

ORIGINAL ARTICLE

A management model for Hospital Hygiene Unit: evidence-based proactive surveillance of potential environmental sources of infection in order to prevent patient's risk

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Keywords

Preventive Medicine • Environmental surfaces • Water safety • Food safety • Patient safety

Summary

Introduction. The aim of this study is to describe a proactive surveillance system of food, water and environmental surfaces, in order to avoid Healthcare-Associated Infections (HAIs) from hospital environment.

Methods. It is a retrospective descriptive study. The surveillance system consists of two integrated phases: pre-analytic and post-analytic. The activities are distinguished in ordinary control activities, performed after scheduled and shared surveys, and compliance activities, performed when it is necessary to establish the adequacy of the destination use, for example opening a new ward.

Results. A total of 1,470 Samples were collected and 539 Reports were generated across the five-year study period. Water for human consumption procedure: a statistically significant trend was found only in the total number of Samples collected ($p < 0.001$). *Legionella* spp. infection water risk procedure: all

Samples and Reports, with the exception of Compliance Report Samples, showed a statistically significant trend ($p < 0.001$). *Pseudomonas aeruginosa* water risk procedure: only Ordinary Reports and Compliance Report Samples trend were statistically significant ($p = 0.002$ and $p = 0.028$ respectively). Effectiveness of surface sanitization procedure: no trend was statistically significant ($p < 0.05$). Hospital catering and food surfaces procedure: Samples and Reports yearly number was constant, no trend analysis was performed. HAIs prevalence was never over 5% in the hospital under study.

Conclusions. This surveillance system of water, food and environmental surfaces represents an innovative way of approaching hospital safety for patients and personnel because it overcomes the limitations due to a classic approach limited to a laboratory analytic phase only, according to the best available scientific evidence.

HIGHLIGHTS

- Highlights 1: Healthcare-Associated Infections (HAIs) still represent a major Public Health problem.
- Highlights 2: we describe a proactive surveillance with regard to water, food and environmental surfaces, in order to prevent and avoid HAIs, according to the best available scientific evidences.
- Highlights 3: the described surveillance system of food, water and environmental surfaces is a proactive surveillance system because it is systematically performed, according to a predetermined periodicity and not only in case of epidemic events or hospital infections.
- Highlights 4: the described surveillance system of food, water and environmental surfaces is an innovative way of approaching hospital safety for patients and *healthcare personnel* because it consists both of a pre-analytic and of a post-analytic phase integrating the analytic one.

Introduction

Healthcare-Associated Infections (HAIs) are infections that occur while receiving care in a hospital or other healthcare facility, that first appear 48 hours or more after hospital admission, or within 30 days after having received treatments such as prosthesis [1].

About 1 in 31 hospital patients has at least one HAI per day. In a 2015 survey 3% of hospitalized patients had one or more HAI. There were an estimated 687,000 HAIs in U.S. acute care hospitals in the same year and about 72,000 hospital patients with HAIs died during their hospitalizations [2].

Environmental contamination and contaminated surfaces may predispose to the development of HAIs because they act as a reservoir if cleaning and disinfection procedures are not correctly known and applied.

In Italy, in the time-period 1st December 2015 - 29th February 2016, a descriptive study was carried out in a hospital in Milan to verify the knowledge and adherence to prevention and control of HAIs procedures by nurs-

ing staff. Questionnaires with anonymous self-reporting method were administered; inspections in the wards using observational grids were carried out. The Authors found the greatest knowledge gap as regards cleaning, disinfection and sterilization, with a number of incorrect answers approaching 50% [3].

Water exposure in healthcare settings can cause infections by water-related organisms such as *Legionella* and *Pseudomonas aeruginosa* (*P. aeruginosa*) and can potentially lead to outbreaks.

Nine to 20% of infections caused by *P. aeruginosa* take place in Intensive Care Units (ICU) and Hematology which are therefore classified as at risk wards. Healthcare facilities should therefore develop and implement water management programs to limit the growth and spread of water-related organisms [4].

Moreover, some HAIs have been related to the consumption of contaminated foods in hospital settings, too. For example, some cases of hospital-acquired listeriosis have been described in recent years [5-7].

Moreover, *P. aeruginosa* poses a significant threat to patients within the healthcare system because its intrinsic and acquired resistance mechanisms significantly limit the choices for antimicrobial therapy, prompting an increase in the research and development of antibacterial agents with enhanced activity against multidrug-resistant (MDR) *P. aeruginosa*. Patients with MDR *P. aeruginosa* infections have extremely limited and often toxic antibiotic options and resistance to all of these agents will likely emerge, so MDR *P. aeruginosa* has to be considered a major Public Health concern and a perpetual therapeutic challenge [8].

Last, regarding to environmental surfaces, it is known that the contaminated surface environment in hospitals plays an important role in the transmission of *Methicillin-Resistant Staphylococcus aureus* (MRSA), *Vancomycin-Resistant Enterococcus* spp. (VRE), *Clostridium difficile* (*C. difficile*), *Acinetobacter* spp., and norovirus [6].

Infection prevention and control is considered a priority for patient safety and should involve healthcare workers (HCWs) at all levels with programs planned by multidisciplinary groups taking into account local guidelines, following a multimodal intervention strategy that emphasizes hands-on training, and be regularly assessed, and adjusted if necessary [9].

The aim of the present study is to describe the proactive surveillance carried out in a large Italian Hospital, with regards to food, water and environmental surfaces, in order to prevent HAIs.

Methods

The number of environmental Samples stratified for year and procedure was matched with the number of Reports stratified for year, procedure and report typology. More specifically data from the procedures named A1, A2, A3 stratified across 2014-2018 were analyzed. In this period, data regarding the number of Samples from envi-

ronmental monitoring were collected. Below are shown report typology names, their meaning and the Areas in which the Hospital Hygiene Unit is organized and environmental matrices surveyed are placed:

- *OR (Ordinary Reports)* drawn up after scheduled and shared surveys;
- *OCR (Ordinary Control Reports)* deriving from an OR with the presence of non-compliance and the implementation of corrective actions decided by a focus group;
- *CR (Compliance Reports)* arises when it is necessary to establish the adequacy of the destination use, for example opening a new ward;
- *CCR (Compliance Control Reports)* is produced after a non-compliant CR;
- *A Area - Water safety*: A1: drinking water; A2: *Legionella* spp. infection risk from hospital water system; A3: *P. aeruginosa* infection risk from hospital water system;
- *B Area*: hospital catering and food surfaces;
- *C Area (C3 Procedure)*: effectiveness of surface sanitization procedures.

A AREA

A1 procedure: water for human consumption

The purpose of this procedure is to ensure quality and safety of cold water for human consumption in the water system, water from tubs, taps and toilets is monitored through the evaluation of microbiological and chemical-physical parameters as indicated by Italian law. Sampling, sample transportation, storage and sample frequency planning are carried out according to proper regulation as well.

A2 procedure: Legionella infection risk from hospital water system

The purpose of this procedure is to perform a systematic environmental surveillance of *Legionella* spp. colonization in the water system of the Hospital.

The Italian National Guidelines establish a quarterly sampling for the High Risk (HR) wards and a semi-annual sampling for Incremented Risk (IR) wards. This surveillance plan involves a systematic sampling of the water system (including each hot water tank) in all of the buildings: a quarterly sampling for the HR wards and a yearly sampling for the IR wards. Since each building contains some IR and some HR wards, most of the water system of each building is in fact monitored multiple times a year. According to the Italian National Guidelines [10], whenever a sample results positive for *Legionella* spp. the colonized area is subjected to decontamination procedures and then sampled again after 1, 3 and 6 months.

Each sampling is composed of a minimum number of 6 Samples from the hot water tanks and return loop and at least 4 Samples from distal outlets (including showerheads, faucets etc.).

In all HR wards, point of use (POU) filters are installed on water taps and replaced every 30 days, according to

the manufacturer's specifications. The Samples in these distal points are carried out without the filters so as to analyse the possible colonization of the water plant.

Our sampling method involves two types of sampling: "pre-flush" sampling and "post-flush" sampling. "Pre-flush" sampling indicates water quality at point of use, it cannot refer possible detections specifically to the water system, the terminal part of the tap or both. This is the method routinely used. "Post-flush" sampling indicates water quality at water system level, it is obtained after flushing water for three minutes. These methods are used in combination whenever a significant detection is made.

Temperature, pH, residual chlorine, hardness and conductivity of the sampled water are also determined at the time of collection according to Italian National Health Institute Technical Report [3].

A microbiological analysis is performed on each sample in accordance to ISO standard [11].

A3 procedure: P. aeruginosa infection risk from hospital water system

The purpose of this procedure is to perform a systematic environmental surveillance of *P. aeruginosa* colonization in the water system of the Hospital.

It consists in periodic monitoring of the points of use (tubs and/or taps) to promptly assess the presence of *P. aeruginosa*, which is a potential pathogen in immunosuppressed patients and an indicator of colonization by Gram-negative Bacteria (some of which show antibiotic resistance) and to indicate, whenever possible, the proper course of action.

The methods in use are based on Public Health England Guidelines [12], Health Technical Memorandum [13] and Health Protection Surveillance Centre Guidelines [14].

Our sampling method involves two types of sampling: "pre-flush" sampling and "post-flush" sampling.

B AREA: HOSPITAL CATERING AND FOOD SURFACES

In order to ensure food safety in hospital, every three months food and food surfaces are checked.

Before sampling foods and food surfaces, a visual inspection of the hospital canteen is carried out, using a structured check-list.

Two ready-to-eat foods are sampled. Sampling is carried out using sterile packages transported to the laboratory in a refrigerated thermic bag, in order to avoid bacterial proliferation.

Total bacterial load and the following indicator organisms are routinely identified: *Salmonella* spp., *Listeria monocytogenes*, *Escherichia coli* (*E. coli*), *Enterobacteriaceae* and *Staphylococcus aureus* (*S. aureus*) [15, 16]. Moreover, since the beginning of the "Cook and Chill" system, *Bacillus cereus* and *Clostridium perfringens* (*C. perfringens*) have been added.

For the microbiological quality of ready-to-eat foods, the "Guidelines for the microbiological quality of some ready-to-eat foods sampled at the point of sale" of the Public Health Laboratory Service are applied [17].

As far as concern food surfaces, sampling of environmental surfaces is carried out to demonstrate the efficacy of cleaning and disinfection procedures. Three food surfaces are sampled each three months, though sterile swabs and Petri-style contact plates, filled with a suitable culture medium, using the RODAC-WEIGHT system.

Total bacterial load and the following indicator organisms are identified: *Salmonella* spp., *Listeria monocytogenes*, *E. coli*, *S. aureus* and Yeasts.

For the microbiological quality of surfaces, the "Microbial limits used for various types of food process surfaces based on case study evaluations" by Wirtanen and Salo (2011) are applied [18].

C AREA (C3 PROCEDURE): EFFECTIVENESS OF SURFACE SANITIZATION PROCEDURES

The purpose of the procedure is to verify, "at rest" condition, the effectiveness of the surface sanitization hospital procedures through the evaluation of the microbiological parameters indicated in the Health Protection Agency Guidelines (December 2010) and to establish a continuous surveillance system in order to promptly detect the presence of pathogenic bacteria and take appropriate corrective actions.

The "High Risk" wards subject to the application of the procedure are identified through Scientific Literature consultation, shared with the Health Department and according to most recent evidence. The *high hand-touch* surfaces subject to controls are those most likely to be in contact with the patient and the operator, such as: beds, lamps, bedside tables, chairs, tables, cabinets, handles and doors, phones, assistance call remote control, bathroom faucet knobs, light switches, etc. [19, 20].

Parameters identified as indicators of correct sanitization are total bacterial load, *Acinetobacter baumannii*, *C. difficile*, *CRE* (*Carbapamen-Resistant Enterobacteria*), *MRSA*, *Multiresistant P. aeruginosa* and VRE, also potentially causes of HAIs.

For surface sampling, the use of contact plates (Contact Plate, RODAC) combined with "RODAC-WEIGHT" system is more reproducible in order to avoid the subjectivity of the operator.

The surfaces are sampled through the application of a Petri-style contact plate (i.e. surface of the plate against surface to be monitored), filled with a suitable culture medium, using the RODAC-WEIGHT system on the surface to be monitored. The standard duration of the application is 10 seconds.

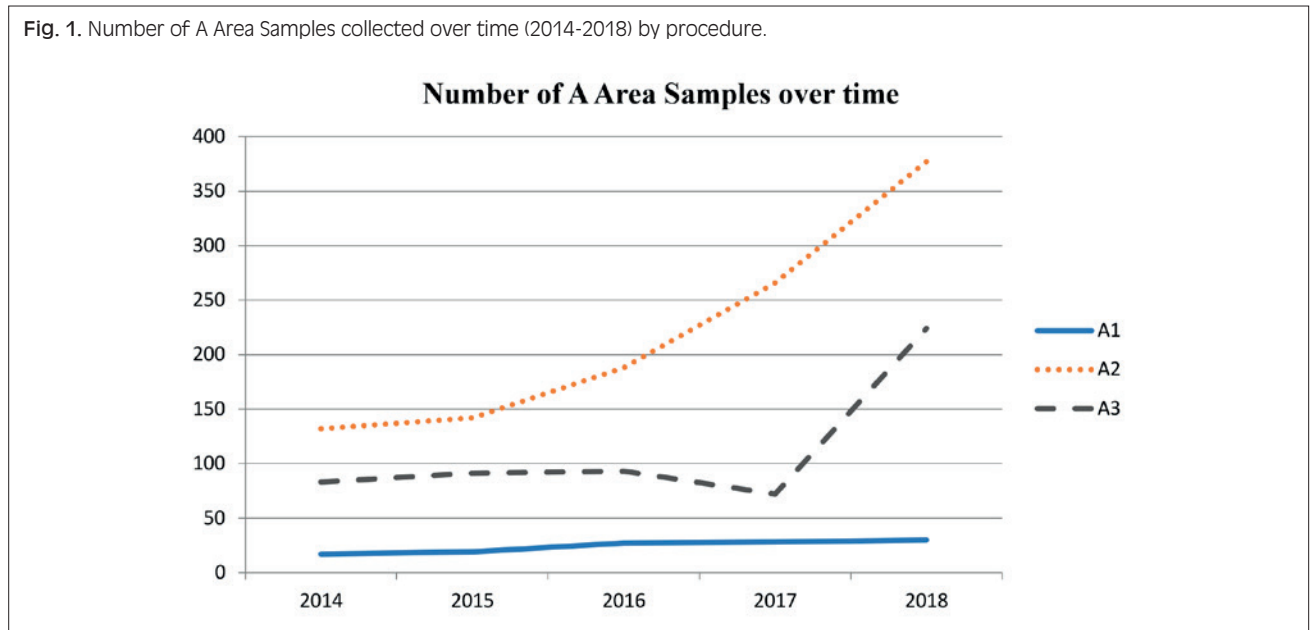
Microbiological surface sampling with sterile disposable cotton swabs is performed by sampling residual microbiological vital cells with the top of a swab on a defined surface area (conventionally 100 cm²) and the subsequent count of the colonies, derived from cells eluted from the tip of the swab and then cultured, in suitable culture media.

The Samples are transported to the laboratory in a refrigerated container (1-4°C) for subsequent analysis within 4 hours from collection.

Tab. I. A Area - Water safety. A1, A2, A3 Samples stratified by the typology of report they were generated from, across 2014-2018.

A1 Samples	2014	2015	2016	2017	2018	P-value
OR	17	18	15	16	22	0.824
OCR	0	0	0	0	8	0.091
CR	0	1	3	9	0	0.802
CCR	0	0	9	3	0	0.876
Total	17	19	27	28	30	< 0.001
A2 Samples	2014	2015	2016	2017	2018	P-value
OR	96	133	149	176	191	< 0.001
OCR	9	2	27	55	127	< 0.001
CR	27	7	12	25	41	0.184
CCR	0	0	0	10	18	< 0.001
Total	132	142	188	266	377	< 0.001
A3 Samples	2014	2015	2016	2017	2018	P-value
OR	58	81	55	52	76	0.960
OCR	7	1	27	4	58	0.119
CR	17	9	11	16	35	0.028
CCR	1	0	0	0	55	0.091
Total	83	91	93	72	224	0.243

Fig. 1. Number of A Area Samples collected over time (2014-2018) by procedure.



STATISTICAL ANALYSIS

An autoregressive integrated moving-average model was used to evaluate trend analysis. The statistical significance level was set at $p < 0.05$ and all the analyses were carried out by using software “Stata IC 13 for Mac”(Stata Corp, Lakeway, USA).

Results

A total of 1,470 Samples were collected and 539 Reports were generated across the five-year study period. As reported in Table I and Figure 1, the number of Samples collected from the procedures A1 and A3 shows a non-homogenous trend among the five years.

A1 PROCEDURE - DRINKING WATER

As shown in Table I and Figure 1, a total of 104 Samples were collected across 2014-2018.

From 2014 to 2017 we found a fluctuating trend in the number of Samples generated from OR followed by a slight increase from 2017 to 2018. In the same period (2017-2018) we registered a clear reduction in both the number of CR and CCR and in the number of Samples they generated. We registered a great increase in the number of both OCR and the Samples they generated from 2017 to 2018. A statistically significant trend was found only in the total number of Samples collected ($p < 0.001$).

With regards to Reports generated, no trend of statistical significance was found ($p > 0.05$). As shown in Figure

2, the number of OR registered a decreasing trend from 2014 to 2017 and a great increase from 2017 to 2018. In addition, we detected a slight increase in the number of OCR from 2017 to 2018 and a decrease in the number of CR and CCR from 2017 to 2018.

A2 PROCEDURE - LEGIONELLA SPP. INFECTION RISK FROM HOSPITAL WATER SYSTEM

As shown in Table I and Figure 1, a total of 1,105 Samples were collected across 2014-2018.

With regards to Reports generated, as shown in Figure 2, we observed an increasing trend for all collected Samples. We found a general increase in the number of Reports generated from 2014 to 2018 as well, as shown in Table II.

A great increase was found in the number of OR, OCR and the number of Samples this Reports generated from 2015 to 2018. In contrast, we registered only a slight increase for CR, CCR and the number of Samples this Reports generated from 2016 to 2018.

All Samples and Reports, with the exception of the Samples generated from CR, showed a statistically significant trend over time ($p < 0.001$; $p = 0.025$ for CR Reports; $p = 0.003$ for CCR Reports).

A3 PROCEDURE - P. AERUGINOSA INFECTION RISK FROM HOSPITAL WATER SYSTEM

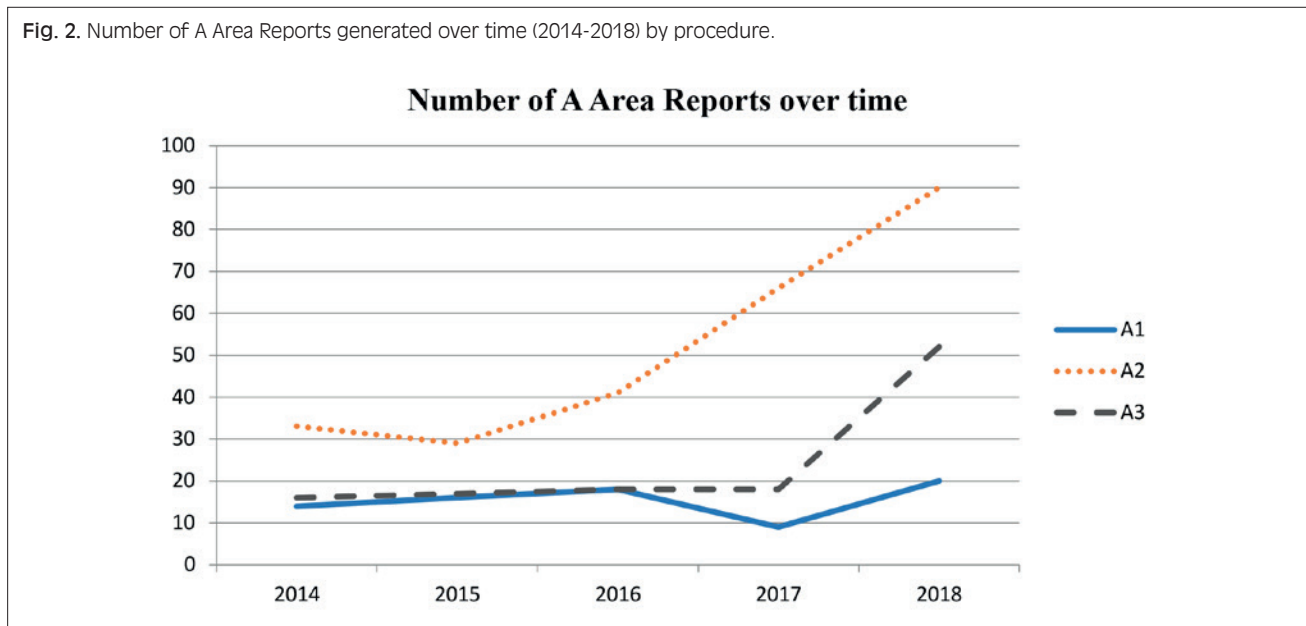
As shown in Table II and Figure 1, a total of 563 Samples were collected across 2014-2018.

From 2015 to 2017, we found a decrease in the number

Tab. II. A1, A2, A3 Reports stratified by typology across 2014-2018.

A1 Reports	2014	2015	2016	2017	2018	P-value
OR	14	15	12	7	18	1.000
OCR	0	0	0	0	2	0.091
CR	0	1	2	1	0	1.000
CCR	0	0	4	1	0	0.907
Total	14	16	18	9	20	0.861
A2 Reports	2014	2015	2016	2017	2018	P-value
OR	21	26	27	34	36	< 0.001
OCR	7	1	11	24	41	< 0.001
CR	5	2	3	6	10	0.025
CCR	0	0	0	2	3	0.003
Total	33	29	41	66	90	< 0.001
A3 Reports	2014	2015	2016	2017	2018	P-value
OR	9	12	12	12	16	0.002
OCR	4	1	4	2	15	0.064
CR	2	4	2	4	11	0.617
CCR	1	0	0	0	10	0.100
Total	16	17	18	18	52	0.068

Fig. 2. Number of A Area Reports generated over time (2014-2018) by procedure.



of Samples generated from OR, an increase followed by a decrease in the number of OCR Samples and a slight increase in the number of CR generated Samples. In the end, a general increase in the number of all Samples from 2017 to 2018 was registered.

With regards to the Reports generated, as shown in Figure 2, we registered a fluctuating trend in the number of both OCR and CR generated with a clear increase from 2017 to 2018. CCR increased from 2017 to 2018.

We found a statistically significant trend in the number of generated OR Reports ($p = 0.002$), with an increase from 2014 to 2015, a plateau from 2015 to 2017 and a final increase from 2017 to 2018, and in CR Samples ($p = 0.028$).

As shown in Tables I and II, all other trends regarding Samples and Reports were not statistically significant ($p > 0.05$).

B AREA - FOOD SAFETY

As far as concern the food safety, during the time-period of five years 40 Samples of ready-to-eat foods have been collected (8 each year, no trend analysis was performed); regarding to food surfaces, 60 sanitized surfaces have been sampled, 12 each year. Yearly, both for food-safety and sanitized surfaces control, 4 Samples were collected and 4 Reports were generated. No OCR have been produced in the analyzed time-period.

C AREA (C₃ PROCEDURE) - ENVIRONMENTAL SURFACES

From the general data, a coherence in number of Samples performed for all the years from 2015 to 2018 can be observed. The procedure "Sanitized surfaces" was not active in the year 2014.

Data have been then stratified by extrapolating those related to compliance controls (construction sites) from the ordinary ones. It is clear that in 2015 and 2016 only the data related to the ordinary procedure were sampled, while in 2017 approximately 45% of the data sampled are related to compliance activities. In 2018 compliance activities have tripled with respect to the ordinary work, in fact 60 ordinary Samples and 137 compliance Samples were performed.

Trend analysis performed both on the total number of collected Samples and generated Reports was not statistically significant across the five-year study period ($p > 0.05$).

Looking at the number of Samples related to compliance, we can observe that in recent years, in addition to a constant surveillance of high-risk departments related to ordinary work, the Health Care Management requires an expertise of the staff of the Hospital Hygiene Unit, during the construction site phases in the hospital and specifically, during the return of the premises before they are allocated to health activities.

Discussion

With regards to the increment of the number of Samples related to A area, it can be determined by not conformed

OR and consequently the generation of more OCR as it in the case of the new operating settings.

More specifically the results shown for A2 Procedure are justified by the application (from January 2016) of the new International Guidelines which prescribe at least 6 Samples per sampling. This caused a growth in the number of Samples produced as a higher number of Samples increases the chance of detection. Furthermore, these Guidelines prescribe a follow-up at 1, 3 and 6 months after the detection of a positive sample and moreover every new control might turn out to be positive, generating a new series of follow-up controls. In addition, every control turning out to be negative still counts as another OR generated.

There has been an increase of CR and consequently of CCR due to the start of "construction and/or renovation working sites" monitoring.

Results shown for A3 Procedure are justified by the application of the new HPA British Guidelines.

In the previous years, however, Reports did not match with the number of Samples as we know that there is not always a linear correlation between the two. This heterogeneity is dependent upon the different ward's risk level. (e.g. a high risk ward such as ICU might cause a higher number of Samples generated by the same ordinary surveillance activity or it might cause a higher number of CR and thus more Samples than an augmented risk or a "normal" risk one).

There has also been an increase of CR and consequently of CCR due to the start of "working sites" monitoring.

As far as concern A1 Procedure, it did not register many changes and, for this reason, our results did not register many changes as well. It does follow, however, the general increasing trend common to all procedures from 2017 up to 2018. In addition, there is not an increase in CR because this is not a procedure used to monitor "construction and/or renovation working sites". This is due to the fact that construction and renovation activities tend to cause the environmental colonization of the bacteria such as *Pseudomonas* spp. or *Legionella* spp. which are already monitored through other procedures, rather than *E. coli* and other faecal bacteria which are the ones checked for by this Procedure.

No compliance activities (Conformity Reports) were needed relatively to this Area.

With regards to the trend analysis performed, as shown in the Results, a statistically significant trend across the five-year study period was found in the total number of Samples collected both for A1 and for A2 Area ($p < 0.001$); the same statistically significant trend was also found for the total A2 Reports ($p < 0.001$).

In addition, as far as concern study limitations, we would like to report that sample size is quite limited for both B and C3 Procedures. Even though the number of Samples and Reports could be enlarged by extending the observation period, this is not to be seen as a true limitation. Instead, the limited number of collected Samples and generated Reports shows that minimal compliance activity is needed as this surveillance system is effective in preventing infections caused by the hospital environment.

Furthermore, we are aware that many confounding factors could affect a proactive surveillance system of food, water and environmental surfaces. For example, the particular typology of food preparation (Cook and Chill system, Cook and Freeze system, mixed system); the choice of a specific disinfectant and its concentration for the surface sanitization; the disinfection method used for *Legionella* infection risk in hospital water system and so on. Anyway, for scientific correctness we would like to underline that none of these variables has been measured as potential confounding factors, because the only measured data are the ones related to the applied Procedures of the Hospital Hygiene Unit.

Lastly, the infectious disease epidemic does not affect the data in this study, because all the collected and reported data are related to the time-period 2014-2018. Also the epidemiology of notified foodborne diseases does not affect the study as it is based on standard epidemiological indicators.

Concerning B Area, it is important to have effective and reliable food safety management systems in place and the correct application of Hazard Analysis and Critical Control Point (H.A.C.C.P.). Safety assurance must be extended to include the whole process up to the point at which food is served to the patients or operators. Many food manufacturers choose to adopt a programme of routine microbiological monitoring as an added measure of quality and this has often been of value in identifying unforeseen problems at an early stage. No compliance activities (Conformity Reports) were needed relatively to this Area.

Conclusions

The final aim of the described system is to avoid HAIs from hospital environment. The hospital environment is subject to targeted and sustainable surveillance in relation to the size and complexity of the same hospital, based both on epidemiological criteria and on scientific evidences. The activities were performed by the Hospital Hygiene Unit (HHU) in a Teaching Hospital of about 1,500 beds in which the prevalence of HAIs was never over 5% during the study period 2014-2018 (data collected yearly, applying the latest ECDC Point Prevalence Survey Protocol) [21].

In conclusion, it is important to underline that this particular approach, primarily set to ensure patient safety, also provides an added value as far as concern a legal-medical point of view for the healthcare professionals, demonstrating the existence and implementation of a proactive environmental surveillance plan in order to know the risk coming from hospital environment and to take it safe as much as possible.

Ethical approval

Ethical approval was not required for this work as no new empirical data were collected.

Acknowledgements

Funding sources: this research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflict of interest statement

The authors declare no conflict of interest.

Authors' contributions

PL formulated the original idea and provided scientific supervision to the paper. GD provided scientific supervision to the paper. GQ, DILM, MW, SV and FP provided the data and contributed to the writing of the paper. MDP contributed to data collection and to the writing of the paper.

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Received on May 15, 2020. Accepted on November 4, 2020.

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How to cite this article: Quaranta G, Di Pumpo M, La Milia DI, Wachocka M, Pattavina F, Vincenti S, Damiani G, Laurenti P; Collaborative Group: Moscato U, Bruno S, Boninti F, Tuti F, Sezzatini R. A management model for Hospital Hygiene Unit: evidence-based proactive surveillance of potential environmental sources of infection in order to prevent patient's risk. J Prev Med Hyg 2020;61:E628-E635. <https://doi.org/10.15167/2421-4248/jpmh2020.61.4.1587>

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