public health service and founded the private test laboratory HygCen, Center for Hygiene and Medicinal Products achieving its accreditation for the area of biological, chemical, microbiological-hygienical, physical, physical-mechanical tests for medicinal products, large equipment and surrounding area monitoring in 1998.

Professor Werner as Convener of WG1 in CEN/ TC 216 for "Disinfectants and Antiseptics in human medicine" has formed the European unification process for more than one decade. Besides that we was Convener of WG 14 in CEN/ TC205 for „OP covering materials, OP-coats and Clean Air clothing“ as well as member of the European delegation of WG 8 „Purification-Disinfecting-Equipment“ in CEN/TC 102. He is a member of all important national boards. More than 200 publications and more than 70 synopses and books are documenting his surpassing and world wide acknowledged expertise.

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