## Original article

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# "Real-life" hygiene routines in the operating room – a critical appraisal

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**Conflict of interest**

All authors confirm that there is no conflict of interest according to the guidelines of the International Committee of Medical Journal editors (ICMJE).

## Summary

**Background:** In 2012, almost 51 million surgeries and medical procedures were carried out on hospital inpatients in Germany. According to national representative prevalence studies on nosocomial infections (NI) in Germany (NIDEP 1 study), postoperative surgical site infections (SSI) accounted for 16% of all NI. With 24.3%, the percentage of SSI in the second national prevalence study was again the highest of all NI. Preventative interventions in order to reduce the rate of postoperative wound infections have been described in scientific literature. In 2011, the Bavarian State Ministry for Health and Long-Term Care issued a joint obligatory concept for the surveillance and monitoring of infection control measures in healthcare institutions by public health authorities. Also in 2011, inspections of all surgery departments of acute care hospitals were prescribed as mandatory. For Bavaria this meant 288 surgical departments in 239 hospitals. In the state capital Munich, 59 surgical departments in 35 hospitals (= 21% of all Bavarian surgical departments) had to be inspected.
**Method:** Within a period of 6 months in 2013 all surgical departments underwent informed audits according to the "four-eye principle". On-site audits of the checklists which had been previously filled out were compared to the actual situation and the required documents were inspected. Subsequently, the staff was interviewed and depending on the size of the department, processes were observed/a delta analysis was performed for a minimum of half a day. The relevant criteria referred to the availability of infection control experts in the hospital, the existence of hygiene and cleaning protocols, staff hygiene during operating hours, prevention measures for postoperative wound infections and sepsis. The inspection results were recorded in tables and evaluated.
**Results:** The following perioperative risk factors for the acquisition of postoperative wound infections were found in a considerable number of hospitals: incorrect preoperative hair removal (15 %), preoperative shaving with single-use razors (19 %), incorrect preoperative skin cleaning and disinfection such as spraying without mechanical action (8 %), incorrect wiping technique (18 %), non-compliance with the required contact time (12 %). Incorrect perioperative antibiotic prophylaxis and/or lack of pertinent standard regulations for the administration of antibiotics was noted for 41 % of hospitals. Other risk factors, which do not have a direct impact on the SSI rate according to scientific literature, are incorrect wearing of protective surgical caps (61 %), facemasks (25 %), non-compliance with the contact time for surgical hand disinfectants (12 %), wearing of cotton gowns as operating room gowns (7 %), inadequate implementation of the indications for hygienic hand disinfection prior to antiseptic procedures (56 %) and after patient contact (71 %). The handling of intravenous medication constitutes a problem: 51 % of hospitals stored drawn-up medication for more than 1 hour, only 51 % used Propofol immediately after drawing up into the syringe.
**Conclusions:** According to the audits conducted in Munich, structural problems or construction deficiencies did not constitute a major problem. Instead, staff behaviour in the OR

**Citation**

Gleich S., Lindner B.
"Real life" hygiene routine in the operating room – a critical appraisal.
Hyg Med 2016; 41(5): E71–E79.

**Dates**

Submitted: May 3rd, 2016
Revised version accepted: April 14th, 2016

has to be questioned. Non-compliance with standard hygiene precautions does not only have potential effects on the health of the patients but also legal consequences on the hospital operator. Non-compliance with KRINKO recommendations, which according to German law represent the-state-of-the-art in hygiene, may in the event of damage such as SSI be a reason for a shift in the burden of proof to the hospital.

**Keywords:** OR · Standard hygiene precautions · Compliance · Public health authority

## Introduction

In 2012, almost 51 million surgeries and medical procedures were conducted on hospital released from inpatient care in Germany. Almost a third of those procedures were surgical interventions (15.7 million), followed by non-surgical therapeutic measures with a share of 26.4 % (13.4 million) and diagnostic measures with 19.5 % (9.9 million). Diagnostic imaging (9.7 million) and complementary measures such as obstetric treatments (1.9 million) and the administration of special drugs (0.3 million) made up the remainder [1].

A first national study on the prevalence of nosocomial infections (NI) in Germany (NIDEP 1 study) showed that postoperative surgical site infections (SSI) accounted for 16 % of all NI [2]. At 24.3 %, the percentage of SSI in the second national prevalence study was again the highest of all NI [3]. The number of surgical departments participating in the OP-KISS module of the National Reference Centre for the surveillance of NI as well as the 2010–2014 reference data are available online [4].

SSI are related to several factors, such as the patient's overall health status (age, nutritional status, diabetes, smoking, obesity, immunosuppression), length of preoperative hospital stay, wound contamination class, duration of the surgical intervention, surgical technique (laparoscopic versus open), pre-existing infections or colonization with multidrug-resistant pathogens [5, 6].

The spectrum of pathogens detected in postoperative wound infections differs according to medical speciality. For example, *Staphylococcus aureus* isolates were the most frequent in traumatology/orthopaedics, accounting for 31.7 % of all isolates from wound infections. In general surgery and in thoracic surgery, the species most frequently encountered were *Enterococcus* spp. (29.4 %) and *Escherichia coli* (30.4 %) [4]. The sources of infection can be endogenous (caused by the patient's own microbial flora), or exogenous (caused by hospital staff or ambient factors). It is estimated that a maximum of 10 % of postoperative wound infections have exogenous sources [7].

### Preventive interventions to reduce the rate of postoperative wound infection

Interventions to reduce the SSI rate due to **endogenous sources** (patient-dependent factors) should include:

- Shortening the duration of the preoperative hospital stay [8]
- Treatment of pre-existing infections, including outside the surgical area [9]
- Decolonization of *S. aureus* carriers [10–12]
- Adequate perioperative antibiotic prophylaxis [13]
- Correctly performed skin and mucous-membrane antisepsis to minimize the microbial flora in the surgical area, as well as the use of VAH-listed preparations while strictly observing the required contact time specified by the manufacturer [6]
- Preoperative hair removal only if required by the surgical technique to be used; shaving more than 24 hours before surgery doubles the risk of infection, so if a shave is necessary, clipping or chemical depilation should be employed [14]
- Avoidance of intraoperative hypothermia [15]
- Avoidance of protracted procedures, as the relative risk of infection increases by a factor of 3 if the duration of the intervention exceeds 3 hours [7]
- Use of sterile surgical drapes that are not made of cotton [6]

Interventions to reduce the SSI rate due to **exogenous sources** (staff-dependent factors) should include:

- Implementation of structural and functional measures and path optimization [16]
- Provision and application of adequate technical measures (structural and functional: suitable heating, ventilation and air conditioning system, HVAC) [16]
- Maintenance of good air quality in the operating room (functional HVAC, closed surgery doors, minimized talking and movement) [6]
- Proper reprocessing of medical devices according to all applicable regulatory requirements [17]
- Proper personal hygiene (proper entrance through access zone, OT garments, hair nets and mouth and nose protection, hygienic and surgical hand disinfection, sterile gloves and protective garments – liquid-proof if required) for invasive procedures/interventions [6]
- Set-up of instrument tables for subsequent operations only after all disposal and disinfection measures are completed [6]
- Decolonization or treatment of infected staff, e.g. with methicillin-resistant *S. aureus* (MRSA) or group A streptococci [6]
- Scheduling of infected staff according to pre-determined rules [6]
- Cleaning and disinfection between operations (surfaces and floors near patients, all contaminated surfaces), making sure to wait until the disinfectant has completely dried before preparing the OT for the next procedure [6, 18]

Inside the OT, preventive measure should be taken against other nosocomial infections, such as vascular catheter-associated infections [19, 20].

### Situation in Bavaria and Munich

In 2011, the Bavarian State Ministry for Health and Long-Term Care (StGMP) issued a joint obligatory concept for the surveillance and monitoring of infection control measures in healthcare institutions by public health authorities [21]. In all Bavarian acute-care hospitals, reviews with an annually changing focus in selected areas are performed in addition to non-incident-related infection control monitoring. These have so far included intensive-care units, surgical departments, hand hygiene, bone marrow transplantation wards, neonatal

intensive-care units, surface disinfection, maternity wards and general emergency rooms. Interviews were conducted to verify the number of hygiene professionals employed by hospitals. Surveillance measures for nosocomial infections and multi-resistant pathogens were also reviewed.

The Bavarian State Office for Health and Food Safety (LGL) has developed standardized audit checklists to be used by all health authorities. Likewise, for each checklist, the LGL issued to medical officers detailed explanatory summaries of the key criteria for the audits. Also in 2011, inspections of all surgical departments of acute-care hospitals were mandated. For all of Bavaria, this meant 288 surgical departments at 239 hospitals. In Munich, the state capital, 59 surgical departments at 35 hospitals (21 % of all Bavarian surgical departments) had to be inspected.

A classification of 35 hospitals with operating theatre according to the number of hospital beds yields the following breakdown:

- 15 hospitals with 16 surgical departments had fewer than 100 beds (small hospitals)
- 9 hospitals with 9 surgical departments had between 100 and 200 beds (medium-sized hospitals)
- 11 hospitals with 34 surgical departments had more than 200 beds (large hospitals)

The three-page OT checklist of the LGL contained specific questions on structural and functional concepts (including staff changing rooms, supply rooms, HVAC systems) and the hospital's infection control policies (including personal hygiene measures, personal protective equipment and infection control policy).

## Methods

Two test teams were formed, each with two persons (one physician and one infection control nurse). Prior to embarking on the audits, the authors systematically trained all team members with respect to the audit guidelines issued by the LGL and on process monitoring during ongoing activities. The Department of Health and the Environment, having announced the audit by email, sent out the LGL's checklist to the clinics with a request to return the completed forms and to make the current floor plans of the surgical departments along with further documentation (infection control and cleaning/disinfection policies, maintenance records, microbiological reports) available for inspection on the day of the audit. The documents sent were reviewed in advance by the audit teams.

On-site audits of the checklists previously filled out were compared to the actual situation; the requested documentation was inspected. The staff was then interviewed on-site. Depending on the size of the department, processes were observed and a delta analysis performed for a minimum of half a day during ongoing activities. This was followed by a correction of the previously completed checklist, if necessary, and a joint debriefing with the participants on the hospital side. Each hospital received a standardized audit report that included a to-do list.

The test results were tabulated and evaluated. Evaluation criteria included the number of hygiene professionals employed by the hospitals, the presence or absence of infection control and cleaning/disinfection policies, staff hygiene in the OT during ongoing activities, the prevention of postoperative wound infections and sepsis prevention. Other verifiable criteria on the LGL checklist related to purely structural and functional aspects of the surgical departments were not evaluated for the present publication. Neither was the surveillance of postoperative wound infections evaluated, as it was not included in the OT checklist.

## Results

### Existing infection control structures

On average, 89 % of hospitals received expert advice from a hospital hygienist; for the 11 medium-sized hospitals, the number was 100 %. Infection control nurses were employed by 100 % of hospitals. Physician infection control officers were installed by 94 % and 89 % of institutions, respectively. The staffing and organization of infection control as broken down by care level (hospital hygienists, infection control nurses; full-time employees vs. external hygiene consultants), had been assessed in a separate study in 2012.

The on-site inspections did not assess the extent to which the recommendations of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute regarding the number of hygiene professionals had been implemented in relation to the number of beds and the risk profile of the hospitals. Nor was there any survey of the number of full-time equivalent positions in relation to the number of beds or risk profiles, as this was not included in the presented checklists. All hospitals had infection control and cleaning/disinfection policies in place. Of the 35 hospitals, 24 (69 %) participated in the "Clean Your Hands" drive, of which 8 large, 7 medium-size and 9 small hospitals.

### Implemented staff hygiene

With regard to the structural requirements in the OT for proper implementation of hand hygiene, 67 % and 66 % of the hospitals provided hand disinfectant dispensers at the anaesthesia workstation and for the circulating nurse, respectively, with the small hospitals scoring below average at 50 %. 90 % and 98 % of staff had no jewellery on their hands/forearms and exercised proper fingernail care. The 10 % and 2 %, respectively, for which this was not true, were anaesthesia staff.

Compliance with the required contact time for the surgical hand disinfectant was observed in 88 % of cases. In these cases, the hand-washing stations featured a clock that allowed the staff to monitor their own contact times. The event-related change of low-germ disposable gloves (when changing from unclean to clean activities) was performed correctly in 27 % of cases; however, this process was not open to observation at up to one-third of on-site inspections. An analysis of four of the five indications for hygienic hand disinfection revealed considerable potential for improvement: hand disinfection prior to aseptic activities, after contact with patients, after contact with contaminated objects and after removing disposable gloves was performed in 41 %, 29 %, 41 % and 32 % of cases, respectively. No suitable opportunity for a pertinent delta analysis presented itself in up to 25 % of cases.

The low percentage (39 %) of operating or instrumenting staff with correctly worn surgical caps, i.e. with completely covered hair, was remarkable; here, neck-knotted astro caps or surgical caps were used. Cloth caps were not used at any of the hospitals. The mouth and nose protection was worn correctly in 75 % of cases. The remainder used the so-called visor technique; the medium-sized clinics achieved the least favourable results.

Table 1: Existing hygiene structure in absolute numbers and percentages.

| Infection control structures | | Large hospitals (> 200 beds) | Medium-size hospitals (100–200 beds) | Small hospitals (< 100 beds) | Overall |
|---|---|---|---|---|---|
| | | 11 hospitals | 9 hospitals | 15 hospitals | All 35 hospitals |
| Hygiene professionals | Hospital hygienists | 11 (100 %) | 8 (89 %) | 12 (80 %) | 31 (89 %) |
| | Infection control nurse | 11 (100 %) | 9 (100 %) | 15 (100 %) | 35 (100 %) |
| | Physician infection control officer | 11 (100 %) | 9 (100 %) | 13 (87 %) | 33 (94 %) |
| | Nurse infection control officer | 11 (100 %) | 7 (78 %) | 13 (87 %) | 31 (89 %) |
| Infection control policy | Available | 11 (100 %) | 9 (100 %) | 15 (100 %) | 35 (100 %) |
| Cleaning/disinfection policy | Available | 11 (100 %) | 9 (100 %) | 15 (100 %) | 35 (100 %) |
| "Clean Your Hands" drive participation | | 8 (73 %) | 7(78 %) | 9 (60 %) | 24 (69 %) |

Table 2: Implemented staff hygiene in absolute numbers and percentages.

| Staff hygiene | | Large hospitals (> 200 beds) | | Medium-size hospitals (100–200 beds) | | Small hospitals (> 100 beds) | | Overall |
|---|---|---|---|---|---|---|---|---|
| | | 11 hospitals | | 9 hospitals | | 15 hospitals | | All 35 hospitals |
| | | 34 surgical depts. | | 9 surgical depts. | | 16 surgical depts. | | 59 surgical depts. |
| | | yes[1] | n.o.[2] | yes[1] | n.o.[2] | yes[1] | n.o.[2] | yes[1] |
| Hand hygiene Structure | HDD at anaesthesia workstation | 25 (74 %) | | 7 (78 %) | | 8 (50 %) | | 40 (67 %) |
| | HDD for the circulating nurse | 24 (71 %) | | 7 (78 %) | | 8 (50 %) | | 39 (66 %) |
| | No jewellery on hands/forearms, no wrist watches | 30 (89 %) | | 9 (100 %) | | 14 (88 %) | | 53 (90 %) |
| | No nail varnish or artificial nails | 32 (94 %) | | 9 (100 %) | | 16 (100 %) | | 57 (98 %) |
| | Compliance with contact time for surgical HD | 30 (89 %) | | 9 (100 %) | | 12 (75 %) | | 51 (88 %) |
| | Event-driven change of disposable gloves | 10 (29 %) | 7 (21 %) | 1 (11 %) | 3 (33 %) | 5 (31 %) | 5 (31 %) | 16 (27 %) |
| | HD before aseptic procedures | 12 (35 %) | 5 (15 %) | 4 (44 %) | | 7 (44 %) | | 23 (41 %) |
| | HD after patient contact | | 5 (15 %) | 4 (44 %) | | 4 (25 %) | 4 (25 %) | 17 (29 %) |
| | HD after contact with contaminated objects | 9 (26 %) | 4 (12 %) | 4 (44 %) | 2 (22 %) | 9 (56 %) | | 23 (41 %) |
| | HD after removing disposable gloves | 10 (29 %) | 6 (17 %) | 4 (44 %) | | 4 (25 %) | 4 (25 %) | 19 (32 %) |
| Use of protective garments | Appropriately worn surgical caps | 11 (33 %) | | 3 (33 %) | | 8 (50 %) | | 23 (39 %) |
| | Appropriately worn facemasks | 14 (41 %) | | 4 (44 %) | | 14 (88 %) | | 44 (75 %) |
| | Use of sterile gowns (surgeon and instrument nurse during procedure) | | | 9 (100 %) | | 13 (8 %) | | 55 (93 %) |
| | Of which disposable gowns | 26 (77 %) | | 7 (78 %) | | 16 (100 %) | | 55 (93 %) |
| OT garments | Scrubs in trousers | 33 (97 %) | | 2 (22 %) | | 9 (56%) | | 24 (41%) |

[1] Measure observed, correct implementation; [2] Implementation not observed, no assessment possible; HD = hand disinfection; HDD = hand disinfectant dispenser

Table 3: Measures implemented to prevent postoperative wound infections in absolute numbers and percentages.

| Prevention of postoperative wound infections | | Large hospitals (> 200 beds) | | Medium-size hospitals (100–200 beds) | | Small hospitals (> 100 beds) | | Overall |
|---|---|---|---|---|---|---|---|---|
| | | 11 hospitals | | 9 hospitals | | 15 hospitals | | All 35 hospitals |
| | | 34 surgical depts. | | 9 surgical depts. | | 16 surgical depts. | | 59 surgical depts. |
| | | yes[1] | n.o.[2] | yes[1] | n.o.[2] | yes[1] | n.o.[2] | yes[1] |
| Preoperative hair removal | Not applicable to procedures performed | 3 (9 %) | | 1 (11 %) | | 5 (31 %) | | 9 (15 %) |
| | Shaving (disposable razor) | 3 (9 %) | | 2 (22 %) | | 6 (38 %) | | 11 (19 %) |
| | Clipping | 27 (80 %) | | 5 (56 %) | | 9 (56 %) | | 41 (69 %) |
| | Chemical | 3 (9 %) | | 1 (11 %) | | 1 (6 %) | | 5 (8 %) |
| | Standards for hair removal available | 30 (88 %) | | 6 (67 %) | | 10 (63 %) | | 46 (78 %) |
| Standards for perioperative antibiotic prophylaxis | Available | 24 (71 %) | | 4 (44 %) | | 7 (44 %) | | 35 (59 %) |
| Implementation of preoperative skin antiseptics | Spraying the skin without mechanical action | 3 (9 %) | 2 (6 %) | 0 (0 %) | | 2 (13 %) | | 5 (8 %) |
| | Appropriate wiping technique | 31 (91 %) | 3 (9 %) | 7 (78 %) | | 10 (63 %) | 3 (19 %) | 48 (81 %) |
| | Compliance with contact time | 31 (91 %) | 3 (9 %) | 6 (67 %) | | 15 (94 %) | | 52 (88 %) |
| | Laparoscopy: skin antiseptic as in conventional surgery | 25 (74 %) | 22 (65 %) | 3 (33 %) | | 9 (56 %) | 6 (38 %) | 37 (63 %) |
| Use of sterile surgical drapes | Single-use | 34 (100 %) | | 9 (100 %) | | 16 (100 %) | | 59 (100 %) |
| Organization | Multiple tables in the same OT | 1(0,03 %) | | 00 (0 %) | | 1 (6 %) | | 2 (0,3 %) |
| | Instrument table set directly prior to procedure | 31 (91 %) | | 9 (100 %) | | 2 (13 %) | | 42 (71 %) |
| | Closed doors during procedure | 34 (100 %) | | 9 (100 %) | | 13 (81 %) | | 56 (95 %) |
| | Patient-specific wound irrigation solution | | 34 (100 %) | 3 (33 %) | 4 (44 %) | 2 (13 %) | 5 (32 %) | 5 (8 %) |
| | Open storage of sterile medical devices (transparent wrapping) | 19 (56 %) | | 6 (67 %) | | 8 (50 %) | | 33 (56 %) |

[1] Measure observed, correct implementation; [2] Implementation not observed, no assessment possible

At 93 % of hospitals, the staff at the operating table wore sterile protective gowns during the procedure. Cotton smocks were still used and reprocessed at 12 % of medium-sized hospitals. The 3 % and 8 % of the hospitals where no sterile protective gowns were worn during the surgical intervention performed otorhinolaryngological and coloproctological procedures. The scrubs were correctly worn inside the trousers at 41 % of clinics, most commonly in the small hospitals (56 %).

## Implemented measures for the prevention of postoperative wound infections

At 15 % of facilities overall, there was no need for preoperative hair removal due to their specific specialization; this trend was more pronounced in small hospitals (31 %). The KRINKO-recommended methods of clipping and chemical hair removal were employed at 69 % and 8 % of hospitals, respectively. The shave with disposable razors – no longer recommended by KRINKO – was still preeminent especially at small hospitals (38 %). The recommended but more expensive clipping procedure was used by 80 %, especially the larger hospitals. Standards for preoperative hair removal were available at 78 % of hospitals overall, with a slightly higher percentage at large hospitals (88 %). A similar situation prevailed regarding standards for perioperative antibiotic prophylaxis: 77 % of large hospitals had them, compared with only 44 % of medium-size and small hos-

Table 3 (continued): Measures implemented to prevent postoperative wound infections in absolute numbers and percentages.

| Prevention of postoperative wound infections | | Large hospitals (> 200 beds) | | Medium-size hospitals (100–200 beds) | | Small hospitals (> 100 beds) | | Overall |
|---|---|---|---|---|---|---|---|---|
| | | 11 hospitals | | 9 hospitals | | 15 hospitals | | All 35 hospitals |
| | | 34 surgical depts. | | 9 surgical depts. | | 16 surgical depts. | | 59 surgical depts. |
| | | yes[1] | n.o.[2] | yes[1] | n.o.[2] | yes[1] | n.o.[2] | yes[1] |
| Surface cleaning and disinfection | Stocked-up cleaning cart available at beginning of procedure | 34 (100 %) | | 9 (100 %) | | 13 (81 %) | | 56 (95 %) |
| | Dry storage of mops on cleaning cart | 32 (94 %) | | 6 (67 %) | | 11 (69 %) | | 49 (83 %) |
| | Documented disinfection of cloths/mops | 6 (18 %) | | 0 (0 %) | | 3 (19 %) | | 9 (15 %) |
| | Surface disinfectant to dry completely after disinfecting floor before next procedure | 25 (73 %) | 6 (18 %) | 6 (67 %) | | 9 (56 %) | | 40 (68 %) |
| | Wipe disinfection of hand contact points (monitors, anaesthesia machines, couches) before next procedure | 26 (76 %) | 6 (18 %) | 6 (67 %) | | 11 (69 %) | | 43 (73 %) |
| | Use of tissue dispensers | 33 (97 %) | | 9 (100 %) | | 14 (88 %) | | 56 (95 %) |
| | Standards-compliant reprocessing of tissue dispensers | 19 (56 %) | | 5 (56 %) | | 13 (81 %) | | 37 (63 %) |
| Decentralized disinfectant dispenser | Type-tested | 32 (94 %) | | 9 (100 %) | | 12 (75 %) | | 53 (90 %) |
| | Maintenance performed | 32 (94 %) | | 9 (100 %) | | 12 (75 %) | | 53 (90 %) |

[1] Measures observed, correct implementation; [2] Implementation not observed, no assessment possible

pitals at 13 % of small hospitals, preoperative skin antisepsis was performed done by spraying the skin without mechanical action: this was almost never observed in the other two groups. The correct wiping technique was most commonly observed at large hospitals (91 %) and most rarely at small hospitals (63 %), although a delta analysis was not possible for 19 % of the latter due to a lack of opportunity.

Compliance with the required contact time for the skin antiseptic was observed most frequently at small hospitals (94 %) and least frequently at medium-size hospitals (67 %). Complete preoperative skin antisepsis as in conventional surgery was performed prior to laparoscopy at 63 % of hospitals overall, most commonly at large hospitals, with no delta analysis possible for 38 % of the small hospitals. Disposable sterile drapes were used at all hospitals; no so-called mixed drapes including reprocessable cotton materials were observed.

In the case of two departments, there were two operating tables in an operation theatre. These were older buildings (departments of gynaecology or phlebology). One department had window ventilation; another department had a class Ib HVAC system.

At the small hospitals, the instrument tables were prepared directly before the procedure in only 13 % of cases; the corresponding value for larger hospitals was 91 %. The OT doors were closed during the procedure at 100 % of medium-size and large hospitals but only at 81 % of small hospitals. In the group of large hospitals, the use of patient-specific wound irrigation solutions could not be verified during the on-site inspections. At the small and medium-size hospitals, 33 % and 13 %, respectively, showed poor results, although here, no review was possible due to a lack of opportunity in 32 % and 44 % of cases. Open storage of sterile medical devices delivered in transparent wrapping (beyond the needs of the day's operating schedule) was observed in 56 % of cases.

A fully equipped cleaning cart was available at all large hospitals but only 81 % of small hospitals. In the remaining 19 % of these hospitals, an intermediate disinfection of the surfaces near patients was performed with tissues from a dispenser between patients; the floor was not cleaned and disinfected until the end of the working day. Dry storage of reprocessed mops was observed at 83 % of hospitals overall, with the large hospitals presenting somewhat better results (94 %). There was substantial room for improvement when it comes to the documented disinfection of the cleaning utensils used; the disinfection results were objectively traceable based on microbiological reports at only 15 % of hospitals.

Another criterion often missed during ongoing activities was waiting for the sur-

face disinfectant to dry between procedures. On average, this was done at 68 % of hospitals, with the small hospitals showing the least favourable result (56 %). Wipe disinfection of hand contact points (monitors, anaesthesia machines, couches) was performed after 73 % of procedures; the best result (76 %) was achieved at large hospitals.

Tissue dispensers have become commonplace in clinical practice; they are used in 95 % of hospitals overall, with the share being smallest at small hospitals (88 %). The reprocessing of tissue dispensers, however, left room for improvement, as it was performed in a standardized manner at only 63 % of hospitals. Type-tested and maintained decentralized disinfectant dispensers should be improved especially at small hospitals, where they were deployed in 75 % of cases compared with 90 % at large hospitals.

### Implemented measures for sepsis prevention

The handling of parenterals (intravenous medications) revealed, sometimes considerable, deficiencies. Disinfectants for rapid surface disinfection prior to preparing parenterals were available at the half of the surgical departments; here the large hospitals performed worst (32 %). Disinfection of the septum before removal took place in 75 % of cases. Labelling according to the standard (type of medication, concentration, date, time) was performed in 66 % of cases; the result for large hospitals was better (74 %) but still not good.

Only half the hospitals demonstrably prepared intravenous medications in syringes for fractionated pre-delivery less than 1 hour before use. Single-dose containers without preservatives were correctly handled in 65 % of cases, with the small hospitals achieving an unacceptable result of 19 %. Medications are stored in household refrigerators even at some hospitals, namely at almost 40 % of the medium-size and small ones. For medical reasons, it is necessary in selected cases to prepare emergency medications or other drugs ahead of time and to store them ready for use, as having to prepare them on demand may result in a medically unacceptable loss of time in emergency situations. Only about 15 % of the large hospitals met pharmacy standards for emergency medications.

The handling of propofol was unexpectedly inappropriate: the rule that the drug, which contains no preservatives, should be administered intravenously immediately after being drawn up into the syringe was followed at only one-half of the facilities. The large hospitals scored best (62 %), while the small ones scored worst (31 %). At the small hospitals, only 69 % adhered to the manufacturer's instruction that propofol may not be withdrawn from bulk containers multiple times for use on different successive patients. A written in-house standard for the appropriate handling of propofol was available at 32 % of the large hospitals, but only 22 % of the medium-size ones and none of the small ones.

## Discussion

In the context of an official medical inspection, structural and functional aspects, mandatory documentation and test reports can be audited to 100 %. This was also evident in the current study regarding criteria such as the presence of construction plans, cleaning and disinfection policies; standards for perioperative antibiotic prophylaxis; availability of hand disinfectant dispensers; operation and maintenance of decentralized disinfectant dosing equipment; and the availability of personal protective equipment (PPE).

However, attempts to systematically assess those processes, during ongoing OT activities, that are important for the prevention of postoperative infections and sepsis prevention, proved difficult and subject to limitations. Thus, the current study has been subject to the methodical limitation that not all the important measures and processes can be observed during ongoing OT activities in the course of an individual inspection, even during a half-day audit. This proved to be true of criteria such as indication-driven hand disinfection, preoperative skin antisepsis, the use of patient-specific wound irrigation solutions, the handling of propofol and appropriate intermediate disinfection of the OT between procedures. In the observational studies, in some cases no delta analysis was possible in any of the three hospital groups, as not every single process was performed during the respective inspection period. A further limitation within observational studies is the Hawthorne effect, first described in the 1920s: participants in a study will modify their natural behaviour because they know they are under observation [22]. Calculating significance levels is not appropriate for a sample of this size. The observed differences between the three groups of hospitals cannot always be systematically and logically evaluated since what procedures are performed where and when and whether they can be observed by the official medical inspector is purely coincidental. Likewise, it is impossible to acquire or evaluate issues that play a role for the quality of treatment results, i.e. postoperative outcomes, such as technical aspects of surgical procedures factors or patient-related postoperative risk factors during an official medical inspection. Therefore, evaluation of the data presented is only possible to a limited extent. However, the authors feel that they clearly indicate areas where there is a need for intervention and OT staff training.

Despite these limitations, the method of OT inspection along with process monitoring was deliberately chosen, as rising demands on hygiene also require an improved and systematic methodology to be employed by the public health authorities, forming an important basis for constructive dialog between the hospitals and the public health authorities. This method of systematic interviews and observation may provide additional data on the level of infection control competence of hospital-based physicians and caregivers, as demonstrated in a study by Wolfering et al. in 2011 [23].

The results of the OT inspections shall be analyzed from different perspectives below.

Three of the perioperative risk factors for acquiring an SSI listed in the KRINKO recommendation entitled "Prevention of Postoperative Infections in the Operating Area" have been identified in a significant number of hospitals:

- Inappropriate preoperative hair removal, preoperative shaving with disposable razors
- Inadequate skin cleaning/disinfection
- Inadequate perioperative antibiotic prophylaxis

Additional risk factors identified for which a direct effect on wound infection rates has been described in the literature include:

- Inappropriately worn surgical caps and mouth and nose protection [24]
- Non-compliance with the required contact time for surgical hand disinfection
- Non-compliance with the required contact time in preoperative skin antisepsis
- Wearing of cotton gowns [25]

- Insufficient implementation of indications for hygienic hand disinfection

Identified criteria with possible effects on postoperative wound infection rates (for which, however, there are no published data) included:

- Non-compliance with the indications for hygienic hand disinfection
- No preoperative skin antisepsis for laparoscopic procedures comparable to those for conventional surgery, in case a switchover to open surgery is required
- No wipe disinfection of hand contact points between procedures
- No waiting for the surface disinfectant to dry between procedures

It was also examined whether the hospital size/number of beds had any impact on the type and number of shortcomings. No differences in structures and processes were observed regarding:

- Availability of hand disinfectant dispensers at anaesthesia stations
- Staff hygiene, hand hygiene, indication-related implementation of hygienic hand disinfection
- Appropriately worn of surgical caps and facial masks
- Appropriately worn of OT garments
- Documentation of the disinfection of mops
- Open sterile-supply storage in the OT (beyond the needs of the day's operating schedule)
- Waiting for the surface disinfectant to dry between procedures
- Wipe disinfection of hand contact points between procedures

However, items were also identified where small hospitals scored lower during on-site inspections:

- Support by external hospital hygienists
- Appointment of a physician infection control officer, to receive appropriate special training
- Preoperative shaving with disposable razors (a procedure no longer recommended)
- Implementation of preoperative skin antiseptics
- Compliance with the required contact time for the surgical hand disinfectant
- Wearing of sterile protective gowns during surgical procedures
- Instrument table set directly prior to procedure
- Keeping doors closed during operations
- Provision of upgraded cleaning cars where reprocessed cleaning utensils are properly presented in dry condition
- No waiting for the surface disinfectant to dry between procedures
- Use and maintenance of decentralized disinfectant dispensers
- Use of tissue dispensers
- Inappropriately labelled parenterals kept available in syringes
- Multiple withdrawal of parenterals from bulk containers without preservatives
- Pharmacy standards for emergency medications
- Handling of propofol
- Use of household refrigerators for storing medications requiring cooling
- Use of patient-specific wound irrigation solutions
- Standards for perioperative antibiotic prophylaxis

The observed handling patterns of wound irrigation solutions – parenterals in general and propofol in particular – is viewed very critically, regardless of hospital size. The literature describes the possible serious effects on patients if hygienic principles are disregarded [26, 27]. Regardless of any hygienic aspects, some aspects of the intravenous administration of drugs posed a potential patient hazard: Parenterals in syringes often lacked proper labelling stating the designation of the drug and its concentration (these data are not shown separately in the tables).

Inspections at Frankfurt hospitals in 2000 and 2007 [28, 29] showed, in addition to some structural optimization potential, incorrectly implemented processes for hand disinfection and for handling OT garments; procedures were often performed with the OT doors open. Compliance with the requirements for cleaning and surface disinfection between procedures and at the end of the working day was relatively good in those inspections. The handling of parenterals was not investigated. The still frequently encountered manual reprocessing/disinfection and sterilization of instruments directly in the surgical area was rated as problematic; this was not an issue in Munich.

More than 47 % of respondents in the OT Barometer, a biennial survey of OT and anaesthetic nurses conducted by the Frankfurt University of Applied Sciences, opined that the overall risk to patients had increased over the previous two years [30]. In 2015 as in 2013, the OT Barometer results related to hygiene were notable: 61 % of respondents said that the hygiene guidelines in their area were strictly adhered to; 23 % said that they were often not adhered to, while 16 % were neutral. The opinion of the staff did not vary depending on their area of responsibility (surgical care, anaesthetic care, technical assistance). This evaluation is basically confirmed by the data collected in Munich. Time constrains and a high patient turnover have resulted in considerable time pressure within hospitals, resulting in deficiencies in basic hygiene and the handling of intravenous medications.

This problem is further aggravated by the separation of responsibilities: OT nurses, anaesthesia nurses and cleaning staff are each responsible for different aspects of intermediate disinfection within the OT, causing significant and discernible difficulties in coordinating these steps, with omitted disinfection steps and non-compliance with drying times as a result. And at times, external staff, such as attending physicians and anaesthesiologists, did not feel bound by the in-house regulations.

## Conclusion

The findings of the public health authorities' results in their audits of surgical departments have resulted in a funding program of the Bavarian State Ministry for Health and Long-Term Care for structural measures and have promoted hospital hygiene by contributing €40 million per year in extra funding for 2013 and 2014. According to the audits conducted in Munich, structural problems or construction deficiencies were not that much of a problem. Instead, staff behaviour in the OT gave cause for criticism. The necessary measures in this area can essentially be implemented without extra cost.

But this would require a clear definition of the responsibilities for infection control issues, the provision of extra staff training and supervisors serving as role models. Unannounced compliance checks on a regular basis by the on-site hygiene professionals could significantly contribute to raising awareness and addressing open questions in a collaborative spirit. On the other hand, employees who consistently fail to comply with infection control requirements should face consequences in terms of their employment situation, something that should be communicated openly and implemented

consistently. Failure to comply with hygiene standards will not only have a potential effect on patient health but may also have hospital operators face legal consequences under liability law. Failure to comply with the KRINKO recommendations, which according to established case law represent the current state of the art, can lead to a reversal of the burden of proof for the hospital in the event of harmful effects, such as postoperative wound infections.

## Acknowledgements:

The authors would like to thank the other members of the testing teams: Dr med Leila Horvath, Dr med Filia Maropaki, Dr med Ulrike Thalmeier, Dr med Agnes Scheffler and Dr med Delia Warburg.

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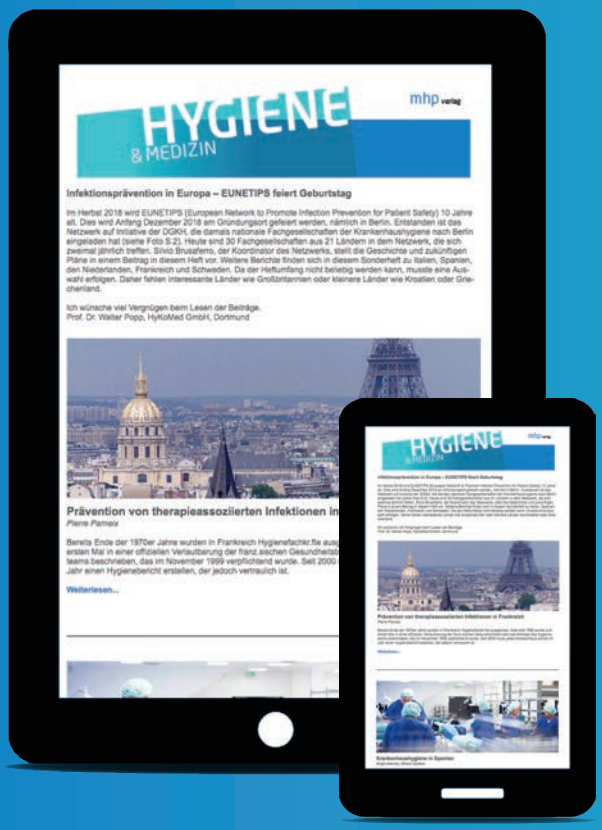


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