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Letters to the Editor

Safety of probiotics used for hospital environmental sanitation

Sir,

There is consensus about the need for efficient control of microbial contamination on hospital surfaces, as these surfaces represent significant pathogen reservoirs that may contribute to transmission of healthcare-associated infections (HCAIs). The emergence of multidrug-resistant pathogens in hospitals is a global concern.[1]

Control of surface bioburden is routinely addressed by use of conventional chemical-based detergents/disinfectants; however, these are ineffective in preventing recontamination, and may select resistant strains. Recently, cleaning agents containing probiotics of the genus *Bacillus* have been proposed for hospital sanitation [Probiotic Cleaning Hygiene System (PCHS); Copma srl, Ferrara, Italy]; these have been shown to stably decrease surface pathogens up to 90% more than conventional disinfectants, and to be genetically stable even after years of continuous contact with surface pathogens.[2,3] The rationale for the use of probiotics as sanitizing agents lies in the idea that a healthy microbiota might protect against colonization by, and expansion of, pathogens in the environment as well as in the human body; this has been called 'bidirectional' hygiene.[4]

The three species contained in the probiotic cleansers (*Bacillus subtilis*, *Bacillus pumilus*, and *Bacillus megaterium*) are considered non-pathogenic for humans.[5] Nevertheless, a theoretical risk of infection exists, and a few anecdotal cases of infection by *B. subtilis* have been reported in surgical patients.[5] However, systematic assessment of adverse events in probiotic intervention studies is lacking, whereas it has recently been proposed that the most appropriate way to investigate whether probiotics are safe is to use the 'totality of evidence' rather than single case reports.[6,7] Active surveillance for cases of probiotic-associated infection in all probiotic-based trials has been advocated.[8] Thus, we have analysed whether the *Bacillus* spp. included in cleaning products may themselves be a source of HCAIs. We investigated whether any infections with *Bacillus* spp. occurred in seven healthcare institutions in the province of Ferrara (Italy) that used the PCHS throughout.

In addition to routine culture of all 32,139 clinical samples from around 90,000 patients and 800,000 hospitalization days, a quota of samples was also analysed by a *Bacillus*-specific real-time quantitative polymerase chain reaction, as previously described.[2] The numbers of analysed samples from each institution, as well as the period of environmental sanitation by PCHS, are shown in Table I. Both culture-based and molecular testing showed complete absence of PCHS-derived bacilli in any clinical sample, for the entire period of the survey. This suggests that probiotic *Bacillus* spp. do not cause infections, even in the subjects at high risk of opportunistic infections.

We think that this surveillance model represents an essential part of the infection control policy associated with the use of probiotics, as it provides ongoing assurance of safety. Accordingly, we are now undertaking a multi-centre study to evaluate a larger number of healthcare institutions for a prolonged period.

Table I
Analyses performed in the years 2011–2015 in the healthcare structures (HS) continuously using the *Bacillus*-based Probiotic Cleaning Hygiene System (PCHS)

Healthcare structures	Analyses per year (with PCHS sanitation system)					Total analyses (per HS)
	2011	2012	2013	2014	2015	
HS-1	429	–	–	–	–	429
HS-2	103	704	701	613	765	2886
HS-3	–	–	6346	7290	7593	21,229
HS-4	–	76	1025	969	1154	3224
HS-5	–	72	631	713	750	2166
HS-6	–	240	403	498	554	1695
HS-7	–	–	–	–	510	510[a]
Total[b]	532	1092	9106	10,083	11,326	32,139

HS-1, Old S. Anna Hospital (Ferrara), PCHS application March 16th to August 28th, 2011; HS-2, S. Giorgio Hospital (Ferrara), PCHS application since November 1st, 2011; HS-3, New S. Anna Hospital (Cona, Ferrara), PCHS application since January 1st, 2013; HS-4, Delta Hospital (Lagosanto, Ferrara), PCHS application since June 1st, 2012; HS-5, Cento Hospital (Cento, Ferrara), PCHS application since July 1st, 2012; HS-6, Argenta Hospital (Argenta, Ferrara), PCHS application since July 1st, 2012; HS-7, Quisisana Hospital (Ferrara), PCHS application since January 1st, 2015.

[a] A quota of these samples was simultaneously analysed also by molecular assays (qPCR).

[b] A unique central Microbiology Laboratory (S. Anna University Hospital, Ferrara) performed the analyses by conventional microbiological assays.

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None declared.

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E. Caselli[a,b,*]
P. Antonioli[c]
S. Mazzacane[b]
[a]*Section of Microbiology and Medical Genetics, Department of Medical Sciences, University of Ferrara, Ferrara, Italy*
[b]*CIAS Interdepartmental Research Centre for Pollution Control in High Sterility Rooms, University of Ferrara, Ferrara, Italy*
[c]*Department of Infection Prevention Control and Risk Management, S. Anna University Hospital, Ferrara, Italy*

* Corresponding author. Address: Section of Microbiology and Medical Genetics, Department of Medical Sciences, University of Ferrara, via Luigi Borsari 46, 44121 Ferrara, Italy. Tel.: +39 0532 455387.
E-mail address: elisabetta.caselli@unife.it (E. Caselli).

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Second case study on the orientation of phaco hand pieces during steam sterilization

Sir,

Steam sterilization is the most commonly used method to sterilize medical devices in hospitals.[1,2] In the last decades, complex instruments (minimal invasive surgery) with hinges and (narrow) channels have been introduced. These developments challenge the establishment of steam sterilization conditions on the inner surfaces of devices with narrow channels, as reported in the literature.[3]

A previous study demonstrated that the orientation of a phaco hand piece influences the result of the sterilization process.[4] It was reported that sterilization conditions are established reproducibly for vertically (upright) oriented phaco hand pieces with free water drainage. However, in daily practice, vertically oriented medical devices may lead to practical problems when loading sterilizers. Therefore, it is of interest to study whether sterilization conditions on the inner surfaces of hand pieces can be established reproducibly with other orientations (angles from 0° to 90°). Additionally, it is interesting to determine whether different sterilizers and processes can establish sterilization.

In this study, each individual phaco hand piece was placed in a ½ DIN basket and wrapped according to the hospital protocol with meatex (SSMMS) regular and heavy duty wrapping material (Interster, Wormerveer, The Netherlands). The phaco hand pieces were fixed in the basket and placed on a specially developed construction in five different angles (0°, 30°, 45°, 60° and 90°). The load was placed in a Sanamij type SAR 6.6 sterilizer with internal dimensions of approximately 116 × 62 × 60 cm (Rotterdam, The Netherlands). Thereafter, the load was processed according to the hospital protocol and processes (Figure 1). During the process, the temperature inside the phaco hand piece was measured as in the previous study.[4] Three brands of phaco hand pieces were used, and will be referred to as Brands A, B and C. Overall, 43 measurements were performed. EN 285 specifies that all measured temperatures should reach sterilization temperature (≥134 °C) at the start of the sterilization phase.[2] The results (Figures 2 and 3) show that 16 and 27 measurements met and failed this requirement, respectively. The hand pieces with 60° and 90° orientation complied better with the standard than the hand pieces with horizontal (0°), 30° and 45° orientation. All of the Brand C hand pieces reached sterilization temperature at 60° and 90° orientation.

Figure 3 presents the temperatures measured in the plateau period of the sterilization cycle in nine horizontally oriented hand pieces. Only one hand piece reached the sterilization temperature at the same time as the theoretical temperature. The time that each phaco hand piece has reached the sterilization temperature (134 °C) varied from 0 to 210 s. In four cases, the sterilization temperature was never reached.

The results of this study are in line with the findings of the previous study.[4] The failure rates were higher among horizontally and 30° oriented hand pieces compared with those