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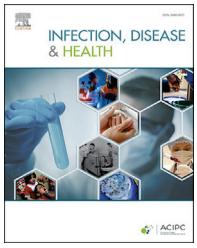

Research paper

A novel approach to stethoscope hygiene: A coat-pocket innovation

Gabriele Messina [a,b,*], Giuseppe Spataro [b], Daniele Rosadini [b], Sandra Burgassi [a], Lorenzo Mariani [c], Marco Tani [d], Gabriele Cevenini [e]

[a] Department of Molecular and Developmental Medicine, University of Siena, via Aldo Moro 2, 53100 Siena, Italy
[b] Post Graduate School of Public Health, University of Siena, via Aldo Moro 2, 53100 Siena, Italy
[c] Rugani Clinic, Hospital Direction, Strada Regionale 222, Chiantigiana, Loc Colombaio, 53035 Monteriggioni, Siena, Italy
[d] FeT Elettronica S.n.c., via A. Volta 28, 53036 Poggibonsi, Siena, Italy
[e] Department of Medical Biotechnology, University of Siena, viale Mario Bracci 16, 53100 Siena, Italy

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Abstract *Background:* The stethoscope is the most widely used instrument in healthcare. Studies have found similar rates of contamination on the stethoscope diaphragm and on physician fingertips after a single examination. Our aim was to test the effectiveness of an innovative portable device for disinfecting stethoscope membranes.
Methods: From November 2016 to May 2017, a cross-sectional study was conducted in four wards of a private clinic: General Ward (GW), Internal Medicine Ward (IMW), Post-Operative Observation Ward (POW) and Permanent Vegetative State Ward (PVSW). Five wearable medical devices, designed to disinfect stethoscope membranes automatically by means of UV-C radiation, were provided to operators. Spot checks were made for microbial counts of stethoscope membranes, classified as treated or otherwise on the basis of whether they were found coupled or otherwise with the devices. The percentage reduction in colony forming units (CFU) was calculated between the two groups.
Results: The number of tests of stethoscopes treated with the device was 116 out of 272. Untreated samples had a mean contamination of 132.2 CFU versus 6.9 CFU of treated samples: a 94.8% reduction (95% CI 91.3%–97.7). Highly significant statistical differences in CFU were found between untreated and treated membranes ($p < 0.001$). In particular, microbial contamination showed a reduction of 88.7% (CI 77.5%–96.05%) in PVSW, 95.9% (CI 88.2%–98.5%) in GW, 84.5% (CI 76.4%–90.5%) in IMW and 95.8% (CI 90.3%–98.1%) in POW.

* Corresponding author. Department of Molecular and Developmental Medicine, University of Siena, via Aldo Moro 2, 53100 Siena, Italy. Fax: +39 0577 234090.
E-mail addresses: gabriele.messina@unisi.it (G. Messina), gspataro85@virgilio.it (G. Spataro), daniele.rosadini@student.unisi.it (D. Rosadini), sandra.burgassi@unisi.it (S. Burgassi), l.mariani@gruppogarofalo.it (L. Mariani), mtani@fet.it (M. Tani), gabriele.cevenini@dbm.unisi.it (G. Cevenini).

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Conclusion: The devices proved effective and efficient in reducing the microbial load of stethoscope membranes. Wearing the device on the coat may act as a reminder of the need for hygiene.

Highlights

- Effectiveness of UV-C LED to prevent cross-microbial contamination due to the stethoscope.
- Easiness use of the device which does not interfere with activities.
- Engineering of device may indirectly, reinforce the awareness of hygiene practices.

Introduction

Healthcare-associated infections (HCAIs) are a major public health problem due to high associated morbidity and mortality and consequently high costs, and also due to the increasing emergence of antibiotic-resistant "superbugs" [1–3]. Hospitals exist to provide healthcare and it is a paradox that patients contract infections during hospitalization. Subjects especially at risk include elderly persons, newborns with immature immune functions, patients with immune deficiency, transplant patients and intensive care patients [2]. Up to 32% of HCAIs could be prevented [4].

A systematic review in 2013 found that HCAIs were attributed to physicians more than to other healthcare personnel. A review of 1022 HCAI cases also found that medical equipment and devices were the most common source of infectious agents responsible for HCAIs [5,6]. A recent review of 28 studies highlighted that 85% of stethoscopes are contaminated with bacteria, including pathogens, and that after just one physical examination, stethoscope contamination is similar or greater that of parts of the dominant hand of the examining physician [4,7]. This is especially significant because two centuries after its invention in 1816 by René Laennec, the stethoscope is increasingly used in many fields of medicine. Countless patients are auscultated daily in emergency rooms, internal medicine wards and general practitioners' offices. Thus a given instrument comes into contact with the skin of many patients [8–10].

There is evidence that two-way transfer of microorganisms, including pathogens, is possible between the skin and the stethoscope [3,4,11,12]. For example, the same strain of *Pseudomonas aeruginosa* (serotype O12) has been found on skin and the stethoscope membrane [13]. Gastmeier et al. reported that in some cases the strain of *Klebsiella pneumoniae* isolated in a neonatal intensive care unit was also found on incubator stethoscopes [14].

The stethoscope is classified as a non-critical object, because it only comes into contact with intact skin. Thus it does not require a high level of disinfection or sterilization: low-level disinfection is recommended to inactivate most microorganisms. Although regular disinfection of stethoscope membranes after each patient is clearly important, most surveys show that 70–90% of physicians do not systematically disinfect their stethoscope after each examination [3,7,10]. Despite widespread interest in preventing the spread of infections, no gold standards for disinfecting stethoscopes have been set and unfortunately healthcare providers are often lax [4]. The principal reasons for poor compliance include inaccessible cleaning agents, high workload, insufficient knowledge of recommended guidelines, lack of awareness of the importance of hygiene programs, forgetfulness, and insufficient time. If informed, however, healthcare staff and doctors understand the importance of disinfecting stethoscope membranes [15]. So although the scientific community stresses the need to disinfect stethoscopes, it struggles to find an easy, practical and really adoptable solution each time a patient is examined. The aim of this study is to evaluate the effectiveness of an innovative device for the disinfection of stethoscope membranes in a real setting.

Methods

Setting and study design

We conducted cohort study into the reduction of microbial contamination on stethoscope membranes, comparing standard stethoscope care with the proposed alternative solution. The study took place between November 2016 and May 2017 in the private Rugani Clinic at Monteriggioni, Siena, Italy. The clinic is accredited with the Italian National Health Service and manages about 2800 hospitalizations per year (data 2008). It hosts a heterogeneous patient population for ophthalmology, otorhinolaryngology, general surgery, orthopaedics, urology, rehabilitation, image diagnostics, rheumatology and laboratory analysis. The study was conducted in four wards: General Ward (GW), Internal Medicine Ward (IMW), Post-Operative Observation Ward (POW) and Permanent Vegetative State Ward (PVSW).

The device

The device, known as *Stet Clean*, is designed to be worn on the coat pocket or belt or to be placed on a desk. When the stethoscope head is coupled with the device, it is automatically disinfected by irradiation with ultraviolet-C from a light emitting diode (LED). Fig. 1 shows some details of the device: A) a slot enabling the user to attach the device to the coat

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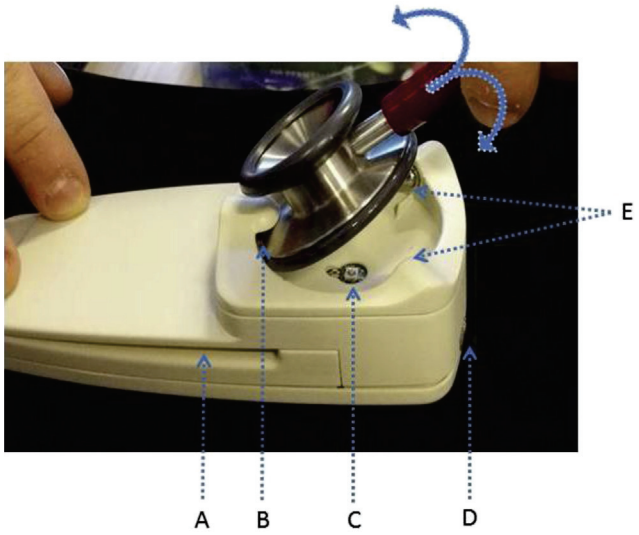

Figure 1 Device showing main physical characteristics. A: Slot to attach device to coat pocket; B: stethoscope holder and micro switch; C: UVC LED; D: LED indicator lights; E: spring holders.

pocket/belt; B) a plastic protuberance that secures the head of the stethoscope when it is inserted and that contains an insertion-activated micro-switch; C) a LED source of UV-C light disposed centrally facing the stethoscope membrane, D) LED indicator lights for device operativity, battery level and electronic malfunction; E) a couple of ball pressors which open when the stethoscope head is inserted and then hold it in place. Thus with a single movement the stethoscope head is attached to or removed from the device on the coat pocket, while remaining around the user's neck.

The device has a microelectronic board with embedded system technology with a UV-C LED as principal component. It includes a battery power supply, rechargeable with a micro USB connector, and a microcontroller that supplies a customized current to the UV-C LED and to the system. The beam angle of the UV-C LED and its location with customized angle of reflection of the light fully illuminates the entire surface of the stethoscope membrane including its rim.

To avoid harm from UV-C light, the device is designed so that UV-C emission is only possible when the stethoscope head is attached. During the coupling phase, a micro switch is activated and a light sensor detects the variation in light between the stethoscope membrane and the device. These two conditions alert the device that a coupling procedure is underway and turns on the UV-C light automatically for 5 min. When the head of the stethoscope is removed prior to 5 min, the UVC LED automatically switches off.

Ultraviolet-C light inactivates microbe DNA, preventing replication [16]. The following conditions make the device efficient: i) minimized distance between LED source and surface; ii) wavelength 255–280 nm; iii) sufficiently prolonged exposure to UV-C; iv) homogeneous surface illumination.

Experimental protocol

The study group informed the clinic staff (nurses and doctors) about microbial contamination of stethoscopes and measures to prevent cross-contamination between patients. The clinic staff consented to enrolment in the study.

Five Stet Clean devices were provided to the Clinic and the staff was instructed how to use them. Four devices were placed in fixed locations on the medication trolleys of each ward and in the medical and nursing rooms, and could if necessary be worn on a coat pocket. Only one device was assigned to a health professional who wore it constantly.

A total of five shared stethoscopes were used by doctors and nurses in the wards studied; a sixth personal stethoscope was worn by a health professional. All stethoscopes underwent microbial counts in the study period.

The study protocol consisted in spot checks when the stethoscopes were sampled for microbial contamination, without alerting the staff of the structure and without changing the standard cleaning procedures. The checks occurred at different times of day and on different days of the week. The samples were obtained from stethoscopes coupled or otherwise to the devices and were recorded as treated and untreated (by Stet Clean), respectively. Stratified comparisons between wards were also performed, as well as comparisons of microbial contamination on the shared stethoscopes versus the personal one.

Plate-count agar plates were incubated at 36 °C and colony forming units (CFUs) were counted after 48 h to assess microbial contamination. Uncountable plates were considered to host more than 400 CFU.

Statistical analysis

Descriptive and inference analysis were performed on the culture counts. Mean number of CFUs was evaluated for treated and untreated samples; the results were also analysed stratifying by ward. The mean percentage reduction in CFUs between treated and untreated groups of stethoscopes was then calculated.

The 95% confidence interval (95% CI) of mean percentage reduction was estimated by the bias-corrected and accelerated bootstrap method which was executed with the MATLAB® software. CFUs were also compared between groups using the non parametric Mann–Whitney test for independent samples and SPSS software.

Results

Two hundred and seventy-two samples were obtained from stethoscope membranes: 156 were untreated (stethoscope uncoupled from the device), while 116 were treated. Highly significant differences ($p < 0.001$) in CFU were found between untreated and treated membranes. Before use of the device, the personal stethoscope showed 13 CFU; during the study it was sampled five times and four measurements showed 0 CFU and one showed 1 CFU.

As shown in Table 1, untreated samples had a mean microbiological count of 132.2 CFU in contrast with 6.9 CFU for treated samples. This was a 94.8% reduction (95% CI 91.3%–97.7%).

The ward with the highest microbiological contamination was PVSW with an average of 232.9 CFU; after UV treatment, the average microbial count dropped to 11.1 CFU, a reduction of 88.7% (95% CI 77.5%–96.0%). The

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Table 1 Mean and 95% confidence interval (95% CI) of CFU reduction by ward.

Ward	No treatment		Treatment		Reduction %	
	Mean	CI	Mean	CI	Mean	CI
GW	27.14	(10.44; 55.38)	1.12	(0.36; 2.12)	95.9	(88.2; 98.5)
IMW	9.54	(6.52; 13.17)	1.48	(0.9; 2.14)	84.5	(76.4; 90.5)
POW	51.71	(16.43; 92.63)	2.19	(1.15; 3.33)	95.8	(90.3; 98.1)
PVS	232.93	(194.43; 271,43)	11.08	(5.9; 16,26)	88.7	(77.5; 96.0)
Overall	132.21	(106.08; 157.57)	6.91	(2.7; 13.46)	94.8	(91.3; 97.7)

GW had an initial mean of 27.1 CFU which decreased to 1.12 CFU after treatment, a reduction of 95.9% (95% CI 88.2%–98.5%). The IMW had an average count of 9.5 CFU against post-treatment contamination of 1.48 CFU, a reduction of 84.5% (95% CI 76.4%–90.5%). The POW had an average contamination of 51.7 CFU which decreased to 2.19 CFU after treatment: a reduction of 95.8% (95% CI 90.3%–98.1%). The nurse's personal stethoscope had an initial mean contamination of 12.50 CFU which decreased to 0.6 CFU after treatment: a reduction of 95.6% (95% CI 94.9%–98.6%).

Discussion

Different levels of contamination were found between wards: all were in the range of the six studies reviewed by O'Flaherty [4]. The only exception related to the Permanent Vegetative State ward where mean CFUs were particularly high (above 232). This finding is a warning signal as this ward hosts patients who are already debilitated, sedated and much more susceptible to infectious risk than other types of patient.

The reason for such a large difference in microbial contamination before adoption of the device was unclear, but suggests that standard disinfection procedures and/or protocols were lacking or not properly run.

The overall mean CFU after treatment was 6.91, which is lower than the mean level of contamination of the French Normalization Standard for cleanness (which is equivalent to <20 CFU per membrane). Ethyl or isopropyl alcohol (70–90%) are the recommended agents for disinfection of non-critical medical devices. In a comparison of ethanol-based cleanser versus isopropyl alcohol for the disinfection of stethoscopes, Paul Lecat et al. achieved a similar disinfection level of about 93% with both. These results are in line with the mean of 95% obtained in our study [17].

Unlike other studies, we only quantified microbial contamination without identifying the species on the stethoscope membranes, since replication of all species is inhibited by UV-C radiation, albeit with different exposure times [18].

The belief that infection is transmitted via stethoscopes was recorded by 76% of a sample of 3208 health professionals, equally distributed between physicians and nurses; however only 24% reported that they disinfected the stethoscope after every use [19]. The reasons for low compliance with stethoscope hygiene have been quantified and predictors influencing it negatively are lack of time, access to disinfecting materials and visual reminders. So although it is important to stress the importance of educational programs on stethoscope hygiene, it is also important to facilitate sanitation by removing other obstacles. The Stet Clean device has characteristics that go in this direction. Firstly, portability makes the device easy and practical to use: the head of the stethoscope (normally carried around the neck) just has to be coupled with the device, which can be worn on the coat pocket. This simple natural gesture safely and automatically triggers the disinfection process: the UV-C LED switches on and irradiates the stethoscope membrane until the process is terminated or the stethoscope head detached. Since the device is wearable, as well as easy, safe and fast to use, it promotes good stethoscope hygiene and limits cross-contamination during use. Secondly, physical disinfection does not require any consumables such as disinfectant, swabs or disposal. Health operators do not need to seek them every time the stethoscope is used; hospitals do not need to order or stock them, and less waste, costly to process, is produced. Finally, the device may be placed in strategic locations (the doctor's surgery, the nursery, dressing trolleys, etc.) and, most importantly, its moderate size makes the device portable and allows users to wear it on the breast pocket of their lab coat or uniform. Its presence on the coat becomes a reminder and symbol of hygiene and good quality service; it induces good hygiene and promotes a habit of hygiene with positive impact at all levels of prevention, not regarding stethoscopes alone.

Although education is important for health professionals and students of medicine and nursing, it may not be enough to influence routine practice. For example, a recent major campaign among students to increase handwashing, a cornerstone of hygiene recognized by all health operators, failed to obtain any significant improvement with respect to the control group, nor did it improve compliance for handwashing and stethoscope disinfection [20,21]. This is why better strategies are needed together with education to improve hygiene standards.

Device maintenance includes removing any visible foreign matter or moisture on the stethoscope membrane so the UV-C light can penetrate. A critical aspect of UV-C is that prolonged and excessive exposure could accelerate deterioration of the stethoscope membrane, although the exposures irradiated by the device are brief and have relatively low radiant power. During the study we did not detect any visual change in the colour or flexibility of the stethoscope membranes and the healthcare personnel did not express any concern regarding performance during use. Other methods of disinfection also damage membranes in the long term. Another aspect that could be a barrier against adoption of the device are the 5 min of irradiation

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that may be too long between patients. In standard healthcare activity, it is unlikely that two patients be examined within 5 min of each other, especially if the device is assigned to single staff members. However, in certain settings, for example an emergency unit or accident site, time is a crucial variable. In our experience, nurses who shared devices and routinely examine patients, reported that a reduction in disinfection time would be preferable or the availability of more devices to use.

In our study, all stethoscopes proved easy to couple with the device, but variations in stethoscope membrane diameter could interfere with device use. For example paediatric or neonatology stethoscopes of smaller diameter would require an adaptor in order to be attached.

The device based on UV-C LED technology is an example of new applications in the disinfection sector that exploit the characteristics of LEDs: device miniaturization, low energy, no consumables, no mercury, no resistant bacteria. The effectiveness of the device remained high throughout the study period, although complete inactivation of microorganisms was not obtained in all cases. However, UV-C LED technology is improving and systems with higher performance are almost ready for the market. This will enable improvements in efficiency and efficacy, significantly shortening disinfection times and further reducing residual contamination.

Lack of perception of the importance of stethoscope hygiene could replicate the history of hand hygiene. The importance of hand hygiene was guessed long before it was demonstrated by Ignaz Phillip Semmelweis in the mid nineteenth century. The bicentenary of the invention of the stethoscope was celebrated in 2016; now it is time to take stethoscope hygiene more seriously. The global health challenge of antimicrobial resistance calls for a comprehensive approach [22].

In conclusion, the UV-C device demonstrates that it can efficiently and effectively disinfect stethoscope membranes, even when highly contaminated, in the normal clinical routine. This is essential, especially in high-risk settings like intensive care units, where immunodeficiency and resistant bacteria may combine, as in the Permanent Vegetative State ward.

Ethics

Ethics committee approval was not required because the device is a certified medical device used in routine practice.

Authorship statement

Q1: The section "Authorship statement" is correct.

G. Messina had the idea for the article, performed the literature research, collaborated in performing the study, carried out the data analysis and collaborated in writing the article, helped to conceptualize ideas; **G. Spataro** collaborated in collecting the data, collaborated in writing the article and performed the literature research; **D. Rosadini** collaborated in writing the article and performed the literature research; **S. Burgassi** collaborated in collecting the data and in the laboratory analysis; **L. Mariani** collaborated in performing the study and in collecting data; **M. Tani** was responsible for the technical aspects of the device; **G. Cevenini** was responsible for the bioengineering aspect of the device and performed the statistical analysis. All the authors contributed to conception of the article, drafting and revision of content. All the authors have approved the content of the paper.

Conflict of interest

GM, SB and GC are co-founders of a start-up company named "egoHEALTH", which is currently endeavouring to implement an innovative approach developed over years of research into the issues described in the article. MT received personal fees from the University of Siena during the study period.

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Provenance and peer review

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