## Original article

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# Quality of structures, processes and outcomes of hygiene in outpatient surgery facilities – observations from 2014 and 2015

## Summary

**Background:** Ambulatory surgery has long been established as the third pillar in patient care besides inpatient treatment and conservative outpatient therapy. Facilities for outpatient surgery are especially common in areas of high population density. The supervisory public health authority for the city of Munich is the Department for Health and the Environment (RGU).

**Methods:** Based on the administrative ordinance issued by the Bavarian Ministry for Public Health and Care Services, the RGU inspected 32 facilities for outpatient surgery in Munich between March 2014 and November 2015 as part of a statewide audit program for these institutions.

**Results:** With regard to the quality of structure, the audits showed that the recommendation published by the German Hospital Hygiene Commission "KRINKO" on "requirements of staffing and organizational structure for the prevention of nosocomial infections" was fully met by 16 % of the inspected facilities for outpatient surgery. 69 % of facilities for outpatient surgery had written infection prevention policies and procedures tailored to their facilities, but these were not always complete. 75 % fulfilled the KRINKO requirements regarding building/structural, functional and technical conditions.

**Conclusions:** The results show that – as compared to hospitals – there is a particular need for facilities for outpatient surgery to optimize their staffing with infection control specialists, the structural and functional requirements, the quality of processes as well as to improve reporting the quality of outcomes.

**Keywords:** Ambulatory surgery · hygiene standards · public health authority · audits

## Introduction

### Background

Outpatient surgery has long become established as the third pillar of patient care besides conservative outpatient therapy and inpatient treatment (at least one hospital night). According to a 2014 publication of the German Association of Outpatient Surgery [1], Germany has a comparatively high population-weighted frequency of surgical interventions, yet the average rate of ambulatory surgical cases seems remarkably low compared to other industrialized countries. The reason that has been given for this is a significantly lower remuneration, by international comparison. Nevertheless, outpatient surgery will continue to gain in importance in future due to potential cost savings, the general rule being that outpatient surgery for the patient under no circumstances may be associated with a higher risk of infection compared to surgical treatment under inpatient conditions.

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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).

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Outpatient surgical facilities or clinics are especially common in areas of high population density. The supervisory public health authority for the city of Munich is that city's Department for Health and the Environment (RGU).

### Legal and technical foundations and standards

The legal basis for infection control surveillance of outpatient surgical facilities is, on a national level, Article 23 of the German Act for the Prevention and Control of Infectious Diseases in Humans (IfSG) [2] and, in Bavaria, the Regulation on Hygiene and Infection Prevention in Medical Institutions (MedHygV) [3]. In addition, further legislation such as the Medical Devices Act [4] and the corresponding implementing regulation {5] as well as a large number of guidelines and standards are of decisive importance for assessing the hygienic situation at outpatient clinics. First and foremost, there are the recommendations developed by the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and regularly updated. They provide a basis in the sense of obligatory standards for measures necessary for the prevention of nosocomial infections, for structural and functional requirements and the organization of operational processes. Additional information can also be found in the regulations on occupational health and safety with interfaces for infection protection, for example in the Technical Rules for Biological Agents (TRBA 250) [6].

Important technical basics regarding requirements for outpatient surgical facilities are laid down in the agreement on quality assurance measures according to Art. 135 paragraph 2 of the Fifth Book of the German Social Code (SGB V) on outpatient surgery [7]. Further technical basics can be found in the publications of various institutions and professional associations such as the Association for Applied Hygiene (VAH), the German Society for Hospital Hygiene (DGKH) and the Working Group "Hospital and Practice Hygiene" of the Association of the Scientific Medical Societies in Germany (AWMF).

### Situation in Bavaria and Munich

In order to ensure a uniform enforcement practice of the supervisory authorities in Bavaria, the responsible Bavarian Ministry of State, together with the Bavarian Association of Statutory Health Insurance Physicians (KVB), the Bavarian State Medical Association (BLÄK) and the Bavarian State Office for Health and Food Safety (LGL), had previously issued definitions for "Facilities for outpatient surgery where medical care comparable to that at hospitals is provided" and "Outpatient surgery facilities" based on the Annex of the Enclosure to Sections 5.1 and 4.3.3 (C5.3) of the recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) entitled "Hygiene requirements for outpatient surgery in hospitals and outpatient clinics" [8].

Given the fact that this Annex is dated 1997 and therefore does not include a large number of recent interventions and surgical procedures, a separate "List for the implementation of the Bavarian MedHygV: Procedures at facilities for outpatient surgery" was compiled, in which interventions were assigned to category A, "operations", category B, "surgical interventions", and category C, "invasive interventions" [9]. The Association of Statutory Health Insurance Physicians played a leading role in compiling this list, together with the professional associations, first and foremost the Bavarian Association for Outpatient Surgery in Bavaria, soliciting expertise from the Bavarian State Ministry for Health and Long-Term Care (StMGP), the State Office for Health and Food Safety, the Bavarian State Medical Association, the Bavarian Dental Chamber and the Association of Bavarian Statutory Health Insurance Dentists.

Based on the administrative ordinance issued by the Bavarian Ministry for Public Health and Long-Term Care, the RGU inspected 32 facilities for outpatient surgery in Munich between March 2014 and November 2015 as part of a state-wide audit program for these institutions. In accordance with the guidelines of the State Office for Health and Food Safety (LGL), only facilities with a higher risk profile in terms of their surgical or intervention spectrum should be included in the audit, i.e., facilities for outpatient surgery where medical care comparable to hospitals is provided (category A) and facilities for outpatient surgery where surgery is performed (category B). Outpatient clinics where only category C invasive interventions are carried out were excluded directly. The categorization was carried out as part of the existing statutory reporting obligation in accordance with Art. 14 of the MedHygV, by self-assessment of the respective facility on the basis of their treatment spectrum.

The inspections were based on standardized modular checklists [10] compiled by the LGL, together with an accompanying text for this particular audit [11], with the aim to systematically record and analyze basic hygiene management in terms of the structural and functional situation (structural quality), process quality and outcome quality.

There are three types of facilities for outpatient surgery or outpatient clinics for surgery, respectively, in the city of Munich:

1. "Outpatient operation centres" used, among others, by physicians in private practice who do not have their own operating or intervention rooms
2. "Practice clinics for surgery" in which, in addition to the outpatient surgery, inpatient care can be performed if needed
3. Doctor's offices or "ambulatory surgical clinics", respectively, in which outpatient surgery is performed.

## Materials and methods

The facilities to be audited were selected based on internet research and comparison with a database provided by the Association of Statutory Health Insurance Physicians of Bavaria or on reports received by the RGU within the framework of the statutory reporting obligation.

Of the 78 facilities registered by the RGU for outpatient surgery in the Munich metropolitan area up to November 2015, 32 were audited between March 2014 and November 2015; 18 of them were in category A and 14 in category B.

Of the 32 facilities, 18 (56%) had complied with their obligation to register on the date of the audit. Also of the 32 facilities, 3 A facilities were outpatient surgical centres; 9 category A facilities and 3 category B facilities were so-called practice clinics; The remaining 17 facilities were clinics in which outpatient surgery is performed.

All practice clinics had a room or rooms used for recovery. According to the facility operators, overnight stays occurred only in exceptional cases in about 25% of practice clinics.

Of the 32 on-site inspections, 26 were first-time inspections, while 6 were follow-up inspections of facilities first inspected in 2006.

Table 1: Equipment with hygiene specialists by categories, absolute numbers and percentages (rounded)

| Facilities with hygiene professionals pursuant to Article 5 of the MedHygV | n = 32 | Category A n = 18 | Category B n = 14 |
|---|---|---|---|
| Legal requirements completely met: | | | |
| Contractual consultations with a hospital hygienist or an infection control nurse and appointment of infection control officers as per the relevant category (see below) | 5 (16 %) | 4 (22 %) | 1 (7 %) |
| Legal requirements broken down: | | | |
| Contractual consultations with a hospital hygienist | 10 (31 %) | 9 (50 %) | 1 (7 %) |
| Contractual consultations with an infection control nurse (or external hygiene consultant) | 19 (59 %) | 10 (56 %) | 9 (64 %) |
| **Consultations with a hospital hygienist and/or an infection control nurse or an external hygiene consultant** | **22 (69 %)** | **12 (67 %)** | **10 (71 %)** |
| Appointment of a physician and a link nurse as infection control officers (required for category A) | | | |
| Appointment of a physician as infection control officer | | 10 (56 %) | (6) (43 %) |
| Appointment of a link nurse or medical assistant as infection control officer | | 11 (61 %) | (8) (57 %) |
| **No consultations with hygiene professionals in accordance with legal requirements** | **10 (31 %)** | **6 (33 %)** | **4 (29 %)** |

In addition to 3 outpatient surgery centres with multiple specialties, the following specialties were represented:
Plastic surgery, 7; coloproctology and anal surgery, 6; general surgery, 6; paediatric surgery, 3; operative dermatology and phlebology, 3; urology, 2; orthopaedics, 2; hernia surgery, 1; gynaecology, 1.

Most announced audits took place outside of ongoing activities by suitably qualified specialist staff physicians who had many years of clinical experience in their respective field of expertise and who had been specially trained for this task and undergone continuing professional development for physician infection control officer.

After a preliminary review of the checklists by the respective institution (self-assessments), the on-site inspection included a preliminary discussion, a review of the documentation, staff interviews, a practice inspection – in 7 of 32 cases (22%) during ongoing activities – and comparison of the completed checklist with the situation on the ground. At the debriefing on the day of the inspection and a final report produced as quickly as possible after, the audit findings were explained and, if any hygiene deficiencies or complaints were noted, an action plan with deadlines, with compliance subsequently monitored.

As a rule, the inspection also involved employees of the trade Inspectorate, which is responsible for the supervision of medical device reprocessing. Specifically, they examined the medical device reprocessing for staff expertise, maintenance of devices and validation of processes, but also aspects of staff protection.

The test results were tabulated and evaluated. Multiple answers to all questions were possible.

## Results

### Structural quality – Infection control management

#### Hygiene professionals

The requirements of the MedHygV [3] and the corresponding recommendation of the German Hospital Hygiene Commission (KRINKO) on "Requirements of staffing and organizational structure for the prevention of nosocomial infections" [12] were considered to be met in category A institutions if, in addition to contractual consultations with an infection control nurse (Hygienefachkraft) and a hospital hygienist (Krankenhaushygieniker), it was demonstrated that a physician (hygienebeauftragter Arzt) and medical assistant (hygienebeauftragter medizinischer Fachangestellter) or link nurse (Hygienebeauftragter in der Pflege) had been appointed infection control officer. In category B, the requirements were met if consultations were shown to have been held with a hospital hygienist and an infection control nurse.

A complete set of hygiene professionals according to MedHygV was thus found at 5 of 32 (16%) facilities. At 19 of 32 outpatient clinics (59%) there were consultations with an external infection control nurse, and at 10 outpatient clinics (31%), with a hospital hygienist. Overall, at 22 of 32 facilities (69%) there were consultations with a hospital hygienist and/or an infection control nurse or an external hygiene consultant of any kind.

A physician or nurse infection control officer had been appointed at 10 (56%) and 11 (61%), respectively, of 18 category A facilities.

Although not required by law, 6 (43%) and 8 (57%) of 14 category B facilities, respectively, had appointed a physician or link nurse/medical assistant infection control officer.

At 10 of 32 outpatient clinics (31%) there had been no consultations with either an infection control nurse or with a hospital hygienist.

#### Infection control policy

All facilities (100%) had an infection control policy. Legal validity through correct release was assured at 23 facilities (72%).

A complete hygiene policy adapted to the needs of the facility was found plus writ-

ten documentation of the information and training obligation according to Art. 12 of the MedHygV [3] were present at 22 of 32 institutions (69%).

At 10 of 32 outpatient clinics (31%) there was a hygiene policy (e.g. a sample hygiene plan) not specifically adapted to the needs of the facility.

## Structural quality – Structural and functional requirements

The structural and functional situation at 24 of 32 outpatient clinics (75%) broadly corresponded to the requirements of the KRINKO recommendation, "Hygiene requirements for surgery and other invasive procedures" [13].

At 8 of 32 facilities (25%), the spatial requirements for a closed surgical or intervention unit were not or not fully met, considering the specific range of operations or intervention spectrum with respect to issues such as the supply and disposal routes and the protective access zone function of staff and patient changing areas.

Operations were performed in intervention units at 5 of 18 category A facilities (28%).

Overall, 27 of 32 outpatient clinics (84%) had their own staff changing rooms for the OT staff; three of them had no access zone function because they were separate from the OT.

At 4 of 27 facilities (15%), the requirement for a clear separation of clean/unclean in the staff changing areas was met; 3 facilities (11%) stored OT garments in the open in the absence of wardrobe space, and at 2 facilities (7%), the surgical hand-washing station was located in the staff access zone.

Regarding rooms for reprocessing medical devices, the conditions for a correct pure/unclean separation were met at 26 of 32 outpatient clinics (81%). A separate cleaning room was available at 24 facilities (75%); 5 of 32 facilities (16%) featured a decentralized disinfectant dispenser.

The requirements for the proper wipe disinfection of permanent furnishings or room surfaces were met at 25 facilities (78%), and complete disinfection of non-permanently installed mobile objects or furniture by wiping was facilitated at 15 facilities (47%).

## Structural quality – Technical requirements – Heating, ventilation, air conditioning (HVAC)

The OTs or intervention rooms at 13 facilities (41%) were equipped with HVAC systems, of which 10 (77%) with class 1 HVAC systems and 3 (23%) with class 2 HVAC systems; at 2 of the latter facilities, the filter equipment was not designed specifically for medical facilities (one category A and one category B outpatient clinic each).

Of these 13 facilities, 7 (54%) could present complete technical maintenance [14, 15] and hygiene inspection documentation pursuant to VDI 6022 [16]; conversely, 6 facilities (46%) did not meet these requirements [17].

At 17 of the 32 outpatient clinics (53%), the OTs or intervention rooms were ventilated by windows (53%). Of these, 11 facilities (65%) had intact insect screens; conversely, the rooms at 6 facilities (35%) had window ventilation without insect screens. At 2 facilities (both category A facilities, 6%), ventilation was effected via the adjacent rooms.

Table 2: Development of an infection control policy, absolute numbers and percentages (rounded)

| Development of an infection control policy | Number of facilities n = 32 |
|---|---|
| Infection control policy available | 32 (100 %) |
| Appropriately release, legally valid | 23 (72 %) |
| Mostly customized and largely complete | 22 (69 %) |
| Information and training obligation laid down in Article 12 of the MedHygV documented in writing | 22 (69 %) |
| Infection control policy incomplete, not customized for the facility | 10 (31 %) |

Table 3: Structural and functional requirements, absolute numbers and percentages (rounded)

| Structural and functional requirements, technical requirements | Number of facilities n = 32 | Number of Category A facilities n = 18 |
|---|---|---|
| KRINKO requirements met | 24 (75 %) | 13 (72 %) |

Table 4: Technical requirements (HVAC), absolute numbers and percentages (rounded)

| HVAC | Number of facilities n = 32 |
|---|---|
| HVAC system present | 13 (41 %) |
| Complete maintenance documentation, including the protocol of the hygiene inspection according to VDI 6022 | 7 (54 %), n = 13 |
| Window ventilation | 17 (53 %) |
| Insect screens present and intact | 11 (65 %), n = 17 |
| Ventilation via adjacent rooms (neither HVAC nor window ventilation) | 2 (6 %) |

Table 5: Patient safety, absolute numbers and percentages (rounded)

| Patient safety | Number of facilities n = 32 |
|---|---|
| Uninterruptible power supply present | 25 (78 %) |
| Qualified staff present in recovery room | 29 (91 %) |
| Enough space available in recovery room | 30 (94 %) |
| Emergency call system present in recovery room | 29 (91 %) |
| Postoperative monitoring possible in recovery room | 31 (97 %) |
| Oxygen available in recovery room | 31 (97 %) |

Table 6: Requirements for appropriate hand hygiene, absolute numbers and percentages (rounded)

| Requirements for appropriate hand hygiene in the surgical tract, in the OT and in the patient examination area | Number of facilities n = 32 |
|---|---|
| Fully equipped with contact-free hand disinfectant dispensers in critical areas | 8 (25 %) |
| Fully equipped with glove box holders | 9 (28 %) |
| Appropriately equipped hand-washing stations pursuant to TRBA 250 in infection-critical areas | 15 (47 %) |
| Special features of the surgical hand-washing stations | |
| Light beam-activated sensor fittings | 6 (19 %) |
| Clock | 28 (88 %) |
| Special features of the hand-washing stations in the patient examination area | |
| Washbasin with overflow | 5 (16 %) |
| Water jet directed directly at the water drain | 3 (9 %) |

Table 7: Hand hygiene and staff hygiene, absolute numbers and percentages (rounded)

| Hand hygiene/personal hygiene<br>Organization and implementation | Number of facilities n = 32 |
|---|---|
| Exclusively use of disposable entities (structural quality), no transfer to unsterilized containers in the absence of clean-room conditions | 29 (91 %) |
| Consistent labelling of hand disinfectant dispensers with date of opening | 25 (78 %) |
| Fully equipped with/non-use of personal protective equipment in infection-critical areas | 18 (56 %) |
| Appropriate handling of mouth and nose protection | 31 (97 %) |
| Appropriate reprocessing of OT shoes | 27 (84 %) |
| For condyloma ablation by laser (n = 5): Equipped with FFP 2/3 masks | 2 (40 %), n = 5 |

In terms of equipment categories, 9 of the 18 category A facilities (50%) had HVAC systems with three-stage filtration; 2 (11%) had HVAC systems with two-stage filtration; 5 facilities (28%) used window ventilation, of which 1 (20%) had no insect screens.

## Structural quality – Patient safety

In terms of patient safety, most of facilities practised postoperative monitoring in a recovery room (97%), had installed an emergency call system (91%) and featured equipment for oxygen administration (97%).

The 7 facilities that did not have an uninterruptible power supply (22%), included 3 category A facilities (43%), including two paediatric facilities and an outpatient clinic for general surgery.

## Structural quality – Hand hygiene requirements

At 8 of 32 outpatient clinics (25%) there was a complete set of touch-free hand disinfectant dispensers in infection-critical areas, pursuant to the KRINKO recommendations on hand hygiene [18].

At 24 facilities (75%) there were hand disinfectant dispensers, but sometimes not enough of them in infection-critical areas like the anaesthesia workstation, in the recovery room, in the medical device reprocessing area or sometimes even in the treatment rooms.

Glove box dispensers for the contamination-free retrieval of disposable gloves were consistently deployed at 9 of 32 facilities (28%); conversely, glove boxes were sometimes deployed in the open at 23 facilities (72%).

Completely equipped hand-washing stations pursuant to TRBA 250 [6] in infection-critical areas such as the recovery room, intervention room, disposal room, cleaning room or the laundry reprocessing room were present at 15 of 32 practice facilities (47%); conversely, at 17 facilities (53%) wall-mounted, touch-free dispensers for soap, hand disinfectant and disposable towels were at least partially absent.

Sensor-activated fixtures were found at the surgical hand-washing stations of 6 facilities (19%). At 28 of 32 outpatient clinics (88%), the surgical hand-washing stations were equipped with a clock.

At 5 facilities (16%), hand-washing stations patient treatment areas were equipped with an overflow, while at 3 facilities (9%) the water jet was directed directly at the drain.

## Process quality – Organization and implementation

The organization or assurance of processes implemented according to the KRINKO recommendations [13, 18, 20, 21, 22, 23, 24] or RKI publications [19] in the field of hand hygiene, personal hygiene and staff protection, measures for the prevention of postoperative wound infections, as well as surface disinfection, environmental hygiene, laundry reprocessing, and the handling of medications, sterile supplies and waste as well as medical device processing were evaluated for process quality.

### Hand hygiene

Of the 32 outpatient clinics inspected, 29 (91%) used hand disinfectants in their original packaging (structural quality) and did not, or no longer, pour disinfectants from bulk containers into smaller unsterilized containers [25].

The hand disinfectant dispensers were labelled with their opening dates at 25 of 32 facilities (78%).

### Staff protection/staff hygiene

A full range of personal protective equipment in infection-critical areas such as the medical device reprocessing room, the disposal or unclean room in the OT or the laundry room were provided at 18 of 32 facilities (56%).

The handling of the mouth and nose protection was organized correctly at 31 facilities (97%).

Properly reprocessed surgical shoes were used at 27 facilities (84%).

Table 8: Strategies for the prevention of postoperative wound infections (POWI), absolute numbers and percentages (rounded)

| Strategies for the prevention of POWI<br>Organization and implementation | Number of facilities<br>n = 32 |
|---|---|
| Preoperative hair removal (where indicated) following KRINKO recommendations, either by clipping or chemically (category 1a) | 24 (75 %) |
| Multiresistant pathogen (MRP) standard integrated in the infection control policy (structural quality) | 10 (31 %) |
| MRP screening established (structural quality) | 6 (19 %) |
| Perioperative antibiotic prophylaxis (PAP) | 22 (69 %) |
| Skin antiseptics in accordance with KRINKO recommendations | 31 (97 %) |
| Use of sterile disposable OT garments | 31 (97 %) |

Table 9: Surface disinfection, absolute numbers and percentages (rounded)

| Surface disinfection<br>Organization and implementation | Number of facilities<br>n = 32 |
|---|---|
| Proper use of tissue dispensers | 17 (53 %) |
| In case of improper use of tissue dispensers | 15 (47 %), n = 15 |
| Use > 28 days, missing/incorrect labelling | 11 (73 %) |
| Improper reprocessing of boxes | 4 (27 %) |
| Proof of compatibility missing (detergent/tissue) | 3 (20 %) |
| Open lid | 2 (13 %) |
| Unsuitable disinfectant | 2 (13 %) |
| Appropriate/rational reprocessing and storage of reusable cleaning utensils | 15 (47 %) |
| Appropriate intermediate and final disinfection in the OT | 22 (69 %) |
| Rapid alcohol disinfection in infection-critical areas, e.g. for cleaning working surfaces before aseptic activities | 23 (72 %) |
| Inappropriate execution of surface disinfection | 14 (44 %), n = 14 |
| Violation of the infection control policy | 4 (29 %) |
| Surface disinfectant left uncovered, no labelling, no measuring aid | 4 (29 %) |
| Use of spray disinfection | 4 (29 %) |
| Use of bristle sweeps or plastic sponges unsupported by hygiene policy | 2 (14 %) |

During condyloma ablations by laser (n = 5), 2 of the affected facilities (40%) used FFP 2/3 masks according to the recommendations of the respective medical societies [26, 27].

## Strategies for the prevention of postoperative wound infections [20, 28, 29, 30]

### Preoperative

Hair removal by clipping or chemically just prior to surgery was performed at 24 of 32 outpatient clinics (75%) only if a strict indication existed.

At 10 facilities (31%) the problem of colonization by or infection with multidrug-resistant pathogens (MRP) in patients in an outpatient environment had been recognized area as relevant and an MRP standard (structure quality) defined as part of the hygiene policy.

At 6 of 32 facilities (19%), predominantly risk-based MRP screening had been established (structural quality).

### Perioperative

Perioperative antibiotic prophylaxis (PAP) was performed as indicated at 22 of 32 facilities (69%), of which 1 (5%) with an unsuitable antibiotic and 1 (5%) following a deviant standard. PAP was regularly combined with postoperative therapy at 5 of 32 facilities (16%).

Antiseptics according to the KRINKO recommendation were performed at 31 of 32 facilities (97%).

The use of sterile surgical clothing was also ensured at 31 of 32 facilities (97%).

### Surface disinfection

Tissue dispensers were properly deployed and used at 17 of 32 facilities (53%).

Cases of improper use (47%) included use of tissues after more than 28 days or incorrect box labelling at 11 of 15 facilities (73%), improper box reprocessing at 4 facilities (27%), no proof of compatibility of the preparation and the tissue used at 3 facilities (20%), and open box lids or use of an unsuitable preparation at 2 facilities each (13%)

Proper reprocessing and storage of reusable cleaning utensils was carried out at 15 facilities (47%).

Intermediate disinfection in the OR was organized correctly at 22 facilities (69%).

Rapid disinfection with a suitable preparation in infection-critical areas was performed at 23 facilities (72%).

All in all, the inspections revealed inappropriate surface disinfection being performed at 4 of 32 facilities (44%), where 4 of 14 facilities (29%) deviated from the hygiene policy when performing wipe disinfections, improper handling of chemicals or generalized use of spray disinfection; also, at 2 facilities (14%), bristle sweeps or plastic sponges were used without being supported by the hygiene policy.

### Ambient hygiene

Proper storage (away from the floor, dust-protected) of medical devices (such as storage aids) and the appropriate use of cardboard kidney dishes (for disposal only) were observed at 25 of 32 facilities (78%).

A recurrent problem is the use of PC keyboards as a frequent hand contact zone. Written instructions for wipe disinfection were sometimes found in the cleaning and disinfection plan, but in most cases, there were no documentation stations present in the OT or intervention rooms. A few institutions had introduced special film covers in the clinic area.

### Laundry reprocessing

At 6 of 32 facilities (19%) at least some of the laundry was cleaned at home; 9 facili-

ties (28%) had their laundry processed externally by service providers, of which 7 (78%) were RAL-certified.

Of the outpatient clinics, 14 (44%) used disposable OT garments.

General laundry as well as working or OT garments and cleaning utensils were cleaned, in whole or in part, using a household washing machine at 21 of 32 facilities (66%). Of these, 18 facilities each (86%) used a VAH-listed detergent [31] or deployed a dryer, 16 facilities (76%) stored the clean laundry protected from dust and contamination, 15 facilities (71%) implemented a strict pure/impure separation regime and 7 facilities (33%) documented the microbiological efficiency of the disinfecting washing process.

Table 10: Laundry processing, absolute numbers and percentages (rounded)

| Laundry reprocessing<br>Organization and implementation | Number of facilities<br>n = 32 |
|---|---|
| Reprocessing at the facility (household washing machine), of which | 21 (66 %)<br>n = 21 |
| Use of a VAH-listed detergent | 18 (86 %) |
| Dryer available | 18 (86 %) |
| Appropriate storage of clean laundry | 16 (76 %) |
| correct separation clean/unclean | 15 (71 %) |
| Microbiological proof of efficacy of the disinfectant washing process carried out by infection control professionals | 7 (33 %) |
| External reprocessing | 9 (28 %)<br>n = 9 |
| Certificate of the laundry facility available | 7 (78 %) |
| Reprocessing at home | 6 (19 %) |
| Use of disposable OT garments | 14 (44 %) |

Table 11: Handling of medications, absolute numbers and percentages (rounded)

| Handling of medications<br>Organization and implementation | Number of facilities<br>n = 32 |
|---|---|
| Use of a household refrigerator as a medication refrigerator | 11 (32 %)<br>n = 11 |
| Storage in the refrigerator door | 9 (82 %) |
| No daily documentation of temperature measurements (no maximum-minimum thermometer available) | 6 (55 %) |
| Presence of expired medications | 7 (22 %) |
| Unlabelled opened medication packages (opening date) | 6 (19 %) |
| Use of single-dose containers as multi-dose container (e.g. Ringer solution, NaCl 0.9%) | 5 (16 %) |
| Presence of unidentified single doses of medications | 1 (3 %) |
| Inappropriate storage of narcotics | 1 (3 %) |

### Handling of medications

Only 8 of 32 outpatient clinics (25%) demonstrated consistently correct handling of medications in terms of expiration dates, labelling with opening dates, the storage of refrigerated medications and the use of parenterals.

At 11 of 32 facilities (34%), a household refrigerator was used as a medication refrigerator. At 9 of them (82%), medications required to be refrigerated were found stored in the refrigerator door. In 6 facilities (55%), the temperature was not documented on a daily basis or no performed or no maximum-minimum thermometer was used.

Expired medications were found at 7 of 32 facilities (22%), 6 facilities (19%) did not label opened packages, 5 facilities (16%) used single-dose containers as multi-dose containers and one clinic each (3%) deployed unrecognizable single drug doses or stored narcotics improperly.

### Handling of sterile supplies

Sterile supplies were handled properly (storage, control of expiry deadlines, handling) at 16 of 32 facilities (50%).

Cases of inappropriate handling of sterile supplies at 16 of the 32 facilities (50%) primarily involved the open storage, unprotected from dust and contamination on shelves, sometimes in cardboard kidney dishes and transport boxes. This was the case at 12 of the 16 facilities concerned (75%). Expired medications were found at 5 of 16 facilities (31%).

### Handling of waste

Waste was handled properly (closed storage, suitable containers, handling of organ waste) at 25 of 32 facilities (78%).

At 6 of the other 7 facilities (86%), open refuse bins or hand-operated bins without a pedal mechanism were used. Organ waste was disposed of improperly at 1 outpatient clinic (14%).

### Reprocessing of medical devices

At 27 of the 32 facilities (84%), critical medical devices were reprocessed on-site, 19 of which (70%) had a WD or WD-E. Manual reprocessing was performed at 12 of 27 facilities (44%), either exclusively or as a supplementary measure.

At 4 of 32 facilities (13%) medical devices were processed externally; 1 clinic (3%) used single-use products exclusively.

The required certificate of competence for the staff engaged in reprocessing could not be produced by 6 of 27 facilities (22%) that reprocessed their own medical devices. At 3 facilities (11%) the risk assessment for the reprocessed medical devices was inadequate; 8 facilities (30%) lacked either a recent validation of the processes and equipment used, or the measures specified by the validator's protocol were not implemented (6 facilities) or were deficient in technical maintenance (2 facilities).

Processes were deficient at 11 of the reprocessing facilities (41%), with packaging affected at 7 facilities (64%) and cleaning, disinfection and intermediate or final rinsing at 3 facilities each (27%).

In the case of exclusively manual reprocessing, the drinking-water sampling ac-

Table 12: Handling of sterile supplies, absolute numbers and percentages (rounded)

| Handling of sterile supplies<br>Organization and implementation | Number of facilities<br>n = 32 |
|---|---|
| Appropriate handling of sterile supplies | 16 (50 %) |
| Inappropriate handling of sterile supplies | 16 (50 %)<br>n = 16 |
| Of which | |
| Open storage, not dust-protected<br>Storage partly in cardboard shells, transport boxes | 12 (75 %) |
| Expiry date passed | 5 (31 %) |

Table 13: Organization of medical device reprocessing, absolute numbers and percentages (rounded)

| Reprocessing of medical devices<br>Organization and implementation<br>(multiple answers possible) | Number of facilities<br>n = 32 |
|---|---|
| Reprocessing of critical medical devices at the outpatient clinic | 27 (84 %)<br>n = 27 |
| Of which | |
| Automated reprocessing (own WD/WD-E) | 19 (70 %) |
| Manual reprocessing (exclusively or additionally) | 12 (44 %) |
| External reprocessing | 4 (13 %) |
| Exclusive use of disposable products | 1 (3 %) |

cording to the drinking-water ordinance was missing in 6 of 12 facilities concerned (50%).

In total, 11 of the 27 facilities with medical-device reprocessing (41%) performed this correctly.

### Outcome quality

The legal requirements regarding the documentation and evaluation of postoperative wound infections (POWI) were met by 8 of 32 facilities (25%); conversely, 75% could not demonstrate any surveillance.

The legal requirements regarding the documentation and evaluation of pathogens with special resistances and multi-resistances separately from laboratory findings in patient records were met at 5 of 32 facilities (16%); conversely, 84% of facilities exhibited deficiencies in this respect.

The continuous/complete documentation of antibiotic consumption including a proper assessment was performed at 6 of the 32 facilities (19%); conversely, this means that in 81% of cases, no record of antibiotic consumption was kept.

## Discussion

The facilities for outpatient surgery form an altogether very heterogeneous landscape with different risk profiles depending on their treatment spectrum. This is taken into account by the Bavarian Hygiene Ordinance [3], which distinguishes between "facilities for outpatient surgery where medical care comparable to hospitals is provided", "institutions for outpatient surgery" and "outpatient clinics where invasive procedures are carried out"; the requirements of each are adapted to their respective risk profiles. According to the German Infection Protection Act [2], all categories of facilities for outpatient surgery are subject to infection control audits by the local public health departments. Outpatient surgery as such continues to gain in importance, especially in large cities such as Munich, although there is a trend favouring facilities with a wider range of treatment options and larger organizational structures. The announcement of an audit to be performed by the Health Ministry had already led, in the run-up to the planned inspections, to facilities completely relocating outpatient surgery and interventions into external centres for outpatient surgery including hospitals with departments for outpatient surgery.

The observations presented here, derived from hygiene audits of outpatient operating facilities (not including outpatient surgery in hospitals) during 2014 and 2015 by the Munich public health department, indicate that the legal requirements on structural quality and result are still being insufficiently implemented many years after the passing of the Infection Protection Act of 2000 and the Act Amending the Infection Protection Act of 2011 and the entry into force of the Bavarian Regulation on Hygiene and Infection Prevention in Medical Facilities of 2010. The observed deficiencies in process quality are correlated with sometimes insufficient consultations outcomes or are due to shortcomings in their implementation by the outpatient clinic owners or managers, respectively. In this respect, they underscore the need for qualified consultations and, additionally, the continued need for training and continued education on hygiene-related topics.

Within the context of an official medical inspection, the structures of a facility in terms of hygiene management, structural and functional as well as technical aspects can be quite reliably evaluated by reviewing the existing documentation, by interviews and by on-site inspections. A systematic audit of process quality is significantly more difficult, since the inspections would for the most part take place outside of ongoing OT activities. At best, this can be roughly compensated by examining the implementation of prerequisites or organizational factors in the context of quality management and by means of "practical" demonstrations, with the unavoidable problems these entail. But at least, deficiencies could be identified in terms of staff hygiene, the handling of multidrug-resistant pathogens, surface disinfection, laundry reprocessing, the handling of medication and the reprocessing of medical devices.

The infection control structures already firmly established in hospitals are not found at the same level of consistency at clinics for outpatient surgery. In many cases, the need to consult with infection control professionals was recognized only upon receipt of the LGL checklist in the context of the required self-disclosure, and consequently, at least the advice of an infection control nurse was sought in preparation for the on-site inspection.

The legal obligation for outpatient practices to formulate a hygiene policy specially adapted to the respective facility has been enshrined in the Infection Protection Act [2], in the MedHygV [3], in TRBA 250 [6] and in the agreement of quality assurance measures according to Art. 135 para. 2 of the Fifth Book of the German Social Code (SGB V) [7]. Hygienic policies were generally found to be in place, although almost one-third of facilities could only provide a generic (non-adapted) hygiene policy. Sometimes a desire was voiced on the day of the inspection to wait for any specific requirements made by the public health authorities before embarking on a long since overdue revision of the hygiene policy.

At facilities for outpatient surgery, the facility manager is legally responsible for infection control. Infection prevention concepts cannot be implemented without the assistance of infection control professionals. KRINKO therefore recommended as early as in 2009 that the responsibilities of the specialist staff should be defined in writing as part of the overall internal quality management efforts [12]. The scope of contractual consultations with an infection control nurse recommended by KRINKO for the outpatient sector indicates a guideline value that is considered appropriate; no fixed scope of consultations with a hospital hygienist has been established, so these depend on the treatment spectrum of the facility. According to Art. 8 para. 3 sent. 1 of the MedHygV, only those facilities for outpatient surgery where medical care comparable to hospitals is provided, that is, category A facilities, must appoint a physician or link nurse or medical assistant with proper qualifications obtained through suitable training as infection control officers. Regarding the necessary qualification of the infection control professionals, a statutory transitional arrangement is currently in place, effective until the end of 2019.

As far as the deficiencies related to the structural and functional as well as technical aspects, possible compensatory measures could be identified in most cases. These included, for example, the replacement of furniture that can no longer be wipe-disinfected or the immediate placement of equipment orders in the absence of technical maintenance or hygiene inspections of the HVAC system, or the installation of insect screens if the OT or intervention room had window ventilation. This was pointed out during the inspections, and possible solutions were suggested directly on-site wherever possible.

In one case, however, the performance of certain procedures on the premises concerned had to be prohibited due to the unavailability of compensatory measures and a lack of insight on the part of the facility manager. Most facilities were explicitly cooperative during the inspections and saw to it that the measures discussed were implemented, or took measures such as providing missing hand disinfection dispensers or completing the equipment at their hand-washing stations to comply with TRBA 250 or removing overflows from sinks where required. Facilities that had installed sensor fittings at surgical hand-washing stations were informed that these generally entailed a higher hygienic risk, especially in sensitive areas.

At 4 of 32 facilities (12.5%) there was a change in risk profile to the effect that they resorted to increasingly relocating their surgical activities while only performing minor invasive procedures on-site.

No infection control chain can be stronger than its weakest link. This is particularly true of the increasing problem with multidrug-resistant pathogens, which was recognized as relevant by less than one-third of outpatient clinics. Deficiencies in process quality were found in term of staff hygiene and strategies for the prevention of postoperative wound infections. Here, for example, the recommendations by the

**Table 14: Deficiencies in medical device reprocessing, absolute numbers and percentages (rounded)**

| Shortcomings in the reprocessing of medical devices at the outpatient clinic | Number of facilities n = 27 |
|---|---|
| Missing certificate of competence for the staff involved in reprocessing | 6 (22 %) |
| Insufficient risk assessment of medical devices to be reprocessed | 3 (11 %) |
| Lack of up-to-date validation of the equipment used in reprocessing, no implementation of the measures specified by the validator in the protocol (6), deficiencies in technical equipment maintenance (2) | 8 (30 %) |
| Processing errors, of which | 11 (41 %) n = 11 |
| During packaging | 7 (64 %) |
| During cleaning | 3 (27 %) |
| During disinfection | 3 (27 %) |
| During intermediate or final rinses | 3 (27 %) |
| In the case of exclusively manual reprocessing, lack of drinking-water sampling according to the drinking-water ordinance | 6 (50 %), n = 12 |

**Table 15: Surveillance of postoperative wound infections, pathogens with special resistance and antibiotic consumption, absolute numbers and percentages (rounded)**

| Surveillance | Number of facilities n = 32 |
|---|---|
| Documentation and evaluation of POWI (Art. 23 para. 1 of the IfSG) separately from patient records | 8 (25 %) |
| Documentation and evaluation of pathogens with special resistances and multi-resistances (Art. 23 para. 1 of the IfSG) separately from the laboratory findings in the patient records | 5 (16 %) |
| Continuous/complete documentation and evaluation of antibiotic consumption (Art. 23 para. 4 sent. 2 of the IfSG) | 6 (19 %) |

medical societies were partially ignored (provision and use of FFP 2/3 masks in laser ablation procedures of anal condylomas) [26, 27]. Sometimes perioperative antibiotic prophylaxis was generally combined with postoperative antibiotic therapy.

Other complaints related to surface disinfection, especially regarding the use of tissue dispensers [32], laundry activities [33], the handling of medication and sterile supplies and the reprocessing of medical devices make it clear that regular compliance checks by the public health department are suitable means to change entrenched thinking, if necessary by pointing that the final responsibility rests with the facility itself.

The aim of all measures for infection control at facilities for outpatient surgery is the prevention of postoperative wound infections. The law provides surveillance according to Art. 23 of the IfSG as an instrument for continuous and objectifiable data acquisition. The law also requires managers of outpatient facilities to record and evaluate the incidence of postoperative wound infections in a separate document and on a continuous basis. At the inspections, only 25% of facilities could produce pertinent documentation that was correct both formally and in spirit. The facilities were often unaware that even in the absence of postoperative wound infections, this fact had to be documented separately.

The offending facilities were referred to the relevant KRINKO recommendation [34] and related publications [35, 36] and encouraged to participate in the Ambu-KISS surveillance module where the number of interventions performed justified this. However, only a few facilities had established a standardized postoperative concept regarding the structured conduct of surveillance monitoring. The legal requirements of separate documentation and evaluation of pathogens from wound swabs identified at microbiological laboratories as carriers of special resistance and multi-resistance was met by only one in five facilities; these were referred to the corresponding notification by the RKI [37]. The same applied to the separate documentation of the use of antibiotics, which varies greatly due to facilities' differences in surgical spectrum and risk profile. In this context, the facilities reported that while such a notification had been announced by the RKI in 2013 [38], which was to take into account the special conditions of outpatient surgical facilities by providing an adapted template, but had yet to be published by the RKI.

In comparison with the publications in the past on inspections in facilities for outpatient surgery in Frankfurt in the years 2003 and 2007/2010 [39, 40, 41, 42] as well as in Cologne, published in 2012 [43], as well as in comparison with the first round of inspections by the Munich public health authority of the own authority in 2006, improvements were observed in both structural quality and process quality. This concerns above all the fact that all facilities now have infection control policies in place (100%, vs. 50% in 2003), hand and skin disinfectants are now only rarely refilled (9%, vs. 50% in 2003), critical medical devices are increasingly reprocessed automatically (70%, vs. 1% in 2003, 23% in 2007/10) and more required certificate of competence for the staff engaged in reprocessing could be produced (78%, vs. 0% in 2003 and 54% in 2007/10). Comparable with previous results remained the fact that in about one-third of cases, no infection control professionals are consulted at all; existing hygiene policies (currently 31%) are still not adapted to local conditions, MRP standards are established by only about one-third of infection control policies, and no strict clean/unclean separation regime is practiced in the context of medical device reprocessing (currently 19%). When carrying out the surveillance, major deviations occurred in that in the survey presented here, significantly fewer facilities complied with the legal requirements in terms of form and spirit.

## Conclusions

Identical operations under inpatient and outpatient conditions require identical bundling strategies for infection prevention measures, irrespective of the fact that risk-increasing circumstances are not identically distributed in inpatient and outpatient settings.

While the legal requirements regarding structural and outcome quality in Munich hospitals are largely being met at this point, as our own findings and regular monitoring activities have indicated, this is far from being the case in all outpatient clinics. Although the restricted number of inspected facilities and the data collected by the RGU do not allow statistically significant conclusions, the deficiencies in process quality, despite a trend towards improvement, continue to indicate a need for further training related to infection control issues and consultations with infection control professionals, as well as the ongoing publication of information in the relevant specialist literature that reach the facility managers. In addition, regular consultations and supervision by the public health authorities are suitable means to support and promote the internal quality management in all aspects of infection control at the facilities. Even if, in some cases, sanctions must be stringently applied in the event of non-compliance, a high degree of willingness to make requisite changes was perceived during the on-site inspections.

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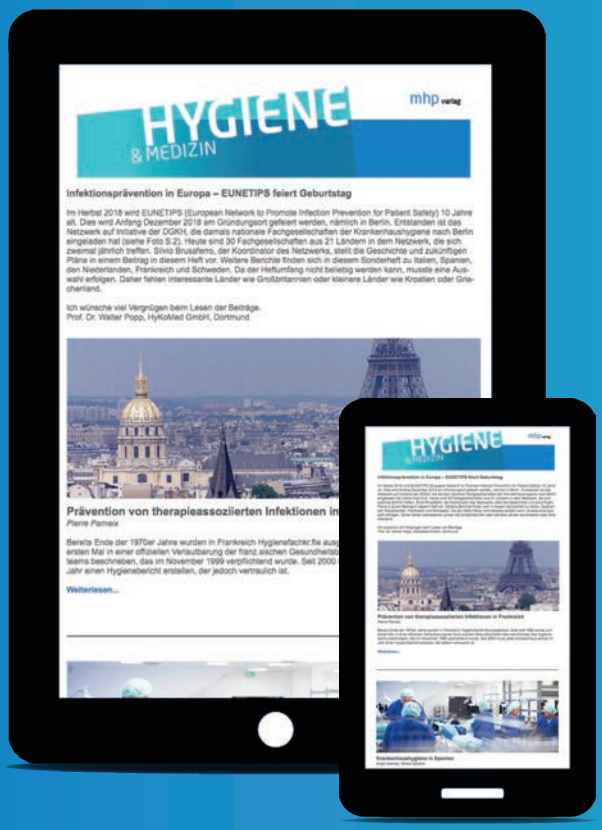


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