## Review of indicators for cross-sectoral optimization of nosocomial infection prophylaxis – a perspective from structurally- and process-oriented hygiene

### Indikatoren für die sektorenübergreifende Optimierung der Prävention nosokomialer Infektionen – ein Überblick aus Sicht der struktur- und prozessorientierten Hygiene

### Abstract

In the care of patients, the prevention of nosocomial infections is crucial. For it to be successful, cross-sectoral, interface-oriented hygiene quality management is necessary. The goal is to apply the HACCP (Hazard Assessment and Critical Control Points) concept to hospital hygiene, in order to create a multi-dimensional hygiene control system based on hygiene indicators that will overcome the limitations of a procedurally non-integrated and non-cross-sectoral view of hygiene.

Three critical risk dimensions can be identified for the implementation of three-dimensional quality control of hygiene in clinical routine: the constitution of the person concerned, the surrounding physical structures and technical equipment, and the medical procedures. In these dimensions, the establishment of indicators and threshold values enables a comprehensive assessment of hygiene quality. Thus, the crosssectoral evaluation of the quality of structure, processes and results is decisive for the success of integrated infection prophylaxis.

This study lays the foundation for hygiene indicator requirements and develops initial concepts for evaluating quality management in hygiene.

**Keywords:** prevention of nosocomial infections, hygiene quality management, structural quality, process quality, outcome quality, hygiene indicators, multi-dimensional hygiene control system

### Zusammenfassung

Im Rahmen der gesundheitlichen Betreuung der Patienten ist die Prävention nosokomialer Infektionen ein elementares Anliegen. Für die erfolgreiche Prävention wird ein schnittstellen- und sektorenübergreifendes Qualitätsmanagement der Hygiene benötigt. Zielsetzung ist die Übertragung des HACCP-Konzepts in die Krankenhaushygiene, um auf der Basis von Hygieneindikatoren ein mehrdimensionales Hygienekontrollsystems aufzubauen, dass die Limitierungen einer nicht prozessual integrierten und nicht schnittstellenübergreifenden Betrachtung der Hygiene überwindet.

Für die Umsetzung des dreidimensionalen Qualitätssicherung der Hygiene im Klinikbetrieb sind drei entscheidende Risikodimensionen identifizierbar: die Konstitution der Menschen, die baulich-technische Umgebung inklusive Medien und die medizinischen Prozesse. In diesen Dimensionen ermöglicht die Festlegung von Indikatoren und Grenzwerten eine gesamthafte Bewertung der Hygienequalität. Entscheidend für den Erfolg der Infektionsprävention ist daher die ineinandergreifende Bewertung der Struktur-, Prozess- und Ergebnisqualität.

Mit dieser Zielsetzung werden Anforderungen an Hygieneindikatoren begründet und erste Vorstellungen zur Bewertung eines Qualitätsmanagement der Hygiene entwickelt.

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**Schlüsselwörter:** Prävention nosokomialer Infektionen, Qualitätsmanagement der Hygiene, Strukturqualität, Prozessqualität, Ergebnisqualität, Hygieneindikatoren, mehrdimensionales Hygienekontrollsystem

## Introduction

Unspecific use of antibiotics [1], new therapeutic developments and their associated medical products combined with hygiene behavior that is no longer up to date have all led to an increase of resistant pathogens and consequent nosocomial infections [2], [3]. Hence, maintaining the highest possible level of hygiene should be ethically and medically self-evident.

Over the past few years in Germany, policy has explicity striven for a more economical health-care system while encouraging competition among high-quality medical care providers. This has been implemented through the KTQ (cooperation for transparency and quality in the healthcare system) certification program and in other approaches which compare outcome quality by publishing pertinent reports. Hygiene quality is a particularly important focus, because the prevention of nosocomial infections poses a central challenge to modern medicine. Legislation has repeatedly reacted to this challenge, most recently with the "Amendment of the Infection Prevention Act and Other Laws" (or simply "Infection Prevention Act") from 28 July 2011. This amendment regulates fundamental alterations in the infection prevention act, the Social Code, and further laws [4].

An essential aspect for assessing the success of hygiene management is determining the hygiene quality. But against which standard is hygiene quality to be measured? Article 3, paragraph 4 of the Infection Prevention Act supplements § 137, paragraph 1 of Volume V of the Social Code, by stating that the Joint Federal Committee (GBA) shall establish "appropriate measures to ensure hygiene" and especially "indicators for assessing hygiene quality" "for the cross-sectoral quality control of hospitals" by 31st December 2012. In doing this, established procedures of recording, evaluating, and communicating feedback on nosocomial infections, antimicrobial resistances, and antibiotic use should be considered based on the recommendations set down by the two commissions formed at the Robert Koch-Institute in accordance with § 23 paragraphs 1 and 2 of the Infection Prevention Act (Bundesgesetzblatt (Federal Law Bulletin) 2011 Part I No. 41, issued in Bonn on 3rd August 2011 [5]). On 20th October 2011, the GBA contracted the AQUA Institute (Institute for Applied Quality Promotion in and Research on the Health-care System Ltd, Göttingen) to develop one quality-assurance procedure for avoiding postoperative surgical site infections and another for avoiding catheter-related bloodstream infection. A scoping workshop was held on 12th December 2011 in Göttingen at the AQUA Institute on this topic.

Based on a talk given at this scoping workshop [6] and on ideas from the "thought model" of the Green Hospital [7], this article presents fundamental considerations on parameters and reliable indicators for the prevention of nosocomial infections from the perspective of structurally and process-oriented hygiene.

### Methods

The purpose of the present study was to develop a multidimensional hygiene control system that will overcome the limitations of a non-integrated and non-cross-sectoral view of hygiene. Infection rates are determined by the type and quality of documentation, the patient pool, crosssectoral treatment models, and regional factors such as the prevalence and spread of multiresistant pathogens, patient demographics, and environmental influences. Within a facility, infection rates can reflect trends, including how successful newly implemented prevention strategies are, but by themselves they are unsuitable for quality assessment, due to the potential influence of direct and indirect factors. As the expected values for rates of nosocomial infections are uncertain, it is necessary to find certain, reproducible means of determining the hygienic safety of previous and subsequent sub-processes beyond the interfaces between sub-processes. The profile for an innovative, reliable total hygiene process could consider the following aspects:

- Infection prevention with provable reduction of nosocomial infections, scaleability and adaptability to changing ambient conditions
- Efficacy in terms of maintaining the required quality and quantity used while minimizing the hazard to humans and environment
- Efficient processes in terms of subsequent costs and factor usage (structures, measures, personnel, time)
- Compatibility with established quality management approaches (e.g. ISO, EFQM,KTQ), and standardizibility of the hygiene monitoring
- Instructions for internal and external evaluation of risks (shareholder and stakeholder)
- Implementation of structured processes allowing cost analysis stratified by individual processes, including cost and cost-saving calculation for hygiene-related processes and measures.

First of all, the attempt will be made to derive threshold values and requirements for hygiene indicators to measure a set level of quality. To create a new procedural understanding of hygiene quality, the Hazard Assessment and Critical Control Points (HACCP) concept provides crucial approaches to modelling a three-dimensional hygiene control.

Based on the concepts of process-oriented hygiene [8], HACCP [9], Donabedian's quality model [10], [11], and



the quality management systems used in the German health-care system, fundamental requirements for indicators are deduced. Given these requirements, measurable indicators of infection prophylaxis – i.e., facts and events which affect the treatment process – will be identified and systemized; on this basis, a three-dimensional hygiene control will be introduced.

### Results

### **Quality definition**

In order to derive suitable indicators to optimize nosocomial infection prevention, it is necessary to define how the quality of such prophylaxis can be objectified. In the following, quality is defined as the degree to which a standard is met or the difference between a measured actual condition and a required nominal condition [9], [11]. Therefore, it is first necessary to define the nominal conditions: they are primarily regulated by law (Infection Protection Act, Medical Product Regulation, medication law, ordinances, etc.) and are normative (Commission for Hospital Hygiene and Infection Prevention). Additional, supplementary sources may be the guidelines of professional societies, HTA (Health Technology Assessment) reports, state working groups, or data from the literature.

### Model of process-oriented hygiene

Process-oriented hygiene regards the "patient pathway" as the central value-added process in the health-care system. The medical services performed (outputs) and patient-related results (outcomes) of this added value [12] are the result of the whole process. The prevention of nosocomial infections must be an integral part of the value-added process and cannot be achieved afterwards. An essential prerequisite for this is solving the interface problems, i.e., the challenges which arise in transferring the patient or the materials and information concerning the patient (e.g., for diagnostics and therapy). Thus, hygiene is inconceivable independent of the treatment process – it can only be implemented as an integral component of all sub-processes and interfaces [8].

### **Requirements for indicators**

Parameters must be determined which 1) describe the infection prophylactic measures along the patient pathway and treatment process as completely and precisely as possible, and 2) once certain, defined value ranges are maintained, set best-practice hygiene. Because the treatment process is typically not limited to one person or station, cross-sectoral thinking and acting is often required.

Since complete and constant recording of all parameters is impossible, quality indicators should serve as surrogate indicators. Measured deviations of indicators from a defined nominal value then point to deviations of the parameters. The indicators must represent parameters to a set, predictable extent (validity, what exists is measured). System-inherent variance between measurments taken at different times must be low and predictable (reliability). The power or desired maximum knowledge gain (likelihood ratio), expressed as sensitivity and specificity, should be known and stable. Ideally, the predictive values should be determined and regularly monitored through systematic evaluation, preferably also using an independent second system of equal or higher quality, to identify the prevalence for the individual situation [13]. As needed and using statistical methods, these indicators should enable expedient power analyses to define least numbers of observations for important issues. In such cases, indicators can reflect parameters of one or more sub-processes, interfaces, or the entire process.

### **Categorizing parameters and indicators**

In keeping with Donabedian [11] and the concepts formulated in the HACCP [9], quality indicators can be categorized into structural, procedural, and outcome indicators. Structural indicators measure whether structures meet the respective standards and enable the required processes, with the goal of primary avoidance of errors. Procedural indicators measure whether processes run according to the standard, and point as directly as possible to the extent and cause of deviations. Outcome indicators serve to measure the accuracy and efficacy of the processes and structures, as well as for verification of the system.

## Examples of structural and procedural parameters and indicators

Table 1 contains important characteristics for representing the entire process, and Table 2 presents sub-processes and interfaces.

### Examples of outcome indicators

Due to this paper's narrow focus on the tendering procedure of the GBA, outcome indicators will only be discussed using the example of post-operative surgical site infection (SSI) and catheter-related bloodstream infection (CR-BSI). The parameter of success for hygiene procedures to prevent SSI is the absence of SSI 30 days or, in alloplastic implants, 1 year post-operatively. In order to usefully record this parameter, defined interventions ("indicator interventions") must be recorded according to uniform criteria [14] for every surgical specialization of the facility after aseptic operations, including a risk-stratification of the patients. This should be conducted as a process-internal procedure by the operating facility, by the facility providing follow-up care, and/or externally (e.g., medical service of the health insurers).

The parameter of success for hygiene procedures to prevent CR-BSI is the incidence or incidence density of CR-BSI. In order to usefully record this parameter, catheter



Parameter	Indicator	Reference
Existence of cross-sectoral network structures	<ul> <li>Obligatory, transparent guidelines for the network</li> <li>Standardized transit management</li> <li>Cross-management of antibiotics</li> <li>Standardized microbiological diagnostics</li> <li>Structured feedback to facilities providing previous treatment</li> <li>Auditing</li> </ul>	[18] [19] [20] [21] [22-24]
Patient information and consulting	<ul> <li>Obligatory, understandable,cross-facility and -sectoral patient information</li> <li>Transparent dealing with hygiene standards</li> <li>Patient empowerment in questions of hygiene and infection prevention</li> </ul>	[25] [26] [27]
Structured dialogue from service providers and insurance agencies	<ul> <li>Interdisciplinary safety iniatives</li> <li>Creating motivation for infection prevention</li> </ul>	[28] [29]

infections must be recorded according to uniform CDC criteria [14] with pathogen and its resistance, indication, material/lumen, equipment/catheter type and location, duration of stay, and nursing care for all aseptically inserted central vein catheters, including a risk-stratification of the patients. This should be conducted procedurally internally by all those involved, from inserting to removing the catheter. In these cases, external recording is hardly possible in any practical sense.

In Germany, to measure nation-wide changes in outcome quality (total trends) and verification of routine surveillance (for instance, by the Robert Koch-Institute), regular (e.g., semi-annual) nation-wide point-prevalence studies should be conducted on SSI for the most common operations and on CR-BSI using questionnaires. Furthermore, the pathogen and resistence should be recorded for every infection.

### Measurement methods for indicators

If possible, indicators should be both internally and externally recorded. The distinction must be made between process-internal recording – i.e., by persons directly involved in the treatment process – and process-external but facility-internal recording, for instance, by the central personnel specialized in hygiene, medical controlling, microbiology (resistence statistics) or pharmacy (antibiotic consumption). Facility-external measurements can be performed for instance by government offices, the medical service of health insurers (MDK), patients, network auditors, and subsequent facilities along the patient pathway. Checklists such as those commonly used in QM audits are recommended for all three measurements [15], [16], [17].

# Integrating indicators in a 3-dimensional approach to infection prevention

As a rule, nosocomial infections occur through the interaction of patient, personnel, and surroundings, for instance, via hand contact as the basis of nearly all medical actions, media contact in the patient's vicinity (equipment, medical products, water, air, gases), and the patient's constitution as well as tolerance to her/his own flora and ambient contamination (Figure 1). Depending on the ambient conditions, an unfavorable interaction can occur. Although individual factors or areas may meet hygiene standards, the interaction of deficits can promote the critical causes of nosocomial infections. Simultaneously, the occurrence probability of undesirable events rises with increasing (potential) contact time with pathogens.

### Individual risk

The personal and private space of a patient or staff is not directly accessible. The factors at work here include socialization, level of education, behavior, overall psychosomatic constitution, influence of the immediate private and occupational environment, and mental and physical competence. The areas which a clinic operator can influence are the flow of information into the patient's records and to external service providers (e.g., insurance agencies) in order to determine risk status before and after diagnostics/therapy. In assessing the individual risk, age must also be taken into account. For instance, patients can be classified into the age groups premature infants, infants, toddlers and pre-school children, and schoolchildren up to 15 years old. The largest group of ca. 15- to 65-year-olds and older refers to the general statistical disease distribution for characteristics of constitution. Some trends are already evident: the demographic development, co-morbidities, and increasing proportions of nursing/therapy in the home or private environment with concurrently fewer outpatient care options in rural areas.



Parameter	Indicator	Reference
Hygiene commission	<ul> <li>Existence of a hygiene commission</li> <li>Frequency of their meetings</li> <li>Personnel composition of hygiene commission and areas of responsibility</li> <li>Communication of decisions</li> <li>Conduction of internal audits / hygiene inspections</li> <li>Frequency of internal audits and areas of responsibility</li> </ul>	[30]
Quality management	<ul> <li>Existence of a QM system</li> <li>Start of evaluation of quality criteria</li> <li>Existence of an incidence reporting system</li> <li>Evaluation and consequence of measured quality results</li> <li>Development of a risk-adapted criteria matrix</li> <li>Communication and dissemination of quality results: internally and externally</li> </ul>	[31-33]
Guidelines and standards	<ul> <li>SOPs for interdisciplinary topics (e.g., infusions, catheters)</li> <li>Concept for dealing with emergencies: immediate measures given blood or secretion contamination</li> <li>Concept for dealing with emergencies: immediate measures given outbreaks and epidemics (e.g., influenza)</li> <li>Surgical-site management regulation</li> <li>SOP for waste disposal</li> <li>Regular monitoring of HVAC systems (frequency, internally or externally)</li> <li>Clearly defined dress code</li> <li>Surgical hygiene regulation</li> <li>Implementation of Commission for Hospital Hygiene and Infection Prevention (KRINKO) or German Association of the Scientific Medical Professional Societies (AWMF) recommendations in facility's own guidelines</li> </ul>	[34-35]
Bundles	<ul> <li>Introduction of bundles</li> <li>List of already implemented bundles</li> <li>List of planned bundles</li> </ul>	[36-38]
Hand hygiene	<ul> <li>Functional equipment</li> <li>Positioning of hand-disinfectant dispenser</li> <li>Disinfection for patient use</li> <li>Guidelines for hand hygiene</li> </ul>	[39-41]
Preparation of medical products	<ul> <li>Conducting a certified preparation of all medical devices</li> <li>Type of preparation: manual or device-based, external or internal</li> </ul>	[42-43]
Screening / Diagnostics	<ul> <li>Conducting screening</li> <li>Screening procedure (risk factors and areas, methods)</li> <li>Recording the screening rate</li> <li>Screening for multiresistant pathogens</li> <li>List of screened multiresistant pathogens (e.g., MRSA, ESBL)</li> <li>Presence of facility's own microbiology laboratory</li> </ul>	[44-46]
Verification of the system	<ul> <li>Surveillance of nosocomial infections</li> <li>Recording infection numbers</li> <li>Methods of infection recording</li> <li>List of recorded infection types</li> <li>Measuring nosocomial infection rates</li> <li>Measuring healing rates given infection</li> <li>Reaction to results</li> </ul>	[37, 47-50]

Table 2: Structural and procedural parameters and respective indicators of sub-processes and interfaces



Parameter	Indicator	Reference
Antibiotics management	<ul> <li>Presence of guidelines for antibiotic use/ antiseptics regulation</li> <li>Monitoring use</li> <li>Presence of regular Antibiotic Stewardship Programs ABS (e.g., part of consultancy service or similar)</li> <li>List of employed methods (e.g., Antibiotic Resistence Surveillance ARS)</li> </ul>	[51-54]
Surface disinfection and cleaning	<ul> <li>Organization and implementation of cleaning procedures (e.g., differently colored rags)</li> <li>Presence of bed preparation rules, mattress and pillow encasing</li> <li>Existence of cleaning and disinfection plan for the facility</li> <li>Procedure of bed preparation</li> <li>Monitoring cleaning performance (e.g., check-ups, lists etc.)</li> </ul>	[55-59]
Personnel	<ul> <li>Number of staff trained in hygiene</li> <li>Presence of written regulations on areas of responsibility for hygiene</li> <li>Evaluation of general personnel situation for the implementation of hygiene measures</li> <li>Areas of responsibility for documentation and evaluation of hygiene data</li> </ul>	[60-64]
Training / continuing education	<ul> <li>Number and duty area of staff members who regularly participate in continuing education</li> <li>Frequency of participation in continuing education</li> <li>Further education option to become hygiene-commissioned physician</li> </ul>	[65-67]
Internal communication	<ul> <li>Type and means of access to, communication of and obligation to follow hygiene rules (e.g., Intranet)</li> <li>Feedback possibilities for staff</li> <li>Regular communication of current events / quality results</li> </ul>	[68-70]
External communication	<ul> <li>Type of communication with patients</li> <li>Composing a hygiene report separately from hospital report</li> <li>Writing an environmental report</li> <li>Evaluation of communication with the highest federal health office / health office</li> <li>Information for patients on dealing with multiresistant pathogens</li> </ul>	[24, 27, 71]
Adherance to "state-of-the- art technology"	<ul> <li>Guaranteeing "state-of-the-art technology"</li> <li>Evaluating the necessity of "state-of-the-art technology"</li> <li>Using special medical products (e.g., antiseptic sutures, antimicrobially coated catheters)</li> </ul>	[72-74]
Building requirements	<ul> <li>List of building measures of hygiene</li> <li>List of isolation categories</li> <li>Number of isolation rooms</li> </ul>	[75-78]
Addressing special problems	<ul> <li>Presence of a disinfection plan</li> <li>Measuring disinfectant consumption</li> <li>Presence of a water safety plan (WHO)</li> <li>Implementation of other international standards</li> </ul>	[79-82]
Quality of documentation	<ul><li>Complete</li><li>Current</li><li>Accessible</li></ul>	[83-85]
Transition management	<ul> <li>Organization and areas of responsibility for transition management</li> <li>Presence of special transition management in cases of multiresistant pathogens</li> </ul>	[86-87]
Cross-sectoral networks	<ul> <li>Participation in cross-sectoral networks, regional hygiene groups and similar</li> <li>Guaranteeing follow-up care for patients in cooperation with third parties (e.g., nursing homes, private-practice physician)</li> </ul>	[88-90]

(Continued) Table 2: Structural and procedural parameters and respective indicators of sub-processes and interfaces



## Clinical core processes: diagnostics and therapy



Figure 1: Simplified process model

Table 3: Examples of individual risk indicators

Disease classification CCP	General category
Acute and chronic diseases	Infections, colonization, excretors/secretors/carriers, immunosuppression, cortisone treatment, oncological therapy Diabetes, asthma, COPD Neurological disease; insult, infarct, thromboses, hemorrhage, lysis therapy angiological and cardiological disease
Deficiencies	Nutrients, liquids, O <sub>2</sub>
Body weight relation	BMI > 27 or < 19

Other factors are BMI, immunosuppression, acute and chronic pre-existing diseases (Table 3).

### **Clinical procedure risk**

In the processes of diagnostics and therapy, the patient and technology meet. Besides the core process, support services of supply and disposal (meals, sterile supplies, clothing/textiles/laundry, processing, preparing medications, application of medicines and medical aids) are also relevant. The management of storage facilities and transport processes of clean/soiled supplies includes essential, critical factors. Exemplary processes include the set-up and preparation of surgical rooms, endoscopy, catheterization, infusion, transfusion, preparation of medical products, and bed preparation (Table 4).

### Building and structurally-inherent risks

The structural quality concerns hygiene factors related to room interiors and technical installations. In this area,

the possibilities and limits for good processes are created. However, it is invalid to conclude the reverse - that optimal architecture and technical structures alone automatically effect good processes. This includes the design of possible hand-contact surfaces (controls, furniture, sanitary installations, room size and division into nursing, surgery, central sterilization). Further factors are media such as drinking water, room air, emissions and gases for medical applications. For instance, in the case of microbial contamination of drinking water, it is decisive where and how measurements are taken. In addition to the maintenance quality of technical facilities, critical control points (CCPs) are also contained in gualified planning and often consequent reconstructions (Table 5). The HACCP-based considerations discussed above on a procedurally-oriented self-monitoring system enable optimal implementation of hygiene quality management. The self-monitoring system builds on extant guidelines. The challenge lies in the analysis of all relevant hazards, determining essential critical control points, and the as-



Possible CCP	General category
Catheterization	Urogenital, central vein catheter, drainages, shunts, connectors
	Tube sets respiration, anesthesia
Electromedical devices	Electrodes, sensors, patient parts, cables
Physical medical products	Medications and medical aids, contact surfaces
Pharmacy	Infusions, transfusions, food processed/made in- house and externally
Electronic devices in general	Controls, handles, switches

Table 4: Examples of possible procedural risk indicators (in relation to clinical pathways)

### Table 5: Examples for possible risk indicators of buildings

Possible CCP	General category
Sanitary installations	House transit station, hydraulic systems in plumbing, built-in equipment, pipes/lines with stagnation, pH values, calcification, temperature Consoles, short circuits with waste water installations
Building	Building physics, moisture penetration/dampening, microbiological nutrient base
HVAC (heating, ventilation, air conditioning)	Air-/water-tight duct systems, filter systems, air intake, maintenance

sociated tolerance thresholds along with definitions of activities in order to ensure controlability at all times. The areas of action mentioned are bound to regulated surveillance. Control and monitoring are necessary to ensure objective key indicators.

### Discussion

The purpose of the GBA tendering procedure is to find indicators which will facilitate cross-sectoral optimization of nosocomial infection prophylaxis and the reduction of complications, while also reflecting measures of hygiene and transition management as well as patient-relevant outcomes using existing structures.

From the perspective of process-oriented hygiene, infection prevention must be an integral part of all sub-processes and interfaces. Only through gap-free hygiene in all sub-processes and in the process as a whole is permanent, uniform achievement of the desired outputs and outcomes possible. It follows that those indicators should be predominantly chosen which measure whether structures and (sub-) processes are designed in a way that minimizes the risk of infection for the patient.

Pursuing this line of argument, it becomes obvious that the solitary measurement of one outcome (e.g., number of infections) is neither expedient nor adequate for evaluating hygiene quality. First of all, it is impossible to provide reference values for infection rates which could reliably demonstrate good hospital hygiene. Second, the infection rate is determined not only by directly involved sub-processes but also by processes with an indirect influence. It is thus impossible to conclude anything about the quality of a sub-process given the infection rate. This is even more true since, in addition to the treatment process, other external and patient-inherent factors beyond the control of the respective facility's personnel also affect the infection rate.

Third, despite clear definitions, the final identification of an infection in practice suffers not only from limited sensitivity and specificity, but observer bias as well. Thus, for the individual case, neither validity, reliability, nor likelihood ratio of the infection surveillance are known. However, even under optimal conditions and with complete recording of all services/treatments/factors (e.g., all patients and all infections), given the expected frequency of infections, the sample size is usually insufficient for making statistically powerful comparisons over time or between facilities.

This was the main reason for abandoning the quality of results of the overall process as an indicator of quality control in industry in the 1930s, when it became clear that this approach did not ensure the fulfillment of the high qualitative demands in weapons production. Food processors and manufacturers soon followed this example. As in point-prevalence data collection on the occurrence of nosocomial infections, the food industry also monitors quality via sampling. In the field of medical care, in addition to the technical inferiority of recording outcome quality, the ethical aspect is paramount: a "reject rate" – usual in industry and part of cost calculations – is of course inacceptable in the context of medical care. Thus, this concept has also gradually been abandoned in medicine. In the preparation of medical products, par-



ticularly sterilization procedures, whose outcome quality cannot be determined, quality assurance or guarantee of sterility is provided solely by validating the processes: that is, measuring, recording, and evaluating structural and procedural parameters and comparing them with standards known to be effective.

Hence, priority should be given to prospective, processoriented hygiene quality assurance. In this system, the efficacy of structures and processes are tested in studies. For use in practice, concrete structures and processes should be designed based on evidence and guidelines, and their practical implementation closely monitored internally and externally. Audits of outcome quality should be conducted in accordance with legal regulations and by sampling during examinations (ring trials) to verify the system.

However, this method also has disadvantages. First, direct evaluation of the actual efficacy of the recommended structures and processes during routine operation is not possible, and would furthermore be hardly implementable given the limited resources in routine operation. Second, it requires that an explanation be given to the staff that the obvious sign, i.e., the infection rate, is not a simple, sure indicator of hygiene quality in their own facility. Third, it is necessary to examine whether the sometimes considerable use of resources for the surveillance of nosocomial infections can be justified in terms of quality management, although it can contribute to the prevention of nosocomial infections in other ways.

Regarding the GBA tendering procedure, this means that the goal of "cross-sectoral optimization of nosocomial infection prevention and reduction of its complications including comparison of facilities and service providers with an appropriate follow-up observation period" is not met by recording marker infections. The suggested use of existing surveillance systems should thus not be considered possible; rather, it represents an abuse of these systems. Hence, when implementing the Amendment to the Infection Prevention Act, efforts must be made to determine parameters for structural and procedural quality in hospital hygiene and to identify possible indicators for adhering to them. The determination of infection rates is methodologically required in controlled studies to prove the efficacy of a particular intervention. In evaluating hygiene quality, infection rates can signal changes within a facility and provide the occasion for auditing the hygiene management. For the reasons mentioned above, they are methodologically unsuitable for comparing hygiene quality between different facilities.

### Conclusions

Three critical risk dimensions can be identified for the implementation of three-dimensional quality control of hygiene in clinical routine: the constitution of the person concerned, the surrounding physical structures and technical equipment, and the medical procedures. In these dimensions, the establishment of indicators and threshold values enables a comprehensive assessment of hygiene quality.

### Notes

### **Competing interests**

The authors declare that they have no competing interests.

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