Aus dem Institut für Hygiene und Umweltmedizin

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der Medizinischen Fakultät der Ernst-Moritz-Arndt-Universität Greifswald

Experimental based experiences with the introduction of a water safety plan for a multi-located university clinic and its efficacy according to WHO recommendations

Inaugural - Dissertation

zur

Erlangung des akademischen

Grades

Doktor der Medizin
(Dr. med.)

der

Medizinischen Fakultät

der

Ernst-Moritz-Arndt-Universität

Greifswald

2007

vorgelegt von:
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geboren am: 02.08.1979
in Greifswald

Die vorliegende Arbeit basiert auf der Publikation von Dyck A, Exner M und Kramer A. Experimental based experiences with the introduction of a water safety plan for a multi-located university clinic and its efficacy according to WHO recommendations. BMC Publ. Health 2007; 7:1-14

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Tag der Disputation:	19.12.2007

Meinen Eltern

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List of abbreviations

CCP	critical control point
cfu	colony forming units
ClO_2	chlorine dioxide
CP	control point
CVC	central venous catheter
DHC	Department of health of the city of Greifswald
E. coli	Escherichia coli
e.g.	exempli gratia
EHEC	entero-hemorrhagic E. coli
HACCP	hazard analysis and critical control point
HPC	heterotrophic plate count
H. pylori	Helicobacter pylori
ICU	intensive care unit
IHEM	Institute of hygiene and environmental medicine
L. pneumophila	Legionella pneumophila
MOTT	mycobacteria other than tuberculosis
M. simiae	Mycobacterium simiae
POU	point of use
ppm	parts per million
P. stutzeri	Pseudomonas stutzeri
radiol.	radiology (therapeutic radiology)
RKI	Robert-Koch-Institut
SOP	standard operating procedure
spp.	species
TMC	total microbial count
TrinkwV	drinking water regulation
VNBC	viable but non-cultivable
WHO	world health organization
WSP	water safety plan

1. Background

The coherence between contaminated water and nosocomial infections is still a common problem in the clinical routine [13]. The dominating pathogens are *Legionella pneumophila* [32] and *Pseudomonas aeruginosa* [36], while i.e. *Aeromonas spp*., *Flavobacterium spp*., atypical Mycobacteria (Mycobacteria other than tuberculosis = MOTT) [8,18], *H. pylori* [29], Acanthamoeba [26], Cryptosporidia [12], Amoebae i.e. Naegleria [7], Viruses [22], Shigella [7], *Salmonella spp.,* EHEC and molds like *Aspergillus fumigatus* [4,39] and fusarium [2] are found less frequently. There are additionally epidemic agents in developing countries like *Vibrio cholerae*, *Entamoeba histolytica* and *Salmonella typhi* [7].

Due to the high number of immunosuppressed or other endangered patients in hospitals, the requirements on the microbiological quality of the drinking water are much higher than in domestic area. The occurrence of pathogenic microorganisms in water pipes is caused by biofilms [5, 14, 24]. These biofilms arise not only in older but also in newly opened hospitals mostly due to water stagnation [1]. Further attention has to be focussed on lavatory sinks, containing up to 10^5 to 10^{10} cfu/ml of bacteria, thereof about 10^3 to 10^6 cfu/ml of gramnegative rods [34].

For prevention of nosocomial waterborne infections a structured quality management and sufficiently operating security system has to be established. In 2004, the WHO published the 3rd guidelines for drinking water quality recommending the introduction of a water safety plan (WSP). It has to include control and preventive measures, based on a multiple-barrier approach and the HACCP (hazard analysis and critical control points) concept [40]. The permanent surveillance of the microbiological water quality as well as the realization of the WHO guidelines is the aim of our efforts for the introduction and evaluation of the WSP for a hospital of maximum care.

2. Purposes

Drinking water is an important source of nosocomial infections [3]. Since it is one of the most used foods and furthermore undeniable for nursing and personal hygiene it is necessary to enforce measures ensuring the quality of drinking water with regard to the extended requirements in hospitals. Therefore a WSP according to the WHO guidelines and the HACCP concept was introduced. Two situations have to be distinguished: the continuous supervision of the microbiological parameters depending on the risk assessment and the so-called worst case management with regard to accidents. The intention of this survey is the evaluation of the WSP over a period of three years under different aspects:

- Implementation of HACCP and WHO recommendations in the WSP
- Execution of risk-adjusted corrective measures as basis for sanitation and thereby prevention
- Efficacy of immediate and measures of decontamination
- Validation of the importance of extended limiting values in risk areas
- Long-term effect of infrastructural corrective actions
- Considerations concerning cost benefit analysis.

3. Relevance of waterborne pathogens

Pathogens like *Legionella pneumophila, Acanthamoeba* and *Pseudomonas aeruginosa* are often related to waterborne nosocomial infections [26, 32, 36]. *P. aeruginosa* causes a widely spread spectrum of infections like pneumonia, sepsis, wound infections, infections of the urinary tract and the pharyngeal area [7]. Anaissie et al. noticed that the number of lethal nosocomial water-associated Pseudomonas pneumonias in the US is about 1400 per year [3]. Fanghänel et al. examined water samples from 8 hospitals in Saxonia/Germany and found that 83 % of the water taps and 69 % of the showers showed more than 100 cfu/ml *P. aeruginosa*. In addition they identified infection chains from water tap to the patient by molecular analysis in 7 ICU patients [15]. In 2002 Reuter et al. made a prospective study on a surgical unit for a period of 40 weeks. They found 58 % positive samples and 87 Pseudomonas isolates in 45 patients with a clonal correlation between the isolates and water samples. They concluded that *P. aeruginosa* positive patients stayed significantly longer on the ICU [30].

Legionella pneumophila causes the Legionnaires disease, a severe atypical pneumonia, which is especially dangerous for immunosuppressed patients with a mortality rate up to 15 % [7]. In 2004 there were 475 reported cases (0.6/100,000) of Legionnaires in Germany with a mortality rate of 6.1 %, while the RKI (Robert Koch Institut) estimated the total number of pneumonias caused by *L. pneumophila* up to 30,000 based on estimation of CAPNETZ [31]. Kober and Werner examined water samples from 14 hospitals in Pommerania/Germany. The result was that 59 % of the samples were positive for Legionella, of which 38 % had a bacterial load of up to 10 cfu/ml, 17 % 10 to 100 cfu/ml and 4 % at least more than 100 cfu/ml [19]. As an example for an emergency outbreak there was a case in Frankfurt/Oder (Germany) in 2002 with 11 infections of which 2 patients died. Amazingly Legionella not only occurred in the warm water circuit but also in the cold water system [32]. Sorger & Werner ran a study on the occurrence of Legionella in hotels, hospitals and homes for elderly people in the county of Salzburg (Austria). They detected Legionella in 59% of the tested buildings and found no differences between hotels and medical facilities referring to the colonization [35]. Van der Kooij et al. analyzed the growth of Legionella in biofilms in a model using pipes of different materials with water at 25 to 35 °C and found that Legionella was able to multiply in the biofilm of all pipes. The water in the electric heaters (not in the pipes) was heated to 70 °C weekly even leading to increased growth [37]. Borella et al. state that Legionella possesses multiple strategies adapting inhospitable conditions including a viable but non-cultivable state (VBNC), persistence and multiplication in a variety of protozoa (i.e. amoebae) and surviving in biofilm. Furthermore biofilms represent an ecological niche for Legionella, providing nutrients and offering shelter through remarkable resistance towards disinfecting agents [6].

The WHO appoints i.e. *Aeromonas spp*., Burkholderia, Acinetobacter, Salmonella, Shigella, atypical Mycobacteria (Mycobacteria other than tuberculosis = MOTT), *H. pylori*, *Salmonella spp.,* EHEC (among other *E. coli*) and Viruses (i.e. enteroviruses) as further relevant waterborne pathogens [40].

Conger et al. recovered *M. simiae* from water taps in patient rooms, points in the flow of water to the hospital as well as in the patients' homes. Moreover they found an association between exposure to hospital water and pulmonary samples positive for the clonal strain of *M. simiae* isolated from water. Three of 22 culture positive patients met criteria for *M. simiae* pulmonary disease. One of these was colonized by a clonal strain from the hospital while the others had undistinguishable strains from tap water they were exposed at home as well. This means a nosocomial outbreak of *M. simiae* [8]. Kline et al. investigated the cause of bacteremias by *Mycobacterium mucogenicum* in bone marrow transplant and oncologic patients. MOTT were isolated from several water sources including tap water from sinks and shower heads. They found that the outbreak was caused by contamination of central venous catheters (CVC) during bathing. Protecting the CVC from water during bathing was followed by no further bacteremias [18].

Hoque et al. refer to waterborne infections of neonates by Flavobacterium (*Chryseobacterium meningosepticum*) on a neonatal ICU [16].

Nwachuku et al. state that further researches on the occurrence of Acanthamoeba are necessary since no sufficient data exists regarding types or amounts in tap water in the US. Particularly concerning Acanthamoeba as a vector for other pathogens (besides its own pathogenic potential) further attention is necessary [26].

Exner et al. underline the relevance of Cryptosporidia as life-threatening waterborne pathogen for immunosuppressed patients and its remarkable resistance to disinfectants [12].

Amoebae i.e. Naegleria, *Hartmanella spp.* and *Vahlkampfia spp.* are relevant waterborne pathogens, even as possible vector for other pathogenic micro-organisms [7] like Legionella [6].

Annaissie et al. examined samples from water, water surfaces, air and other sources from a bone marrow transplantation unit. They found that hospital water systems serve as potential indoor reservoir of Aspergillus and other molds aerolizing fungal spores. Furthermore they report about the molecular relatedness between a clinical and a water-related strain [4].

The relevance of biofilm as a reservoir of several pathogenic organisms and thereby source of nosocomial infections is pointed out by Exner et al. [13], while Momba et al. state the deterioration of the drinking water quality by biofilms [24].

Due to the importance of drinking water as a source of pathogenic organisms and thus nosocomial infections the WHO recommends the introduction of WSP in health care facilities according to the established HACCP concept [40].

4. Methods

4.1. Realization of the HACCP concept in routine

CCP and CP were introduced by identification of microbiological, chemical and physical risks and the definition of concrete points of threat (control points; at least every fact which has an influence on the water quality) and points of steering (critical control points; threats which offer the possibility of exerting influencing control and avoidance of risks). Both are considered under two situations: routine (figure 1) and critical contamination (figure 2).

The following critical control points (CCP) were defined:

- CCP 1 incoming temperature in the warm water system at least ≥ 60°C
- CCP 2 monthly thermal disinfection of the warm water system at a temperature of 73°C for at least 10 min
- CCP 3 concentration of disinfecting agents for the chemical disinfection at point of entrance and taps; limiting values according to the German law for the quality of drinking water (TrinkwV 2001) have to be maintained
- CCP 4 compliance of the temperature-time relation according to thermal disinfection in case of positive Legionella results in the water
- CCP 5 compliance of limiting values after chemical decontamination at the outlets
- CCP 6 changing frequency of point of use (POU) filters
- CCP 7 surveillance of the processing of POU filters

The following control points (CP) were detected:

- CP 1 transgression of microbiological limiting values
- CP 2 water inlet in the pipeline system of the hospital
- CP 3 handling and processing of the aerators
- CP 4 scalding risk at thermal disinfection including outlets

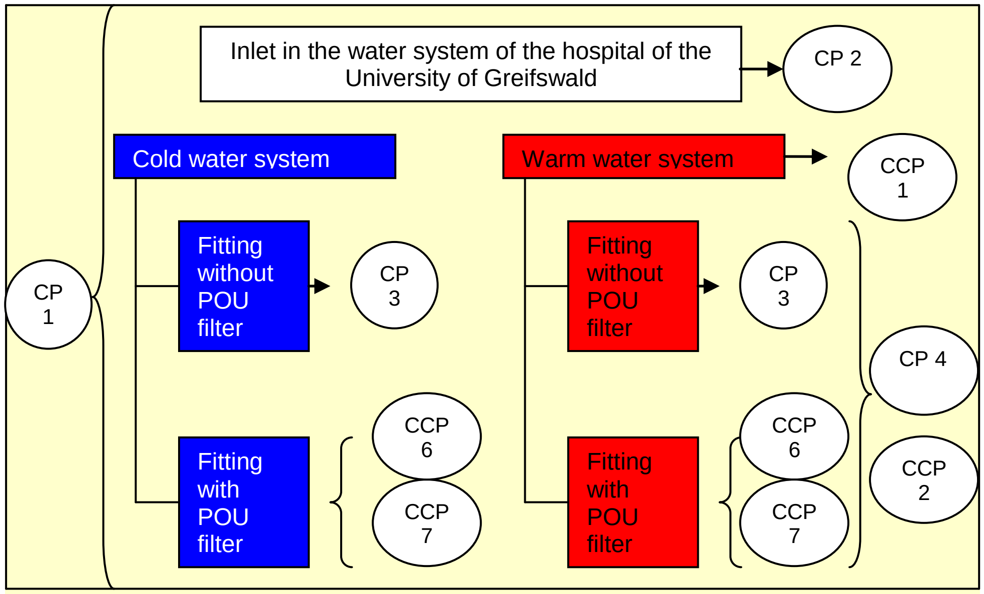


Figure 1: CP and CCP in routine

As a result of the definition of CP and CCP the redevelopment and basic decontamination of the water pipe system was the first preventive measure. Rarely used taps and dead ends were detected and removed. Concrete measures to be performed in case of exceeding 80% of the legal defined limit value of 100 cfu/ml were predetermined (so-called warning value, table 1). The intention behind this sub-set limit value is the prevention of critical contamination.

The following measures were established:

- TMC $\geq$ 80 cfu/ml in the immediate sample after opening the tap as sign for local contamination, but no pathogens: processing of the aerators
- TMC $\geq$ 80 cfu/ml after 3 min of running as indicator for central contamination, but no pathogens: flooding of water system, control, if still positive (> 100 cfu/ml), ClO_2 decontamination with 6 ppm 1 h
- *Pseudomonas spp.* in 100 ml: temporarily installation of POU filters in risk areas until decontamination
- *Legionella spp.* in 100 ml: POU resp. closing of showers until decontamination, permanent heating level of 60 °C in the hot water system, additionally monthly thermo disinfection of hot water system including all outlets; permanent installation of point of use (POU) filters in risk wards as well as for the last washing cycle for endoscope

instruments. The heating up minimal to 73 °C for at least 10 min is necessary for killing intra-amoeboid Legionella [20]. In case of contamination of the cold water system the same procedure is realized.

4.2. Realization of the HACCP concept in case of water stagnation (i.e. reconstructed or new buildings)

In case of stagnation, i.e. during times of reconstruction of elder or new building under construction the following measures are executed:

- Flushing of the water system beginning 4 weeks before opening
- Parallel water sampling
- If flushing is not sufficient; decontamination depending on the microbial burden and the risk assessment

4.3. Realization of the HACCP concept in case of emergency

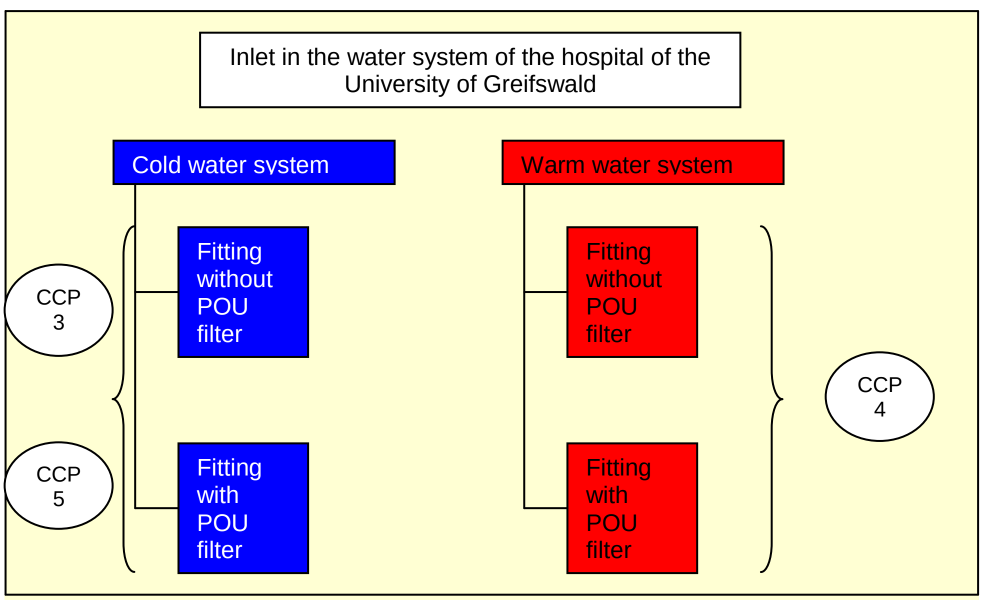


Figure 2: CP and CCP during the process of decontamination

The task force water safety releases immediate measures in case of contamination:

- No withdrawal of water until the end of decontamination
- Avoid hand washing as far as possible; prefer disinfection

- If hand washing is necessary, disinfect the hands subsequently, or use filtrated water (POU filter)
- Use heated water (≥ 73°C 10 min) for washing the patients
- Showering is forbidden during the hole process of sanitation
- Water for brushing teeth has to be taken from fountains or mineral water bottles
- Contaminated water may not be used for cleaning surfaces near to patients
- All outlets in working areas have to be equipped with POU filters.

The process of decontamination is executed during the night shift. Staffs needs to be informed about the measures, every ward has a responsible employee. The first step is the de-installation and processing of all aerators. Afterwards the hot water system is heated up to a temperature of ≥ 73°C for at least 10 min, starting when achieving target temperature at the most distant outlet. The cold water system is decontaminated with ClO_2 (10 ppm). The concentration is checked at the most distant outlet just as in the hot water system. When achieving the default concentration, the acting time of 1 h begins. Afterwards the loss of chlorine is determined, if loss is more than 50 %, the process needs to be repeated. The whole water system is flushed until a concentration of ≤ 0.2 ppm ClO_2 is attained. Machines, like drinks dispenser, with connection to the drinking water system are disconnected before.

4.4. Implementation of a microbiological control program and predetermined measures

According to the German drinking water ordinance (TrinkwV 2001) the drinking water must be examined for the indicator organisms Coli-like, *E. coli*, Heterotrophic plate count (HPC) in cold water at 22 °C and 36 °C and *Legionella spp.* in water > 21 °C once a year. Further controls were introduced basing on risk assessment: Risk area 1 (high infectious risk), risk area 2 (moderate infectious risk), risk area 3 (infectious risk not increased). The frequency of controls is 3, 2 resp. 1 per year (table 2).

SOP’s were introduced for water sampling and processing of the samples steered by a sampling plan. The sampling is performed immediately after opening the tap and after 3 min running. The microbiological diagnostic follows national recommendations [9, 10, 11, 25, 38], while Legionella is determined in 1000 ml water instead of 100 ml recommended by the Federal Environmental Office (Umweltbundesamt).

Table 1 Definition of extended microbiological thresholds according to the risk areas

Risk area	Parameter	Warning*	Threshold	Alert*	Worst case*
1 and 2	**TMC 22°C and 36°C**	80 - 100 CFU/ml	>100 CFU/ml**	>200 - 500 CFU/ml	>500 CFU/ml
	Coliforme, E. coli, Enterococci		0 CFU/100 ml**	1-10 CFU/ 100 ml	>10 CFU/ 100 ml
	P. aeruginosa		0 CFU/100 ml**	1-10 CFU/ 100 ml	>10 CFU/ 100 ml
	Legionella spp. (shower, tap)		0 CFU/100 ml*	1-100 CFU/ 100 ml	>100 CFU/ 100 ml
	fungi		0 CFU/100 ml*	10-100 CFU/ 100 ml	>100 CFU/ 100 ml
3	**TMC 22°C and 36°C**		>100 CFU/ml**	>500 CFU/ml	>1000 CFU/ml
	Coliforme, E.coli Enterococci		0 CFU/100 ml**	1-10 CFU/ 100 ml	>10 CFU/ 100 ml
	P. aeruginosa		0 CFU/100 ml**	1-50 CFU/ 100 ml	>50 CFU/ 100 ml
	Legionella spp. (shower)		0 CFU/100 ml*	>5-50 CFU/ 100 ml	>50 CFU/ 100 ml
	Legionella spp. (tap)		0 CFU/100 ml*	>200 CFU/ 100 ml	>500 CFU/ 100 ml

*our in-house recommendation ** law (2001) resp. water guideline (2004)

Table 2 Allocation of the different facilities according to the risk assessment

Risk area	Clinic	Ward / Department
1 POU filter	**anaesthesia and intensive medicine**	ICU
	gynecology	delivery room-birth tub
	otorhinolaryngology	water for processing of endoscopes
	internal medicine	ICU, hematology-oncology
	pediatrics	milk kitchen, hematology-oncology, ICU, processing of incubators
2	**anaesthesia and intensive medicine**	weaning
	surgery	intermediate care
	gynecology	senology-breast center
	otorhinolaryngology	radiol. ward
	internal medicine	cardiologic monitoring ward
	oral and maxillofacial surgery	recovery room
	nuclear medicine	ward
	neurorehabilitation	all wards/divisions
3	**anaesthesia and intensive medicine**	stroke unit
	ophtalmology	all wards
	surgery, gynecology, dermatology otorhinolaryngology	all other wards
	internal medicine	dialysis, nephrology, gastroenterology, endocrinology, admission ward, cardiology, emergency
	pediatric surgery, oral and maxillofacial surgery, pediatrics, neurosurgery neurology, orthopedics, urology	all other wards
	center for dentistry	all divisions
	hospice	ward

Risk area 1:* use of self disinfecting siphon ** planned use of self disinfecting siphon

In risk area 1 permanent pathogen-free water is required. Because permanent supervision is impossible single-use or reprocessable point of use (POU filters) are provided. Filters are automatically reprocessed in a washer disinfector at the certified university-own Central Sterile Supply Department and finally dryed at 115 °C with sterile filtrated air. For safe handling (touching and cleaning is prohibited, changing frequency is 4 resp. 8 weeks) a hygienic information sheet was deposited at all places of usage.

Additionally the self disinfecting siphons BioRec® (BIOREC UmweltBioTechnologie& BioRecycling-Systeme Lauta, Germany), which acting by self-heating, antimicrobial coated, and emitting ultrasound, to prevent the emission of aerosols [34], were installed in risk area 1.

The extended limiting values beside the limiting value (according to the TrinkwV) are the warning value, the alert, and worst case value, based on a risk assessment (table 1).

4.5. Predetermined measures resulting from risk assessment according to HACCP

Table 3 gives an overview measures that were established.

Table 3 The different schemes in case of exceeding microbiological limit values for risk and non risk areas

<table>
<tr><th>Risk area</th><th>Parameter</th><th>Warning</th><th>Threshold</th><th>Alert</th><th>Worst case</th></tr>
<tr><td>1</td><td colspan="5">POU filter</td></tr>
<tr><td rowspan="2">2</td><td>TMC 22, 36 °C</td><td>inspection,
flushing,
control within 3 days</td><td>inspection,
flushing, POU filter,
control within 1 day,
If negative → finish use of POU filter
If still positive → disinfection</td><td>meeting of taskforce water safety,
Inspection,
Flushing,
disinfection,
POU filter,
control within 1 day</td><td>meeting of taskforce water safety,
stop of withdrawal,
disinfection,</td></tr>
<tr><td>P. aeruginosa,
Legionella spp.,
E. coli
Enterococci,
fungi</td><td rowspan="3"></td><td colspan="2">inspection,
POU filter,
flushing,
control within 1 d,
if negative → finish POU usage
if still positive→ disinfection</td><td>meeting of task force water safety,
stop of withdrawal or POU filter,
disinfection,
control within 1 d,
If negative→ withdrawal allowed with POU for 5d,
parallel water sampling</td></tr>
<tr><td rowspan="2">3</td><td>TMC 22,36°C</td><td colspan="2">inspection, flushing, control within 3 days,
If still positive→ disinfection,
flushing,
control within 7 d</td><td>meeting of task force,
flushing,
disinfection,
control within 1 d</td></tr>
<tr><td>P. aeruginosa,
Legionella spp.,
E.coli,
Enterococci,
fungi</td><td colspan="2">inspection,
POU filter,
flushing,
control within 1 day,
if negative → finish POU usage
if still positive→ disinfection</td><td>meeting of task force water safety,
stop of withdrawal or POU, if negative → release of withdrawal,
POU for 5d,
parallel sampling</td></tr>
</table>

4.6. Documentation

The documentation for the WSP includes information about the ward, the isolated strain and content of cfu/ml, characteristics of the location (i.e. cold or warm water system; shower, tap) and the date of sample taking and provides information about performed measures (table 3).

4.7. Formation of the task force “water safety”

To ensure the interdisciplinary cooperation of all responsible persons the task force water safety was introduced under direction of the head of the Institute of Hygiene and Environmental Medicine (IHEM), including two infection control nurses, experts of the institute of microbiology, hospital hygiene-supervising physicians from the different facilities and the department of engineering. The department of health of the city of Greifswald (DHC) supports our measures as external quality control authority.

5. Results

5.1 Outbreak management by the task force Water safety

In 2004 very high concentrations of micro-organisms occurred in a new opened part of the hospital. The department of health (DHC) had declared negative water probes within three month before the opening. Own controls at the day of official opening showed *P. stutzeri* at a concentration of 2.3×10^5 cfu/100 ml. The task force water safety initiated all measures now established in the WSP. The whole process of decontamination lasted at least 6 hours and took place during the night shift. All aerators were de-installed, processed and disinfected; the cold water system was decontaminated with 10 ppm ClO_2 for one hour, followed by 0.2 ppm ClO_2 over one week. The hot water system was heated up to 73 °C for minimum 10 minutes. Water samples after sanitation until today indicated no further contamination.

5.2 Permanent control of water safety

To evaluate the efficacy of the WSP the microbiological results were recorded from May 2004 to April 2006. Figure 3 shows the number of examinations (by means of comparability of ratios inspections are normalized to 100). The total numbers for 2004 were 56 inspections, 19 1st, 9 2nd and 1 3rd re-inspection, in 2005 respectively 78 inspections, 57 1st, 11 2nd and no 3rd re-inspection and 2006 finally 94 inspections, 20 1st, 4 2nd and 1 3rd re-inspection.

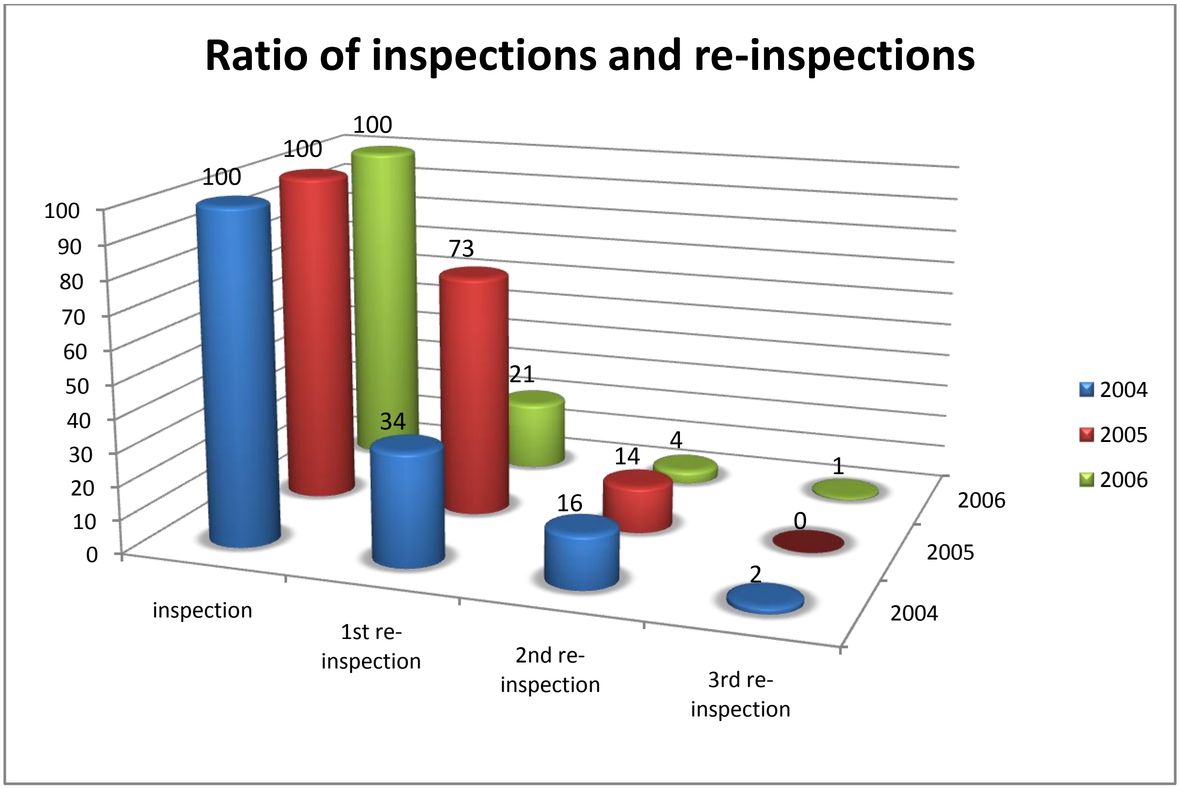
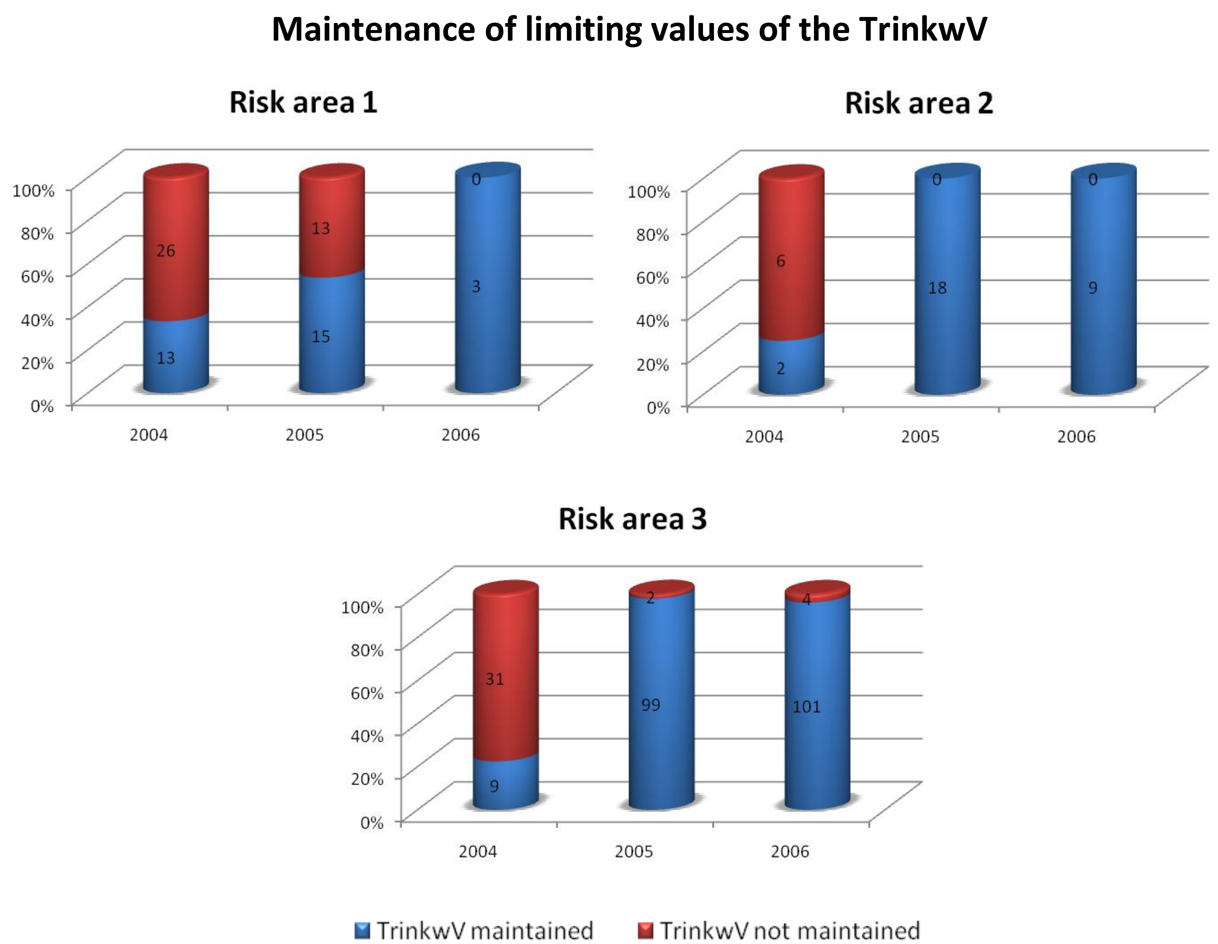


Figure 3 Ratio of the number of inspections and re-inspections by the IHEM comparing the three years of the survey

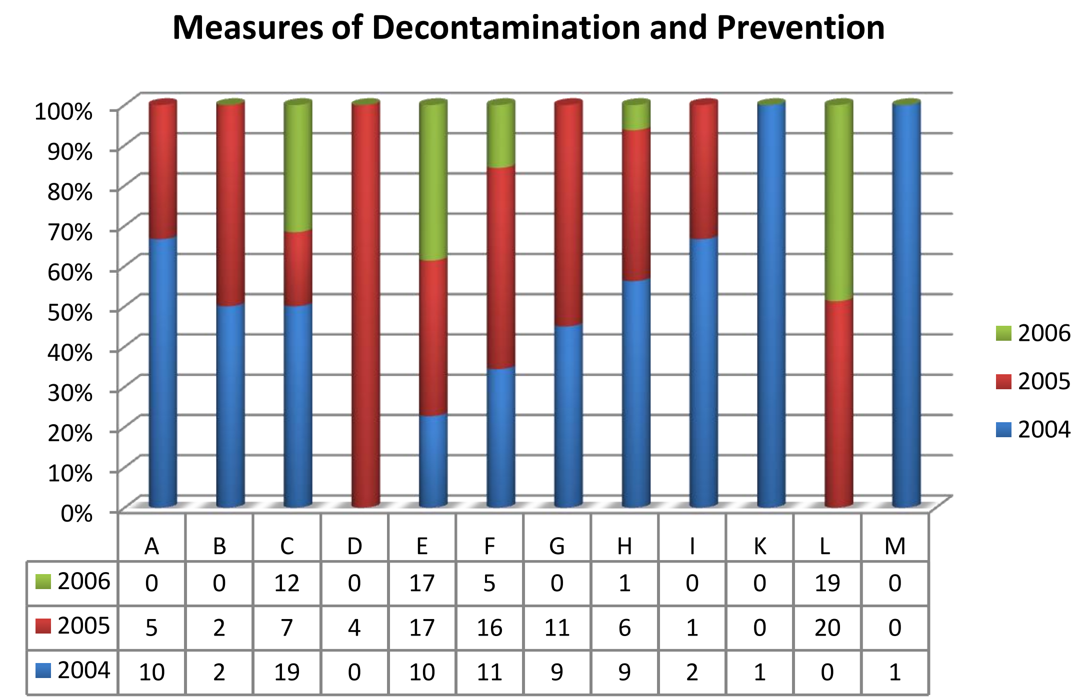
Figure 4 gives an overview about the maintenance of limiting values and the significance in terms of decrease of necessary inspection and re-inspections.



Risk area 1	2004 – 2005	X2 (1) = 2.744	p = 0.133
	2004 – 2006	X2 (1) = 19,286	p = < 0.0001
Risk area 2	2004 – 2005	Fisher exact test	p = 0.0001
	2004 – 2006	Fisher exact test	p = 0.002
Risk area 3	2004 – 2005	X2 (1) = 91,156	p = < 0.0001
	2004 – 2006	X2 (1) = 85.897	p = < 0.0001

Figure 4 Development of the compliance of results according to the limiting values of the TrinkwV in the three risk areas (surveillance of IHEM)

Figure 5 illustrates number and character of enforced measures comparing the three years of the survey, Table 4 explains abbreviations.



	A	B	C	D	E	F	G	H	I	K	L	M
2006	0	0	12	0	17	5	0	1	0	0	19	0
2005	5	2	7	4	17	16	11	6	1	0	20	0
2004	10	2	19	0	10	11	9	9	2	1	0	1

Figure 5: Measures executed for preventive and reasons of decontamination over the period from 2004 till 2006 (surveillance of IHEM)

Table 4 Explanation of abbreviations used in figure 5

A	Immediate re-inspection	G	ClO_2-decontamination
B	Re-inspection within 7 days	H	Installation of POU filter
C	Re-inspection within 14 days	I	POU reversal
D	Re-inspection without POU filter	K	POU remains
E	Re-inspection / processing of aerators	L	Heating up
F	Flushing	M	Closure of tap

To demonstrate the outcome of the performed measures inspections by the DHC in 2005 provide a basis for considering their efficacy. In total 21 inspections were performed in risk area 1, 28 in risk area 2 and 89 in risk area 3. Figure 6 to 9 express the microbiological results of the examinations by the DHC. There were only few complaints, mostly due to local contamination.

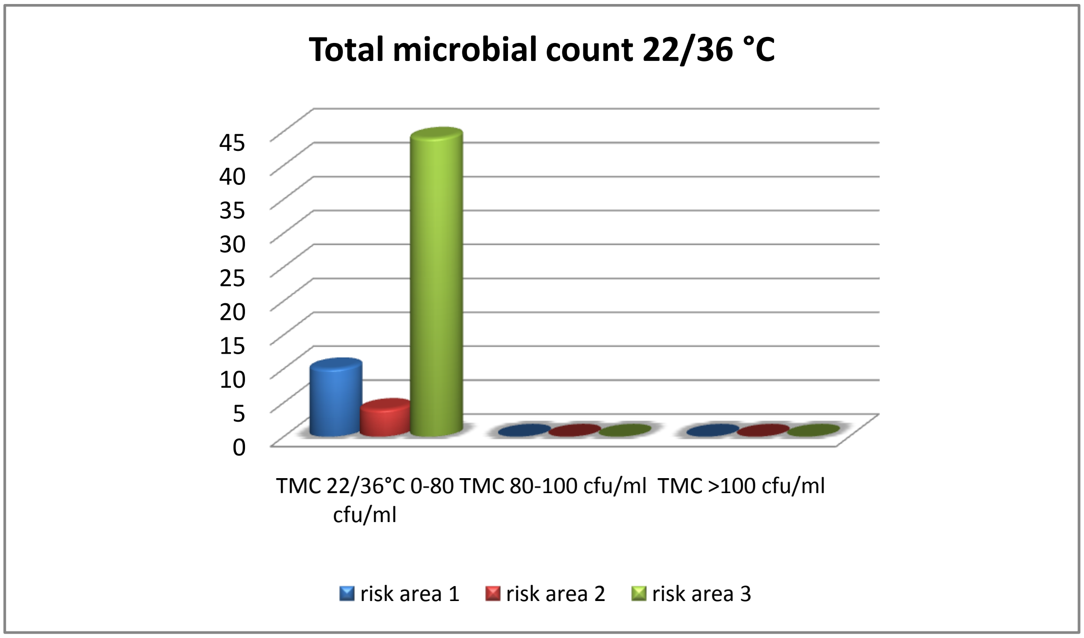


Figure 6 Results of examinations for total microbial count in the three risk areas (DHC 2005)

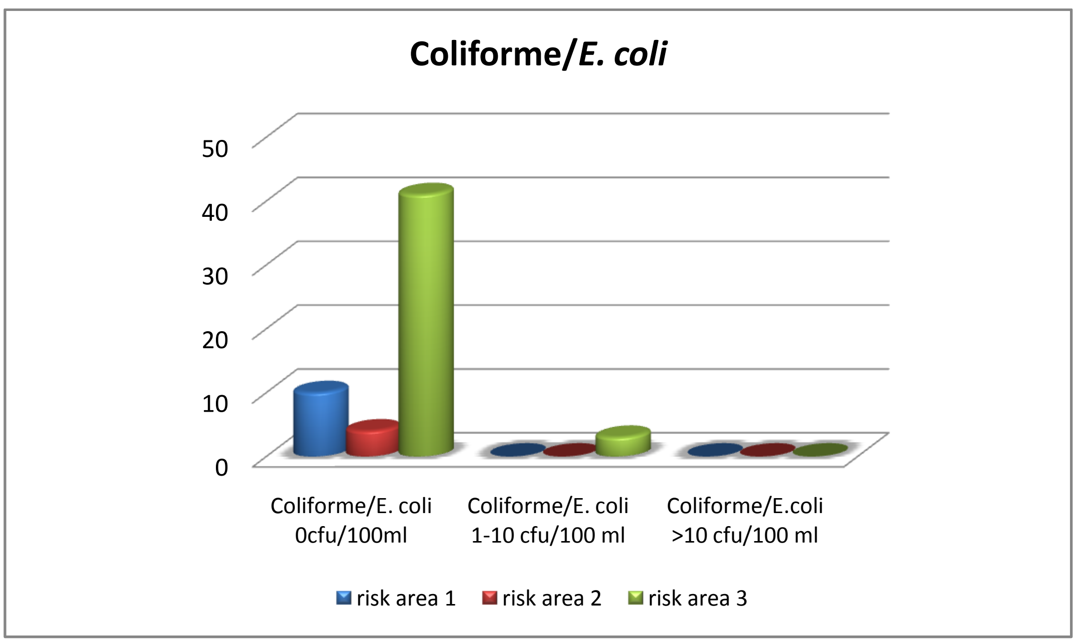


Figure 7 Results of examinations for Coliforme resp. *E.coli* in the three risk areas (DHC 2005)

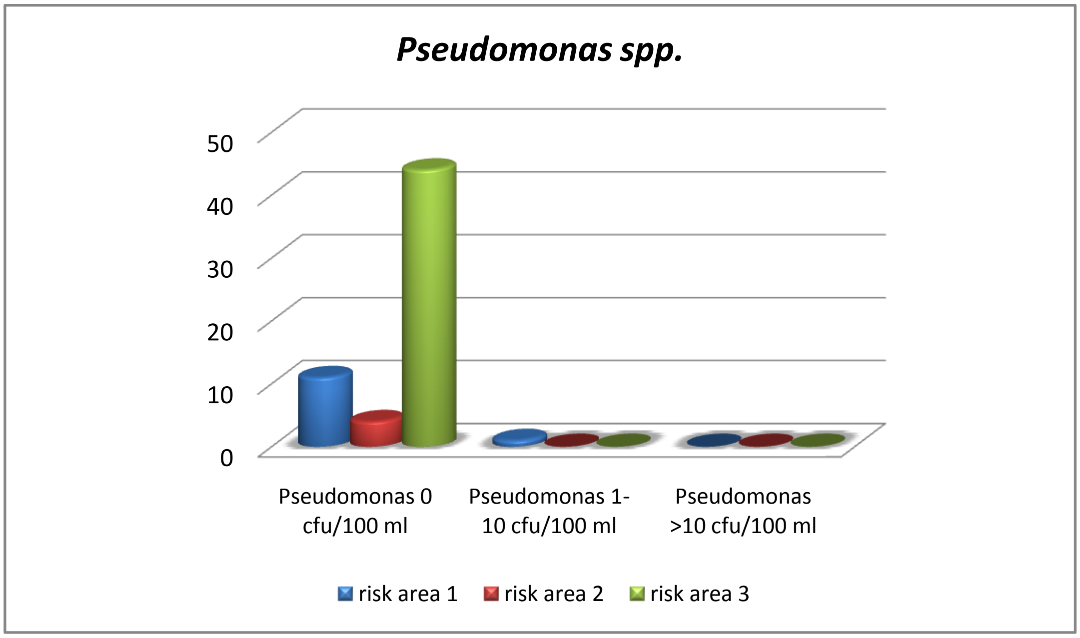


Figure 8 Results of examinations for *Pseudomonas spp.* in the three risk areas (DHC 2005)

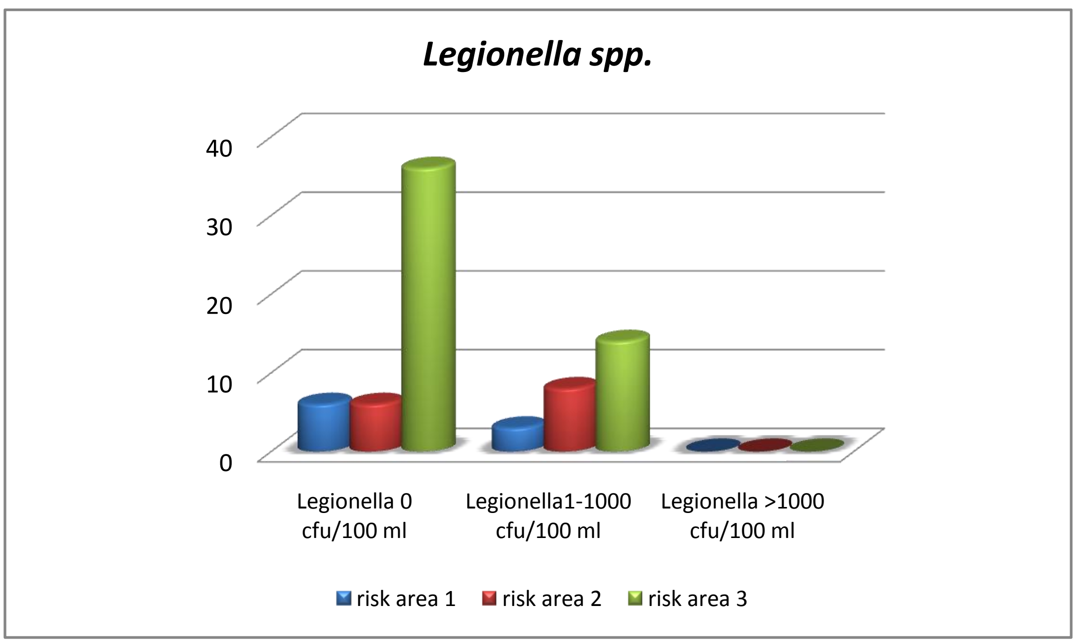


Figure 9 Results of examinations for *Legionella spp.* in the three risk areas (DHC 2005)

6. Discussion

The first step for the introduction of a WSP is the revision of infrastructural failures regarding the possibility of a certain contamination. Therefore the infrastructure of the water system was analyzed and dead ends and rarely used taps were eliminated as far as possible in the elder parts of the hospital. These experiences were also adopted for the design of buildings now under construction. Those technical respectively infrastructural failures can result in extensive additional costs or even temporarily closure of parts of the clinical complex. Furthermore there are lots of other infrastructural conditions affecting the water quality. Leprat et al. [21] identified i.e. non-touch fittings as another special source of *Pseudomonas aeruginosa* and *Legionella spp.* We experienced wetting of press-fittings during construction followed by stagnation as main reason of contamination. Therefore press-fittings now have to be moistened with water of proven drinking water quality to avoid a contamination.

To permanently ensure the water quality in high-risk areas terminal POU filters were established in risk area 1 [13, 28, 33]. The current number of POU filters in the clinical complex of the University of Greifswald is 63 at round about 900 beds. The annual costs therefore add up to € 60,000. Except for the ethic aspect the costs of a single case of a severe sepsis add up to € 25,000 [23]. Only considering the rate of sepsis in very low birth neonates in our hospital the reduction from 2004 (46 %) to 2005 (11 %) underline the cost effectiveness.

As a result of these aspects the costs of the POU filters as an essential element of the preventive measures in high risk areas are more than justified even under economic considerations.

The next step is the definition of extended limiting values according to a risk assessment. Therefore we introduced the so-called warning, alert and worst case value. Especially the warning value is considered under aspects of primary prevention as one of the central requests on the WSP. The long term effect of this sub-set limit value is the avoidance of nosocomial infections. The alert and worst case values were established regarding to accidental and even situations of bioterrorism where immediate and more than ever efficient measures have to be predetermined.

In progression of the three years there is a trend from many re-inspections, flushing of the water system and installation of additional POU filters to heating up - even if only small amounts of *Legionella spp.* occur - and processing of aerators, as a reaction to a local contamination.

Summarizing all mentioned premises the WSP adapts the principles of primary prevention especially regarding to ethical aspects, in contrast to perform measures only as a response to increased quantities of nosocomial infections or even severe outbreaks. Impressive is the difference between 2004 and 2005, when the WSP and its defined measures were fully put into action with an awesome success compared to the outcome of former procedures.

To enforce basically ideas of WSP in developing countries for immunocompromised patients as well we suggest the following measures: boiled water for drinking and food preparation, use of medical devices (e.g. nebulizers), wound care, especially burns no showering, no curtains for showers [3]. If boiling is not possible, sun exposition of water in plastic bottles has disinfecting effects [27].

7. Conclusions

After the implementation of the WSP in all parts of the hospital the number of transgressions decreased continuously. Another argument for the efficacy of the WSP is the fact that there was no case of nosocomial Legionnaires' disease since the year 2000 although the institute of microbiology screened each case of pneumonia for Legionella.

The WSP offers the possibility starting measures in case of a contamination immediately by using previously defined actions according to a risk assessment. The advantage of a central recording and assessment of all results referring to the water quality combined with the possibility of a process control is an unalienable part around the efforts of the water safety plan. Beside the ethical aspect a WSP is cost effective.

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Thesen

zur Dissertation: "Experimental based experiences with the introduction of a water safety plan for a multi-located university clinic and its efficacy according to WHO recommendations"

vorgelegt von Alexander Dyck

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1. Einleitung

- Wasserassoziierte nosokomiale Infektionen führen zu erhöhter Morbidität und Mortalität. Neben *Pseudomonas aeruginosa* und *Legionella spp.* verursachen eine Vielzahl weiterer hauptsächlich gramnegativer Bakterien wasserassoziierte nosokomiale Infektionen. Einige Erreger, z.B. MOTT, Cryptosporidien usw. stellen ein spezifisches Risiko für immunsupprimierte Patienten dar. Neben Bakterien ist das Trinkwasser auch ein Reservoir für Schimmelpilze, sowie für Protozoen und Viren.
- Trinkwasser ist ein unersetzbares Lebensmittel und darüber hinaus unverzichtbar für die körperliche Hygiene und die Pflege. Da zahlreiche Pathogene zu einer Kontamination des Trinkwassers führen können, ist eine kontinuierliche stringente Überwachung der Trinkwasserqualität gerade in Bereichen mit besonders gefährdeten Patienten (Immunsupprimierte, z.B. Granulozytopenische Patienten < 1000 Granulozyten/µl) unerlässlich.
- Einer der Gründe, die das Auftreten von Krankheitserregern begünstigen, ist die Bildung von Biofilmen, welche als Reservoir bzw. ökologische Nische zahlreicher Bakterien dienen und außerordentlich resistent gegen Desinfektionsmittel wie zum Beispiel ClO_2 sind.
- Neben Biofilmen in Leitungsnetzen sind Geruchsverschlüsse ein weiteres Reservoir für v.a. gramnegative, oft multiresistente Bakterien.

2. Zielsetzung

- Ziel eines WSP ist die Vermeidung nosokomialer Infektionen unter der Prämisse der primären Prävention.
- Zur Erarbeitung des WSP sollten die WHO-Empfehlungen bezüglich der Umsetzung des HACCP Konzepts aus der Lebensmittelindustrie im Bereich der Trinkwasserhygiene umgesetzt werden.

- In Verbindung mit der Einführung des WSP sollte der langfristige Effekt präventiv durchgeführter Umbaumaßnahmen sowie begleitender Sanierungsmaßnahmen evaluiert werden.
- Neben dem Nutzen hinsichtlich der Trinkwasserhygiene erfolgte eine Analyse ökonomischer Faktoren (Kosten und Nutzen).

3. Bedeutung wasserassoziierter Pathogene

- Eine Vielzahl v.a. gramnegativer Keime, aber auch Pilze, Protozoen und Viren verursachen nosokomiale Infektionen, die durch erhöhte Morbidität, Mortalität und durch eine Verlängerung der Hospitalisierung zur Entstehung enormer zusätzlicher Kosten führen.

4. Methoden

- Die Implementierung des HACCP Konzepts in den WSP fand unter zwei Aspekten statt, einerseits für den Routinefall, andererseits für den Fall einer massiven Kontamination/Havarie. Im Ergebnis einer Risikobewertung wurden die Kliniken drei Risikobereichen, die sich hinsichtlich der Gefährdung der Patienten durch wasserassoziierte Infektionen unterscheiden, zugeordnet.
- Da eine permanente Überwachung der Trinkwasserqualität nicht realisierbar ist, wurden in Hochrisikobereichen im Ergebnis einer Risikoanalyse endständige Sterilfilter installiert sowie erweiterte Grenzwerte etabliert. Das sind zum Einen der sog. Warnwert im Risikobereich 1 und 2, der einen sub-level Grenzwert darstellt (80-100 KBE/ml 22 und 36°C) und anderseits der Warn- und worst-case Wert, die massive Kontaminationen anzeigen. Das Ausmaß einer Belastung, die als “massiv” bezeichnet wird, unterscheidet sich definitionsgemäß in den verschiedenen Risikobereichen.
- Unabhängig davon wurden Maßnahmen zur Prävention von Kontaminationen des Wassernetzes durchgeführt, die in baulichen, d.h. infrastrukturverändernden Maßnahmen bestanden.
- Zur Gewährleistung einer umgehenden Sanierung im Falle von Kontaminationen wurden darüber hinaus risiko- und situationsangepasste Sanierungsmaßnahmen etabliert.

5. Ergebnisse

5.1. Ausbruchmanagement

- Aufgrund einer massiven Kontamination nach Eröffnung eines Neubaus wurde im Jahre 2004 innerhalb von 12 h eine Sanierung mittels Umsetzung des konzipierten Ausbruchmanagements durchgeführt; im Ergebnis der Sanierungsmaßnahme kam es zu keiner erneuten Grenzwertüberschreitung.
- Die während des Ausbruchsmanagements gewonnenen Erkenntnisse wurden zur Optimierung des festgelegten Konzeptes herangezogen.

5.2. Permanente Überwachung

- Zur Evaluation der im WSP festgelegten Maßnahmen wurden die Ergebnisse der Wasserproben der Jahre 2004 bis 2006 verglichen. Im Verlauf des Untersuchungszeitraums kam es zu einer ständigen Verbesserung der Trinkwasserqualität des Klinikums. Parallel nahm die Anzahl der notwendigen Sanierungsmaßnahmen kontinuierlich ab
- Eine erneute Havarie trat während des Beobachtungszeitraums nicht auf.
- Die Ergebnisse des Gesundheitsamtes im Rahmen der externen Qualitätskontrolle bestätigten die Effektivität der Maßnahmen des WSP.

6. Diskussion

- Eine Revision der Wassernetzinfrastruktur ist der erste Schritt zur Umsetzung eines WSP.
- Die Erkenntnisse der Ursachenanalyse der Havarie in 2004 wurden in die Planung neuer Gebäudeabschnitte einbezogen.
- Neben verzweigten Leitungsnetzen wurde auch das Verbauen von press fittings unter Verwendung von verunreinigtem Wasser als Kontaminationsquelle identifiziert und modifiziert.
- Um Kontaminationen in Hochrisikobereichen (Risikobereich 1) zu verhindern, wurden Sterilfilter installiert; die finanziellen Aufwendungen dafür sind zum Einen aus ethischen Gründen, aber auch unter dem Aspekt einer Kosten-Nutzen-Analyse gerechtfertigt.
- Zur bedarfsgerechten und risikoangepassten Planung der Sanierungsmaßnahmen wurde erweiterte Grenzwerte festgelegt; das sind der Warnwert - ein sub-level

Grenzwert als Indikator für eine drohende Kontamination in Risikobereichen - sowie der Alarm- und Worst case-Wert als erweiterte Grenzwerte im Rahmen des Ausbruchsmanagements.

- Der WSP ist im Gegensatz zur bisher praktizierten Strategie - der Reaktion auf Kontamination - angewandte primäre Prävention.
- Grundprinzipien des WSP, die auch in Entwicklungsländern mit eingeschränkter Infrastruktur praktikabel sind, sind das Abkochen des in medizinischen Einrichtungen verwendeten Wassers bzw. die Sonnenexposition des Wassers im Sinne einer UV-Dekontamination.

7. Schlussfolgerungen

- Der WSP bietet die Möglichkeit einer risikoangepassten, situationsgerechten Überwachung sowie einer umgehenden Dekontamination im Fall einer Kontamination.
- Seit der Einführung des WSP ist die Zahl der Grenzwertüberschreitungen der Trinkwasserproben signifikant gesunken.
- Eine nosokomiale Legionellose ist seit dem Jahr 2000 nicht mehr aufgetreten.
- Die zentrale Erfassung der Befunde ermöglicht eine Prozesskontrolle im Rahmen des Qualitätsmanagements.

Eidesstattliche Erklärung

Hiermit erkläre ich, dass ich die vorliegende Dissertation selbständig verfasst und keine anderen als die angegebenen Hilfsmittel benutzt habe.

Die Dissertation ist bisher keiner anderen Fakultät vorgelegt worden.

Ich erkläre, dass ich bisher kein Promotionsverfahren erfolglos beendet habe und dass eine Aberkennung eines bereits erworbenen Doktorgrades nicht vorliegt.

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Danksagung

An dieser Stelle möchte ich mich bei all denen bedanken, die das Entstehen dieser Doktorarbeit ermöglicht haben.

Mein besonderer Dank gilt hierbei meinem Doktorvater Herrn Prof. Dr. Kramer, der mir dieses interessante Thema überlassen hat. Er hatte stets ein offenes Ohr für mich und hat durch seine Kreativität und unermüdliche Schaffenskraft maßgeblich zum Entstehen dieser Arbeit beigetragen.

Frau Brigitte Sümnicht danke ich für die unersetzbare Unterstützung bei der Erfassung und Aufstellung der Daten sowie ihr Engagement bei der Erstellung und Umsetzung des Projektes.

Herrn Dr. Daeschlein, Herrn Dr. Below, Frau Lindstedt, Frau Schultz, Frau K. Sümnicht und Frau Bildat danke ich für die Ratschläge und die tatkräftige Unterstützung während der Durchführung der Experimente.