Antimicrobial Copper Surfaces for Reducing Healthcare-associated Infection Risk

Antimicrobial copper surfaces (e.g., countertops, door handles, light switches, bedrails) used in healthcare settings are made from copper alloys or composite materials infused with copper oxides, both of which release copper ions that are toxic to microorganisms. Antimicrobial copper surfaces are intended to supplement standard hygiene practices to reduce healthcare-associated infection (HAI) risks. Antimicrobial copper surfaces may provide sustained antimicrobial effects independent of human activity and pose minimal toxicity risks, but cost more than standard surfaces.

The Evidence Bar™

Evidence is somewhat favorable in ICU setting

A meta-analysis of 3 randomized controlled trials (RCTs) and 1 additional nonrandomized study show that antimicrobial copper use on high-touch surfaces can reduce HAI rates in the intensive care unit (ICU) setting. However, evidence is inconclusive (too few data) for other clinical settings, for particular patient groups, or for preventing specific infection types. Large, prospective, multicenter comparison studies are needed to address these gaps. Three clinical guidelines offer mixed recommendations use of these surfaces.

Evidence limitations. Three RCTs synthesized in a meta-analysis and a nonrandomized study consistently show that antimicrobial copper use on high-touch surfaces can reduce overall HAI rates in the ICU setting. However, the evidence has some major limitations. Two nonrandomized studies are at risk of bias from lack of randomization, blinding, and/or single-center focus. Furthermore, findings may not fully generalize across clinical settings because of differences in intervention protocols and patient demographics. The studies also provide too few data to draw conclusions on specific pathogens or infection types. Large, multicenter studies are needed to validate antimicrobial copper use in specific clinical settings and circumstances (e.g., outbreaks versus routine care). Economic studies weighing additional costs of copper surfaces and benefits from HAI reduction would also be useful to guide evidence-based decisions.

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Executive Summary

Conclusions

One systematic review with meta-analysis and two additional comparative studies were assessed pertaining to copper surface use in ICU and nursing home care settings.

- ICUs: A meta-analysis of 3 RCTs (Pineda et al. 2017, n = 1,569) found that antimicrobial copper used on “high touch” surfaces (e.g., workstations, doorknobs, handrails) reduced HAI risk (incidence rate ratio [IRR]: 0.74, 95% CI: 0.56 to 0.97, p = 0.03). One prospective nonrandomized study (Marik et al. 2020; 21,059 patient-days) also reported HAI incidence reduction at a single hospital after ICU relocation to a building equipped with copper-enhanced ECOUS Preventive/ Biocidal Surface™ products (IRR: 2.9, 95% CI: 1.5 to 5.7, p = 0.0002).

- Nursing homes: One prospective nonrandomized study (Zerbib et al. 2020, n = 556) comparing residential wings at a single nursing home over 17 months reported 2 keratoconjunctivitis outbreaks in the control wing and none in the wing equipped with antimicrobial copper doorknobs and handrails. However, an influenza outbreak affected mostly patients in the antimicrobial copper wing (relative risk: 21.0, 95% CI: 2.8 to 158.2), and a norovirus outbreak affected the same number of patients in each wing.

Evidence

Search dates: January 1, 2015, to March 6, 2020. We reviewed full text of 1 systematic review with meta-analysis and 2 nonrandomized cohort studies reporting on 2,125 patients and 21,059 patient days.

- To avoid double-counting patients, we reviewed the most comprehensive or recent of any 2 overlapping studies. We excluded studies of porous materials or textiles.

- 1 systematic review (Pineda et al. 2017, 3 RCTs, n = 1,569) compared HAI and mortality rates in ICUs equipped with standard high-touch surfaces or antimicrobial copper high-touch surfaces.

- 1 prospective nonrandomized study (Zerbib et al. 2020, n = 556) compared HAI incidence over 27 months in 2 residential wings equipped with standard (control) or antimicrobial (experimental) copper doorknobs and handrails at a single nursing home.

- 1 prospective nonrandomized study (Marik et al. 2020; 21,059 patient-days) compared HAI rates in ICUs at a single hospital before and after relocation to a new building equipped with ECOUS Preventive/ Biocidal surfaces.

- Evidence limitations. Some results are at risk of bias from lack of randomization or single-center focus and may not fully generalize across clinical settings because of differences in intervention protocols, clinical settings, and patient demographics. A single study reported on specific pathogens, and a single study reported on infection type (e.g., urinary, bloodstream, catheter-related).

Guidelines

Searches of PubMed, EMBASE, and other web-based resources identified three relevant documents published between January 1, 2015, and March 6, 2020.

- Association of periOperative Registered Nurses. Design and Maintenance of the Surgical Suite. 2018. The guideline states: “self-disinfecting surfaces (eg, copper, silver, antimicrobial surfactant, quaternary ammonium salt) may be used in the surgical suite. [Conditional Recommendation].”

- International Society for Infectious Diseases. Guide to Infection Control in the Hospital: Chapter 56: New Technologies in Infection Prevention. 2018. This document discusses multiple technologies, including antimicrobial surfaces and textiles, cleaning robots, fluorochrome contamination markers, and automated hand-hygiene monitors. Regarding copper surfaces, the document includes the following: “Copper has also been used in clinical environments, though with conflicting results in terms of ability to prevent hospital acquired infections. Copper coating of hospital surfaces carries a substantial financial investment.”

- Public Health Ontario. Best Practices for Environmental Cleaning for Prevention and Control of Infections in All Health Care Settings. 2018. The guideline states “there is insufficient evidence to recommend for or against the installation of copper surfaces.”
Table of Contents

Executive Summary .................................................................................................................................. 2
Background ............................................................................................................................................. 4
Clinical Guidelines ............................................................................................................................... 5
Clinical Literature ................................................................................................................................ 6
Selected Resources and References ..................................................................................................... 9
The Evidence Bar™ ............................................................................................................................ 12
Policy Statement .................................................................................................................................. 12

Tables

Table 1. Systematic Review .................................................................................................................. 7
Table 2. Clinical Trials ......................................................................................................................... 8
Background

Healthcare-associated Infections

According to the U.S. Centers for Disease Control and Prevention (CDC), HAIs occur in approximately 3% of patients treated in U.S. hospitals. About 687,000 HAIs occur in U.S. acute care hospitals annually, and nearly 72,000 patients with HAIs die during their hospitalizations. More than 50% of HAIs occur outside ICUs. Hospital surfaces serve as a reservoir for pathogenic microbes and may play a key role in the transmission of HAIs. Pathogens may persist for weeks or months on common hospital surfaces, such as bedrails, bed trays, call buttons, doorknobs, faucet handles, or medical devices. Pathogens on contaminated surfaces can spread directly to patients by touch, directly or indirectly through a healthcare worker. (For more information, see the Medscape article Hospital-Acquired Infections.)

Environmental cleanliness and hand hygiene are essential components of HAI control. Standard cleaning procedures include wiping work surfaces with detergents and disinfectants (e.g., alcohols, bleaches, quaternary ammonium salts, phenol) and ultraviolet light–emitting devices. However, most standard cleaning methods do not provide sustained disinfection, and hospital surfaces may again become contaminated with pathogens shortly after cleaning. Hand hygiene, another key component of reducing HAI risk, relies on proper technique and compliance, which may be poor. Despite widespread adoption of standard hygiene procedures, HAIs continue to have a large impact on patient care and associated healthcare costs. (For more information, see the CDC infection control guidelines and the review Economic Burden of Healthcare-Associated Infections: An American Perspective.)

To address the challenges of HAIs, some hospitals have implemented enhanced hygiene technologies that seek to limit reliance on human factors, such as automated hydrogen peroxide vaporizers, ultraviolet irradiators, ozone generators, and cleaning robots. Antimicrobial copper surfaces and textiles have also emerged as a possible means of reducing HAI risk; this report focuses on the use of copper alloys or copper oxide laced composites on hard, nonporous surfaces in hospitals and residential healthcare facilities. (For information on antimicrobial copper textiles, see the 2019 ECRI Custom Rapid Response Antimicrobial Copper Oxide–infused Textiles for Reducing Healthcare-associated Infection Risk.)

Antimicrobial Copper Surfaces

The antiseptic properties of copper and other heavy metals (e.g., gold, silver, lead, zinc) have been known since antiquity, and the biocidal activity of copper ions was recognized as early as the 19th century. However, the exact nature of copper’s antimicrobial action remains unclear and likely involves several mechanisms, including membrane permeabilization, disruption of enzyme catalytic sites, and production of reactive oxygen species through copper oxidation. At sufficient concentration, copper ions are toxic to all life forms; however, regular contact with hard, nonporous copper or copper oxide surfaces is harmless to humans and animals. In contrast, >99% of bacteria deposited on metallic copper surfaces die within two hours. Limited research studies have also shown that metallic copper surfaces inactivate several types of viruses, including some coronavirus, influenza, and norovirus types. (For more information, see the review Metallic Copper as an Antimicrobial Surface.)

Antimicrobial copper materials used in healthcare applications include copper alloys containing 60.0% to 99.9% copper and copper oxide-impregnated material (e.g., EOS™ Preventive/Biocidal Surface; EOS™ Inc., Norfolk, VA, USA) containing 16% copper and made by combining copper powder additives and a polymeric substrate. The two types of surfaces have similar indications for hospital use but different physical and chemical properties. Possible antimicrobial copper alloy surfaces include a broad range of metallic components, such as IV poles, countertops, grab bars, tray tables, door hardware, carts, handles, sinks, bedside tables, railings, faucet levers, and switch plates. Copper-oxide-impregnated surfaces can be made from a variety of materials in the form of nonporous hard surfaces. The end products made from copper-oxide-impregnated solid surfaces include countertops, bed rails, sinks, shower pans, and foot boards. (For more information, see the Environmental Protection Agency [EPA] Copper Alloy Stewardship.)
In the United States, antimicrobial copper alloys and copper oxide composites are subject to EPA registration and to regulations governing product testing, manufacturing, and labeling. According to EPA, products registered as antimicrobial copper alloys have been shown, when regularly cleaned, to:

- Continuously reduce bacterial contamination (Staphylococcus aureus, Enterobacter aerogenes, methicillin-resistant Staphylococcus aureus, Escherichia coli 0157:H7, Pseudomonas aeruginosa, and vancomycin-resistant Enterococcus faecalis), achieving 99.9% reduction within two hours of exposure.
- Kill greater than 99.9% of Gram-negative and Gram-positive bacteria within two hours of exposure.
- Deliver continuous and ongoing antibacterial action, remaining effective in killing greater than 99.9% of bacteria* within two hours, even after repeated wet and dry abrasion and recontamination.
- Kill greater than 99.9% of bacteria within two hours, and continue to kill more than 99% of bacteria* even after repeated contamination.

According to EPA, when regularly cleaned, the Antimicrobial Cupron Enhanced EOS Surface (now ECOUS Preventive/Biocidal Surface):

- Continuously reduces bacterial contamination (Staphylococcus aureus, Enterobacter aerogenes, Methicillin-Resistant Staphylococcus aureus, Escherichia coli 0157:H7, and Pseudomonas aeruginosa), achieving 99.9% reduction within two hours of exposure.
- Kills greater than 99.9% of Gram-negative and Gram-positive bacteria within two hours of exposure.
- Kills greater than 99.9% of bacteria (Staphylococcus aureus, Enterobacter aerogenes, Methicillin-Resistant Staphylococcus aureus, Escherichia coli 0157:H7, and Pseudomonas aeruginosa) within two hours and continues to kill 99% of bacteria* even after repeated contamination.
- Helps inhibit the buildup and growth of bacteria (Staphylococcus aureus, Enterobacter aerogenes, Methicillin-Resistant Staphylococcus aureus, Escherichia coli 0157:H7, and Pseudomonas aeruginosa) within two hours of exposure between routine cleaning and sanitizing steps.

The International Copper Association and its U.S. affiliate, the Copper Development Association, have established an Antimicrobial Copper Cu+ mark that certifies EPA registration in the United States or equivalent, experimentally proven antimicrobial activity for copper alloys. The International Copper Association and the Copper Development Association are nonmarket organizations that jointly promote the correct and efficient use of copper and its alloys and provide policy and market development guidance for the copper industry. (For more information, see the 2016 ECRI Emerging Technology Report Antimicrobial Copper Surfaces for Reducing Hospital-acquired Infection Risk.)

Clinical Guidelines

Searches of PubMed, EMBASE, and other web-based resources identified three relevant guidelines published between January 1, 2015, and March 6, 2020:

- Association of periOperative Registered Nurses. Design and Maintenance of the Surgical Suite. 2018. The guideline states: “self-disinfecting surfaces (eg, copper, silver, antimicrobial surfactant, quaternary ammonium salt) may be used in the surgical suite. [Conditional Recommendation].”
- International Society for Infectious Diseases. Guide to Infection Control in the Hospital: Chapter 56: New Technologies in Infection Prevention. 2018. This document discusses multiple technologies, including antimicrobial surfactex and textiles, cleaning robots, fluorochrome contamination markers, and automated hand-hygiene monitors. Summary recommendations are as follows:

  New technologies may have a place in infection prevention programs as part of a multimodal approach, assuming that sufficient resources exist to ensure the basic components of the improvement strategy are in place.

  The available data and experience with these new technologies supports their use as an adjunct to existing, evidence based, infection prevention practices. They should not be used to replace traditional cleaning processes or hand hygiene monitoring strategies.
On copper antimicrobial surfaces, the document states:

Several antimicrobial coatings are under pre-clinical study for their potential application to surfaces in healthcare centers.

Of these coatings, copper has been studied most extensively. It has been shown to decrease bioburden on surfaces, primarily in short term studies.

Copper has also been used in clinical environments, though with conflicting results in terms of ability to prevent hospital acquired infections.

Copper coating of hospital surfaces carries a substantial financial investment.

Long term development of bacterial resistance to copper is a theoretical concern. A 24 week study of bacteria exposed to copper did not find evidence of resistance.

— Public Health Ontario. Best Practices for Environmental Cleaning for Prevention and Control of Infections in All Health Care Settings. 2018. The guideline states “there is insufficient evidence to recommend for or against the installation of copper surfaces.”

Clinical Literature

We searched PubMed, EMBASE, the Cochrane Library, and selected web-based resources for clinical studies published between January 1, 2015, and March 6, 2020, and reporting on HAI rates in clinical centers equipped with hard antimicrobial copper surfaces. We excluded studies of copper-enhanced bedding and linens and studies that reported only on microbial burden, a surrogate of infection risk that may not accurately reflect HAI risks depending on clinical practices and patient characteristics. We identified and reviewed full text of three studies, as follows:

— 1 systematic review (3 RCTs and 1 nonrandomized comparison study, n = 1,569) compared HAI and mortality rates in clinical centers equipped with standard or antimicrobial copper “high touch” surfaces (e.g., doorknobs, handrails, workstations) in ICUs.(1)

— 1 prospective nonrandomized study (n = 556) compared HAI incidence over 27 months in 2 nursing home residential wings equipped with standard or antimicrobial copper doorknobs and handrails.(2)

— 1 prospective nonrandomized study (21,059 patient-days) compared HAI rates in ICUs at a single hospital before and after relocation to a new building equipped with commercial copper-enhanced surfaces (ECO Preventive/ Biocidal Surface).(3)

Table 1 summarizes the systematic review. Table 2 summarizes clinical studies. We reviewed full-text articles available with open access. We also identified but excluded three publications(4-6) and a prior ECRI report:

— 1 ECRI Emerging Technology Report (2016) (This report updates that report.)

— 2 systematic reviews whose included studies overlapped with the systematic review we included, but had fewer studies and patients

— 1 clinical study reporting on concurrent copper-enhanced hard surface and linen adoption at a clinical center

Evidence limitations. Three RCTs synthesized in a meta-analysis and a nonrandomized study consistently showed that antimicrobial copper use on high-touch surfaces can reduce overall HAI rates in the ICU setting. However, the evidence is subject to some major limitations. Two additional nonrandomized comparison studies are at risk of bias from lack of randomization, blinding, and/or single-center focus. Furthermore, findings may not fully generalize across clinical settings because of differences in intervention protocols and patient demographics. Studies also provide too few data to draw conclusions on specific pathogens or infection types. Large, multicenter prospective comparison studies are needed to validate antimicrobial copper use in specific clinical settings and circumstances (e.g., outbreaks versus routine care). Economic studies weighing additional costs of copper surfaces and benefits from HAI reduction would also be useful to guide evidence-based decisions.
# Table 1. Systematic Review

<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Review Purpose</th>
<th>Resources Searched and Inclusion Criteria</th>
<th>Results as Reported by Authors</th>
<th>Authors’ Conclusions</th>
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<tr>
<td>Pineda et al. 2017(1)</td>
<td>“To assess the role of copper surfaces on the reduction of healthcare-associated infections [HAIs].”</td>
<td>Searched MEDLINE, EMBASE, LILACS, Cochrane CENTRAL, EBSCO, and Epistemonikos between 2000 and April 2016 for any studies reporting on infection risk reduction with antimicrobial copper surfaces. Included 3 randomized controlled trials reporting on HAI rates in intensive care units (n = 1,569).</td>
<td>“Overall, the introduction of antimicrobial copper alloys surfaces in high-touch surfaces reduced the incidence of HAIs by around a quarter (IRR 0.74, 95% CI 0.56 to 0.97; p = 0.03; three trials; 1569 participants; moderate quality of the evidence [GRADE Working Group strength of evidence (SOE)]).”</td>
<td>“Three studies the total number of participant’s deceased in both arms and only one of them reported the HAIs related mortality rate, founding no difference between both groups (IRR 1.17, 95% CI 0.3 to 4.36; p = 0.81) [GRADE SOE: Very Low].”</td>
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<tr>
<td>Reviewed full text</td>
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## Table 2. Clinical Trials

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<th>Reference</th>
<th>Number of Patients</th>
<th>Treatment</th>
<th>Results</th>
<th>Conclusions Presented in the Abstract</th>
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<tbody>
<tr>
<td>Marik et al. 2020(3)</td>
<td>United States</td>
<td>Prospective, nonrandomized study of 3 intensive care units (ICUs) (general, neuro-intensive, and burn trauma units) at a single hospital (21,059 patient-days)</td>
<td>Standard care before (9,890 patient-days) and after (11,169 patient-days) ward relocation to a new facility equipped with EOSCu Preventive/Biocidal Surface on workstations, bedside and vanity tables, bathroom fittings, bedrails, and door handles</td>
<td>“There was a significant reduction in the total number of HCAIs [healthcare associated infections] (3.9 per 1000 vs 1.3 per 1000 patient-days); incidence rate ratio: 2.9 (95% CI: 1.5–5.7; P = 0.0002), and infections due to C. difficile (2.4 per 1000 vs 0.7 per 1000 patient-days; incidence rate ratio: 3.3; 95% CI: 1.4–8.7; P = 0.002) in period 2 compared with period 1. The rate of infection due to CLABIs [central line associated bloodstream infections] and CAUTIs [catheter associated urinary tract infections] did not differ between these two time-periods. “Our data suggest that copper-oxide-treated hard surfaces reduced the rate of infections due to <em>C. difficile</em>, however, important confounders cannot be excluded [e.g., new ventilation system].”</td>
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CLINICAL EVIDENCE ASSESSMENT
Antimicrobial Copper Surfaces for Reducing Healthcare-associated Infection Risk

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<tr>
<th>Reference</th>
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<th>Treatment</th>
<th>Results</th>
<th>Conclusions Presented in the Abstract</th>
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</table>
| Zerbib et al. 2020(2)  | France Reviewed full text | Prospective, nonrandomized study of 556 elderly residents at a single nursing home | Housing in a residential wings equipped with standard (n = 289) or antimicrobial copper (n = 267) door handles, handrails, and support bars | “Four outbreaks occurred during the study period [February 1, 2015 to June 30, 2016]: 1 influenza, 1 keratoconjunctivitis, and 2 gastroenteritis outbreaks. The risk of hand-transmitted health care-associated infection was significantly lower in the area equipped with copper surfaces (RR 0.3, 95% CI 0.1-0.5).”
“The pathogens identified were Influenza A virus for outbreak 1, and Norovirus for outbreak 4. No germ could be positively identified for outbreaks 2 (keratoconjunctivitis) and 3 (gastroenteritis).”
“For outbreak 1 (flu), the risk of infection was significantly increased among patients residing in the wing equipped with copper surfaces [relative risk (RR): 21.0 (95% confidence interval (CI):2.8 to 158.2)]. For outbreaks 2 [RR: 0.1 (95% CI: 0.01-0.5)] and 3 [RR: 0.1 (95% CI: 0.02 to 0.9)] (keratoconjunctivitis and gastroenteritis), the risk of infection was significantly lower in the wing equipped with copper surfaces.”
“Finally, for outbreak 4 (gastroenteritis), there was no significant difference in the risk of infection between the wing equipped vs the wing not equipped with copper surfaces.” | “In our study, copper was shown to reduce the incidence of hand-transmitted health care-associated infections and could represent a relatively simple measure to help prevent HAIs in nursing home.” |

Selected Resources and References

Search Summaries

The following databases were used to identify the literature and related materials.


Search Strategy: copper surfaces; healthcare associated infections; infection control

Universal Medical Device Nomenclature System (UMDNS) Codes:

Results: We identified six related reports and no records in the Health Devices Alerts database.


We did not identify any results in the Health Devices Alerts database. [searched 2016 Jan 1, through 2020 Mar 6].


Search Strategy:

- #1 copper[tiab] AND (antibacterial OR antimicrobial* OR bacteria* OR bioburden OR clean* OR decontaminat* OR disinfect* OR infection* OR infectious OR microbial*)
- #3 facility OR facilities OR “health care” OR healthcare OR hospital OR hospitalis* OR hospitaliz* OR hospitals OR “intensive care unit” OR ICU OR ICUs OR ward OR wards
- #4 #1 AND #2 AND #3

Results: we identified 32 records.


Search Strategy:

- #1 copper:ti,ab AND (antibacterial OR antimicrobial* OR bacteria* OR bioburden OR clean* OR decontaminat* OR disinfect* OR infection* OR infectious OR microbial*)
- #2 fomites/de OR bar:ti,ab OR bars:ti,ab OR bed:ti,ab OR beds:ti,ab OR cart:ti,ab OR carts:ti,ab OR chair:ti,ab OR chairs:ti,ab OR counter-top*:ti,ab OR countertops:ti,ab OR door*:ti,ab OR handle*:ti,ab OR faucet*:ti,ab OR fomite*:ti,ab OR pole:ti,ab OR poles:ti,ab OR rail:ti,ab OR railing*:ti,ab OR rails:ti,ab OR room:ti,ab OR rooms:ti,ab OR seat:ti,ab OR seats:ti,ab OR sink:ti,ab OR sinks:ti,ab OR surface*:ti,ab OR table*:ti,ab
- #3 facility OR facilities OR “health care” OR healthcare OR hospital OR hospitalis* OR hospitaliz* OR hospitals OR “intensive care unit” OR ICU OR ICUs OR ward OR wards
- #4 #1 AND #2 AND #3

Results: We did not identify any unique records.

Guidelines and Standards [searched January 1, 2015, through March 6, 2020].

Search Strategy: antimicrobial surfaces; copper surfaces; environmental cleaning; healthcare association infections; hospital surfaces; infection control

Results: We identified three relevant documents:

Antimicrobial Copper Surfaces for Reducing Healthcare-associated Infection Risk


Selected Web Resources. [searched March 6, 2020].

Manufacturers

Other Selected Web Resources
- Barnes S. Antimicrobial surfaces as a tool to support HAI prevention. 2017 Feb 13.
- Canadian Agency for Drugs and Technologies in Healthcare (CADTH). [cited 2020 Mar 6].
  - Antimicrobial copper surfaces in hospital settings: clinical effectiveness. [last updated 2016 Sep 30].
  - Environmentally active agents for infection prevention in health care facilities: Clinical effectiveness, cost-effectiveness, and guidelines. [last updated 2015 Apr 29].
  - HAI data. [cited 2020 Mar 6].
  - Types of healthcare-associated Infections. [cited 2020 Mar 6].
- Environmental Protection Agency (EPA). The antimicrobial testing program hospital disinfectant and tuberculocidal products tested or pending testing. 2018 Mar.

References Reviewed (PubMed, EMBASE, and Cochrane search dates were January 1, 2015, through March 6, 2020)

The Evidence Bar™

ECRI developed The Evidence Bar™ to provide a visualization of our judgment about the balance of benefits and harms of the technology after assessing the available published clinical evidence in light of key outcomes and comparisons of interest. The Evidence Bar™ rubric shows five possible choices for our expert judgment. After review and analysis of evidence identified through literature searches conducted by master’s level medical librarians, ECRI research analysts, extensively trained in methods of evidence assessment, weigh potential benefits and harms of a technology to arrive at their expert judgment.

Policy Statement

This Clinical Evidence Assessment addresses a specific inquiry from an ECRI member about a particular brand-name healthcare product and its safety and efficacy. The information contained in this Clinical Evidence Assessment is highly perishable and reflects the available information we identified at the time this Clinical Evidence Assessment was prepared. The comments and opinions expressed were accurate to the best of our knowledge at the time of preparation, but are subject to change if and when new information is published. Information was identified through searches conducted by medical librarians and compiled by research analysts from the available, published peer-reviewed clinical literature, conference proceedings, regulatory agencies, trade publications, World Wide Web sites, and manufacturer information. The Clinical Evidence Assessment summarizes the identified clinical literature (i.e., human studies) and other information that we deemed relevant to the topic within the search dates noted in the clinical literature description. The clinical studies were reviewed by ECRI in one or more of the following forms: full published articles, article abstracts, FDA summaries of safety and effectiveness data, and/or conference abstracts or posters. Conference abstracts and posters of clinical studies typically do not provide complete information by which to assess study design or validity of the final published results of a study. Therefore, results presented in these sources of information must be considered with caution. Any and all product claims described in this Clinical Evidence Assessment were made by the manufacturer in materials it has presented or published about its products. ECRI’s description of these claims in this Clinical Evidence Assessment does not imply any endorsement or agreement. This Clinical Evidence Assessment is not intended to provide specific guidance for the care of individual patients. ECRI makes no express warranties or any implied warranties regarding the products discussed in this Clinical Evidence Assessment, including any implied warranty of merchantability or fitness for a particular use. ECRI assumes no liability or responsibility for how members use the information, comments, or opinions contained in Clinical Evidence Assessments. All material in this Clinical Evidence Assessment is protected by copyright, and all rights are reserved under international and Pan-American copyright conventions.