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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 (HCAs). 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.⁶ 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.^{7–7} 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 HCAs. 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.⁷ The numbers of analysed samples from each institution, as well as the period of environmental sanitation by PCHS, are shown in Table 1. 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 1

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

Healthcare structure	Analyses per year (with PCHS sanitation system)				Total analyses (per HS)	
	2011	2012	2013	2014–2015		
HS-1	429	–	–	–	429	
HS-2	103	304	301	613	2686	
HS-3	–	–	6346	7290	7593	21,329
HS-4	–	76	1025	969	1154	3224
HS-5	–	72	631	713	730	2166
HS-6	–	340	403	498	554	1695
HS-7	–	–	–	–	510	510 ^a
Total^b	532	1072	9106	10,083	11,326	32,139

HS-1, Dio S. Anna Hospital (Ferrara), PCHS application March 16th to August 28th, 2011; HS-2, S. George Hospital (Ferrara), PCHS application since November 1st, 2011; HS-3, New S. Anna Hospital (Cossu, Ferrara), PCHS application since January 1st, 2013; HS-4, Delta Hospital (Lagoraino, Ferrara), PCHS application since June 1st, 2012; HS-5, Carlo Hospital (Cento, Ferrara), PCHS application since July 1st, 2012; HS-6, Argenta Hospital (Argenta, Ferrara), PCHS application since July 1st, 2012; HS-7, Quisisane Hospital (Ferrara), PCHS application since January 1st, 2015.

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

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