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Major Article

Antimicrobial copper alloys decreased bacteria on stethoscope surfaces

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Background: Stethoscopes may serve as vehicles for transmission of bacteria among patients. The aim of this study was to assess the efficacy of antimicrobial copper surfaces to reduce the bacterial concentration associated with stethoscope surfaces.

Methods: A structured prospective trial involving 21 health care providers was conducted at a pediatric emergency division (ED) (n = 14) and an adult medical intensive care unit located in tertiary care facilities (n = 7). Four surfaces common to a stethoscope and a facsimile instrument fabricated from U.S. Environmental Protection Agency-registered antimicrobial copper alloys (AMCus) were assessed for total aerobic colony counts (ACCs), methicillin-resistant *Staphylococcus aureus*, gram-negative bacteria, and vancomycin-resistant enterococci for 90 days.

Results: The mean ACCs collectively recovered from all stethoscope surfaces fabricated from the AMCus were found to carry significantly lower concentrations of bacteria (pediatric ED, 11.7 vs 127.1 colony forming units [CFU]/cm², $P < .00001$) than their control equivalents. This observation was independent of health care provider or infection control practices. Absence of recovery of bacteria from the AMCus surfaces (66.3%) was significantly higher ($P < .00001$) than the control surfaces (22.4%). The urethane rim common to the stethoscopes was the most heavily burdened surface; mean concentrations exceeded the health care-associated infection acquisition concentration (5 CFU/cm²) by at least 25×, supporting that the stethoscope warrants consideration in plans mitigating microbial cross-transmission during patient care.

Conclusions: Stethoscope surfaces fabricated with AMCus were consistently found to harbor fewer bacteria.

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Reducing the frequency of healthcare-associated infections remains a top priority of health care. According to the Centers for Disease Control and Prevention health care-associated infections account for approximately 1.7 million infections and 99,000 associated deaths each year in U.S. hospitals, leading to annual direct and indirect costs totaling between \$96 and \$147 billion.^{1,2}

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Solid copper and alloys containing >60% copper by weight are known to kill bacteria on contact. Copper surfaces have been found to continuously decrease the bacterial bioburden within the built hospital environment, with a concomitant reduction in the incidence of hospital-associated infections.³⁻⁵ The intrinsic antimicrobial activity of copper has been confirmed for a number of surfaces under a variety of clinical conditions (reviewed by O'Gorman and Humphreys⁶ and Muller et al⁷).

Several studies have suggested that stethoscopes may serve as a vehicle for the transmission of bacteria from one patient to another.⁸⁻¹⁴ In one study, cultures from 200 stethoscopes were analyzed. Eighty percent of the stethoscopes harbored bacteria. Most of the identified microbes were gram-positive; 24 of the stethoscopes contained the pathogen *Staphylococcus aureus*, whereas 4

others harbored methicillin-resistant *S aureus* (MRSA).¹⁵ Another study found an 87% contamination rate among diaphragms of 300 stethoscopes.¹⁶ In an emergency department setting, there were levels of contamination found on 133 of 150 stethoscopes.¹⁷ Forty of the contaminated instruments harbored staphylococci, and *S aureus* was only recovered from 38% (n = 15). In experiments using defined concentrations of *Micrococcus luteus*, it was shown that bacteria were easily transferred from stethoscopes to human skin on contact.¹⁸

In a survey conducted at Boston Children's Hospital, 76% of the respondents believed that transmission of infections were facilitated by stethoscopes, but only 24% of nurses and physicians reported routine disinfection of their stethoscope after every use.¹⁹ Expanding on this observation, Zaghi et al learned that by providing stethoscope disinfection supplies and visible reminders in close proximity to patient rooms, the rates of stethoscope disinfection between patient encounters significantly increased.²⁰ This practice has yet to become widespread.

In this study there were 2 objectives. The first was to understand the relative bioload associated with stethoscope surfaces likely touched by clinicians. The second was to assess how replacing those same surfaces with antimicrobial copper alloys would affect the base bioload of these surfaces independent of the recommendation of care suggested for cleaning and disinfecting between patient encounters.

METHODS

Protection of human participants

Protected health information was not recorded from the patients examined by the subjects using the study stethoscopes, and the identity of the examining clinical study participants was not

known to the investigators analyzing the data. Because this was a multicenter trial, North Shore University Hospital (adult settings) and Medical University of South Carolina (MUSC) (pediatric emergency division [ED]) each obtained the necessary institutional review board approvals prior to conduction of the study.

Study volunteers were recruited from the staff associated with the 2 study locations. All volunteered their time and did not receive any remuneration for his or her participation. All the stethoscopes were collected at the end of the study and returned to the sponsors, 3M Littmann and the Copper Development Association.

Stethoscopes

The study involved the evaluation of a manual stethoscope, which is classified as a mechanical device used to project the sounds associated with the heart, arteries, and veins and other internal organs and is classified as a class I device by the U.S. Food and Drug Administration (general controls). The device was exempt from the premarket notification procedure as specified in subpart E of part 807.²¹

The control instrument was a 3M Littmann Master Cardiology Stethoscope (3M Littmann, Brookings, SD) and was fabricated from stainless steel (chest piece), polyvinylchloride (PVC) tubing (binaural), aluminum (flexible ear tubes), G-10 epoxy (diaphragm), and urethane (snap on rim). The device used in the intervention arm of the trial was identical in design to the control instrument but was custom fabricated from antimicrobial copper alloys as defined by the U.S. Environmental Protection Agency. The alloys were C87610, silicone bronze (chest piece), and C70600, copper nickel (ear tubes, braiding over the PVC binaural tubing, and diaphragm). The sound performance of the copper diaphragm was sufficient to qualify the device as a stethoscope (Fig 1).



Fig 1. Antimicrobial copper reduced the concentration of bacteria on stethoscope surfaces. Four surfaces associated with a control Master Cardiology Stethoscope or an intervention stethoscope fabricated from AMCu alloys were sampled and assessed for the presence of bacteria as described in the methods. The total ACCs were determined as described in the methods. The mean microbial burden observed for individual stethoscopes with either SS cast bells (chest piece) or a bell cast from C87610 silicon bronze alloy and the respective mean values observed from 3 stethoscope surfaces (ear tubes, binaural tube, and diaphragm) are described. ACC, aerobic colony count; Al, aluminum; AMCu, antimicrobial copper alloy; PVC, polyvinyl chloride; SS, stainless steel.

Inclusion criteria

Participants alternated between using a control stethoscope or a copper alloyed stethoscope (study or copper stethoscope) that was selected for them by the study team. The devices were collected after approximately 1 week of use on 4 separate occasions whereupon they were measured for microbial burden as prescribed in the sampling methodology.

Study participants were attending, fellow, and resident physicians or Pediatric Nurse Practitioners. The trial was conducted at 2 independent sites. The first involved 14 participants and was conducted in the pediatric ED of a large tertiary care specialty hospital, MUSC, in Charleston, South Carolina. The second involved 7 clinical staff and was conducted in a variety of adult medical-surgical settings, including surgical intensive care and medical intensive care of another tertiary care specialty hospital, North Shore University Hospital, in Manhasset, New York.

Sampling methodology

Participants were not briefed on the antimicrobial properties of the copper alloyed materials and were blinded as to the true intent of the trial. They were initially consented by being asked to participate in a study to evaluate the performance of a modified design of the 3M Littmann Master Cardiology Stethoscope. On completing the study, participants were told that the microbial burden associated with the stethoscopes was assessed. All data were stored in a bespoke database (Filemaker, An Apple Subsidiary, Santa Clara, CA) and were analyzed with Epi-Info 7.0 (Centers for Disease Control and Prevention, Atlanta, GA). The microbial burden of each item sampled, either copper or noncopper, was calculated as an average from the number of samples collected for each surface sampled. The Kruskal-Wallis test was used to compare means. A P value $\leq .05$ was considered to be statistically significant.

The stethoscopes were used in 2 clinical settings. The first was at MUSC in the pediatric ED. Here the microbial burden was assessed from 4 common surfaces located on the device: the ear tubes, binaural tube, diaphragm, and flexible urethane rim (Fig 1, panel A). In the second clinical setting at North Shore University Hospital, the stethoscopes were used in a variety of adult medical-surgical settings, including surgical and medical intensive care units. Here only the burden associated with the urethane rim and the diaphragm of the study stethoscopes was evaluated. Sampling was conducted using 2.54 cm \times 5.08 cm wipes, premoistened with 200 μ L of sterile phosphate-buffered saline plus lecithin and Tween 80, stored aseptically in 50-mL screw-top conical tubes.²² For sampling the face of the stethoscope, a sterile glove was used and a sterile circular template was aseptically placed over the diaphragm allowing only the urethane rim to be wiped using a circular motion of 10 strokes. This process was repeated using another sterile glove and a sterile open circle template that only allowed the diaphragm to be sampled. For assessment of the binaural tube, a defined length (34 cm) was marked off on each stethoscope prior to distribution. This entire length was sampled using a sterile glove and wipe using 10 up and down strokes. The ear tubes were similarly marked off (13 cm) prior to distribution. Each ear tube was sampled independently, using a sterile glove and wipe, with both wipes being pooled in one tube for analysis. Sample wipes were processed by adding 3 mL of phosphate-buffered saline–lecithin–Tween diluent per wipe or tube and vortexed for 1 minute.²² The processed samples were plated (100 μ L) onto 5 separate media: Trypticase Soy Agar containing 5% Sheep Erythrocytes (BD Diagnostics, Sparks, MD), Mannitol Salt Agar (BD Diagnostics), MacConkey II Agar (BD Diagnostics), Bile Esculin Azide plus Vancomycin Agar (Hardy Diagnostics, Santa Maria, CA), and Spectra MRSA (Remel Products, Lenexa, KS). All plates

were incubated for 48 hours at 37°C except the Spectra MRSA plates, which were incubated for 24 hours as prescribed by the manufacturer. Colonies were counted and reported as colony forming units (CFU) per square centimeter. The limit of detection for the diaphragm was 3 CFU/cm², the urethane rim was 3 CFU/cm², the binaural tube was 0 CFU/cm², and the ear tubes was 1 CFU/cm².

Study power methodology

It was anticipated that the antimicrobial activity of copper alloys would reduce the bacterial bioburden associated with stethoscope surfaces within the health care setting by at least 2 orders of magnitude. Assuming that the bioburden would be reduced by at least 90% on the copper stethoscopes and powering the study to a 95% chance of detecting a difference, a total of 14 (7 and 7) microbial burden samples were required.

RESULTS

Stethoscope surfaces harbor substantial concentrations of bacteria

Microbial burden was assessed from 276 samples collected from 32 stethoscopes used by 21 clinical providers. Substantial bacterial concentrations were routinely recovered from the noncopper surfaces sampled as illustrated by comparing the concentration of bacteria found associated with the urethane rim used to secure the diaphragm to the chest piece of both devices. No significant difference was observed between the urethane rim of the control (mean value, 302 CFU/cm²; $n = 27$) and copper stethoscopes (mean value, 317 CFU/cm²; $n = 28$) used within the pediatric ED, and there was not a significant difference detected when comparing the mean burden observed from urethane rims from stethoscopes used among adult settings (control, 125 CFU/cm²; $n = 14$; copper, 83 CFU/cm²; $n = 14$) (Fig 1).

Antimicrobial copper reduced the concentration of bacteria on stethoscope surfaces

The mean concentration of bacteria recovered from the copper surfaces (3 surfaces sampled) from stethoscopes used in the pediatric ED was 11.7 CFU/cm². This concentration was found to be significantly lower than the collective concentrations recovered from similar surfaces from control stethoscopes (127.1 CFU/cm², $P < .00001$).

Considering the areas sampled separately revealed that the mean concentration of bacteria associated with the copper diaphragm (4 CFU/cm²) of the stethoscopes used in the pediatric ED was approximately 80-fold lower than the levels found associated with the urethane rim (317 CFU/cm²) of the same devices (Fig 2). A mean value of 16 CFU/cm² was found associated with the G10-epoxy/control diaphragm used with the stainless steel chest piece, whereas a mean value of 4 CFU/cm² was found associated with the copper diaphragm used with chest pieces cast from antimicrobial copper ($n = 55$). Although the difference between the 2 types of material was 4-fold, the difference between the 2 groups failed to reach significance ($P = .089$) (Fig 1). However, in the stethoscopes evaluated from the adult settings, the difference between the 2 materials was significant ($P = .0051$). Here the mean value associated with the epoxy diaphragm was found to be similar to that seen in the pediatric ED where a mean value of 10 CFU/cm² was recovered as compared with the mean value of 5 CFU/cm² that was recovered from the copper diaphragm in the adult setting ($n = 28$; Fig 2).

Two other touched surfaces were similarly assessed for burden in the pediatric ED. The first was the binaural tube that transmits the sound from the bell to the ears. Here the difference between the 2 materials was significant ($P < .0001$). A mean concentration

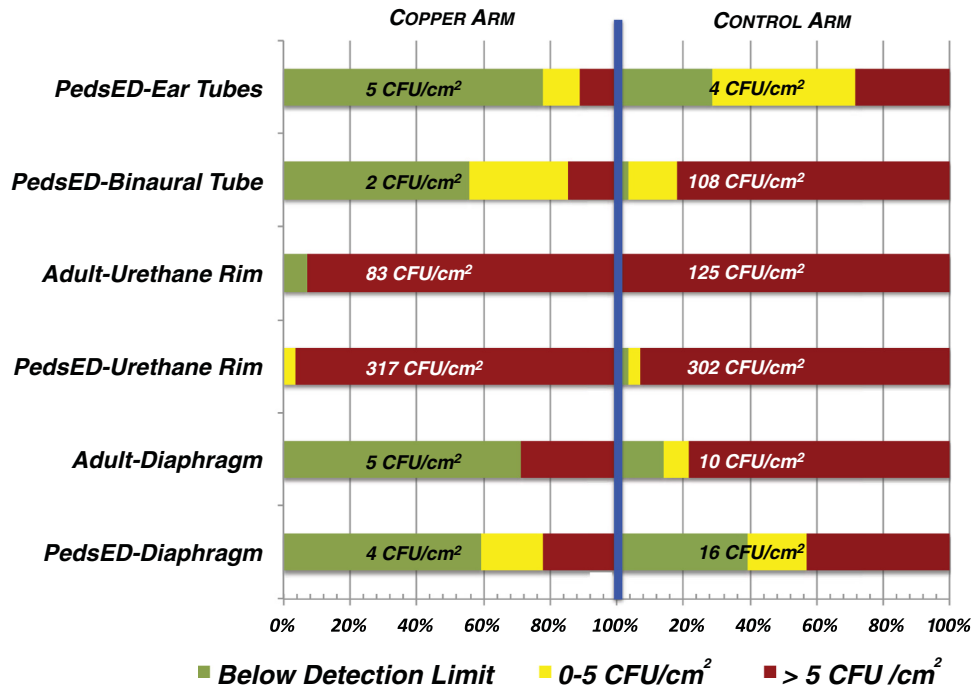


Fig 2. Copper surfaces were consistently able to limit the concentration of bacteria associated with the diaphragm, binaural tube, and ear tubes of stethoscopes used in pediatric and adult populations. The antimicrobial consistency of antimicrobial copper alloys was assessed by determining the frequency at which stethoscopes fabricated from U.S. Environmental Protection Agency–registered antimicrobial copper alloys were able to limit the concentration of bacteria associated with those surfaces to <5 CFU/cm². The frequency that the microbial burden was below the limit of detection (<5 CFU/cm²; green bars), above the limit of detection but less than the risk threshold of (<5 CFU/cm²; yellow bars), or exceeded the risk threshold (>5 CFU/cm²; red bars) was determined by scoring the number of occasions that the ACC for individual samples was observed (pediatric emergency division: n = 55; adult settings: n = 28). The limit of detection for the diaphragm was 3 CFU/cm², the urethane rim was 3 CFU/cm², the binaural tube was 0 CFU/cm², and the earpiece was 1 CFU/cm². ACC concentrations listed within category represent the mean concentration observed. ACC, aerobic colony count; *Adult*, adult settings; *CFU*, colony forming units; *PedsED*, pediatric emergency division.

of 108 CFU/cm² was recovered from the control binaural tube, whereas a mean value of 2 CFU/cm² was recovered from the binaural tube sleeved with braided antimicrobial copper (Fig 2). The second was the aluminum ear tubes, and in contrast with the other copper surfaces evaluated, they had a lower mean microbial burden (4 CFU/cm²) than that observed with the antimicrobial copper ear tubes (5 CFU/cm²); this difference achieved significance (*P* = .0020) (Fig 2).

Copper surfaces limited the frequency of recovery of mannitol-fermenting microbes from stethoscopes

Surfaces from stethoscopes used in the pediatric ED and adult settings were also assessed for the presence of mannitol-positive microbes (eg, staphylococci, including MRSA and streptococci;

enterococci, including vancomycin-resistant *Enterococcus* and gram-negative bacteria). All copper surfaces sampled were found to have a significantly reduced presence of mannitol-fermenting microbes than equivalent control surfaces. Of the 27 copper diaphragms assessed in the pediatric ED, only 18.5% of them were found to harbor mannitol-fermenting microbes, whereas 55.6% of the control G-10 epoxy disks were found to harbor mannitol-fermenting microbes (*P* = .005). In the adult setting the frequency was similar. Mannitol-fermenting microbes were only recovered from 21.4% of the sampled copper stethoscopes, whereas 78.6% of the controls yielded this microbe, with the difference being significant (*P* = .0025) (Table 1).

Sampling of the copper binaural tubes found that 26% of the stethoscopes carried mannitol-fermenting staphylococci that were recovered at a significantly reduced rate than that of the control (96.4%; *P* < .00001). Finally, 14.8% of the copper ear tubes were found

Table 1
Antimicrobial copper surfaces lessened the likelihood of recovering mannitol-fermenting staphylococci from stethoscope surfaces

Diaphragm: pediatric ED			Diaphragm: adult			Binaural tube: pediatric ED			Ear tubes: pediatric ED		
Control (n = 28)	Copper (n = 27)	<i>P</i> value	Control (n = 14)	Copper (n = 14)	<i>P</i> value	Control (n = 28)	Copper (n = 27)	<i>P</i> value	Control (n = 28)	Copper (n = 27)	<i>P</i> value
55.6%	18.5%	.005	78.6%	21.4%	.003	96.4%	25.9%	<.0001	50.0%	14.8%	.005
Snap on urethane rim: pediatric ED						Snap on urethane rim: adult					
Control arm (n = 28)			Copper arm (n = 27)			Control arm (n = 14)			Copper arm (n = 14)		
89.3%			92.6%			100%			78.6%		

NOTE. The frequency of recovery of mannitol-fermenting bacteria from mannitol salt agar from sampled copper and control surfaces was determined and assessed for significance. Each copper surface was found to have a significantly lower likelihood of recovering mannitol fermenters than the equivalent control surfaces sampled. Significance was not detected when comparing the recovery rate from the urethane snap rims. *Adult*, adult settings; *ED*, emergency division.

to yield this microbe, and again mannitol-fermenting staphylococci were recovered at a significantly reduced rate than that of the control (50% positive; $P = .005$).

MRSA was not recovered from any of the study stethoscopes. Vancomycin-resistant *Enterococcus* (control, urethane rim, adult) and a nonfermenting lactose gram-negative rod (control, binaural tube, pediatric ED) were only recovered once, respectively.

DISCUSSION

This study represents the first time a continuously active antimicrobial material was used to fabricate components of a stethoscope that was then evaluated for the ability of copper alloys to control or reduce the concentration of bacteria commonly associated with this ubiquitous medical device during routine use. Stethoscopes come in frequent contact with the unsanitized skin of patients and the hands, face, neck and clothing of health care workers. In contrast with hands, where an almost universal and prescriptive guideline governs sanitation between clinical encounters, a consistently applied routine of cleaning and disinfecting a stethoscope between patient encounters lacks adoption and application. In fact, it is generally recognized that health care providers rarely disinfect or clean their stethoscopes unless overtly soiled. Surveys have been conducted and reported that between 70% and 90% of physicians acknowledge that they fail to disinfect this ubiquitously used, noncritical clinical instrument after every patient encounter.^{12,19,23,24} Here, we learned that the microbial burdens associated with the urethane rims of the study and control stethoscopes were remarkable in that they were between 17- and 63-fold greater concentrations of aerobic colony counts (ACCs) thought to increase the risk of microbial transference for high-touch, noncritical environmental surfaces within clinical environments (5 CFU/cm²)²⁵ and were significantly higher (>5 CFU/cm²) than the burden thought to increase the likelihood of acquiring an health care-associated infection.³

The data reported here illustrate that the continuous antimicrobial activity of copper alloys used in the fabrication of this clinical device was successful for its ability to control and limit the concentration of bacteria on 3 touched surfaces. Collectively, the mean burden observed between the copper and stainless steel stethoscope groups achieved significance. Additionally, a comparison of the frequency distribution between the copper and control groups of the likelihood that a given surface would harbor a concentration of bacteria above which the risk of health care-associated infection acquisition or microbial transference would increase^{3,25} was conducted and similarly found to be significant for each of the surfaces compared. Antimicrobial copper surfaces were consistently superior compared with the surfaces assessed from the control stethoscopes (Fig 2). Collectively, only 22% of the copper diaphragms from the pediatric ED were found to harbor a concentration >5 CFU/cm², whereas 43% of the polypropylene diaphragms were found above this threshold. Similarly, in stethoscopes used in the adult setting, 79% of the control stethoscopes were found above this level, whereas only 29% of the copper diaphragms were found to exceed this level of risk (Fig 2). Copper was similarly found to be significantly antimicrobial for the binaural tube and ear tubes. Here the frequencies that a bacterial concentration was >5 CFU/cm² were 15% and 11% respectively. This was remarkable given that the mean concentration for the ear tubes was found to be significantly higher than their control, or aluminum, counterparts. However, scrutiny of the raw data revealed that within the data set for the copper ear tubes, there was one occasion where the concentration recovered from a single stethoscope was >100 CFU/cm². This outlier suggested a lack of consistently applied cleaning and disinfection standards for the surfaces of stethoscopes. Most previous studies evaluating the microbial burden of stethoscopes have been point

prevalence studies where workers have seen similar, substantial variation in the burden. In our study, copper was able to suppress this variability because its antimicrobial activity is continuous.

Further evidence supporting an inconsistent application of effective cleaning and disinfection plans for stethoscopes can be discerned from the mean values recovered from urethane rims, common to stethoscopes evaluated. The bacterial burdens recovered from the pediatric ED and adult settings all exceeded the risk threshold of 5 CFU/cm² by at least a factor of 20. This observation was also supported by the distribution analysis (Fig 2). It was found that 96% (copper arm) and 93% (control arm) of the urethane rims evaluated from the pediatric ED and 93% (copper arm) and 100% (control arm) of the samples from adult settings exceeded this threshold (Fig 2).

The results here confirm the potential infectious risks associated with stethoscopes and hands of physicians after physical examination recently described by Longtin et al.²⁶ They found a median ACC concentration of 3.6 CFU/cm² for the diaphragm of stethoscopes.²⁶ This value was similar to the median ACC determined (7.5 CFU/cm²; interquartile range, 15) from samples collected from the G-10 epoxy diaphragm of the control stethoscopes used in the adult settings and pediatric ED. However, their median ACC value for the binaural tube was 37 times lower (0.7 CFU/cm²) than the median ACC observed (26 CFU/cm²; interquartile range, 63.5) from samples recovered from the PVC binaural tubes in our study. One possible explanation accounting for the difference between this study and the results of Longtin might be attributed to the frequency with which stethoscopes were sampled. Longtin et al sampled each instrument immediately on completion of an examination of a single patient,²⁶ whereas here it was after a prescribed, generally a >1-week period, where the number of patients examined varied. Nevertheless, both studies confirm that stethoscopes harbor a substantial microbial burden that requires consideration as a potential reservoir of infectious agents on par with that of the dominant hand of health care workers.

There were limitations to this study. First, there was the absence of a matched assessment of bacterial burden from the stethoscopes used between the adult settings and pediatric ED. However, given the similarities observed between the bacterial burden recovered and types of microorganisms from the equivalent urethane rims and diaphragms, this limitation was not considered to have biased the conclusion that antimicrobial copper was effective at controlling the inherent burden recovered from stethoscopes in both clinical circumstances.

A second limitation is that although MUSC (pediatric ED) and NHUS (adult settings) have recommendations for the routine cleaning and disinfection of stethoscopes between patient encounters, the study intentionally did not inquire as to the routine cleaning and disinfection practiced by the study participants. It was thought, that, given the longitudinal nature of the study and the likelihood that study participants often overestimate compliance rates to infection control recommendations and guidelines, it was likely prudent not to bias the true intent of the study, assessing the effectiveness of copper for its ability to passively and without intervention control the level of bacteria associated with surfaces of stethoscopes. Moreover, in the adult settings, transmission by caregivers is considered a likely contributor to an increased risk of health care-associated infection acquisition as a consequence of the acuity and stochastic nature of care.

A third limitation was that the burden was assessed after the stethoscope was used for a minimum of a week. Estimated patient encounters were reported by the study participants; however, it was acknowledged by the participants that the values were only estimates, and therefore imprecise. The number of patient contacts per hour has been reported in the literature at having a mean of 21.²⁷

Additionally, although the study instruments provided to the participants were cleaned and disinfected subsequent to sampling, there was no way to assess the length of time the bacteria were present on the surfaces when the devices were evaluated.

A fourth limitation was that the presence of viruses and fungi was not assessed. Antimicrobial copper alloys have been reported to inactivate viruses, specifically influenza, rhinovirus, rotavirus, and norovirus,²⁸⁻³⁰ and many medically relevant fungi.³¹ Although their presence was not specifically measured, it was assumed that their concentration would have been similarly reduced to values reported in the literature.

Significantly lower concentrations of bacteria were routinely recovered from stethoscopes fabricated from the continuously active antimicrobial intervention. Our results suggest that fabrication of this common and regularly used medical device in concert with a bundled infection control program would likely limit the spread of infectious agents within health care. Copper and its alloys have been used for >5 millennia as a natural disinfecting agent and sanitizer. The mechanism of its antimicrobial activity is attributed to the inherent quantum action of copper. It continuously kills bacteria as a consequence of multiple, independent processes, leading to rapid and irreversible lethal catalytic cascades commencing with the collapse of the membrane potential required from the bacterial cytoplasmic membrane, resulting in cytoplasmic leakage and transport of copper into the cell, with subsequent spontaneous generation of substantial concentrations of reactive oxygen species ultimately resulting in the destruction of the nucleic acids of the microbe.³² Consequently, the incorporation of copper alloys offers a passive solution to an intrinsically challenging problem facing health care and infection control practitioners.

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