

Automated Uv- C Led Stethoscope Decontamination: A Useful Barrier Against Nosocomial Infections

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ABSTRACT

The use of incorrectly cleaned or disinfected hospital's equipment can also pose an infection risk and may contribute to the dissemination of microorganisms. Generally, stethoscopes are not considered a main infection risk, but the stethoscope is the most-used medical tool in the world. A new light-emitting diode (LED) disinfection option has recently been introduced by the LED industry. We wanted to determine where and when this new disinfection system would be useful in reducing contamination and whether any specific type of patient would benefit more from the use of this device.

The evaluation was conducted using a multidisciplinary approach and has provided an analysis of the 7 domains recommended by EUnetHTA (Health problem and current use of the technology, technical characteristic, clinical effectiveness, safety, economic evaluation, organizational aspects, ethical aspects).

We observe the use of stethoscope while delivering routine care in three different intensity of care departments on at least one hour every week for three months. Between one patient and another, a disinfection or cleaning procedure is never performed by most operators. We collected 248 samples from different departments to evaluate the efficacy of a new device. We observed a reduction in the bacterial load in 70% of the cases after using the UV-C LED device.

Discussion and Conclusion: This device could be useful in encouraging the adoption of good hygiene practices and could reduce the risks associated with the treatment of infections. The tool has proved to be particularly useful in the intensive care unit.

Key Words: Stethoscopes decontamination, HAI prevention, UV-C disinfection, intensity of nursing care, UV-C LED, Healthcare worker's habits, nursing education, HTA

Introduction

The outbreak of COVID 19 is drawing attention to the accuracy of the execution of simple hygienic manoeuvres to prevent the direct and indirect transmission of pathogens by use of all possible ways of blocking cross infections inside hospitals (1, 2).

Healthcare-associated infections (HAIs) remain a prominent healthcare topic and affecting both developed and developing countries alike.

While washing hands and the use of disposable gloves and masks are universally recognized as effective step to be taken to reduce the risk of

infection especially in the operating room (3, 4), there are no universally recognized procedures for the disinfection of commonly used devices.

Small medical equipment may contribute to the dissemination of microorganisms, but the evidence supporting this hypothesis is less strong than that for unwashed hands and the role of such equipment in the propagation of microorganisms is poorly understood. Generally, the stethoscope is not considered a main infection risk, but the stethoscope is the most-used medical tool in the world and could acquire microorganisms after each contact with a source patient (5-8).

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Every year, the Emergency Care Research Institute (ECRI) presents its list of new technologies that were introduced in hospitals and should be monitored with a focus on whether the new technologies create a high value, balancing costs, quality and outcomes. We found “Deep ultraviolet (UV) -C- light-emitting diodes (LEDs) for disinfection” among the new technologies on the 2017 list. Recently the use of this technology has been described in the literature as an effective disinfectant in a healthcare environment (9-15). A new LED disinfection device that produces an immediate disinfection of the membrane of the stethoscope has recently been introduced by the LED industry in Italy (16, 17). The HTA Committee of University Hospital “G. Rodolico” of Catania received the purchase request form for 10 devices that employ germicidal LED UV radiation to disinfect stethoscopes. Starting with the questions suggested by the ECRI, we wondered whether this device could be effective, safe, necessary for our organization, ethical and cost saving.

The aim of this study was to evaluate, with the health technology assessment (HTA) methodology (18, 19), the adoption of a new promising device that uses deep UV-C as a disinfection technique. We wanted to determine where and when this new disinfection system would be useful in reducing contamination and thereby reduce the risk of hospital infections and whether any specific type of patient would benefit more from the use of this device.

Material and Methods

The study was discussed and approved on 27th September 2018 (Protocol number 001062 dated 28th November 2018) by HTA Committee of Azienda Ospedaliero Universitaria Policlinico – V.Emanuele- Catania.Italy.

We asked our Infection Prevention Team and HTA Team to work together to observe health care professionals who were using stethoscopes and to test a new disinfection device in different contexts within our hospital at different intensities of nursing care (high, medium and low intensity). The data were collected between October 2017 and January 2019. The instrument has been tested in the departments that will be more easily involved by the outbreak of pulmonary pathology (general clinics, pulmonary department and ICU) and has demonstrated sure validity in the reduction of the bacterial charge.

The evaluation was conducted using a multidisciplinary approach and included an analysis of the following 7 domains:

CUR domain – Health problems and current uses of the technology

TEC domain – Description and technical characteristics of the technology

EFF domain – Clinical effectiveness

SAF domain – Safety

ECO domain – Costs, economic evaluation

ORG domain – Organizational aspects

ETH domain – Ethical aspects

We reported a summary for each analysed domain and the conclusions of the HTA Committee. We adapted the results to the local situation to the extent required for an HTA report.

We have observed the use of the stethoscope in daily practice in three different wards at different intensity of care for at least an hour a week for three months. We have reported on an observation scheme the number of times the stethoscope has been used and how many times it has been cleaned between one patient and another.

Results

CUR domain – Health Problems and Current Uses of the Technology: The phonendoscope is used daily by intensive care physicians and nurses on all patients during the control visit. In the intensive care unit (ICU), and based on the observation of the operators, each tool is used an average of 12 times during each single work shift, if there are no complicated cases.

In the Internal Medicine and Pulmonology Units, physicians used a phonendoscope an average of once a day per patient, if there were no complicated cases.

In the outpatient department, we observed that consultants rarely used phonendoscopes, with an average of three or four times each day.

We observed that between one patient and another, a disinfection or cleaning procedure is never performed by most operators.

TEC Domain–Description and Technical Characteristics of the Technology: According to the Spaulding classification, the stethoscope is considered a non-critical device, but the disinfection of this instrument is always preferable to simple cleaning. There is no disinfection protocol, and no checks are performed. The



Fig. 1. Portable Version of the Device

stethoscope is often wrapped around itself and stored in the pocket of a gown or resting on a table or shelf; alternatively, it is often worn around the neck.

We tested a device that uses LEDs for stethoscope disinfection. We have a portable version of the device or a table version, which works the same way (Figure 1a, b). This device emits light in the “deep UV” range, also called UV-C, which is a range below 290 nm (wavelengths between 250 and 280 nm are known to have the greatest germicidal effect). UV-C light inactivates microbes within a few seconds and prevents their replication (spores included) on exposed surfaces.

The technical characteristics of UV-C LED device are as follows:

- automatic treatment at two levels: 3 minutes for standard disinfection, 2 minutes more for a deeper disinfection;
- automatic activation with the placement of a stethoscope;
- double control system – optical and mechanical sensors – for use under operational safety conditions, with a microprocessor for irradiation and security controls;
- a light weight (100 grams) and pocket-sized (limited footprint);
- status light indicator (ongoing treatment, treatment complete, low battery, malfunction), with a rechargeable battery using a standard micro USB cable; and
- high battery autonomy.

EFF domain – Clinical effectiveness: The new device was tested in different departments of the hospital. We evaluated the contamination on stethoscopes by measuring the bacterial load before and after the disinfection technique. Total bacterial counts at 36 °C and 22 °C, *Staphylococcus spp.*, moulds, *Enterococcus spp.*, *Pseudomonas spp.*, *E.*



Fig. 2. Table Version of the Device

coli and total Coliforms bacteria were evaluated. Samples were streaked onto blood agar at 37 °C and 22 °C, as well as onto MIUT, CLED, Herellea, cetrimide, Slanetz-Bartley, and Baird-Parker agars.

Samples were obtained by swabbing the stethoscope membrane with sterile cotton pads for approximately 5 seconds per sample. The first sample was obtained from the stethoscope membrane after the patient visit had been performed, and the second sample was obtained after decontamination using the device.

We collected 248 samples in three different departments of the hospital with different intensities of nursing care:

- High intensity- ICU, 88 samples;
- Medium intensity- Internal Medicine and Pulmonology wards, 104 samples; and
- Low intensity- Outpatient department, 56 samples.

The samples were seeded onto the different culture media. After sampling, the plates were incubated at 37 °C for 24-48 hours, and the numbers of colony-forming units (CFUs) were then counted to determine the contamination level of the stethoscope diaphragm, before and after UV-C decontamination. The numbers of colony-forming unit growth onto the different cultura media before UV-C treatment and after UV-C treatment were reported on Table 1. While pre-

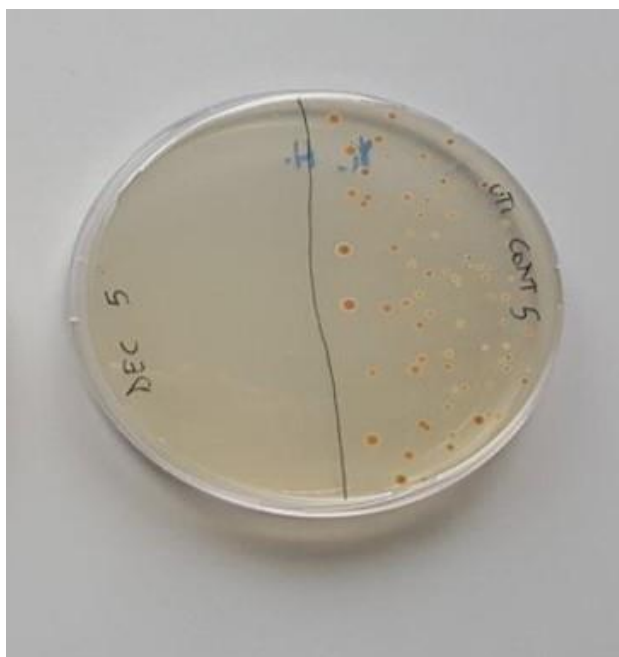


Fig. 3. Examples of the culture of swabs (CFU 36°) taken from a stethoscope taken pre and post -UV-C decontamination. On the right side we see CFU growth from the sample obtained after the patient visit had been performed and on the left side there is no growth after the decontamination with the device

decontamination CFU's are dramatically greater in high intensity of care units as compared with medium and low intensity of care units, after UV-C treatment CFU's in ICU reduce to a range from 10% to less than 2% of pre-decontamination values.

Bacterial colonies were found in 58 out of 248 cultures (Figure 2). In the ICU setting, 41% of the pre-decontamination samples presented microbial growth. Regarding the samples obtained in the medical departments, there was microbial growth in 17% of the cases. In the outpatient department, microbial growth pre-decontamination was observed in only 7% of the cases.

We observed a global reduction in the bacterial load in 91% of the sample post-decontamination. In cases where growth had previously occurred, we observed the total absence of growth in 65% of the cases. Using exact binomial distribution, the difference between presence and absence of growth in 58 pre decontamination positive samples was significantly different even in two sided comparisons ($P=0,0247$). There was also reduction in 26% of these cases, as shown in Table 2. Increased exposure times guaranteed even higher levels of disinfection (greater than 99%). In no case did we have a greater number of colonies than that observed in the pre-decontamination data.

ECO Domain–Costs, Economic Evaluation:

We compared the costs between two different devices that use different methods, but that were both designed to reduce the bacterial contamination of the stethoscope. There are no other devices on the market that use UV rays. A comparison was made with a single-use germicidal sponge supposed to be useful for infection control policies. The device is simple to use: just place the diaphragm into the chamber after each use, thus maintaining a clean stethoscope. It has a magnetic clip that attaches directly to the uniform. The starter package contains 6 clips, in which the refills must be inserted. It has 20 refills and costs \$57.00. The refills must be inserted after each use. The refill package costs \$47.00 and contains 20 refills.

For the LED UV-C disinfection device, the unit cost of each piece in Italy is €149.00 plus VAT. No consumable material or accessories are required. The battery for the LED needs to be replaced every 10,000 applications.

Economically, LED UV-C disinfection device is advantageous when compared with the other system, as shown in Table 3; the UV-C device does not require additional costs once purchased and has a battery that is electrically rechargeable. The battery included in the system allows the performance of 5,000 procedures.

Given the greater effectiveness demonstrated in the ICU, we have calculated the cost of the equipment for this unit, and we consider it useful to provide each of the medical and nursing staff with a device. We calculated that, if we have 3 attending physicians and 3 nurses per shift in the ICU, we would need 10 devices, costing 1490 euros plus VAT.

The devices can be recharged simultaneously through a single power outlet and made available to the users when needed. No additional costs are required.

ETH Domain–Ethical Aspects (Pain): No aspects that could have a negative impact were noted.

Failing to disinfect stethoscopes could constitute a serious patient safety issue similar to ignoring hand hygiene. It seems ethically correct to invest in these devices to ensure protection from the risk of infection, if such a practice does not entail excessive burdens, does not take time away from operators, and has been proven effective, even if not completely effective.

We must also consider the new idea that is spreading among patient associations, suggesting

Table 1. Numbers of colony-forming units (CFU) growth onto the different coltura media before UV-C treatment and after UV-C treatment. Samples are grouped according to intensity of care in different Units

Intensity Of Nursing Care		Blood agar		Agar MIUT	CLED	Herellea	Cetrimide	Slanetz-Bartley	Baird Parker
		22°C	37°C						
High (ICU)	pre-decontamination	66	7	356	183	1	0	0	147
	post-decontamination	5	0	32	2	0	0	0	2
Medium (Internal Medicine and Pulmonology wards)	pre-decontamination	2	63	74	9	3	14	0	37
	post-decontamination	0	15	19	0	1	0	0	8
Low (Outpatient department)	pre-decontamination	4	0	0	9	0	0	0	2
	post-decontamination	2	0	0	2	0	0	0	0

that patients request that their doctor or nurses clean the phonendoscope before using it. Soon, this request could also imply to attorneys that not cleaning this tool is an incorrect practice, even if it is yet to be proven that the damage was caused by this practice, leading to the initiation of legal disputes in the event of infectious complications, from which it may be difficult to remain immune.

SAF Domain–Safety: Similar to any piece of medical equipment, stethoscopes have the theoretical capacity to be vectors for pathogens. Additionally, it is known that stethoscope contamination from microorganisms may increase after each visit.

The device we evaluated does not use disinfectant solutions or chemicals, does not require any additional costs, and does not produce any waste. It was proven to be safe for both patients and the healthcare professionals. Healthcare workers who use it don't have to touch the diaphragm to sanitize it. This procedure is safer than cleaning with disinfectant also because it is independent of the operator.

ORG Domain–Organizational Aspect: The tool we evaluated facilitates daily practice and can accompany the doctor or nurses anywhere, in the pocket of a gown, in a briefcase, or on a desk. Time required per use is 3-5 minutes.

Given the greater effectiveness demonstrated in the ICU, we calculated the organizational needs of

this unit. Considering that three physicians and three nurses were present at each shift, we calculated that we should buy 10 devices to ensure that each health care provider can always access an efficient, always-charged instrument and a safely disinfected stethoscope. While the doctor continues the examination of the patient or prepares the medical record, the device is decontaminated without requiring any assistance. It takes only three minutes for standard disinfection and the next re-use. Two minutes more are necessary for a deeper disinfection in the case of a presumed pathogenic contamination.

No training period is required for the correct use of the device.

The instrument works with a battery that needs to be recharged. With a charged battery, the device allows approximately 30/40 disinfection procedures. The battery is rechargeable via a standard micro USB cable that must be connected to a PC or power bank. The complete charging time is approximately 5 hours. For a faster recharge, it is preferable to connect the device to an electrical outlet, perhaps via a multi-outlet such as a “recharge station”.

Discussion

Healthcare policy are extremely important for an appropriate management of infections (20, 21). For the prevention and control of the infections,

Table 2. Bacterial contamination of stethoscope before UV-C treatment and after UV-C treatment. Number of samples in which there was CFU growth on the stethoscope surface before UV-C decontamination and after UV-C decontamination. Samples are grouped according intensity of nursing care

Intensity of nursing care	Sample (n)	Positive (n)	Pre-decontamination			Post- Decontamination			
			%	CFU Absent (n)	%	Reduction in CFUs (n)	%	Invariant CFUs (n)	%
High	88	36	40.9	29/36	81	5/36	14	2/36	5
Medium	104	18	17.3	8/18	44	7/18	39	3/18	17
Low	56	4	7.1	1/4	25	3/4	75	0	/
	248	58		38/58	65	15/58	26	5/58	9

n - Number

CFU - Colony forming unit

Table 3. Economic evaluation. Comparison between the two described devices used to disinfect stethoscopes

	Clean stethoscope	Stet- clean
Cost per unit (in euros)	46 (6 clips, 20 refill)	149
Replacement kit cost (in euros)	38 (20 refill)	0
Cost for 20 daily procedures (in euros)	38	0
Total cost for 30 days (in euros)	1140	0

it is essential to identify the reservoirs of microorganisms in healthcare settings. In the vast majority of cases, nosocomial infections are not due to visitors, but pathogens are transported by healthcare professionals (22). The presence of microorganisms was found on keyboards, trolleys and they can easily be transported by hands on the diagnosis and treatment tools (23). Health care personnel hand washing is the most important intervention in interrupting transmission between patients (24), and plays a key role as to prevent infection in the operating room setting (25, 26).

Hands are the main sources, followed by medical devices, such as catheters, ventilators, endoscopes, graspers, sphygmomanometers, otoscopes, thermometers, and stethoscopes (27, 28). Microorganisms can survive on such an object for at least several minutes and can then be transferred to the skin of a second patient during subsequent use (29). Furthermore, it has been demonstrated that the level of contamination on a stethoscope correlates with that on the physician's own hands.

The daily cleaning of stethoscopes has been shown to reduce the bacterial contamination from >90% to <35% (30, 31). Traditional disinfection methods are currently limited to wiping the membrane with a solution of isopropyl alcohol or ethanol, but current cleaning behaviors are

inadequate. Recent scientific data permits to affirm that contaminated stethoscope can act as a source of nosocomial pathogens (32).

It is recognized that physicians and nurses do not usually disinfect their stethoscope (33, 34) and it is very rare that physicians systematically disinfect their stethoscope after every patient contact. This behaviour probably occurs because these professionals think that they do not have enough time or that the practice is not necessary.

While doctors and nurses are well aware of the usefulness of hand-washing before visiting a patient and nurses are well trained to wear gloves when handling biological samples (35), no one teaches these professionals the importance of disinfecting the stethoscopes, that are probably the most common medical device used by healthcare providers. These instruments are a vector for bacteria and can play a role in the spread of HAIs (36-40). Chlorhexidine, isopropyl alcohol, triclosan can inhibit decontamination of stethoscope and may be used easily but only a minority of health care providers disinfect their stethoscope after every use (41). Recent studies have shown that a copper coating on stethoscope can produce an antibacterial effect and can reduce the bacterial load and consequently mitigate microbial cross transmission during patient care (42, 43).

We have shown that the stethoscope membrane can be effectively and efficiently disinfected using UV-C LEDs. The initial cost of acquisition is relatively low for the device, but the real questions are as follows:

- 1) Is this device effective?
- 2) Is it really necessary for our organization?
- 3) What kind of patient gains the most from the use of this device?
- 4) Does this device meet the strategic goals of our hospital company?

1) The device is effective. The effectiveness evaluation had positive results. CFUs of common pathogenic microbes were significantly reduced when the stethoscopes were treated with UV-C LEDs.

2) A hand sanitizer or alcohol swabs should be used to clean stethoscopes between uses. Since these other methods of decontamination are not used in clinical practice for various reasons, it is considered useful to adopt UV irradiation to reduce the risk of transmitting microorganisms.

3) The tool was proven to be particularly useful in the ICU, where a higher percentage of membranes presented with microbial growth, and thus, the effectiveness of decontamination was greater. The major bacterial load found may be due to this particular type of unconscious patient, who is connected to a number of devices (urinary catheter, lines to the central and peripheral veins, intubation, ECG and various monitors), thereby increasing the possibility of spreading the germs of the patient from one site to another. These patients are not autonomous and are always assisted by the staff, who provide everything and touch the patient or use a phonendoscope several times a day. Very often, the same doctor is in charge of the assistance and visits multiple patients at the same time. This practice increases the risk of transferring the germs present in one patient's environment through tools to another patient.

The device was proven to be moderately useful in the Medical or Pulmonology units, where the phonendoscope is always used for the patient visits, while there was no difference in microbial growth when the instrument was adopted in the outpatient clinic.

4) We are a university health authority; therefore, one of our obligations is to provide accurate information on what is available on the market to improve patient care.

It has been suggested that doctors, nurses and medical students may be deficient in their knowledge of this area and consequently fail to clean their stethoscopes regularly (44). The main reasons why no cleansing of the phonendoscope is performed are limited education on the topic, poor availability of cleaning materials, poor role-modelling, and the need to raise the awareness in each health professional. Our doctors and nurses will guide students enrolled in undergraduate courses in medicine and surgery or nursing and can use this device to teach good practice and be models for greater and better quality of care.

During global health emergencies such as the current COVID-19 pandemic, the decontamination of single-use personal protective equipment or any devices used in healthcare setting becomes a necessary means to keep up with the growing demand from healthcare workers and patients alike.

The germicidal properties of ultraviolet-C are well known. Some authors recently ipotize UV-C decontamination to adopt a standardized approach to phone disinfection (45) or to reduce contamination on respirators (46), or for optimization of infection control and operating room management (47).

Based on the available scientific evidence UV-C light emitted in a range of 200 to 280 nanometers can kill SARS-CoV-2 but peer reviewed studies have to be published. There is a preprint [48], although not yet peer reviewed, which supports through some experimental observations, potential virucide effects of UV-C on a range 200-290 nanometers against SARS-CoV-2. This result, if definitively confirmed, may represent a new disinfection perspective towards pandemic control of COVID-19.

It is considered useful to suggest the effectiveness of this device also because this device is definitely used in the diagnosis, treatment and monitoring by the health care staff of the respiratory pneumonia (illness) that is being discussed today worldwide.

Technological advancements in disinfection practices offer significant promise to improve infection control. The use of this device focuses on the sanitization of instruments and indirectly favours the frequency of cleaning the stethoscope.

While there is a clear perception of hands as the main vehicle for the transmission of microbes to patients, the majority of health personnel have not received any education regarding stethoscope hygiene.

The device we studied simplifies decontamination of the phonendoscope by acting independently without the need for any product and promotes a natural change in daily actions and the adoption of good hygiene habits. Educational campaigns must be studied to improve stethoscope disinfection practice and to encourage further research into the role of stethoscopes as possible transmission vectors.

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