Theraworx Protect: Clinical Value, Mechanism of Action, and Evidence

Supplier Submission

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Introduction

Core Product - Avadim Health's flagship clinical product is Theraworx® Protect, a novel, advanced skin hygiene product that has been clinically proven, published and documented effective in several clinical areas of infection prevention, skin integrity and barrier maintenance. It is a combination of 18 different ingredients which are designed to enhance and preserve the natural protective elements of the stratum corneum, the outer layer of the epidermis, as described in detail under the Mechanism of Action Section.

Theraworx Protect formulation focuses in on the pathophysiology and skin science around epidermal pH. This gives Theraworx Protect an efficacy and safety profile unlike other products in the market. Theraworx is published in the American Journal of Infection Control as non-inferior to 4% CHG at the 10 minute and 6 hour markers while being safe for use in mucosa thus allowing for use in the meatus, perineum, and on the face.

The combination of Safety and Efficacy allows for Theraworx Protect to fill several current Gaps in Care that can lead to infections and skin breakdown. Most notable is managing pathogens when and where CHG can't be used filling Gaps in Care in Pediatric, and Adult Hospitals, and Post-Acute Settings as part of the following bundles:

- CAUTI Bundle: for Insertion and Maintenance of Indwelling Catheters and Pericare to Reduce HAIs. CHG Contraindicated for use in Mucous Membranes.
- CLABSI & SSI Bundle for Pediatric and Adult Hospitals
    - ICU Bathing Standardization 1 product that is safe and effective to be used head - toe.
    - CHG bathing alternative for ICU & surgical patients who cannot use CHG. Peds: Birth to 2 months & Hema/Onc and adults with Skin Conditions & Allergies
- Skin Integrity and Barrier Maintenance Bundle: Topical application to aid in the prevention and assist in healing of compromised skin due to Moisture Associated Skin Damage (MASD) and similar skin issues

Product Configurations - Theraworx Protect is available in multiple configurations to help support nursing practice: a 2 pack of pre-moistened disposable wipes, an 8 Pack of pre-moistened disposable wipes, an 8 oz and 4 oz foamer, a 2 oz spray, and our UPAK with 60ct wipes and 4 oz foam for at home use. Samples available.

Mechanism of Action

To fully understand the benefits of Theraworx Protect and the science behind it, it is important to know the most recent advances in the knowledge of the protective elements of the stratum corneum, the outer layer of the skin. The following summary provides a detailed recap of this science. The key protective elements of the outer layer of the epidermis, the stratum corneum, have been the subject of substantial research over the last 50 years.

It was not until the 1960's that research dermatologists were able to overcome faulty staining methods and initiate intensive study of this tissue, and to begin to gain understanding of its basic structure, and its relative importance to overall survival and protection against the many environmental challenges of life in a terrestrial environment. Understanding of the stratum corneum's basic "bricks and mortar" structure, with the enucleated terminal keratinocytes, called corneocytes, surrounded by a unique and biochemically active lipid matrix to a depth of approximately 28 microns, has increased steadily. So too has the study of the basic physiology of this tissue, and the many biochemical processes that occur within it, to the point where we now understand the criticality of maintaining the basal low pH condition of this tissue. Normal adult human stratum corneum is at a pH of about 4.9, more than 100 times more acidic than neutral pH of 7, and it is this acidic environment that is critical to several of the most significant protections to the body provided by this outer layer of the skin. Specifically:

1. The "acidic mantle" of the stratum corneum is naturally antimicrobial, for several reasons. The nominal low pH of this tissue is a perfect environment for the multitude of various bacteria, yeast, and fungi that inhabit the outer layer of the stratum corneum, and comprise the normal healthy microbiome of the skin. The importance of this normal microbiome to overall health, both on the skin, in the gut, brain, and throughout the human body, is now the subject of significant research. The healthy skin microbiome, thriving in its optimal low pH environment, competes successfully for nutrition and space on the skin surface, protecting against invasion by pathogens and resulting infections. This healthy microbiome creates acidic metabolites which reinforce its own healthy low pH environment, and also secrete substances which are naturally antimicrobial to pathogens. But when pH rises, the normal healthy microbiome suffers, and pathogenic organisms begin to thrive. It is therefore essential that health care facilities select topical skin care products for use which will protect and enhance the natural low pH condition of the skin, thus supporting the health of the normal skin microbiome and the protective biochemistry active in this environment.

2. The nominal low pH environment in the stratum corneum also supports normal structure and development of the stratum corneum lipids, the "mortar" that provides not only additional structural protection against invasion by pathogens, but also provides perhaps the most critical of all protections, the establishment and maintenance of the "permeability barrier" of the skin, without which normal osmotic action, between the very high moisture content of the interior body and the relatively dry environment in which we live, would result in increasing desiccation and eventual death, particularly in low humidity conditions. The three key lipids which form the basis of this protective lipid barrier--cholesterol, ceramides, and long chain free fatty acids--are all produced lower in the skin, in metabolic "factories" called lamellar bodies, and this lipid production requires the normal low pH environment to effectively produce and maintain the proper lipid ratio which is key to skin health and protection. In the face of insult or injury, signaling molecules "crank up" lipid production, as well as additional infection prevention through the production of antimicrobial peptides. And, as it also relates to infection prevention, one of the three types of lipids, free fatty acids, also has very effective antimicrobial action. So once more, the importance of maintaining low stratum corneum pH is critical to the production of lipids which form the key protective element of the stratum corneum, the body's permeability barrier, and which also support the natural antimicrobial protection of the skin.

Mechanism of Action cont.

3. A third key protective element of stratum corneum is its ability to control the proper rate

of skin sloughing ("desquamation"). Every layer of the epidermis is constantly moving upward, as keratinocytes are formed in the lower level to replace terminal corneocytes as they are constantly sloughing off at the skin surface, maintaining skin health and suppleness. The key to the correct rate of skin sloughing are small protein rivets that bind the corneocytes together, called corneodesmosomes, and the enzymes that control the "holding power" of these corneodesmosomes are pH dependent. Under nominal low pH conditions, the desquamation rate is perfect, and skin cohesion and integrity is maintained. However, when the skin pH increases, the strength of the corneodesmosomes is lessened, and skin sloughing proceeds at too fast of a pace. In addition, external biological factors and substances can impact skin integrity and cohesion. Hospital or long-term care patients who are either urine or fecal incontinent, or both, create substances which have dramatic pH elevating impact on the skin surface. Urine byproducts, urea and ammonia, are both high in pH, up to 9.5, and fecal material contain proteases which are extremely active in a high pH environment, becoming literally digestive to human skin. Both incontinent conditions, particularly in situations where active steps are not regularly taken to reverse the higher pH conditions they produce, can quickly lead to degradation in skin quality, incontinent-associated dermatitis, and eventually to aggressive skin breakdown, ulceration, and open wounds.

The primary reference for the science discussed above is a review paper written by Dr. Peter Elias, a dermatology research expert who has published more than 700 papers
on the stratum corneum. The title of the paper is **"The Skin Barrier As an Innate Immune Element"**,

4. Colloidal Nano Silver Particles (AgNPs)

The mechanism of action of silver nanoparticles (AgNPs) involves their unique physical and chemical properties, which enable them to interact with microbial cells and disrupt essential cellular processes. AgNPs exert their antimicrobial effects through several mechanisms, making them effective against bacteria, fungi, and viruses. Here are some key mechanisms of AgNPs' action:

1. Cell Membrane Interaction: AgNPs can interact with the microbial cell membrane due to their small size and high surface area. They can disrupt the lipid bilayer structure of the cell membrane, leading to increased permeability and leakage of cellular contents. This disruption can disturb essential cellular functions and ultimately result in cell death.

2. Reactive Oxygen Species (ROS) Generation: AgNPs can induce the generation of reactive oxygen species (ROS) within microbial cells. ROS, such as superoxide radicals (O2-) and hydroxyl radicals (OH-), are highly reactive molecules that can cause oxidative stress by damaging cellular components like DNA, proteins, and lipids. The accumulation of ROS can lead to cellular dysfunction and death.

3. DNA Binding and Damage: AgNPs can interact with microbial DNA, leading to DNA damage and inhibition of DNA replication and transcription. This interference with genetic material disrupts vital cellular processes, preventing the microorganisms from proliferating.

4. Protein Inhibition: AgNPs can bind to microbial proteins and enzymes, altering their structure and function. This disruption of protein function can hinder essential metabolic pathways and enzymatic processes necessary for microbial survival.

5. Intracellular Ion Disruption: AgNPs can enter microbial cells and disrupt ion homeostasis by interfering with ion channels and transporters. This disruption can disrupt cellular signaling and vital ion-dependent processes.

6 Biofilm Disruption: AgNPs have been shown to inhibit the formation of microbial biofilms and disperse existing biofilms. Biofilms are complex communities of microorganisms encased in a protective matrix, making them highly resistant to antibiotics and immune responses.

References:
1.Rai, M., Yadav, A., & Gade, A. (2009). Silver nanoparticles as a new generation of antimicrobials. Biotechnology Advances, 27(1), 76-83.
2.Li, P., Li, J., Wu, C., Wu, Q., Li, J., & Synergistic antibacterial effects of silver nanoparticles@ usnic acid composites. Colloids and Surfaces B: Biointerfaces, 184, 110521.
3.Sondi, I., & Salopek-Sondi, B. (2004). Silver nanoparticles as antimicrobial agent: a case study on E. coli as a model for Gram-negative bacteria. Journal of Colloid and Interface Science, 275(1), 177-182.
4.Chernousova, S., & Epple, M. (2013). Silver as antibacterial agent: ion, nanoparticle, and metal. Angewandte Chemie International Edition, 52(6), 1636-1653

Antibacterial Properties:
Numerous studies have demonstrated the potent antibacterial activity of nano silver in solution against both Gram-positive and Gram-negative bacteria. The mechanism of action involves the release of silver ions that interact with bacterial cell membranes, leading to disruption of membrane integrity, oxidative stress, and inhibition of bacterial growth. Nano silver has exhibited efficacy against antibiotic-resistant strains, such as methicillin-resistant Staphylococcus aureus (MRSA) and multidrug-resistant Pseudomonas aeruginosa. [Reference 1]

Antifungal Properties:
Nano silver in solution has also shown antifungal activity against various fungal pathogens, including Candida species, Aspergillus species, and dermatophytes. The mode of action against fungi involves the penetration of silver nanoparticles into fungal cells, leading to disruption of cell membranes and interference with vital cellular processes. Nano silver has demonstrated potential as an alternative or adjunct treatment for fungal infections, particularly in cases of drug-resistant fungal strains. [Reference 2]

Antiviral Properties:
Emerging research suggests that nano silver in solution possesses antiviral properties that can inhibit the replication of a range of viruses. The interaction between silver nanoparticles and viral particles can disrupt viral envelopes or protein coats, thereby preventing viral attachment and entry into host cells. Studies have shown promising results against enveloped viruses like influenza virus, human immunodeficiency virus (HIV), and herpes simplex virus (HSV). [Reference 3]

References:

1.Rai M, Yadav A, Gade A. Silver nanoparticles as a new generation of antimicrobials. Biotechnology Advances. 2009;27(1):76-83.
2.Lara HH, Ayala-Nuñez NV, Ixtepan-Turrent L, Rodriguez-Padilla C. Mode of antiviral action of silver nanoparticles against HIV-1. Journal of Nanobiotechnology. 2010;8:1.
3.Elechiguerra JL, Burt JL, Morones JR, et al. Interaction of silver nanoparticles with HIV-1. Journal of Nanobiotechnology. 2005;3:6.

Theraworx Benefits and Competitive Comparison

According to the NHSN data in Pediatric Hospitals there are 15 pathogens that account for over 88% of healthcare aquired infections (HAIs). Of these 15 pathogens, 9 are considered gut-related. 53% of all Pediatric HAIs are caused by gut-related pathogens, including 85% of CAUTIs and 48% of CLABSIs.

In the Adult Hospital setting there are 15 pathogens that account for over 86% of HAIs. Of these 15 pathogens, 11 are considered gut related and cause over 57% of HAIs including 87.8% of CAUTIs, 50% of SSIs, and 46.9% of CLABSIs.

Managing gut-related organisms at the source requires a unique safety and efficacy profile that Theraworx using pH possesses being hostile to pathogens while being non-cytotoxic to mucous membranes. The issue for HCP is that antiseptics are toxic to mucous membranes and not recommended and non-antiseptic products like soap and water do not have the efficacy to manage these pathogens. Leaving no recommended safe and effective options to manage gut related pathogens at the source perineum, with the exception of Theraworx -which proven as both safe and effect.

Some topical substances, most notably the 50-year-old standard of topical skin infection prevention, chlorhexidine gluconate (CHG), while initially low in pH, can damage the lipid structure of the skin, particularly with repeated use, and lead to negative impact on the permeability barrier, as well as both skin drying and irritation. In addition, with the increasing awareness of the importance of maintaining the healthy microbiome of the skin, there is growing concern that CHG's antimicrobial activity is so dramatic that not only are pathogens killed by the use of this substance, but also healthy microbiome is negatively impacted.

The CDC guidelines for actions recommended to protect against surgical site infections were published, and the CDC officially removed CHG from the list of products recommended for use in pre-surgical bathing- JAMA Surg. doi:10.1001/jamasurg.2017.0904 Published online May 3, 2017.

Theraworx Protect technology is the first topical solution which has been proven to be non-toxic, mucous membrane-safe, and biocompatible, while demonstrating the ability to support the healthy low pH condition of the stratum corneum, thus preserving all four of the key protective elements described above—the antimicrobial acidic mantle of the skin, the body's permeability barrier, and skin cohesion and integrity, even in incontinent patient populations. The low pH Theraworx formulation not only penetrates the stratum corneum, but demonstrates a persistent characteristic for an extended period of time. This ability to penetrate and persist allows low stratum corneum pH to be supported with periodic applications, and its nontoxic and mucous membrane-safe nature allows the use of the product in every area of the body, even the face and the perineum, where the caustic nature of other topical solutions like CHG make them not suitable, and not recommended for use.

The non-toxic, biocompatible, "skin-friendly nature" of Theraworx allows our bathing system, foams and sprays to be used in and around mucous membranes unlike CHG/alcohol. It is this safety in and around mucous membranes, as well as the challenges of hygiene in the face, perineal/ perianal area, that has resulted in the increasing adoption of Theraworx as a preferred product in both the high acuity perineal cleansing and preparation for insertion of indwelling urinary catheters, and also in the maintenance hygiene associated with care of these patients. While good sterile technique can prevent "insertion CAUTI's," the risk of CAUTI increases exponentially with longer term indwelling catheterization, and Theraworx has proven to be a key tool in helping to maintain the catheter and lower CAUTI/CLABSI rates in hospitals using the product.

Helen Devos Children's hospital had a CAUTI rate above national benchmark in the PICU. As part of their intervention stratgey they implemented Theraworx bathing product becasue it is designed for CAUTI prevention and recognized 0 CAUTI for 498 days and a 77% reduction overall.

In a peer-reviewed, published multifacility retrospective analysis of outcomes achieved by hospitals using Theraworx Protect for this application in the high acuity setting, the most challenging environment and the units most likely to see long-term catheterizations, the mean reduction in CAUTI rates, comparing periods averaging 22 months prior to implementation to 14 months after implementation of Theraworx products and protocols, was 54%. This peer-reviewed, published study is included in the reference material.

Theraworx Benefits and Competitive Comparison Cont.

A second application where Theraworx offers an innovative alternative to other topical products, and particularly chlorhexidine gluconate (CHG), is the use of a Theraworx-impregnated 8-cloth bathing system to do daily bathing of patients in Pediatric and Adult hospitals ICU's. The practice of including antimicrobial bathing as part of the multifactorial clinical protocol in these patients daily, to reduce the presence of pathogens, has become standard in these units, in large part as a strategy to reduce the possibility of central line-associated blood stream infections (CLABSI).

CHG has been the product of choice over the last several years. Concerns about the drying and irritation of patients' skin, ICU patients with Skin and allegic conditions not able to use CHG, and limited usage in the Peditarice Populations from birth to 2 months and with Hemotology Oncology patients, have resulted in many hospitals moving to Theraworx.

A safe alternative to CHG that still has efficacy is critical in these patients as part of Infection Prevention Bundles.

Lucile Packard Children's Hospital - Stanford did a six month trial comparing Theraworx to CHG wipes in Hem/ONC and Stem Cell Transplant patients with tunneled central lines. They found an increase in bathing compliance of 23% with Theraworx (75% with CHG to 92% with Theraworx) and a CLABSI reduction of 75% with Theraworx (n=1 vs n=4).

In the Journal of Critical Care Nursing National Teaching Institute, Theraworx Protect when used in place of CHG 2% was associated with a significant reduction in rate of CLABSI per 1000 catheter days in a high acuity ICU and the ICU remained CLABSI free for more than two years.

An additional benefit of the use of Theraworx for this application is the fact that the Theraworx bathing system contains eight cloths, instead of six in CHG systems, since the nontoxic nature of Theraworx allows it to be used in both the facial area, and the perineum, in addition to the front, back and four extremities. Keep in mind that NHSN data shows that close to 50% of CLABSIs in Pediatric and Adult Hospitals are caused by gut-related organisms. Managing gut-related organisms in the Perinuem or at the source has a profound effect on reducing CLABSIs. For the first time, true "full body ICU bathing" is possible utilizing the Theraworx 8-cloth system. This important distinction is gaining support among physicians and ICU clinicians.

In a significant poster study which will be presented at ANCC National Magnet Hospital Association Meeting Fall Session by a large two-hospital system in northern California, John Muir Health, Theraworx was added to the CLABSI prevention protocols. The system reported a 46% and 35% reduction in CLABSI, in the Walnut Creek and Concord campuses respectively, after this addition. This poster is included in the reference material.

A third clinical application for the use of Theraworx, and perhaps the highest potential application in the 16,000 nursing homes, and approximately two million residents of these facilities in the U.S., is for the treatment of skin issues, most notably incontinence-associated dermatitis (IAD), in urine and/or fecal incontinent patients within these facilities (on average, up to 70% of all long term care residents have incontinence (fecal, urine or mixed) and 70% of those with incontinence are diagnosed with chronic Incontinence Associated Dermatitis (IAD). There are similar patients in the acute care setting as well, but the largest market for this application is certainly the long-term care facilities.

The presence of urine and high pH urine byproducts urea and ammonia, as well as fecal material in fecal incontinence, create a highly damaging environment in the perineal area, driven by the increase in pH, destruction of the healthy skin microbiome and normal antimicrobial protections, as well as degradation in standard skin integrity and cohesion also resulting from declining acidity. A poster study presented at the Symposia for Advanced Wound Care (SAWC) spring 2017 session, showed patients with severe grade 2 skin damage, who were refractory (not responsive) to traditional barrier treatment, Theraworx use resulted in a 93% resolution overall. This poster is included in the reference material.

Another significant potential application for Theraworx in the long-term care market is for prevention of non-catheter associated urinary tract infections (UTI) in this same urine and/or fecal incontinent population. While the use of indwelling catheters in the nursing home population is not as prevalent as in hospitals, the rise in pH in the perineum resulting from presence of high pH urine byproducts results in much higher UTI rates in this incontinent population. Regular perineal hygiene protocols using Theraworx as the hygiene agent have demonstrated significant impact on UTI rates in the long-term care patient population. In a poster study done over a two-year period by clinicians at 17 long term care homes in the Peterson Healthcare system, a large system in the Midwest U.S., the incidence of UTI in the urine/fecal incontinent population within the system was reduced from a rate of approximately 2.0 UTI/1000 resident days to 0.5 UTI/1000 resident days after implementation for perineal care and cleanup after incontinent events, a reduction of 75% during the nine-month period after implementation of Theraworx protocols. This study is included in the reference material.

It is important to note that Theraworx, is not a drug such as CHG, or an antiseptic such as alcohol or triclosan. Like many cosmetic products, it does contain some preservatives like EDTA, and colloidal silver, in a small quantity (less than 1%), which is used by many medical companies, but is not recognized currently by the FDA as an antimicrobial product. It is our strong belief that the data presented within this document which shows either the ability of Theraworx to be effective in reducing the population of pathogens, or in reducing infection rates in a clinical settings, is due primarily to the action of the product on the stratum corneum, and particularly its ability to help maintain a low pH condition on the stratum corneum, providing natural antimicrobial activity within the stratum corneum, thus also encouraging preservation of the normal healthy skin microbiome, producing additional naturally pathogenic action.

It is the fact that Theraworx does not contain any antiseptic FDA approved drugs but has demonstrated proven and published outcomes in high risk patient populations that substantiates the breakthrough Innovative technology of the Theraworx mechanisms of action.

Competitive Comparison

Head to Head Comparisons with Standard Practice Approaches Including Chlorhexidine Gluconate, Alcohol, Benzalkonium Chloride, Soap and Water Wipes

1. Chlorhexidine Gluconate:

(A.) In a randomized controlled study comparing Theraworx Protect Towels to 4% CHG in the inguinal crease, axilla, sub clavicular and mid-line abdomen and knee which are areas of the body traditionally considered high areas of bioburden. Theraworx Protect demonstrated greater log reduction or equivalent in all areas when used as a hygiene and barrier product.

(B.) In a second head to head comparison following FDA final tentative monograph standard testing method E1173-15 Theraworx Protect was shown to be non-inferior to CHG 4% (Hibiclens) and is published in the American Journal of Infection Control.

(C.) In a third study Theraworx Protect was shown to be superior to CHG when measuring TEWL (Transepidermal Water Loss) and skin breakdown in a repeated application design study.

(D.) In a fourth head to head study Theraworx Protect was shown to be superior to CHG when measuring cell death in mucosa including Epi-Airway Mucosa, Gingival, Vaginal and Instestinal.

(E.) In a fifth head to head study conducted at St Jude Children's Theraworx Protect was shown to be non-toxic in children with graft vs host disease receiving hematopoietic stem cell transplantation whereas CHG was shown to drive stage IV toxicities.

2. Alcohol:

(A.) Duration of action testing to evaluate the antimicrobial performance of Theraworx® Protect vs 67% alcohol against Methicillin Resistant Staphylococcus Aureus was performed using a collagen based repeat inoculation model. At 15 minutes, 30, 60, 120 and 180 minutes when challenged repeatedly Theraworx Protect was shown superior to alcohol at all time intervals.

(B.) Duration of Action testing at 15, 30, 60, 120, 180 minutes with Theraworx Protect vs alcohol 62% vs the Corona Virus OC43 to determine persistence related efficacy. Theraworx Protect was shown to be superior to alcohol 62% at all time intervals.

(C.) Duration of Action Testing in human subjects comparing Theraworx Protect to Alcohol 62% was performed using a repeat inoculation model and at 15, 30, 60, 120 ad 180 minutes Theraworx Protect was shown to demonstrate a 3-fold + greater efficacy on human skin than alcohol 62% vs the corona virus OC43.

3. Benzalkonium Chloride:

(A.) Theraworx Protect was compared to BZK bathing towels was superior when challenged with Vancomycin Resistant enterococcus, Candida Albicans and MRSA.

4. Soap and Water Equivalent Wipes:

(A.) These wipes have a similar safety profile to regarding cytotoxic response when used on skin with that of Theraworx Protect, however these products lack the evidence of being able to manage pathogens including resistant Pathogens that lead to Healthcare Acquired Infections. Typically used for general floor bathing and in ICU or critical care areas where and when CHG is not used in areas like the Perineum and for bathing of ICU Peds from birth to 2 months. However, lack of evidence against pathogens causing HAIs is a concern for these products.

Evidence Based Innovation

Much of our claim substantiation is based on the science of the stratum corneum, and the two published, peer-reviewed review papers on specific protections to the body by this critical tissue are critical to the understanding of the mechanism of action of Theraworx. These papers, previously referred to in the Important Features and Benefit Section, are key reference documents for our application.

1. "The Skin Barrier as an Innate Immune Element" Research review published in peer-reviewed Seminars in Immunopathology journal, 2007.
2. "pH Directly Regulates Epidermal Permeability Homeostasis, and Stratum Corneum Integrity/Cohesion" Research paper published in peer-reviewed Journal of Investigative Dermatology, 2003.

Full Value Concept - The individual elements of the Full Value Concept for Theraworx are discussed below.

CAUTI BUNDLE

Quite simply, Theraworx, as a skin-friendly, non-drying or irritating cosmetic product, has demonstrated strong patient care outcomes in both infection rate reduction and in improved skin cohesion and integrity, outcomes which are non-inferior or superior to other antiseptic and drug products, while also eliciting a strong staff acceptance and patient satisfaction profile.

The most widely-accepted application of Theraworx is for perineal prep prior to insertion of a Foley catheter, as well as subsequent perineal cleaning and care throughout insertion and maintenance. The following published studies and verifiable information on clinical outcomes are submitted within our reference document package, at the end of this application.

The clinical compendium around CAUTI and UTI reduction shows a 50% to 100% reduction when Theraworx is added to institutions bundles.

Additional benefit is the ability of Theraworx to manage the gut-related organisms in the perineum of these patients that have shown to cause additional HAIs like CLABSI and SSIs.

Theraworx Protect is safe for use in Mucous Membranes where CHG isn't, filling a crucial gap in care knowing that 57% and 53% of HAIs in Adult and Pediatric Hospitals come from gut-related organisms.

Theraworx Protect UPAK includes an option for patients to do Catheter Maintenance in the home setting to support reducing CAUTI and Readmissions.

1. "One Year Cauti Free A multi-disciplinary Team approach to Reducing CAUTI in Pediatric Intensive Care Unit. Helen Devos Children's Hospital Grand Rapids, Michigan Auth: Jessica McClusky, MSN, RN, CPN, CIC.
2. Zero CAUTI, Zero CLABSI: evaluating the evidence-based effectiveness of a silver, PH acidic, multi modal skin decolonizing wipe to reduce CAUTI and CLABSI in the ICU setting: a retrospective review. Doctors Medical Center of Modesto, 2020 Auth: Asif Saiyed, MBA, CIC, Director of Infection Prevention
3. Can't Attribute UTI To Insertion: Utilizing Data to Prevent CAUTI. University of Washington Medical Center, Seattle, WA Auth Smith, N.C, Granich, M. Lien, H. Schipper, A.
4. Evaluating the effectiveness of a multidimensional bundle to reduce urinary tract infection in long-term care spinal cord injury/disordered patients: a retroactive review. Journal of Wound Ostomy and Continence Nursing, May 2020
5. "Innovative Microbiome friendly skin care formulation reduces nosocomial associated CAUTI rates when used for insertion and maintenance of urinary catheters". Moderated presentation, American Urological Association meeting, May 2017. (reference document no. 16, pp) Also published peer-reviewed study in Journal of Medical and Surgical Investigations, Volume 2 (2) 1-3, April 2017. Grade 3 multi-facility non-randomized cohort study.
6. "Targeting Zero—One Hospital's Journey to Reduce CAUTI." Article in Journal of Nursing Management 18-20, December 2014. Grade 3 non-randomized historical cohort study.
7. "Equipping Clinicians with Advanced Care Options Leads to Reductions in Urinary Tract Infections". Poster presentation by Nexion Meadowview Health and Rehab Center at American Healthcare Association (AHCA) Spring Session 2017. Grade 3 non-randomized historical cohort study.
8. "Preventing Chronic Urinary Tract Infections from Urinary and Fecal Incontinence: The Impact of Theraworx" Poster presentation September 2016 by Peterson Healthcare, Grade 3 non-randomized cohort study.
9. "Impact of Theraworx for the Prevention of Catheter-Associated Urinary Tract Infections: Results from John Muir Health Concord." Poster from John Muir Health and the University of Louisville Department of Infectious Diseases, September 2017. Grade 3 non-randomized cohort study.
10. "Strategies to Prevent Urinary Tract Infection from Foley Catheter Insertion in the Emergency Department." Peer-reviewed published study from Augusta Medical Center, Augusta GA. November 2010, peer-reviewed Journal of Emergency Nursing. Grade 3 non-randomized cohort study.
11. "Effects of Education and Improved Foley Catheter Care on Nurse's Knowledge and Associated Urinary Tract Infections." Poster by First Health Carolinas, February 2013. Grade 3, non-randomized cohort study.

Evidence Based Innovation

ICU Bathing & SSI Bundle: Alternative to CHG

A second major application for Theraworx that is growing in acceptance is the use of the product for full body ICU & Pre Surgical bathing in Pediatric and Adult Hospitals. The skin-friendly, biocompatible, non-toxic cosmetic characteristic of the product, even in long term use, compares very favorably to CHG.

Theraworx was compared to CHG 2% in two randomized controlled in-vivo comparison studies implementing two FDA mandated testing methods (ASTM E1173) and (ASTM E 2783) to compare the efficacy for decolonization and time to kill across a broad array of microbes. A two factor analysis of variance (ANOVA) showed the two products were statistically equivalent for decolonization and time to kill.

In a second head to head comparison following the FDA final tentative monograph standard testing method E1173-15 Theraworx Protect was shown ot be non-inferior to CHG 4% (Hibiclens) and is published in the American Journal of Infection Control. Full Study Included

With the emergence of a resistant Candida (AURIS) which has been shown to be resistant to Azoles and Endochins we tested Theraworx efficacy to be considered for patients colonized with C-Auris. Theraworx was shown to have a 6- log reduction at 24 hours when challenged with 5b isolates.

In addition, staff acceptance of the product has been very positive, particularly when compared to CHG. The following studies, observations, and publications are also included in the reference document package, with full details, and address outcomes, specific decolonization results and comparisons, and two key safety and patient comfort areas, skin drying and safety around mucosal tissue.

Lucile Packard Children's Hospital (Stanford Medicine) in a 6 months trial comparing Theraworx to CHG wipes in the Hematology Oncology and Stem Cell Transplant patients found and increase of compliance of 25% with Theraworx (75% CHG to 92% Theraworx) and a decrease in CLABSIs of 75% to CHG (CHG 4 - Theraworx -1). This has lead to them implementing Theraworx bathing for all ICU units.

Theraworx has been used at OU Children's Hospital at 34 weeks gestational age for over 1 year with no major adverse events. It has been used at 38 weeks gestational age for several years at McLane's Children's Hospital with no Major Adverse Events. McLane's is starting a trial at 28 weeks gestational age + 7 days after birth in August of 2023, will share data as soon as it is available.

Theraworx ICU bathing to be used as a Standardized bathing protocol for ICUs and as an alternative to CHG bathing for patients in Pediatric and Adult Hospitals that cannot use CHG.

1. "Effectiveness of Bath Wipes After Hematopoietic Cell Transplantation: A Randomized Trial." St. Jude Children's Hospital. Journal of Pediatric Oncology Nursing 2020.
2. Beyond the Bundles: A Pilot to Evaluate a Silver Based Bathing Product to Reduce Central Line-Associared Bloodstream Infections. Lucile Packard Chidlren's Hospital (Stanford Health) Auth: Lisa Pinner, RN, MSN, CNS, CPON, BMTCN, Rachel Frisch, BSN, BMTCN, Jenna Kruger, MPH, CPHQ and Lianna Marks, MD. Published 2021
3. Zero CAUTI, Zero CLABSI: evaluating the evidence-based effectiveness of a silver, PH acidic, multi modal skin decolonizing wipe to reduce CAUTI and CLABSI in the ICU setting: a retrospective review. Doctors Medical Center of Modesto, 2020 Auth: Asif Saiyed, MBA, CIC, Director of Infection Prevention
4. "Theraworx vs. Chlorhexidine Gluconate Bathing and Peri-operative Skin Cleansing Study." St. John's Medical Research Institute, September 2009. Grade 2 compare contemporary simulated patient intervention, selection bias not controlled.
5. "CLABSI (Central Line Associated Blood Stream Infections) Reduction Seen with Multifactorial Nurse Initiative". Poster presentation ANCC National Magnet convention. non-randomized cohort study.
6. "Efficacy and Safety of a novel skin cleansing formulation versus Cholrhexidine Gluconate" Study published in the peer-reviewed American Journal of Infection Control
7. "Efficacy of novel skin antiseptic against carbapenem-resistant Enterobacteriaceae." Study published in peer-reviewed American Journal of Infection Control. simulated skin study of effectiveness of Theraworx against two different strains of CRE.
8. "Duration of Action of Theraworx Against Methicillin-Resistant Staphylococcus Aureus Utilizing an Inoculated Collagen Model." St. John's Medical Research Institute, September 2009 report. In-vitro comparison of duration of action against this organism vs. alcohol skin cleanser.
9. "Forearm Controlled Application Test for Evaluating Relative Mildness and Skin Moisturization Effectiveness of Two Products" BioScience Laboratories, June 2017. Unpublished independent study using non-invasive instrument testing of Theraworx versus CHG. non-randomized controlled study.
10. "Cytotoxicity Sensitivity Response in Epi-airway, Epi-gingival, Epi-vaginal, Epi-intestinal Mucosa: Theraworx Vs. Chlorhexidine Gluconate." BioScience Laboratory independent study using MTT assays. non-randomized controlled study.
11. "Non-inferiority Testing, Randomized Controlled- in-vitro and in-vivo decolonization in a pre-operative US FDA mandated ASTM E1173 test method Theraworx compared the 2% CHG- unpublished submitted for publication by Biosciences of America-
12. "Non-inferiority Testing, Randomized Controlled- in-vitro and in-vivo decolonization in a pre-operative US FDA mandated ASTM E1173 test method Theraworx compared the 2% CHG- unpublished submitted for publication by Biosciences of America- , non-randomized controlled study
13. "Non-inferiority Testing Randomized Controlled- in-vitro and in-vivo Time to Kill Efficacy Study following the FDA ASTM E2783 test method across a broad range of microbes vs 2% CHG- unpublished submitted for publication by Biosciences of America- , non-randomized controlled study
14. AN EVALUATION OF ONE TEST PRODUCT FOR ITS ANTIMICROBTAL PROPERTIES WHEN CHALLENGED WITH THREE MICROORGANISMS USING AN IN.VTTRO TIME-KILL- Candida Auris testing- A time to kill and duration study- unpublished- prepared for publication. non-randomized controlled study

Evidence Based Innovation

Skin Integrity and Barrier Maintenance Bundle:

A third and rapidly growing Theraworx application in both acute care high acuity settings and post-acute care is in the treatment of Incontinence Associated Dermatitis and other types of Moisture Associated Skin Damage including intertrigo, peristomal dermatitis and peri wound dermatitis. The following published articles, studies and observations deal with the skin cohesion/ integrity advantages of Theraworx and its unique, low pH promoting activity on the stratum corneum protections in this area. Full details available at www.hcp.theraworxprotect.com/learn-all.

1. "Non-toxic Skin Formulation Promotes Healing of Dermatitis and Skin Injuries That are Prone to Infection in Long-Term Care Facility Residents (Case Report). Published in peer reviewed Annals of Infectious Disease and Epidemiology, November 2016.

2. "Successful Healing of IAD when Traditional Barriers Fail, Using an Innovative Topical Formulation." Poster presentation at Symposia for Advanced Wound Care, Spring Session 2017.

3. "Novel Skin Care System Helps in Healing Skin Wounds and Other Problematic Skin Disorders in Patients in Long-Term Care Facilities." Poster presentation at W.O.W. (Wild on Wounds) National Conference, Fall Session 2016.

4. "Harnessing the microbiome to rapidly resolve peristomal complications." Poster presentation at Symposium on Advanced Wound Care, Spring Session 2019

5. Effect of an innovative pH lowering wound Therpeutic on MMP levels and bacterial bifofilm colonization of chronic non-healing wounds. Poster presentation at Symposium on Advanced Wound Care, Fall 2019

6. "Effect of an innovative pH lowering wound Therapeutic on MMP levels and bacterial biofilm colonization of chronic non-healing wounds." Poster presentation at Symposium on Advanced Wound Care, Fall 2018

Additional Benefits

Theraworx patent-pending protocols in the clinical applications described above have been developed. Compliance with these protocols has been shown to be a key element of the positive outcomes that have been achieved while using Theraworx product and protocols. An example, the graphic depiction of the protocol for regular re- establishment of the "zone of inhibition" for Foley catheterized patients, is included in our package. These protocols are what guide our field in-service efforts. Our goal here is to reinforce proper technique and provide the very best opportunity for improved outcomes among all customers of our product.

Additionally, we have a discharge product called Theraworx Protect U-PAK that is designed for patients discharging with Indwelling Urinary Catheters to be able to use at home. Considering population health and giving hospitals access to a product that can help continue therapy at home to help reduce the risk of hospital readmission

Managing Emerging Infection Concerns:

Most recently with the emergence of **SARS COV-2, RSV, and Candida Auris** Pediatric, Adult Hospitals, and Post Acute Care Facilities have employed Theraworx Protect technology as the biochemical barrier for the Transmission Zone (eyes, nose, mouth). Theraworx has been studied with excellent results in vivo against Covid, RSV, and Candida Auris providing an option to Clinicians that has both Efficacy and Safety data against these most challenging viruses. This gives clinicans the opportunity to safely use a product in and around the entry points for these pathogens -eyes, nose, mouth, and even ears. We are investing in further evidence with studies in patients in the hospital and post-acute care settings looking at decolonization and containment.

1. "Another tool in the toolbox: a novel, multimodal, surfactant-based skin cleanser vs 62% ethanol on the human corona-virus OC43 on human tissue." Journal of Clinical and Medial Investigations, October 2020

2. "Activity of a novel, multimodal, surfactant-based skin cleanser on coronaviruses, in-vitro." Journal of Clinical and Medical Investigations, September 2020

3. "An Evaluation of One Test Product for It's Antimicrobial Properties when Challenged with Three Microorganisms Using an In-Vitro Time-Kill Candida Auris Testing." Unpublished Bioscience Laboratories, Inc.

4. "Evaluation of One Test Article for Virucidal Properties upon the ASTM E1052-20 Method when Challenged with Respiratory Syncytial Virus (RSV). Unpublished Nelson Labs.

Clostridioides difficile (C. Diff): Has emerged as a difficult issue in the health care system. According to the CDC there are almost half a million infections in the US each year. About 1 in 6 patients who get C. Diff will get it again in the subsequent 2-8 weeks. One in 11 people over age 65 diagnosed with a Healthcare-associated C. diff infection die within one month. This is very concerning and drives home the importance of being able to control spread and minimize impact in clinical settings. Our low pH formulation and in-vivo data shows good results against C Diff spores.

We have 2 published posters both showing a significant reduction in CDI:

- 60% (Peconic Bay) when replacing Soap and water wipes with Theraworx and
- 68% (Levindale) when replacing CHG with Theraworx in their CDI bundles: (Published Studies in Reference Materials)

1. "Preventing Hosptial Acquired Clostridum Difficile Infection in ICU Patients: The Efficacy of Theraworx, a Novel Silver-Based Cleanser." Peconinc Bay Medical Center Northwell Health

2. Reducing the Incidence of Clostridium Difficile Infections, Antibiotics and Costs In A Long-Term Acute Care Setting - A surveillance Expereince. Levindale Hebrew Geriatric Center and Hospital

Financial Benefits

Product cost is the most direct and measurable savings in this area, and it is our experience that Theraworx is priced lower than many products which it would replace, particularly those containing CHG. Our bathing system is typically offered at a price that is less than the comparable CHG Preoperative Skin Cleansing Products used for bathing, even though the non-toxic, mucous membrane-safe properties of Theraworx allow us to package 8 cloths in our system, versus 6 for CHG. In terms of demonstrated deletion of certain processes of care, the use of our product for IAD prevention and treatment typically allows for the reduction in use of several other products used in peri-anal care, including moisturizers, barrier creams, and anti-fungal creams.

Success against IAD in both the long-term care and the acute care clinical setting would potentially prevent physician consultation and involvement in a condition that is typically a nursing responsibility, a direct savings as well. In addition, while Theraworx is only approved for use on intact skin, its ability to resolve IAD type skin issues quickly and successful may avoid skin breakdown and pressure skin injuries, and additional care required, some of which may be unreimbursed.

Considering the volume of evidence presented within the reference documents showing many instances of the improved outcomes demonstrated through the use of Theraworx for infections, we believe Theraworx can quantitatively impact several key elements of the CMS programs that are now in place as they push the industry away from the historical fee-for-service approach and move it to a new paradigm of overall cost, quality and outcomes. Value Based Payment and the Healthcare Acquired Conditions (HAC) Penalty include Infections Rates.

More significant is the Hospital Acquired Conditions (HAC) penalty, where approximately 800 of the largest hospitals in the country are subject to loss of 1% of total CMS reimbursement, if the individual hospital scores in the bottom 25% of this group in key measures, which again, are heavily weighted on CAUTI and CLABSI, and include other hospital acquired infections (HAI) that Theraworx has data on, MRSA, C. Diff, and SSIs.

The challenge of the HAC penalty is that “standing still” on controlling HAC’s may not be enough, since the scores are re-calculated every year, so a hospital can find itself scored the same as prior year, but see other improving hospitals move above them in scoring, pushing that hospital down into the bottom 25% level.

Finally, several studies have shown that of the patients readmitted to the hospital within 30 days of discharge, 20-35% experienced an HAI during their primary admission. The Readmission Penalty, which can be high, is based on an extremely complicated formula, but the bottom line is that avoidance of an HAI during primary admission gives the hospital a much better chance of avoiding at least some readmits that will impact their scoring on the Readmission Penalty. Put it all together, and a total of 6% of total CMS reimbursement is at risk, with infections playing a major role in the scoring of the penalties. For a hospital with high Medicare/Medicaid payment mix, these programs can be the difference between the bottom line being black or red.

Theraworx Protect UPAK discharge program is designed to help patients care for their catheter at home after discharge from the hospital.

Product Classification, Regulatory & Safety

Classification - Theraworx is Manufactured and distributed by Avadim Holdings, Inc. DBA Avadim Health. Avadim Manufactures Theraworx in compliance with "Good Manufacturing Practices" as required by the Food and Drug Administration's statuary requirements of CFR 211 for monographed drugs. In addition, Avadim's manufacturing processes are in substantial compliance with the ISO 13485:2003 Standard for Medical Devices.

Regulatory - Theraworx has met and exceeds the Biocompatibility Safety Testing requirements for acute systemic, skin irritation, skin sensitivity and cytotoxicity as required for Medical Devices. Theraworx is classified as a cosmetic skin cleanser with preservatives: therefore a 510(k) is not required. Cosmetic firms are responsible for substantiating the safety of their products and ingredients before marketing. Avadim has compiled numerous clinical abstracts and white papers substantiating the safety and effectiveness of Theraworx. A summary document on biocompatibility testing results with Theraworx is enclosed in the reference documents.

Safety Profile - The primary safety benefit of the Theraworx range of products is to the patient. The reference documents include results of cytotoxicity, irritant and biocompatibility testing. Avadim has tested the safety profile of Theraworx versus CHG in mucosal tissue, and those results are also included in the reference documents. The advantage of having a skin-friendly product which helps protect the natural microbiome through its low pH characteristics, and is also safe for use in all body areas, while still having significant effectiveness, is a key part of why we feel that the product represents a New and Innovative Technology. Having effective potency, and non-toxic biocompatibility, at the same time represents unique skin hygiene technology. Compared to CHG, Theraworx presents a safety profile that mitigates potential concerns of nurses regarding irritation or allergic reactions.

Clinical Evidence - Listing of all Studies (Full Studies available at ***www.hcp.theraworxprotect.com/learn-all****)*

Head to Head Studies

1. **Another tool in the toolbox: a novel, multimodal, surfactant-based skin cleanser vs. 62% ethanol on the human coronavirus OC43 on human tissue.**
   Paulson DS. Journal of Clinical and Medical Investigations, October 2020 .....

2. **Activity of a novel, multimodal, surfactant-based skin cleanser on coronaviruses, in-vitro.**
   Paulson DS. Journal of Clinical and Medical Investigations, September 2020 .....

3. **Efficacy and safety of a novel skin cleansing formulation versus chlorhexidine gluconate.**
   Paulson DS, Topp R, Boykin RE, Schultz G, Yang Q. American Journal of Infection Control, 2018 .....

4. **Antimicrobial effectiveness of rinse-free hospital bathing cleansers after 24 h of initial exposure to common pathogenic micro-organisms.**
   Olivi J, Austin CL, Thompson SJ. Journal of Patient Care, 2018. .....

5. **Forearm Controlled Application Test for Evaluating the Relative Mildness and Skin Moisturization Effectiveness of Two Products**
   Independent Testing by BioScience Laboratories, Phoenix, AZ .....

6. **Theraworx V. Chlorhexidine Gluconate Bathing and Peri-Operative Skin Cleansing Study**
   St. John's Research Center, Huckfeldt R, et al, controlled comparative study .....

7. **Duration of Action of Theraworx Against Methicillin-resistant Staphylococcus Aureus Utilizing an Innoculated Collagen Model**
   Huckfeldt R, St. John's Research Institute, controlled comparative study.....

Institutional Quality International Studies

8. **Effectiveness of bath wipes after hematopoietic sStem cell transplantation: a randomized trial- St Jude Children's.**
   Margie K, Qudeimat A, Browne E, Keerthi D, Sunkara A, Kang G, et al. Journal of Pediatric Oncology Nursing, 2020. .....

9. **Change has arrived: antimicrobial bathing and CLABSI. University of Southern California (Verdugo Hills) EB8**
   Sung P, Virgallito M, Murphy T, Boghossian R, Young R. Journal of Critical Care Nursing, April 2020 .....

10. **Closing the gap: targeting CAUTIs with a novel approach to perineal care. (University of Maryland Health)** EB9
    Hargett L, Anderson T. Journal of Critical Care Nursing, April 2020.....

11. **Evaluating the effectiveness of a multidimensional bundle to reduce urinary tract infection in long-term care spinal cord injury/disordered patients: a retroactive review.**
    Chaiken N, Pazzaglia J, Polakkattil B, Tower-Woods W, Schwartz R, Lombardo R. Journal of Wound Ostomy & Continence Nursing, May 2020. .....

12. **Zero CAUTI, zero CLABSI: evaluating the evidence-based effectiveness of a silver, pH acidic, multimodal skin decolonizing wipe to reduce catheter associated urinary tract infection and central line blood stream infections in the ICU setting: a retrospective review.** Saiyed A. Tenet Health - Medical Center of Modesto,2020. .....

13. **Preventing hospital acquired clostridium difficile infection in ICU patients: the efficacy of Theraworx, a novel silver-based cleanser.** Mupo P, Fischer H, Dhansew T, Masih M, Collins A, Orlov V. Journal of Critical Care Nursing, 2019.....

Clinical Evidence - Listing of all Studies (Full Studies available at www.hcp.theraworxprotect.com/learn-all)

14. **Innovative "Eco-Friendly" skin care formulation reduces nosocomial associated CAUTI rates when used for insertion and maintenance of urinary catheters.** George A Turini III M.D, MSc., Joseph F. Renzulli II M.D., Department of Urology - Section of Minimally Invasive Urologic Surgery.....

15. **Theraworx Skin Care Formulation Reduces Nosocomial Associated CAUTI Rates When Used For Urinary Catheter Insertion and Maintenance**
Renzulli J, Journ of Clin and Med Investg. Vol 2(2): 1-3 .....

17. **Strategies to Prevent Urinary Tract Infection from Urinary Catheter Insertion in the Emergency Department**
Journal of Emerg Nursing, 36(6) November 2010 .....

18. **CLABSI Reduction Seen with Multifactorial Nurse Initiative** John Muir Health, CA. Poster submittal, ANCC Magnet Association, Fall Session, 2017.....

19. **Impact of Theraworx for the Prevention of Catheter-Associated Urinary Tract Infections: Results from John Muir Health Concord**
JusterRet.al.,Posterpresentation.....

20. **Effects of Education and Improved Foley Catheter Care on Nurse's Knowledge and CAUTI**
First Health of the Carolinas, Walters G, Lee J, Riddle L, Poster presentation .....

21. **Preventing Chronic Urinary Tract Infections From Urine and Fecal Incontinence: The Impact of Theraworx**
PetersonHealthcare,PeoriaIL,Posterpresentation.....

22. **Assessing the Efficacy and Cost-Effectiveness of Theraworx Protect to Existing Regimens and Products- a 120- day Intervention: Emergency Department, ICU, SDU, Neuro** Sutter Health Infectious Disease: Jeffery Silvers, MD.....

23. **Equipping Clinicians with Advanced Care Options Leads to Reduction in UTI**
Theraworx Works Wonders Meadowview Health and Rehab Center, Poster presentation, AHCA Spring Session, 2017 .....

24. **Targeting Zero: One Hospital's Journey to Reduce CAUTI** Roser L, Piercy EC, Altpeter, T. Journ. Of Nurs Mgt 18-20 Dec 2014.....

25. **Can't Attribute Uti To Insertion: Utilizing Data to Prevent CAUTI**
University of Washington Medical Center, Smith, N.C., Granich, M., Lein, H., Schipper, A.Poster Presentation, 2018.....

26. **Reducing The Incidence of Clostridium Difficile Infections, Antibiotics and Costs in a Long-Term Cre Setting - A surveillance Experience**
Levindale Hebrew Geriatric Center and Hospital, Susan M Johnston, BSN, CIC Director of Infection Prevention & Control, Poster Presentation, 2018.....

27. **Beyond the Bundles: A Pilot to Evaluate a Silver Based Bathing Product to Reduce Central Line-Associated Bloodstream Infections.**
Lucile Packard Children's Hospital -Stanford Medicine, Lisa Pinner, RN, MSN, CNS, CPON, BMTCN, Rachel Frisch, BSN, BMTCN, Jenna Kruger, CPHQ, and Lianna Marks MD, Poster Presentation June 2021.....

28. **One Year CAUTI Free: A Mutli-Disciplinary Team Approach to Reducing CAUTI in a Pediatric Intensive Care Unit.**
Helen DeVos Children's Hospital Spectrum Health, Jessica McClusky, MSN, RN, CPN, CIC, Poster Presentation 2018.....

Clinical Evidence - Listing of all Studies (Full Studies available at www.hcp.theraworxprotect.com/learn-all)

Wound and Skin Integrity

29. **Effect of an innovative pH lowering wound therapeutic on MMP levels and bacterial biofilm colonization of chronic non-healing wounds.**
Marston W, Schultz G. Poster presentation, Symposium on Advanced Wound Care, Fall 2019. .....

30. **Harnessing the microbiome to rapidly resolve peristomal skin complications.**
Gallagher D, Juergens J. Poster presentation, Symposium on Advanced Wound Care, Spring 2019. .....

31. **Successful healing of IAD when traditional barriers fail using an innovative topical formulation.**
Gallagher D, Miller J. Poster presentation, Symposium on Advanced Wound Care, Fall 2018.....

32. **Non-toxic skin formulation promotes healing of dermatitis and skin injuries that are prone to infection in long-term care facility residents.**
Miller J, Renzulli JF. Annals of Infectious Disease and Epidemiology, November 2016. .....

33. **Novel Skin Care System Helps in Healing Skin Wounds and Other Problematic Skin Disorders in Patients at Long-term Care facilities**
W.O.W.Caseseries(WildonWounds)NationalConfFallsession2016.....

Safety

34. **Cytotoxicity Sensitivity Response in Epi-airway, Epi-gingival, Epi-vaginal, Epi-Intestinal Mucosa: Theraworx Versus Chlorhexidine Gluconate**
Independent Testing by BioScience Laboratories, Phoenix, AZ .....

Organism Studies

35 **Efficacy of a Novel Skin Antiseptic Against Carpapenum-resistant Enterobacteriaceae** American Journ of Infection Control, April 2015 1-3 .....

36.. **Summary of Theraworx Biocompatiblity and Microbial Testing Executive Summary test results**.....

37. **An Evaluation of One Test Product For It's Antimicrobial Properties When Challenged with Three Microorganisms Using An Tn.Vttro Time-Kill**
Candida Auris testing - A time to kill and duration study unpublished, prepared for publication .....

38. **Evaluation of One Test Article for Virucidal Properties Based Upon the ASTM E1052-20 Method. Respiratory Syncytial Virus (RSV)**
Nelson Labs January 2023 .....

Relevant Study Summaries

Full Text Studies Available at

www.hcp.theraworxprotect.com/learn-all

Oklahoma Children's Hospital OU Health

Guidelines for use of Theraworx for Prevention of CLABSI/CAUTI in the NICU

Theraworx is a colloidal silver impregnated wipe shown to safely decrease infectious organisms on the surface of the skin. The wipes also contain the moisturizing ingredients allantoin, aloe, and Vitamin E.

The wipes should be used on infants greater than or equal to 34 weeks gestation who have an indwelling central line (subclavian, UVC, UAC, or PICC) or an indwelling urinary catheter. Infants less than 34 weeks may not have the mature skin structure needed to prevent over absorption of the silver content in the wipes. Do not use on infants with congenital skin disorders such as icthyosis or epidermolysis bullosa.

Theraworx is safe to use on the face and perineum area. Avoid the mouth, eyes and inside of ears. The wipes may replace routine baths for infants with central lines or urinary catheters. If a bath with soap and water is given, apply Theraworx directly after the bath.

CHG bathing wipes should still be used prior to surgery.

Theraworx instructions:

1. Remove any stool prior to using wipes.
2. Move the wipe in circular or back and forth motion across the skin
   - Wipe 1: Use on face, neck, chest, then abdomen
   - Wipe 2: Use on arms, then legs
   - Wipe 3, Use on back
   - Wipe 4: Use on perineum, then buttocks
3. Allow to dry on the skin. Check skin fold to ensure the product dries completely.
4. Once dry, emollient can be applied.

References:

Oranges T, et al. Skin Physiology of the Neonate and Infant: Clinical Implications. Adv Wound Care 2015;4(10):587-595.

Khattak AZ, et al. A randomized controlled evaluation of absorption of silver with the use of silver alginate (Algidex) patches in very low birth weight (VLBW) infants with central lines. J Perinatol 2020;30(5):337-342.).

Kjellin M, Qudeimat A, Browne E, Keerthi D, Sunkara A, Kang G, Winfield A, Giannini MA, Maron G, Hayden R, Leung W, Triplett B, Srinivasan A. Effectiveness of Bath Wipes After Hematopoietic Cell Transplantation: A Randomized Trial. J Pediatr Oncol Nurs. 2020 Nov/Dec;37(6):390-397. doi: 10.1177/1043454220944061. Epub 2020 Jul 24. PMID: 32706285; PMCID: PMC7802025.

Executive Summary

Microbial Testing

1.0 Objective

1.1 The objective of this summary is to briefly delineate the scope of testing that has been conducted to assure the safety and effectiveness of the Theraworx platform.

2.0 Scope

2.1 The scope of this report shall cover the original testing completed as part of the patented process (2002), as well as all subsequent antimicrobial and biocompatibility testing recently conducted.

3.0 References

3.1 AATCC Method 100: Antibacterial Finishes on Textile Materials: Assessment of

3.2 ISO/DIS 10993: Biological evaluation of Medical Devices - Part 1: Evaluation and Testing

4.0 Attachments

4.1 Test reports available upon request.

5.0 Definitions

5.1 Theraworx - A Patented, pH and Hygiene Management System.

6.0 Testing Data

6.1 Original Testing

6.1.1 Antimicrobial Activity Testing

Testing was conducted by Microbiological Consultants, Inc. on behalf of Harod Enterprises, Inc. on January 15, 1998.

Test Organism	ATCC No.	Initial Inoculum	Percent Reduction
E. Coli	11229	2.32×10^3	>99.9%
S. aureus (MRSA)	33591	1.06×10^3	>99.9%
C. albicans	10231	1.06×10^4	>99.9%

6.1.2 Antimicrobial Efficacy Testing

Testing was conducted by Microbiological Consultants, Inc. on behalf of Harod Enterprises, Inc. on June 12, 2000

Test Organism	ATCC No.	Initial Inoculum	Percent Reduction
E. faecalis	29212	1.36×10^4	>99.9%
S. aureus (MRSA)	33591	6.6×10^4	>99.9%

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Executive Summary

Microbial Testing

6.1.3 Antiviral Efficacy Testing

Testing was conducted by Microbiological Consultants, Inc. on behalf of Harod Enterprises, Inc. on July 3, 2000.

Test Organism	Initial Inoculum	Percent Reduction
Influenza A	$1.0 \times 10^{4.5}$	>99.9%
Herpes Simplex	$1.0 \times 10^{4.5}$	>99.9%

6.2 Antimicrobial Testing

6.2.1 AATCC Method 100 Antimicrobial Testing

Testing was conducted by Apptec Laboratories on behalf of Avadim, LLC between September 5, 2007 through June 12, 2008

Test Organism	ATCC No.	Initial Inoculum	Percent Reduction
C. albicans	10231	1.1×10^5	>99.9%
M. luteus	49732	1.1×10^5	>99.9%
C. ammoniagenes	6872	1.7×10^5	>99.9%
S. epidermidis	12228	1.3×10^5	>99.9%
S. aureus (MRSA)	33591	1.3×10^5	>99.99%
Acinetobacter baumannii	15308	1.4×10^6	>99.99%
E. faecalis	51575	1.4×10^6	>99.99%
E. coli	8739	1.6×10^6	>99.99%
P. aeruginosa	9027	1.2×10^6	>99.99%
C. difficile	9689	2.4×10^7	>99.99%
Carbapenem resistant E. Coli	A15667	7.8×10^6	>99.9%
Klebsiella pneumoniae Carbapenem resistant	A15666	7.8×10^4	99.30%

6.2.2 Antimicrobial Efficacy Duration Study

Testing was conducted by St. John's Research Institute on behalf of Avadim, LLC on November 14, 2007. This study was based upon a one-time application of collegen and re-inoculated at various time periods.

Time	Test Organism	Initial Inoculum	Percent Reduction
15 minutes	S. aureus (MRSA)	3.0×10^5	>99%
30 minutes	S. aureus (MRSA)	3.0×10^5	>99%
60 minutes	S. aureus (MRSA)	3.0×10^5	>99%
120 minutes	S. aureus (MRSA)	3.0×10^5	>99%
180 minutes	S. aureus (MRSA)	3.0×10^5	>99%

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Executive Summary

Microbial Testing

6.3 Biocompatability Testing

6.3.1 Outline

Theraworx has been subject to *in vitro* and *in vivo* biocompatibility testing (ISO Intracutaneous Reactivity Test, ISO Acute Systemic Injection Test, ISO Guinea Pig Maximization Sensitization Test, and MEM-Elution using L-929 Mouse Fibroblast Cells(ISO) (Cytotoxicity)). These tests support the safe use of TheraworxTM in contact with breached or compromised skin.

6.3.2 MEM Elution Using L-929 Mouse Fibroblast Cells (ISO) (Cytotoxicity)

6.3.1.1 Reference:	ISO 10993-1
6.3.1.2 Report No.	66958
6.3.1.3 Date Tested:	November 9,2007
6.3.1.4 Conducted By:	Apptec Laboratories
6.3.1.5 Results:	Test was considered valid as the control results were within acceptable parameter. The test article PASSED and is considered NON-TOXIC under the test conditions employed.

6.3.3 ISO Intracutaneous Reactivity Test

6.3.2.1 Reference:	ISO 10993-1
6.3.2.2 Report No.	66959
6.3.2.3 Date Tested:	December 10,2007
6.3.2.4 Conducted By:	Apptec Laboratories
6.3.2.5 Results:	The test article is considered a NON-IRRITANT.

6.3.4 ISO Acute Systemic Injection Test

6.3.3.1 Reference:	ISO 10993-1
6.3.3.2 Report No.	101611
6.3.3.3 Date Tested:	February 11,2008
6.3.3.4 Conducted By:	Apptec Laboratories
6.3.3.5 Results:	No potential toxic effects as a result of a single-dose systemic injection were observed; test article PASSED the test.

6.3.5 ISO Guinea Pig Maximization Sensitization Test

6.3.4.1 Reference:	ISO 10993-1
6.3.4.2 Report No.	101612
6.3.4.3 Date Tested:	March 13, 2008
6.3.4.4 Conducted By:	Apptec Laboratories
6.3.4.5 Results:	None of the test animals challenged with the test article extracts were observed with a sensitization response greater than "0". Test article did NOT elicit a sensitization response.

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American Journal of Infection Control- 0196-6553/ https://doi.org/10.1016/j.ajic.2018.04.232

Efficacy and safety of a novel skin cleansing formulation versus chlorhexidine gluconate

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BACKGROUND

Health care–associated infections (HAIs) continue to plague patients in the United States. Annually, there are >1.7 million HAIs in the United States resulting in almost 100,000 deaths and costs to the medical care system of $6.5 billion. The Centers for Disease Control and Prevention estimate that 1 in 25 patients will contract an HAI during their inpatient hospitalization, underscoring the need for novel prevention strategies. The recent compendium of strategies to prevent HAIs strongly recommends the use of topical antiseptics for HAI risk reduction in acute care settings. Chlorhexidine gluconate (CHG) has been widely used as an antiseptic for decolonizing the skin before surgery and for daily bathing while hospitalized because of its proven immediate and persistent antimicrobial activity after skin application. However, not all trials have been positive,8 and reports have implicated CHG in cases of site irritation, allergic and anaphylactic reactions, and patient discomfort. This is problematic, particularly for already compromised skin. Further, continued antimicrobial resistance has been documented, suggesting greater control may be necessary from an antimicrobial stewardship perspective. In particular, establishing antisepsis in the inguinal area before urinary catheter insertion is important in preventing urinary tract infections. Because of this, it is important to continue to explore skin antiseptics that provide broad-spectrum antimicrobial activity. The objective of this study was to evaluate if a novel, multi-ingredient surfactant colloidal silver technology was noninferior to a commonly used 4% CHG containing skin antiseptic in terms of immediate and persistent antimicrobial activity.

Test period

Clinical efficacy testing was performed based on procedures outlined in the Food and Drug Administration's (FDA) Tentative Final Monograph9 and the ASTM Method E1173-15 for a simulated preoperative skin preparation.

Statistical Analysis

Table 1
Results from 10-minute kill studies

Product	Sample size	Recovery	Average treatment effect	95% Confidence interval (upper limit)
Colloidal silver	40	3.83 (0.82)	0.21	0.58
4% CHG	41	3.64 (0.96)		

CHG, chlorhexidine gluconate.

Table 2
Results from 6-hour kill studies

Product	Sample size	Recovery	Average treatment effect	95% Confidence interval (upper limit)
Colloidal silver	40	3.49 (0.97)	0.18	0.61
4% CHG	41	3.34 (1.18)		

RESULTS

A total of 40 subjects were enrolled and tested in the colloidal silver arm and 41 were enrolled in the 4% CHG arm. For efficacy 10 minutes after application, the mean recovery for the colloidal silver product was 3.83, whereas the mean recovery for the 4% CHG was 3.64. The average treatment effect was 0.21, with the upper limit of the 95% CI at 0.58. Because the upper bound of the 95% CI for the noninferior statistic was 0.58 (Table 1), this was lower than 0.65, so the colloidal silver was noninferior to the 4% CHG. For efficacy of the 6-hour time point, the mean for the recovery of the colloidal silver was 3.49 and for the 4% CHG it was 3.34. The average treatment effect was 0.18. The upper bounds of the 95% CI was 0.61, which was within the limit of 0.65, so the colloidal silver was noninferior to the 4% CHG (Table 2).

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Effectiveness of Bath Wipes After Hematopoietic Cell Transplantation: A Randomized Trial- St Jude Children's

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Abstract:

Objective: Bacteremia is a leading cause of morbidity and mortality in children undergoing hematopoietic cell transplantation (HCT). Infections of vancomycin-resistant enterococci (VRE) and multidrug resistant (MDR) gram negative rods (GNRs) are common in this population. Our objective was to assess whether experimental bath wipes containing silver were more effective than standard bath wipes containing soap at reducing skin colonization by VRE and MDR GNRs, and nonmucosal barrier injury bacteremia.

Study Design: Patients undergoing autologous or allogeneic HCT in a tertiary referral center were randomized to receive experimental or standard bath wipes for 60 days post-HCT. Skin swabs were collected at baseline, discharge, and day +60 post-HCT. The rate of VRE colonization was chosen as the marker for efficacy.

Results: Experimental bath wipes were well tolerated. Before the study, the rate of colonization with VRE in HCT recipients was 25%. In an interim analysis of 127 children, one (2%) patient in the experimental arm and two (3%) in the standard arm were colonized with VRE. Two (3%) patients had nonmucosal barrier injury bacteremia in the standard arm, with none in the experimental arm. MDR GNRs were not isolated. The trial was halted because the interim analyses indicated equivalent efficacy of the two methods.

Conclusions: VRE colonization was substantially lower than the 25% incidence noted in the pre-study period in patients using soap and water for bathing. CLABSI rates were also substantially lower compared with previously published St. Jude reports of an 8% risk of CLABSI in the first 28 days after allogeneic and autologous HCT, predominantly due to non-MBI bacteremia in patients using soap and water for bathing Srinivasan et al., 2013;
Srinivasan et al., 2014).

Satisfaction Data

Variable	Overall (n = 127)	Experimental (n = 61)	Standard (n = 66)	p value
Patients completing survey	78 (61)	42 (69)	36 (55)	.11
Did your child experience skin irritation as a result of using the wipes?				.85
Moderate	1 (1)	1 (1)	0 (0)	
Minimal	9 (7)	4 (7)	5 (8)	
None	68 (53)	37 (61)	31 (47)	
How easy were the bath wipes to use?				.15
Neither easy nor difficult	1 (1)	1 (1)	0 (0)	
Easy	19 (15)	13 (22)	6 (9)	
Very easy	58 (45)	28 (46)	30 (46)	
How often did you use the bath wipes?				.84
Some days	8 (6)	5 (8)	3 (5)	
Most days	25 (20)	14 (23)	11 (17)	
Every day	45 (35)	23 (38)	22 (33)	
How satisfied were you with the feel of the wipes on your child's skin?				.65
Very dissatisfied	1 (1)	0 (0)	1 (1)	
Neither satisfied nor dissatisfied	11 (8)	5 (8)	6 (9)	
Satisfied	31 (24)	16 (26)	15 (23)	
Very satisfied	35 (28)	21 (35)	14 (22)	
How well do you think the wipes cleaned your child's skin?				.21
Poorly	3 (2)	0 (0)	3 (5)	
Moderately well	8 (6)	6 (10)	2 (3)	
Well	28 (22)	15 (25)	13 (20)	
Very well	39 (31)	21 (34)	18 (27)	

Note. Data are number of patients (%), unless otherwise indicated.

Beyond the Bundles: A pilot to Evaluate a Silver Based Bathing Product to Reduce Central Line-Associated Bloodstream Infections. Lucile Packard Chidren's Hospital Stanford, 2021

Background: Central Line Associated Bloodstream Infection (CLABSI) is associated with poor outcomes in Hematology/Oncology and Stem Cell Transplant patients.
Despite adopting multiple initiates:

1. In 2012 we initiated CHG wipes for patients with central lines.
2. In 2015 we instituted CLABSI bundle prevention rounds.
3. In 2019 we trialed a Hibiclens 4% CHG solution for patients old enough to shower.

Our unit's non-mucosal barrier injury (non-MBI) CLABSIs continued to be a significant problem. Adherence to CHG daily bathing has been challenging to achieve with an average rate of 75% despite the multiple improvement efforts. Therefore, alternative strategies were needed to help achieve our goal of reducing CLABSI rates.

Conclusion: Bathing compliance increased by 23% by the end of the trial (75% w/ CHG compared to 92% with Theraworx).
•Of the 322 unique patients receiving the new bathing product, only 1 had a documented allergy.
•The non-CLABSI rate during the trial decreased by 75% compared to the historical 6-month data (n=1 vs. n=4).
•86% of patients and families were satisfied/very satisfied with Theraworx.
•The cost of the silver-based wipes is projected to save approximately $15,000 a year compared to CHG.
•The estimated cost avoidance for CLABSIs during the trial is $135,000 (approximately $45,000 for each CLABSI eliminated)

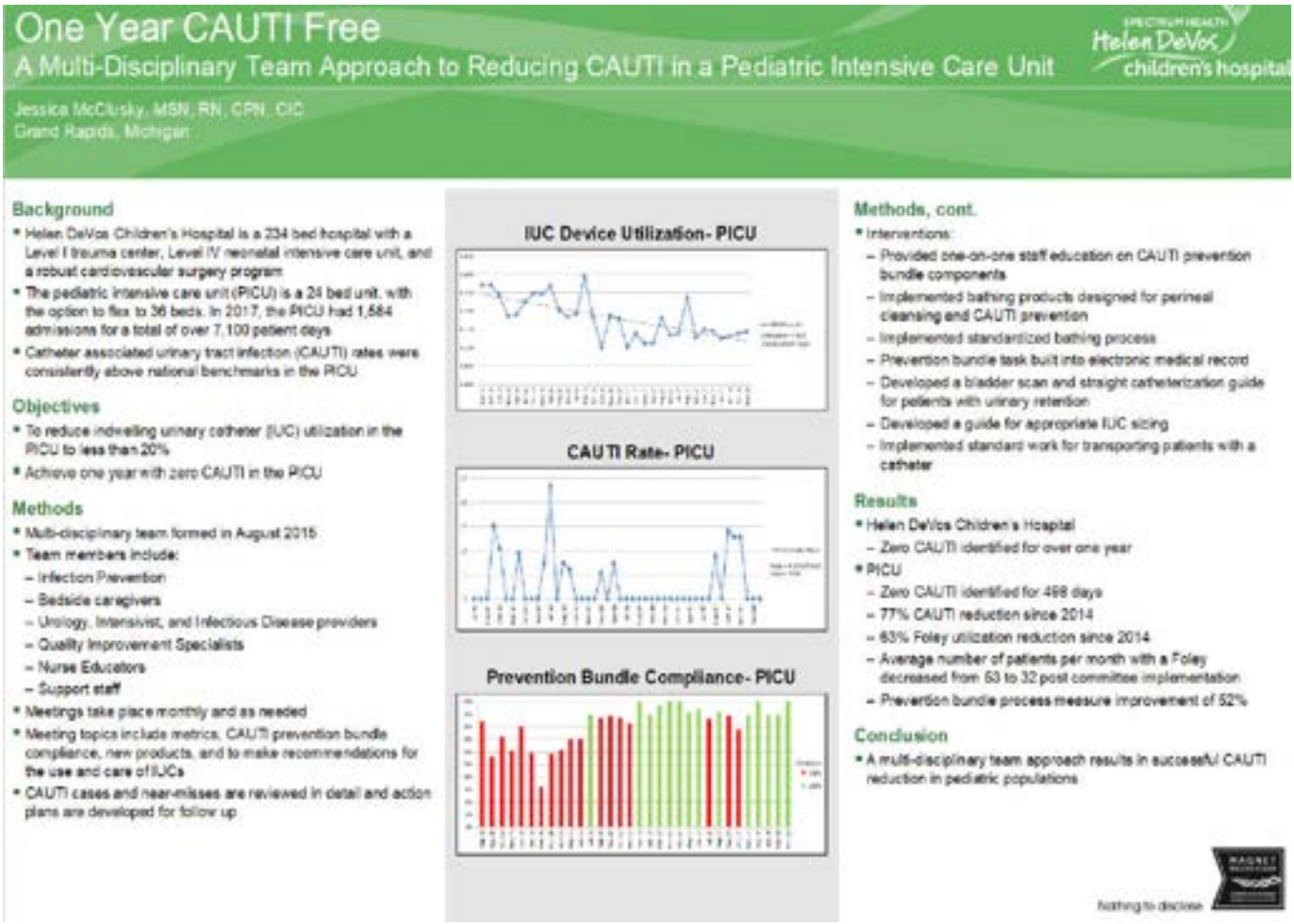
One Year CAUTI Free: A multi-discilinary Team Approach to Reducing CAUTI in a Pediatric ICU. Helen DeVos Children's Hospital Spectrum Health

Background: Helen DeVos Children's Hospital is a 234 bed hospital with a Level I trauma center, Level IV neonatal intensive care unit, and a robust cardiovascular surgery program.
The pediatric intensive care unit (PICU) is a 24 bed unit, with the option to flex to 36 beds. In 2017, the PICU had 1,584 admissions for a total of over 7,100 patient days.
Catheter associated urinary tract infection (CAUTI) rates were consistently above national benchmarks in the PICU.

Conclusion:
Helen DeVos Children's Hospital
Zero CAUTI identified for over one year

- PICU

-Zero CAUTI identified for 498 days
-77% CAUTI reduction since 2014
-3% Foley utilization reduction since 2014
-Average number of patients per month with a Foley decreased from 53 to 32 post committee implementation
Prevention bundle process measure improvement of 52%



Quality Intervention: Hine Veterans Hospital In Patients with Spinal Cord Injury and Brain Trauma

Evaluating the Effectiveness of a Multidimensional Bundle to Reduce Urinary Tract Infection in Longterm Spinal Cord Injury/Disordered Patients: A Retroactive Review

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Published Journal of Wound Ostomy Nursing

Background:

Urinary Tract Infections remain the most frequently encountered secondary health condition in the Spinal Cord Injury/Disorder (SCI/D) population that adversely impacts overall health and quality of life. Efforts to reduce CAUTI/UTIs have historically been unsuccessful in this population.

Methods:

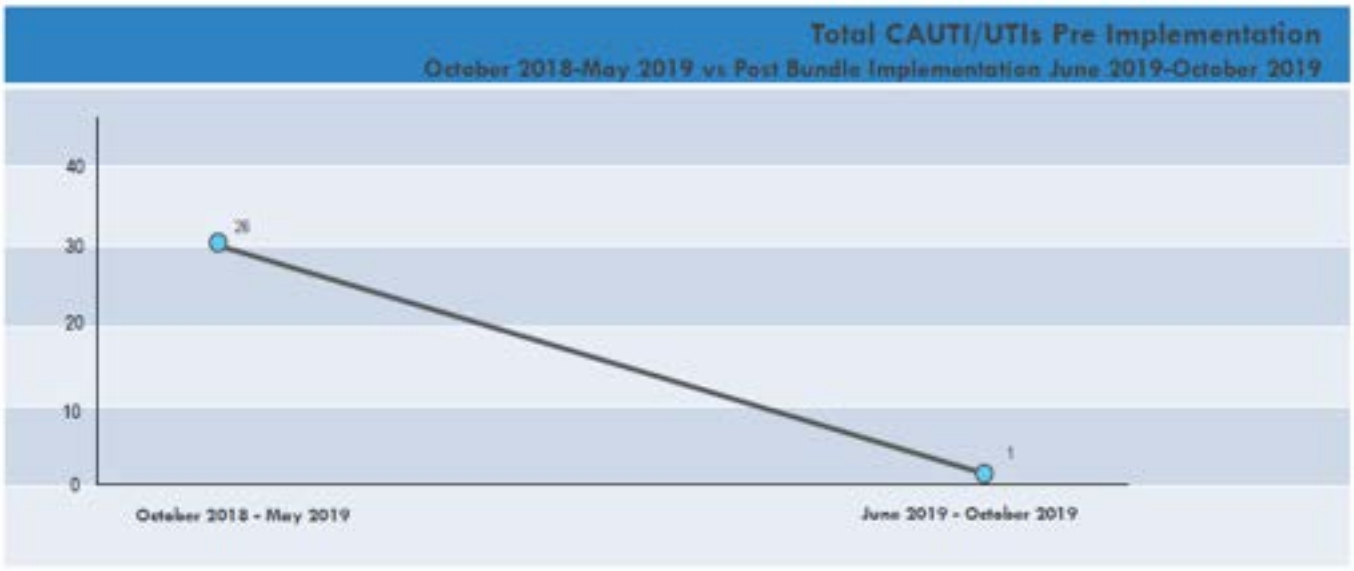
The methodology utilized was a retrospective, pre- and post -implementation analysis of a multi-factorial process approach to reduce CAUTIs and UTIs in the long-term care spinal cord unit. The relationship between the multi-factorial process approach and CAUTI/UTI rates were reviewed. The five interventions that made up the multi-factorial process approach included the addition of a novel topical adjunctive therapy*

1. The addition of a novel topical adjunctive therapy*
2. Reduction of bath basins in daily hygienic care
3. Implementation of 100% silicone catheters for those veterans that experienced catheter leakage
4. Standardized Education
5. Reduction of routine catheter flushing

*Theraworx Protect

Results:

CAUTI/UTI rates were substantially reduced from twenty-six (18 CAUTI & 8 UTI) to one (1 CAUTI and 0 UTI) after implementation of the quality improvement bundle. The multifactorial bundle achieved the projects aim in reducing CAUTI/UTI rates by 96%. Post intervention patients also demonstrated a 60% relative risk reduction in the need for IV antibiotics secondary to UTI.



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Efficacy of a novel skin antiseptic against carbapenem-resistant Enterobacteriaceae

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Background
Infections caused by carbapenem-resistant Enterobacteriaceae (CRE) are increasing on a global scale and represent a significant public health concern.1,2 Prevention and control of the spread of CRE can be difficult because Enterobacteriaceae are enteric organisms and are consistently shed to the environment and to the hands of health care workers from colonized or infected hosts. Reduction in skin and environmental bioburden are important prevention interventions for organisms transmitted via this route. The highest quantities of CRE are likely to be on colonized or infected patients, making source control important. Although primarily present in the gastrointestinal tract, these organisms are identified on inguinal and axillary surfaces nearly as often as in the rectum.3 These data support the concept that daily bathing with antiseptic solutions may decrease the CRE skin bioburden4 and therefore reduce transmission. To provide a safe health care environment for patients, it is critical to continue to identify products that are nontoxic and effective for daily bathing while maintaining activity against epidemiologically important organisms, such as these multi -drug resistant Enterobacteriaceae. The current study describes the efficacy of a novel skin antiseptic against 2 different CRE.

Methods
This was a laboratory-based efficacy study evaluating a nontoxic, silver-based skin antiseptic (Theraworx, Avadim Technologies, Asheville, NC) against carbapenem-resistant Escherichia coli and carbapenem-resistant Klebsiella pneumoniae. To evaluate the potential efficacy of this product for antisepsis on human skin, the VITRO-SKIN model (IMS, Portland, ME) was used. This model consists of a substrate that simulates human skin, with similar topography, pH, surface tension, and ionic strength. Organisms E coli and K pneumoniae isolates were obtained from the American Type Culture Collection, numbers 81,371 and BAA-1705, respectively. The modified Hodge test was used to document carbapenem resistance in each isolate.

Table 1
Efficacy of a novel silver-based skin antiseptic against carbapenem-resistant *Escherichia coli* using a skin model in the presence of 5% bovine serum

	Survivors			
	Replicate 1	Replicate 2	Replicate 1	Replicate 2
Dilution volume	15-min exposure		60-min exposure	
10^{0} (1.00 mL)	60	40	185	41
10^{-1} (1.00 mL)	8	6	20	6
10^{-1} (1.00 mL)	1	0	2	0
10^{-2} (1.00 mL)	0	0	0	0
10^{-3} (1.00 mL)	0	0	0	0
CFU/carrier	1.2×10^{3}	8.2×10^{2}	3.7×10^{3}	8.2×10^{2}
$\log_{10}$ CFU/carrier	3.08	2.91	3.57	2.91
Average $\log_{10}$	3.00		3.24	
Geometric mean (CFU/carrier)	1.00×10^{3}		1.74×10^{3}	
$\log_{10}$ reduction	3.84		3.60	
Percent reduction	>99.9		>99.9	

NOTE. Data represent CFU unless otherwise noted.
CFU, colony forming units.

Table 2
Efficacy of a novel silver-based skin antiseptic against carbapenem-resistant *Klebsiella pneumoniae* using a skin model in the presence of 5% bovine serum

	Survivors			
	Replicate 1	Replicate 2	Replicate 1	Replicate 2
Dilution volume	15-min exposure		60-min exposure	
10^{0} (1.00 mL)	>300	>300	>300	>300
10^{-1} (1.00 mL)	132	>300	109	107
10^{-1} (1.00 mL)	24	40	22	22
10^{-2} (1.00 mL)	3	2	2	3
10^{-3} (1.00 mL)	1	1	0	1
CFU/carrier	2.64×10^{4}	8.0×10^{4}	2.18×10^{4}	2.14×10^{4}
$\log_{10}$ CFU/carrier	4.42	4.90	4.34	4.33
Average $\log_{10}$	4.66		4.34	
Geometric mean (CFU/carrier)	4.57×10^{4}		2.19×10^{4}	
$\log_{10}$ reduction	1.86		2.18	
Percent reduction	98.6		99.3	

NOTE. Data represent CFU unless otherwise noted.
CFU, colony forming units.

Our study documents that this particular silver-based antiseptic may be useful for skin antisepsis in patients colonized or infected with CRE because of its confirmed activity against 2 of these organisms on a human skin analog. Being silver based, it may have excellent activity against a broad range of organisms other than CRE.5 Furthermore, this antiseptic provides many benefits over soap and water, including (compared with data available for hand hygiene)6 antibacterial activity, skin nourishment, pH maintenance, and promotion of cell growth and skin barrier protection. Each ingredient is considered nontoxic and has been tested in whole for biocompatibility and toxicity (testing results and safety data sheet available from Avadim Technologies). These properties make it an attractive option for skin antisepsis in hospitalized patients, and the enhanced antibacterial activity should reduce transmission of pathogens similarly to other available skin antiseptics.

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FINAL REPORT #2211575-402

TITLE **EVALUATION OF ONE TEST ARTICLE FOR VIRUCIDAL PROPERTIES BASED UPON THE ASTM E1052-20 METHOD**

PURPOSE

This study evaluated virucidal properties of one test article when challenged with Respiratory Syncytial Virus. The testing was based upon ASTM E1052-20, *Standard Practice to Assess the Activity of Microbicides against Viruses in Suspension*. All testing was performed in accordance with Food and Drug Administration Good Laboratory Practices, as specified in 21 CFR Part 58, with the exception that the characterization of the identity, strength, purity, composition, stability, and solubility of the test article remained the responsibility of the sponsor and was not performed by the testing facility (GLP 58.105).

SCOPE

This study was designed to evaluate the virucidal properties of one test article versus Respiratory Syncytial Virus strain Long (ATCC #VR-26) using a Virucidal Suspension Test (*In-Vitro* Time-Kill method) based upon ASTM E1052-20, *Standard Practice to Assess the Activity of Microbicides against Viruses in Suspension*. The percent and $\log_{10}$ reductions from the initial population of the viral strain were determined following exposure to the test article for 30 minutes, 3 hours and 6 hours. Testing was performed in one replicate. Plating was performed in four replicates.

The protocol, included in the addendum to this final report, presents the study methodology, in detail. No deviations from the protocol or from applicable standard operating procedures occurred during the course of this evaluation.

TABLE 3

Test Article: Theraworx Protect Foam (Lot #520669)
Virus: Respiratory Syncytial Virus strain Long (ATCC #VR-26)
Host Cell Line: HEp-2 (ATCC #CCL-23)

Dilution (- $\log_{10}$)	Virus Control	Test	Neutralization Control	Neutralizer Toxicity Control	Cytotoxicity Control	Cell Control
		30 Minutes				0000
-2	NT	0000	NT	NT	0000	N/A
-3	++++	0000	++++	++++	0000	
-4	++++	0000	++++	++++	0000	
-5	++++	0000	00++	+0+0	NT	
-6	0000	0000	0000	0000	NT	
-7	0000	0000	0000	0000	NT	
$TCID_{50}$ ($\log_{10}$)	5.50	≤1.50	5.00	5.00	≤1.50	
$\log_{10}$ Reduction	N/A	≥4.00	N/A			
Percent Reduction		≥99.99%				

\+ Virus infected cells present
0 Virus infected cells not detected
NT Not tested
N/A Not applicable

Independent Laboratory Study: Bioscience Laboratories Final Report #1703130-201

AN EVALUATION OF ONE TEST PRODUCT FOR ITS ANTIMICROBTAL PROPERTIES WHEN CHALLENGED WITH THREE MICROORGANISMS USING AN INVTTRO TIME-KILL METHOD- CANDIDA AURIS

Background

Candida auris is an emerging fungus that presents a serious global health threat. CDC is concerned about C. auris for three main reasons: 1. It is often multidrug-resistant, meaning that it is resistant to multiple antifungal drugs commonly used to treat Candida infections. Some strains are resistant to all three available classes of antifungals.2. It is difficult to identify with standard laboratory methods, and it can be misidentified in labs without specific technology. Misidentification may lead to inappropriate management. 3. It has caused outbreaks in healthcare settings. For this reason, it is important to quickly identify C. auris in a hospitalized patient so that healthcare facilities can take special precautions to stop its spread.

Methods/Results

An In-Vitro Time-Kill evaluation of one test product was performed versus three microorganisms - Candida auris (AR-Bank #0385), Candida auris (AR-Bank #0389), and Candida auris (AR-Bank #0390). All testing was performed based upon the method described in ASTM 82783-17, Standard Test Method for Assessment of Antimicrobial Activity of Waler Miscible Compounds Using a Time-Kill Procedure.

Results

The percent and $\log_{10}$ reductions from the numbers control population of the challenge microorganism was determined following exposure to the test product for 4 hours, 8 hours, and 24 hours. All agar-plating was performed in duplicate. Test Product, Broad Spectrum Hygiene Management, 4 oz Foam (Lot #16180-I), reduced the populations of the three challenge microorganisms -- Candida auris (AR-Bank #0385), Candida auris (AR-Bank #0389), and Candida arris (AR-Bank #0390) by greater than 0.5 $\log_{10}$ following a 4 hour exposure time, by greater than 1.0 $\log_{10}$ following a 8 hour exposure time, and by greater than 6.0 $\log_{10}$ following a 24 hour exposure time.

TABLE 2
Test Product: Broad Spectrum Hygiene Management (4 oz Foam)
Lot Number: 16180-1

Microorganism Species (ATCC #)	Initial Population (CFU/mL)	Exposure Time	Numbers Control Population (CFU/mL)	Post-Exposure Population (CFU/mL)	$\log_{10}$ Reduction	Percent Reduction
Candida auris (AR-Bank #0385)	5.050×10^9	4 hours	5.00×10^7	1.320×10^7	0.5784	73.6000%
		8 hours	5.150×10^7	4.250×10^5	1.0834	91.7476%
		24 hours	4.00×10^7	$< 1.00 \times 10^1$	6.6021	99.9999%
Candida auris (AR-Bank #0389)	5.10×10^9	4 hours	5.950×10^7	9.350×10^6	0.8037	84.2857%
		8 hours	6.250×10^7	3.90×10^5	2.2048	99.3760%
		24 hours	5.750×10^7	$< 1.00 \times 10^1$	6.7597	99.9999%
Candida auris (AR-Bank #0390)	5.950×10^9	4 hours	4.00×10^7	1.4550×10^6	1.4392	96.3625%
		8 hours	5.10×10^7	1.4050×10^5	3.5599	99.9725%
		24 hours	4.80×10^7	$< 1.00 \times 10^1$	6.6812	99.9999%

Journal of Clinical and Medical Investigations: ISSN: 2398-5763 Clin Med Invest, 2017 doi: 10.15761/CML1000129

Theraworx skin care formulation reduces nosocomial associated CAUTI rates when used for urinary catheter insertion and maintenance

Multi-Center Study Conducted in High-Risk Neurological, Cardiovascular and Trauma Critical Care Settings, and Joseph F Renzulli*
Associate Professor of Surgery (Urology), Alpert Medical School of Brown University and CMO, Avadim Technologies, USA

Background

Catheter associated urinary tract infections (CAUTI) continue to be the most challenging of all hospital and institutional acquired conditions. According to the Centers for Disease Control and Infection Prevention urinary tract infections (UTIs) are the most common type of healthcare-associated infection reported to the National Healthcare Safety Network (NHSN) [1]. Urinary infections are the source for more than 50% of all infections in long term care facilities and more than 40% of all hospital acquired infections [2]. Despite extreme efforts, including the off-label use of topical drugs, the CAUTI rate world-wide continues to rise. This is only further complicated by the emergence of multi-drug resistant organisms (MDROs). Considerable personnel time, direct and indirect costs are expended by health care institutions to reduce the rate of hospital acquired infections, especially those that occur in patients with signs and symptoms referable to the urinary tract. UTIs are classified as either uncomplicated or complicated infections and treatment often differs based on this classification. However, all nosocomial and catheter associated urinary tract infections are considered complicated. Nosocomial infections are further complicated by advanced patient age and multiple comorbidities [3]. The likelihood of treatment failure and serious complications, particularly the development of antimicrobial resistance, is more common in CAUTI. Multiple drug resistant organisms including Carbapenem Resistant Enterobacteriaceae (CRE), in particular, an E coli isolate, adds to the complex challenge as many ICU patients with indwelling catheters experience fecal incontinence [4]. The removal of macroscopic debris during cleansing of incontinent patients is not sufficient to prevent infections. Therefore, topical antiseptic solutions and cleansers should have proven efficacy demonstrating the ability to decolonize these resistant organisms on human skin and mucosa without disrupting the normal host immunity, while preserving mucosal integrity and the microbiome [5,6].

Results

Ten of the hospitals from which data was requested provided both pre- and post-intervention data. Eight of the ten reporting hospitals complied with recommended clinical protocols. The average pre-intervention period for these eight hospitals was 22.9 months. The average post-intervention period was 14 months. All eight hospitals reported that Theraworx use markedly reduced their CAUTI rate. The reductions ranged from 22.47% (UHS-San Antonio in San Antonio, Tex.) to 100% at two hospitals (Centennial Hospital, in Frisco, Texas and Peace health St. Joseph Medical Center, in Bellingham, Washington). CAUTIs were completely eliminated at the latter two sites. The mean pre-intervention CAUTI rate for the eight compliant hospitals was 3.65/1,000 catheter days. The mean post-intervention CAUTI rate for those same hospitals was 1.72/1,000 catheter days, a difference of 1.93/1,000 catheter days. Therefore, the mean change in CAUTI rate was a reduction of 52.88% for compliant institutions. Evaluation of the two hospitals that acknowledged that proper protocols for Theraworx use were not consistently followed during the study period revealed troubling data. One of these hospitals reported no change in CAUTI rates; while the other reported a 30.31% increase.

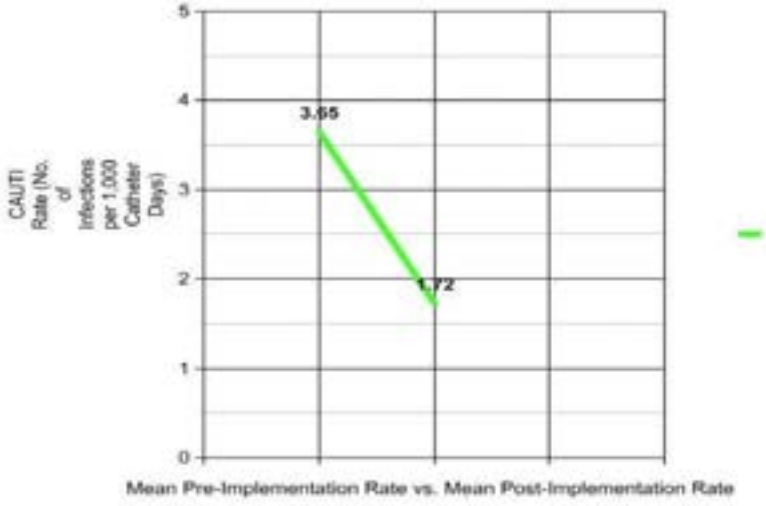

Figure 1. Mean CAUTI Rate Reduction with Theraworx Use.

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Can't Attribute UTI TO Insertion: Utilizing Data to Prevent CAUTI. Univeristy of Washington Medical Center 2018

Background: • Per the CDC, urinary tract infections (UTI) are the 4th most common type ofhealthcare-associated infection and virtually all arecaused by instrumentation of the urinary tract

- On average, 12-16% of all adult inpatients will have anindwelling urinary catheter(IUC)
- Each day the IUC is in placethe patient has 3-7% increased risk of acquiring a CAUTI
- Estimated cost of CAUTI~ $11,000 per case
- Aside from medical complications such as cystitis, pyelonephritis, & bacteremia, CAUTI maycause patients discomfort, extend hospitalizations, &increased costs and mortality

Conclusion: Through multi-disciplinary engagement & review of epidemiologic data, high riskpopulations for CAUTI wereidentified

- The high risk populations related to maintenance ofIUC, not insertion
- With the implementation of a NDP & a trial of a novel peri-care product, CAUTI rates reduced 46%
- Colloidal silver wipes are now available for CAUTI prevention hospital-wide

Can't Attribute UTI To Insertion: Utilizing Data to Prevent CAUTI

Smith, N.C., Granich, M., Lien, H., Schipper, A.
University of Washington Medical Center, Seattle, WA

PURPOSE

- To utilize data to identify populations at risk & develop focused initiatives to further decrease catheter associated urinary tract infections (CAUTI)

BACKGROUND

- Per the CDC, urinary tract infections (UTI) are the 4th most common type of healthcare-associated infection and virtually all are caused by instrumentation of the urinary tract
- On average, 12-16% of all adult inpatients will have an indwelling urinary catheter (IUC)
- Each day the IUC is in place the patient has 3-7% increased risk of acquiring a CAUTI
- Estimated cost of CAUTI ~ $11,000 per case
- Aside from medical complications such as cystitis, pyelonephritis, & bacteremia, CAUTI may cause patients discomfort, extend hospitalizations, & increased costs and mortality

INITIATIVES

Multidisciplinary Engagement

A multidisciplinary steering committee created to address rising CAUTI rates including:

- Nursing Leadership and Staff Nurses from ICU, Med-Surg, ED, OR
- Providers
- Infection Prevention Specialists
- Informatics

Identify High Risk Populations

Intensive case review of CAUTI identified these factors:

- Prolonged catheterization - 96% occurred 3 days after placement
- 82% Fecal incontinence
- 78% Enteric pathogens
- Patient risk factors: female gender, obesity, immobility, multiple organ failure
- Primary Services: Cardiology, Cardiothoracic Surgery, Abdominal Surgery, Medicine

Implement Nurse Driven Protocol (NDP)

NDP empowers nurses to insert, maintain, & remove urethral catheters based on specific criteria.

Indications for IUC:

- Intensive monitoring (q1-2 hrs)
- End of Life request
- Profound prolonged immobility (unstable spine)
- Urinary incontinence & perineum wound breakdown
- Urinary outlet obstruction
- Urological surgery
- Bladder dysfunction

Trial Novel Peri-Care Product & EMR Enhancements

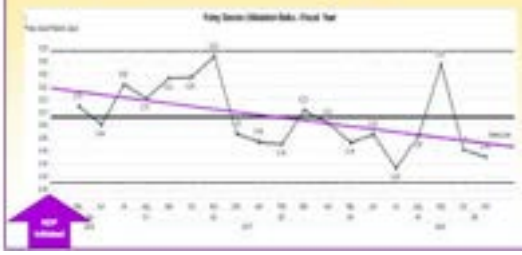
A trial of colloidal silver wipes (bactericidal & bacteriostatic) in all 4 intensive care units & 2 step down units.

Colloidal silver wipes (Theraworx®) utilized with peri-care twice a day, & as needed after incontinence.

EMR documentation of peri-care revised to improve workflow & to facilitate data capture of CAUTI prevention bundle elements.

EVALUATION/OUTCOMES

- Urinary catheter device utilization decreased since NDP implemented
- CAUTI rate per 1,000 catheter days decreased
- 46% reduction in CAUTI events during trial



IMPLICATIONS FOR PRACTICE

- Through multi-disciplinary engagement & review of epidemiologic data, high risk populations for CAUTI were identified
- The high risk populations related to maintenance of IUC, not insertion
- With the implementation of a NDP & a trial of a novel peri-care product, CAUTI rates reduced 46%
- Colloidal silver wipes are now available for CAUTI prevention hospital-wide

FUTURE WORK

Further implications for study include:

- The development of an automated report based on nursing documentation that identifies patients at high risk for CAUTI in real-time
- Identifying potential barriers to NDP adherence & develop strategies to enhance use
- Consider alternate uses of colloidal silver wipes – alternative for CLABSI, total body decolonization

ACKNOWLEGEMENTS

UWMC CAUTI Steering Committee & Staff

NTI Abstracts-2020 National Teaching-Institute Evidence-Based Solutions Abstracts
Journal of Critical Care Nursing: American Association of Critical-Care Nurses
doi:https://doi.org/10.4037/ccn2020670
CriticalCareNurse Vol 40, No. 2, APRIL 2020

Change Has Arrived: Antimicrobial Bathing and CLABSI

Patricia Sung, Mary Virgallito, Theresa Murphy, Raffi Boghossian, Rose Young;
University of Southern California, Verdugo Hills Hospital, Glendale, California

Purpose: Persistent central catheter–associate bloodstream infections (CLABSIs) occurred each quarter from 2014 to 2016 in our 12-bed intensive care unit (ICU), prompting an infection prevention (IP) assessment in November 2016. Low compliance with the bathing protocol was identified as a gap in practice. Staff surveys indicated confusion about chlorhexidine (CHG) application and dissatisfaction with effects on patients' skin. A topical immune health system was introduced to replace CHG bathing products in an effort to improve staff satisfaction, raise compliance, and reduce CLABSI rates.

Evaluation/Outcome: Pre -implementation assessment identified gaps in practice. Staff indicated CHG was "too sticky," and "too complicated; patients don't like it." In July 2019, a questionnaire was
administered to ICU nurses after the change to the new antimicrobial bathing product. Of 20 responses received from nurses, all stated they like the product. In response to an open-ended question asking why staff and/or patients like the product, 4 nurses (20%) cited the ease of use, and 7 (35%) cited the protective effects on the patients' skin. A random sample audit of patient bathing compliance before (5 of 10) and after (10 of 10) implementation identified a statistically significant difference (P = .02).
The ICU achieved a rate of 0 CLABSI in February 2018 and has remained at zero through April 2020.

***Statistical Significance in ICU Bathing Compliance after implementing Theraworx Protect at (P= .02)**

***CLABSI Rate since converting to Theraworx Protect from CHG 2% has remained at zero since February 2018**

NTI Abstracts-2020 National Teaching-Institute Evidence-Based Solutions Abstracts
Journal of Critical Care Nursing: American Association of Critical-Care Nurses
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CriticalCareNurse Vol 40, No. 2, APRIL 2020

Closing the Gap: Targeting CAUTIs With a Novel Approach to Perineal Care

Lisa Hargett, Theresa Anderson; University of Maryland
St. Joseph Medical Center, Towson, Maryland

Purpose: Persistent catheter-associated urinary tract infections (CAUTIs) occurred in University of Maryland St. Joseph Medical Center's 28-bed critical care unit despite a robust prevention bundle. Root-cause analyses identified poor compliance with perineal and urinary catheter care as a gap in evidence-based practice. A change from applying soap and water with a washcloth from a basin to a topical immune health system wipe–based product was implemented to standardize process, improve compliance, and eliminate CAUTIs.

Summary: Despite continuous efforts to reduce infections, patients in the medical-surgical intensive care unit (MSICU) continued to have CAUTIs. Although a 44% reduction from fiscal year (FY)14 to FY15 was achieved, 1 infection was still too many. Root-cause analyses were performed on each CAUTI to identify a potential reason for the infection. Compliance with perineal and urinary catheter care was identified as a potential root cause and an opportunity to improve. In November 2015, the MSICU implemented a new process for managing bowel incontinence and enhancing perineal and urinary catheter care. These interventions included baby wipes for incontinence care and a topical immune health system wipe for perineal and urinary catheter care. The topical immune health system is used during the following situations: before and after insertion of a urinary catheter; to clean every 6 hours, or every 4 hours for catheters indwelling longer than 5 days, patients with urinary catheters; as a final cleaning step for any incontinence events; as a final cleaning step during the daily CHG bath; and before straight catheterization. With this new practice, perineal and urinary catheter care increased from once per day to up to 6 times per day, based on the duration of the catheter. Frontline staff were involved in the solution and implementation processes.

Evaluation/Outcome: Staff satisfaction was very high with the new standard of care. Staff survey results were notable for ease of use (100%), preference over previous practice (97%), and catheter care being worth the extra step (100%). Compliance with perineal care also improved. After implementation, the MSICU celebrated 351 days without a CAUTI. The success has continued: the unit recently celebrated 365 days CAUTI free. Our standardized infection ratio also decreased by 49% from before to after implementation of the new interventions. It is important to acknowledge that this success is not the result of a single intervention but rather multiple interventions designed to reduce CAUTIs.

100% Staff Satisfaction

Improved Compliance

365 continuous Days Zero CAUTI

Reduction in Standardized Infection Ratio by 49%

Quality Intervention: Tenet Healthcare- CLABSI/CAUTI Intervention

Zero CAUTI, Zero CLABSI: Evaluating the evidence-based effectiveness of a Silver, pH Acidic, Multimodal Skin decolonizing wipe to Reduce Catheter Associated Urinary Tract Infection and Central Line Blood Stream Infections in the ICU setting: A Retrospective Review

Tenet Health - Doctors Medical Center Modesto, CA
Asif Saiyed, MBA, CIC, Director Infection Prevention

Background

CAUTI and CLABSI continue to be a significant problem for patients in the ICU setting. Despite successful implementation of recommended protocol bundles, Acute care hospitals, still struggle with these infections. Compliance with CHG bathing wipes can be challenging because of skin irritation and allergic reactions. Microbe resistance and antiseptic contamination recalls mean that Hospitals should investigate safe, effective alternatives to the status quo antiseptics. Non-antimicrobial urinary catheter bathing products do not effectively address the root cause of CAUTI. In order to improve CAUTI and CLABSI rates an evidence based, safe, effective, skin friendly, approach was implemented. The focus was to improve patient satisfaction, efficiency, bathing compliance, promote antimicrobial stewardship and significantly reduce both CAUTI and CLABSI rates.

Methods

A retrospective, 6- month, pre- and post -implementation infection rate analysis was used to measure changes in CAUTI rate per 1,000 catheter days and CLABSI rates per 1,000 central line days consistent with the CDC reporting nomenclature and AHRQ standards. Clinical evaluation was completed in CCU, NCCU, SICU, CVICU between November 2019 and April 2020. April 2019 and September 2019 were used for comparison. October 2019 was the product transition month.

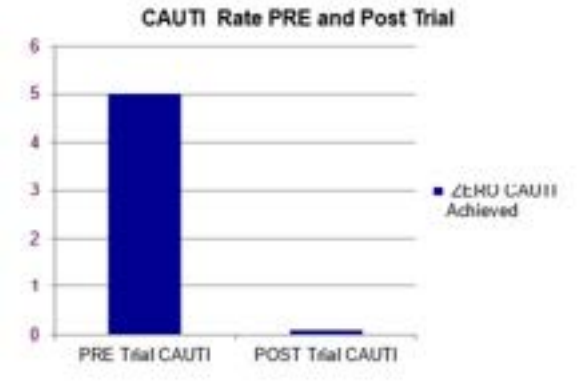
Pre-and post-implementation CAUTI and CLABSI surveillance was completed monthly using electronic medical record chart audits during the study intervention period and compared them with retrospective analysis of past infection rates within the same units. Historically CAUTI and CLABSI rates are analyzed and reported monthly by Infection Control Services.

Nurse satisfaction survey to measure ease of use, efficiency of use, patient satisfaction, patient refusal, and perception of improved over compliance.

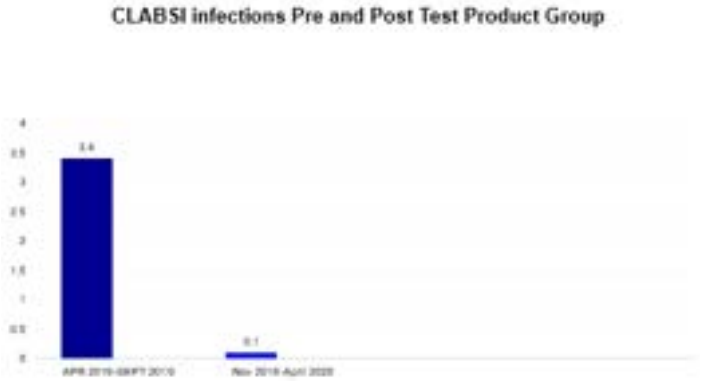
Results

This retrospective analysis involved CCU, NCCU, SICU, CVICU patients with central line catheters and / or indwelling urinary catheters. The new impregnated wipes test product trial started on SIR rate 2019 .442 Data collected from chart reviews and monitoring of electronic records were reviewed and infections were recorded when they met NHSN reporting guidelines for either CAUTI or CLABSI. SIR rate January 1 – June 30, 2020 0.00

CAUTI rates were substantially reduced from a SIR rate of .442 Pretrial group to a SIR rate of in the Post test group



CLABSI Rates were reduced from an SIR rate of .348 in 2019 in the pre-test group to a SIR of 0.0 Jan 1 – June 30 in the Post – test product and protocol group



Quality Intervention: Northwell Health- Theraworx Protect Protocol Effect on C. diff Rates

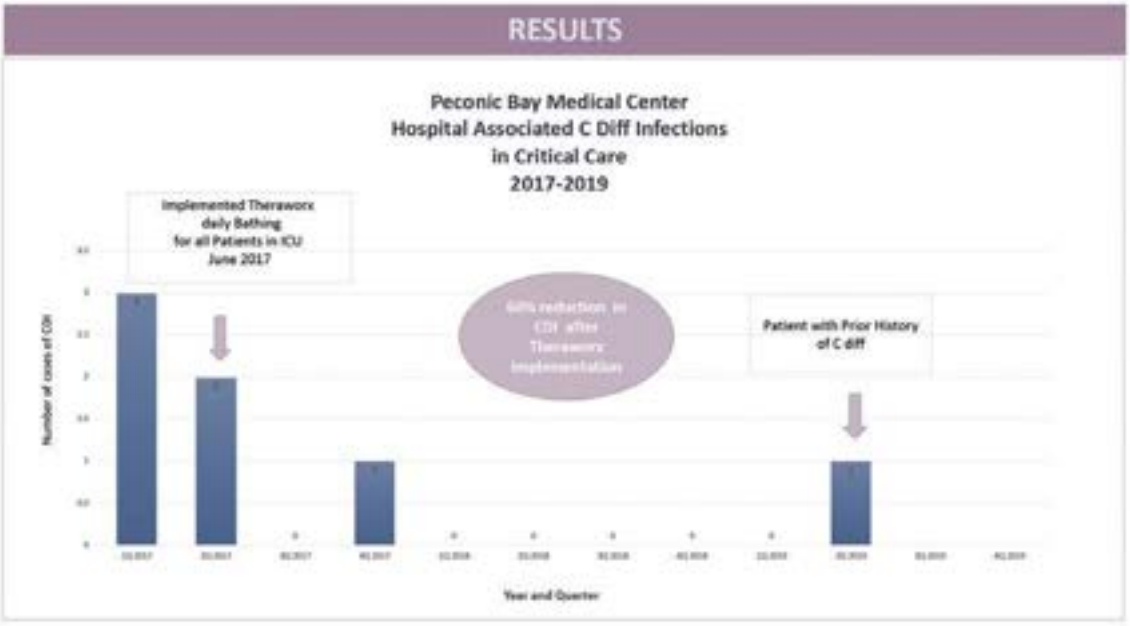
Preventing Hospital Acquired Clostridium Difficile Infection in ICU Patients: The Efficacy of Theraworx, a Novel Silver-Based Cleanser: Journal of Critical Care Nursing

Patty Mupo, RN, BSN; Holly Fischer, RN, BSN; Tarayn Dhansew, DO; Maria Masih, MD; Ashley Collins, DO; Vladimir Orlov DO; Faculty Advisor: Pooja Paunikar MD, MPH

Background

Prevention of hospital acquired clostridium difficile infection (CDI) continues to be an ongoing concern due to the prevalence, increase in patient morbidity and mortality, and impact on health care costs. It is estimated that 75% of CDI cases are hospital acquired with an estimated annual healthcare cost is $1.5- 3.2 billion [5]. Literature has shown a multimodal approach is required for effective transmission prevention. Patient bathing aims to reduce skin contamination and eliminate spores that can survive for up to five months. However, Studies have shown that spores are resistant to the commonly used disinfectants, including Chlorhexidine gluconate (CHG) [5]. A global review of infection prevention strategies revealed significant gaps in consistency and standardization of policies regarding patient bathing techniques [7]. Lack of standardization leaves room for non-compliance and variance, ultimately affecting patient outcomes and increasing the risk of CDI. Review of literature examining the efficacy of CHG bathing shows gaps in CDI prevention. A study evaluating CHG bathing on the rates of CDI in SICU patients was inconclusive [1]. A review of 17 trials examining CHG bathing against health-care associated infections in ICU patients did show evidence for reduction against CLABSI and CAUTI. However, effectiveness against other HAI, including CDI, were inconclusive [4]. A clinical trial has also showed a concern that CHG bathing may increase microbial resistance and CHG was not effective against multi-drug resistant bacteria [4, 3]. To address the gap in current practice, a study conducted to evaluate the safety and efficacy of Theraworx showed the colloidal silver-based product was non-inferior to the 4% CHG product [2]. Theraworx also has antimicrobial activity against gram positive and gram-negative organisms even at low concentrations and has components that supports the skin's innate immune system [2,8]

RESULTS



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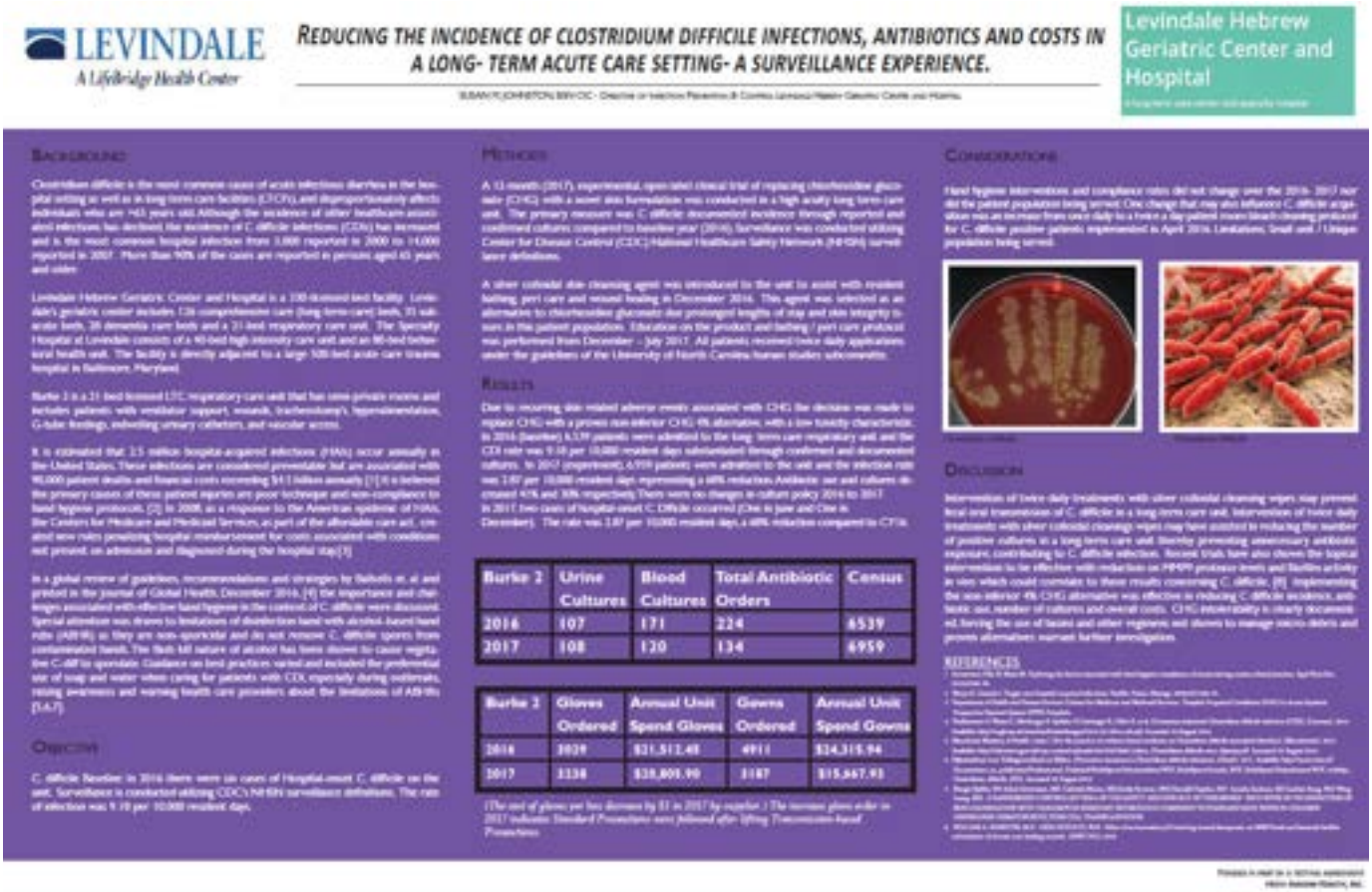
Reducing the Incidence o Clostridium Difficile Infections, Antibiotics and Costs In A Long-Term Acute Care Setting - A Surveillance Experience. Levindale Hebrew Geriatric Center and Hospital 2018.

Background: Clostridium difficile is the most common cause of acute infectious diarrhea in the hospital setting as well as in long-term care facilities (LTCFs), and disproportionately affects individuals who are >65 years old. Although the incidence of other healthcare-associatedinfections has declined, the incidence of C difficile infections (CDIs) has increasedand is the most common hospital infection from 3,000 reported in 2000 to 14,000 reported in 2007. More than 90% of the cases are reported in persons aged 65 years and older. Levindale Hebrew Geriatric Center and Hospital is a 330-licensed-bed facility. Levindale's geriatric center includes 126 comprehensive care (long-term care) beds, 35 subacutebeds, 28 dementia care beds and a 21-bed respiratory care unit. The Specialty Hospital at Levindale consists of a 40-bed high intensity care unit and an 80-bed behavioral health unit. The facility is directly adjacent to a large 500-bed acute care trauma hospital in Baltimore, Maryland. Burke 2 is a 21-bed licensed LTC respiratory care unit that has semi-private rooms and includes patients with ventilator support, wounds, tracheostomy's, hyperalimentation, G-tube feedings, indwelling urinary catheters, and vascular access. It is estimated that 2.5 million hospital-acquired infections (HAIs) occur annually in the United States. These infections are considered preventable but are associated with 90,000 patient deaths and financial costs exceeding $4.5 billion annually. [1] It is believedthe primary causes of these patient injuries are poor technique and non-compliance to hand hygiene protocols. [2] In 2008, as a response to the American epidemic of HAIs, the Centers for Medicare and Medicaid Services, as part of the affordable care act, created new rules penalizing hospital reimbursement for costs associated with conditions not present on admission and diagnosed during the hospital stay.[3] [5,6,7].

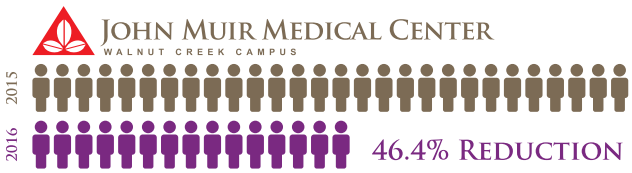
Results: Due to recurring skin related adverse events associated with CHG the decision was made to replace CHG with a proven non-inferior CHG 4% alternative, with a low toxicity characteristic. In 2016 (baseline) 6,539 patients were admitted to the long- term care respiratory unit and the CDI rate was 9.18 per 10,000 resident days substantiated through confirmed and documented cultures. In 2017 (experiment), 6,959 patients were admitted to the unit and the infection rate was 2.87 per 10,000 resident days representing a 68% reduction. Antibiotic use and cultures decreased 41% and 30% respectively. There were no changes in culture policy 2016 to 2017. In 2017, two cases of hospital-onset C. Dfficile occurred (One in June and One in December). The rate was 2.87 per 10,000 resident days, a 68% reduction compared to CY16.

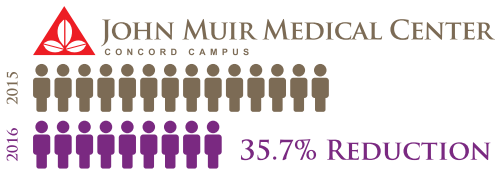


CLABSI (Central Line Associated Blood Stream Infections) Reduction Seen with Multifactorial Nurse Initiative.

****To be presented at the Fall ANCC national convention****

John Muir Health includes two of the largest medical centers in Contra Costa County: John Muir Medi-cal Center, Walnut Creek, a 554-licensed bed medical center that serves as Contra Costa County's only designated trauma center; and John Muir Medical Center, Concord, a 245-licensed bed medical center in Concord. Together, they are recognized as preeminent centers for neurosciences, orthopedics, cancer care, cardiovascular care and high-risk obstetrics. John Muir a two-hospital health system observed an unacceptable increase in central line-associated bloodstream infections (CLABSIs) reported to National Healthcare Safety Network. Hospital acquired infections (HAIs) are a well-recognized cause of morbidity and mortality in the United States, and catheter-related bloodstream infections are 1 of the top 4 causes of HAI.1 It sought to reduce CLABSIs in a manner consistent with Magnet Hospital values. CLABSI's rep-resent a major source of HAIs and can significantly impact a patient's clinical course. Identification of an increased rate of CLABSI's prompted a multi-disciplinary approach to critically evaluating and then alter-ation and implementation of a protocol to reduce these infections thus optimizing patient outcomes. This nursing led initiative exemplified the Magnet criteria by involving clinical nurses, administrative nurses and infection prevention experts. Originally, an evidence-based central line insertion/maintenance bun-dle was adopted that included bathing central-catheterized patients with chlorhexidine gluconate (CHG). CHG proved harsh on patients' skin, compromising compliance and isn't indicated for mucous membranes where MDRO's colonize and was abandoned. It was replaced with a novel non-toxic skin formulation that has natural antimicrobial properties- Theraworx®. (A CHG scrub was still used at the local site prior to invasive procedure.) In January 2016, a performance improvement team was formed to support adherence to the bundle. In March 2016, the novel formulation (Theraworx®) was added to CHG use at the catheter insertion site. Upon, introduction of a novel non-toxic skin formulation (Theraworx®) to the central line insertion and maintenance protocol a marked reduction in CLABSIs was realized. At one hospital CLABSIs dropped from 28 in 2015 to 15 in 2016, (46.4% reduction). At the other hospital they dropped from 14 in 2015 to 9 in 2016 (35.7%). These data demonstrate a significant clinical reduction in CLABSIs, a major hospital acquired infection.





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Clinical Poster: Symposia For Advanced Wound Care Fall 2019

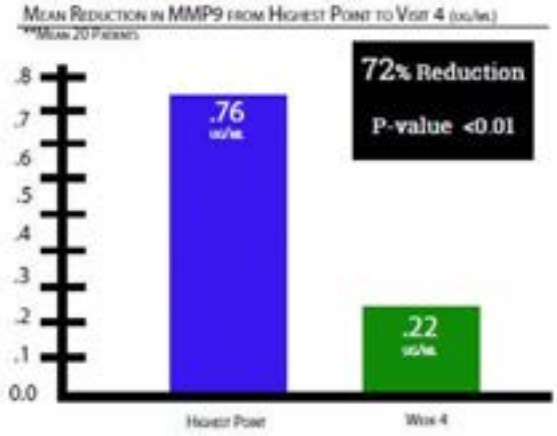
Effect of an Innovative pH Lowering Wound Therapeutic on MMP Levels and Bacterial Biofilm Colonization of Chronic Non-Healing Wounds.

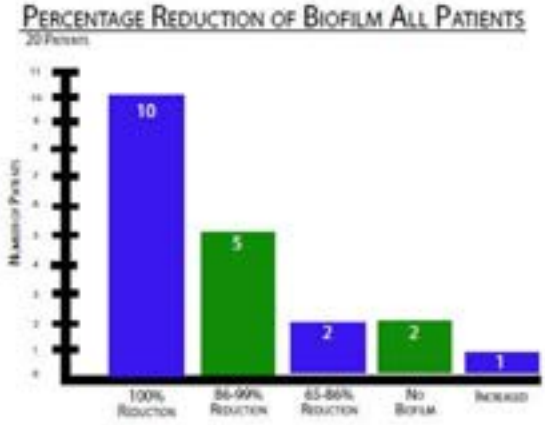
William Marston, MD.
Greg Schultz, PhD

Background:
Patients with chronic non-healing lower extremity wounds often are found to have chronic inflammation associated with biofilm bacterial colonization of the wound bed. Eradication of this biofilm and control of upregulated inflammation can be difficult to achieve without the use of long courses of systemic antibiotic administration. A novel wound therapy, Theraworx Protect (TWX), has been developed that reduces the pH of skin and wound tissue, increasing their resistance to bacterial colonization. This product has been shown to be effective at reducing the incidence of catheter-associated UTIs and central line associated infections. In this study we have applied TWX to chronic non-healing leg ulcers and measured matrix metalloproteinase (MMP) levels in wound fluid and bacterial biofilm involvement of the wound bed before and after 4 weeks of TWX therapy.

Methods:
Twenty patients with chronic non-healing lower extremity ulcers of >4 weeks duration were identified and agreed to participate. Patients were included with diabetic foot ulcers, venous leg ulcers and ulcers associated with chronic arterial insufficiency. Baseline patient demographics and wound characteristics were recorded. Prior to treatment with TWX, samples of wound fluid and tissue samples were obtained for MMP and bacterial biofilm analysis. MMP activities were measured using a synthetic seven amino acid peptide with a fluorochrome-quencher pair that generates a fluorescent signal when the peptide is cut by MMPs. 1 Colony forming units (CFU) of viable bacteria in biofilm phenotype were measured by standard dilution plating technique following brief (10 minute) exposure of ultrasonically dispersed biofilm communities to dilute bleach (0.1%) followed by neutralization with 0.15% sodium metabisulfite.2 The patients were treated for 4 weeks with standard treatment for the wound etiology plus application of TWX to the wound and peri-wound areas at all dressing changes. At weekly visits, wound characteristics were obtained and repeat wound fluid and tissue samples were obtained for MMP and bacterial analysis. At the completion of 4 weeks of treatment, wound size was re-measured to determine the percentage of wound healing over the 4 weeks of treatment. The study was approved and conducted under the guidelines of the University of North Carolina human studies subcommittee.

Results:
Sixty-seven percent of patients healed >30% over the 4-week treatment phase. The mean wound size decreased significantly from 29.8 ± 27.2 cm2 at baseline to 20.1 ± 20.5 cm2 after 4 weeks (P = .01). At peak level as opposed to baseline, the mean MMP-9 level was 0.76 ug/ml. After 4 weeks of TWX treatment, this level decreased to 0.22 ± 0.1 ug/ml (P < 0.01). At baseline, 15 of 20 patients had detectable levels of biofilm activity with a mean of 207,144 CFU/ml of homogenate. Among the 18 patients with detectable biofilm during the study, 10 had elimination of all detectable biofilm activity after 4 weeks of TWX treatment. Five patients experienced reduction of biofilm activity by > 86%. The total mean activity after 4 weeks of TWX treatment was 3109 CF U/ml of homo genate (P= 0.10).



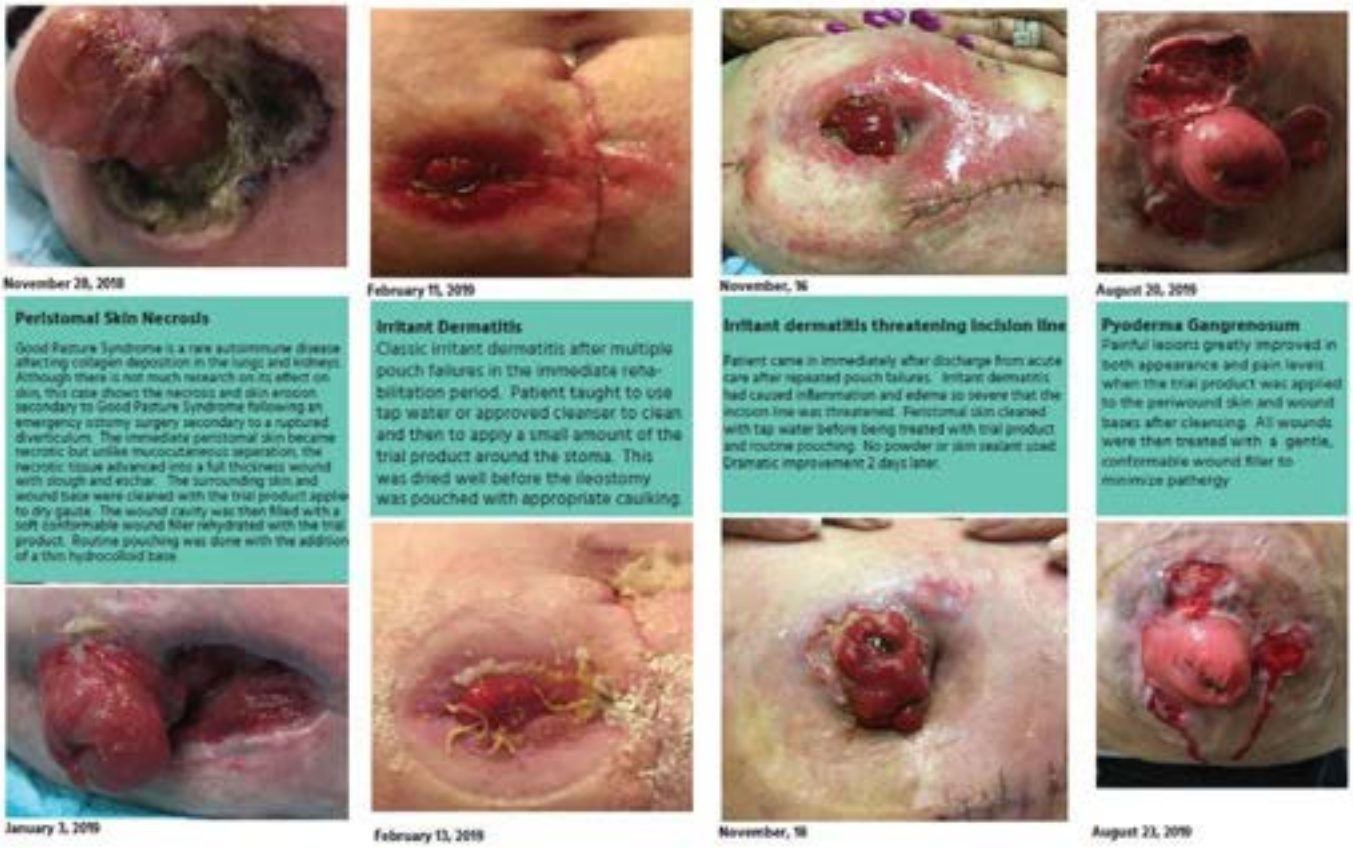


Clinical Poster: Symposia For Advanced Wound Care Spring 2019

Harnessing the Microbiome to Rapidly Resolve Peristomal Skin Complications

Authors: Diana L. Gallagher, MS, RN, CWOCN, CFCN
Jennifer Juergens, BSN, RN, CWOCN, CFCN

Almost all ostomates experience peristomal complications at some time. In one study, the incidence ranged from 18-55% but is thought be grossly under-reported. Factors that predispose patients to complications include poorly sited and poorly constructed stomas, obesity, wound complications, and disease. Common peristomal complications include irritant dermatitis, candidiasis, folliculitis, trauma, contact dermatitis and pseudoverrucous lesions. These alterations in skin integrity result in inflammation, pain, pruritus, and changes in trans-epidermal water loss. All of these changes interfere with successful pouching. Pouch failures result in embarrassing leaks and worsening of these skin conditions with additional exposure to stool, urine, and trauma with frequent pouch changes. In the specific cases of Irritant Dermatitis and Pseudoverrocous papules and nodules (PPN), it is commonly believed that the underlying cause is prolonged exposure to liquid stool and/or urine. Along with the added moisture, the effluent increases the alkalinity of the skin. This damages the important acid mantle integral to skin's ability to withstand skin damage. This study expands the research on managing refractory Incontinence Associated Dermatitis (IAD) and the importance of pH with chronic wounds employing a technology which has shown the ability to down modulate tissue and wound pH. Prior research with IAD, showed this intervention lowered inflammation, enhanced skin's adhesion, cohesion, and integrity by down regulating a group of enzymes that leads to shedding of the stratum corneum. This study with over 20 patients resulted in rapid resolution or significant improvement of peristomal complications in 24-72 hours with a simple application before pouching. This was a marked improvement over standard of care.



Clinical Poster: Symposia For Advanced Wound Care Fall 2018

Successful Healing of IAD when Traditional Barriers Fail Using an Innovative Topical Formulation

Diana Lynn Gallagher MS, RN, CWOCN, CFCN
Janalynn Miller FNP-C, GNP, CWCN-AP

Problem

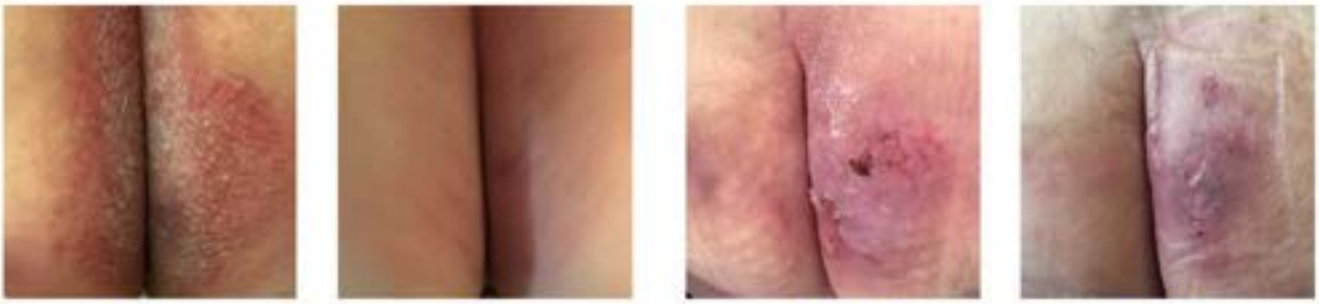
Incontinence Associated Dermatitis (IAD) is the result of urine and/ or feces damaging skin. IAD results in over-hydration, edema, and breakdown of the Stratum Corneum. This damage increases skin's susceptibility to friction, elevates pH, and escalates erythema and erosion. In spite of traditional management programs including gentle cleansing and protection with various barriers, IAD remains a major problem that can persist indefinitely. Affected individuals
experience discomfort and increased risk for complications (secondary infections and pressure injuries). With effective management, visible improvement is expected in 1–2 days with complete resolution in 1–2 weeks. Patients with IAD deserve a better approach than traditional management.

Research

Twenty residents with IAD unresolved with traditional barriers were recruited from 7 post-acute care facilities across two states. Two had fecal incontinence, four had urinary incontinence and the remainder had mixed incontinence. Education and data collection tools were provided to guide the process. Staff assessed affected skin daily using a 3- point IAD differentiation scale (0 for normal skin, 1 for erythema, and 2 for open lesions). The two- week treatment plan included discontinuation of other barrier products, gentle cleansing after incontinence followed by the application of a continuous topical barrier spray at least 4 times/24 hours. The spray optimizes skin quality and an acidic pH. Results In spite of education aimed at both nursing and nursing assistants and simple data collection tools, strict adherence to the plan was a significant challenge. In spite of compliance issues, results showed a significant improvement over traditional barrier products.

Results

In spite of education aimed at both nursing and nursing assistants and simple data collection tools, strict adherence to the plan was a significant challenge. In spite of compliance issues, results showed a significant improvement over traditional barrier products. Further research is needed, but this preliminary study holds promise for a paradigm shift and improved, cost-effective health outcomes.



Fecal Incontinence	Mixed Incontinence	Urinary Incontinence
100% Resolution	93% Resolution	50% Resolution*

*A family switched back to traditional barriers, in spite of open lesions healing completely

BioScience Laboratories
May 2017

Cytotoxicity Sensitivity Response in Epi-airway, Epi-gingival, Epi-vaginal, Epi-Intestinal Mucosa: Theraworx® Versus Chlorhexidine Gluconate.

The purpose of this testing is to compare the Cytoxicity of Theraworx® versus Dyna-Hex® a chlorhexidine gluconate formulation. MTT assays were used. The MTT assay is a colorimetric assay for assessing cell metabolic activity. NAD(P)H-dependent cellular oxidoreductase enzymes may, under defined conditions, reflect the number of viable cells present. These enzymes are capable of reducing the tetrazolium dye MTT 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide to its insoluble formazan, which has a purple color. Other closely related tetrazolium dyes including XTT, MTS and the WSTs, are used in con-junction with the intermediate electron acceptor, 1-methoxy phenazine methosulfate (PMS). With WST-1, which is cell-impermeable, reduction occurs outside the cell via plasma membrane electron transport. Tetrazolium dye assays can also be used to measure cytotoxicity (loss of viable cells) or cytostatic activity (shift from proliferation to quiescence) of potential medicinal agents and toxic materials. MTT assays are usually done in the dark since the MTT reagent is sensitive to light. The MTT assay is a colorimetric assay for assessing cell metabolic activity.

The clinical purpose for this study was to determine if Theraworx®, in comparision to CHG would be vi-able for mucosal therapy if proven to be non-cytoxic. The researchers selected airway mucosa (the most sensitive), vaginal, intestinal and gingival mucosas. Theraworx® in comparision to CHG was significantly less toxic to epi-airway, gingival, intestinal and vaginal mucosa. When considering managing macro and micro debris topical formulations have to have the best balance of potency and biocompatibility. Thera-worx® is conluded to be a non-cytoxic formulation in mucous membrane tissues.

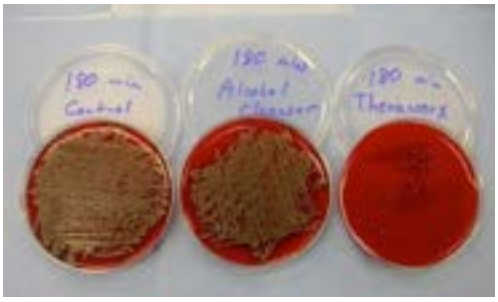
Tissue	Hours of Contact Before Seeing a Cytotoxic Response	
Epi-Airway	Theraworx® Dyna-Hex® (GHG)	5.07 0.05
Epi-Gingival	Theraworx® Dyna-Hex® (CHG)	399.36 8.86
Epi-Intestinal	Theraworx® Dyna-Hex®	56.13 1.42
Epi-Vaginal	Theraworx® Dyna-Hex®	34.19 6.16

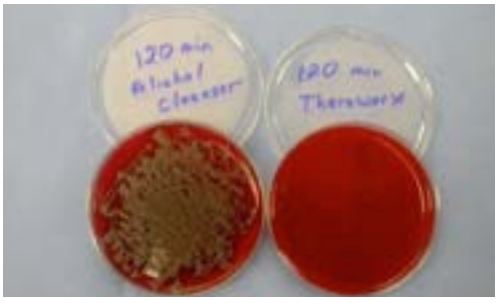
Duration of Action of Theraworx® Against Methicillin Resistant Staphylococcus Aureus Utilizing an Inoculated Collagen Model

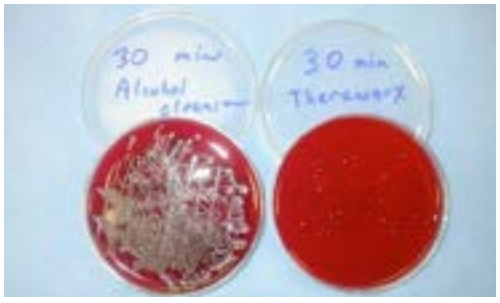
Roger Huckfeldt, MD, FACS / St John's Medical Research Institute / Springfield, Missouri

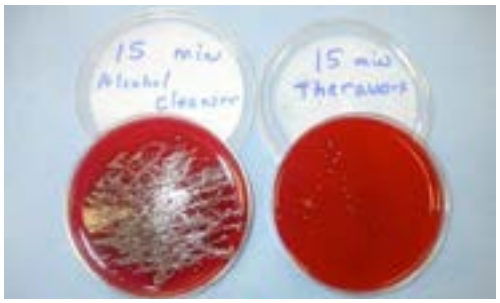
In an in-vitro duration of action study the duration of action against methicillin resistant staphylococcus aureus (MRSA) of Theraworx®, an alcohol-based skin cleanser, and a control (normal saline), Theraworx® demonstrated significant duration of action, up to 180 minutes, against this potentially harmful pathogen. Even at the first interval tested, 15 minutes, the alcohol skin cleanser demonstrated no measurable duration of action, showing that alcohol-based cleansers have only short term disinfection capability.

Time	Normal Saline Control	Alcohol based skin cleanser	Theraworx®
15 minutes	Too numerous to count (TNTC)	Too numerous to count (TNTC)	>99% effective
30 minutes	TNTC	TNTC	>99% effective
60 minutes	TNTC	TNTC	>99% effective
2 hours	TNTC	TNTC	>99% effective
3 hours	TNTC	TNTC	>99% effective









Journal of Patient Care: Olivi et al., J Pat Care 2018, 3:3 DOI: 10.4172/2573-4598.1000134

Antimicrobial Effectiveness of Rinse-Free Hospital Bathing Cleansers after 24 h of Initial Exposure to Common Pathogenic Micro-Organisms

Joe Olivi1, Cindy L Austin1* and Simon J Thompson2
1Mercy Hospital, Springfield, Trauma and General Surgery, USA
2Mercy Hospital, Springfield, Trauma and Burn Research, USA

Abstract

Rinse-free disposable bathing clothes are increasingly more popular in the patient and home healthcare setting due to the antimicrobial properties, skin protection and convenience. Several rinse-free hospital bathing products are available for patient hygiene, but limited data exist regarding the comparative reduction in bioburden for epidemiologically important microorganisms causing hospital acquired infections. This study compared the antimicrobial effects of three common rinse-free hospital bathing cleansers. The antimicrobial effects of each cleanser (colloidal silver, benzalkonium chloride and methylpropanediol) were examined against ATCC bacterial strains (E. coli, VRE, MRSA) and one fungus (C. albicans). In addition, a patient derived sample of C. albicans and VRE was tested. With the exception of E. coli, across all test organisms and all cleansers, the Colloidal Silver solution sustained a substantially higher reduction in microbial growth proving after 24 h as an effective antimicrobial against multiple organisms including: MRSA, VRE, and C. albicans. Each pathogen presents unique risks to patients and challenges for the healthcare provider; therefore, the use of rinse-free bathing cleansers containing Colloidal Silver is warranted.

Methods

This was an in-vitro hospital laboratory-based study evaluating the effectiveness in reducing the bioburden of three FDA approved rinse free pre-packaged bathing cleansers: (i) A surfactant based formulation developed to sustain a skin pH based environment, containing colloidal silver (Colloidal Silver), (ii) A pH balanced formulation containing Benzalkonium chloride (Benzalkonium Chloride 0.12%), and (iii) A skin pH focused formulation containing methylpropanediol (Methylpropanediol) (Supplementary Data). Test organisms include three bacterial and one fungal pathogen; Escherichia coli, (E. coli ATCC 25922), Vancomycin-resistant Enterococci (VRE ATCC 51299), Methicillin-resistant Staphylococcus aureus (MRSA ATCC 43300) and Candida albicans (C. albicans 10231), respectively. ATCC biological standard specimens were used to ensure reliability and quality control applications [13]. Two clinical isolates were also derived from hospital patients to demonstrate effectiveness using higher resistance organisms. In order to reduce variables of the bathing wipes material and viscosity, cleansing liquid was aseptically extracted from each bathing wipe and placed in sterile tube to ensure equal volume.

Results

Overall, the Colloidal Silver solution demonstrated a substantially higher percentage reduction in every microorganism tested with the exception of E. coli (Figure 1). Methylpropanediol demonstrated kill power in C. albicans and MRSA. Benzalkonium Chloride demonstrated kill power C. albicans, MRSA, E. coli and VRE. The results are summarized in (Figure 1 and Table 1) as follows: C. albicans patient derived: The Colloidal Silver solution demonstrated a significantly higher reduction (56.2%) in fungal growth at 24 h with Methylpropanediol and Benzalkonium Chloride at 8.6% and 7.3%, respectively. C. albicans ATCC 10231: The Colloidal Silver solution demonstrated the highest percentage reduction (54.8%) in fungal growth in at 24 h with Methylpropanediol (9.7%) and Benzalkonium Chloride (12.8%). E. coli ATCC 25922: The Benzalkonium Chloride solution demonstrated the highest percentage reduction (6.3%) in growth followed by Colloidal Silver solution (3.0%). Methylpropanediol solution showed no reduction. MRSA ATCC 43300: The Colloidal Silver solution demonstrated the highest percentage reduction (29.8%) in microbial growth at 24 h with Benzalkonium Chloride (18.9%) Methylpropanediol (4.8%). VRE patient derived: The Colloidal Silver solution demonstrated the only microbial reduction (66.4%) at 24 h. No reduction in Benzalkonium Chloride or Methylpropanediol solution. VRE ATCC 51299: The Colloidal Silver solution demonstrated the highest percentage reduction (28.1%) and Benzalkonium Chloride (5.6%). Methylpropanediol solution showed no reduction.

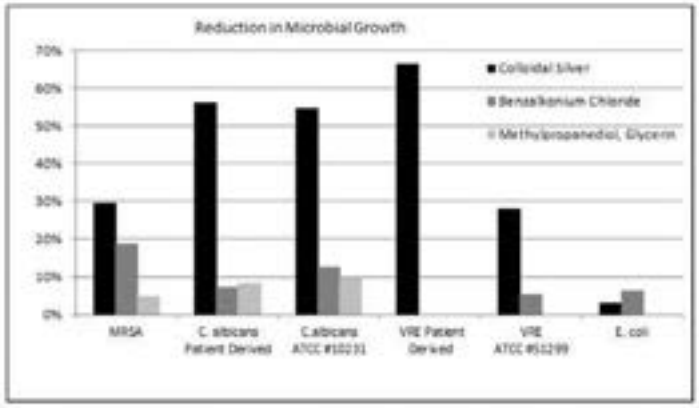


Figure 1: Depicts percentage reduction in microbial growth for each organism and each cleansing solution.

Journal of Clinical and Medical Investigations- ISSN: 2398-5763
Clin Med Invest, 2020 doi: 10.15761/CMI.1000215

Title: Activity of a Novel, Multimodal, Surfactant-Based Skin Cleanser on Coronaviruses, In-Vitro

Author: Daryl S. Paulson PhD.

Background: The primary objective of these tests was to evaluate the efficacy of a novel, multi-ingredient colloidal silver skin cleanser (Theraworx Protect, Avadim Technologies, Asheville, NC) on a seasonal coronavirus as a proxy for SARS-CoV-2 and 7 additional challenge microorganisms in vitro.

Methods: The coronavirus test measured percent and log10 reductions from the initial population of the viral strain(s) following exposure to the test product(s) at 1 minute, 30 minutes, and 1 hour. Plating was performed in four replicates.

The challenge microorganisms test used an In-Vitro Time-Kill Method to assess the antimicrobial properties of the test product and measured percent and log10 reduction in the microbial population of each challenge strain following exposure to each test material for 60 seconds, 10 minutes, and 30 minutes. Testing was performed in triplicate. All agar-plating was performed in duplicate.

Results: At 1 and 30 minutes, there was a 1.75 log reduction (98.22%) in SARS-CoV-2 virus. At 60 minutes, there was a 2.25 log reduction (99.44%) in virus.

The test product, Theraworx Protect (Lot #16180-1), reduced the populations of 7 challenge microorganisms – multidrug-resistant (MDR) Acinetobacter baumannii (ATCC#BAA-1605), Hemophilus influenzae (ATCC#19418), Pseudomonas aeruginosa (ATCC #15442), Staphylococcus epidermidis (ATCC #12228), Staphylococcus hominis (ATCC #700236), Streptococcus pneumoniae (ATCC #49619), Streptococcus pyogenes (ATCC #19615) - by an average of greater than 3.4 log10 following 1 minute and maintained or increased these reductions through all the remaining appropriate time points.

Conclusion: The results confirm the test product's efficacy as a waterless, leave-on, skin-compatible, topical solution to augment the use of flashing ethanol-based hand sanitizers.

TABLE 1

Test Formulation #1: Theraworx Protect
Virus: Coronavirus strain OC43 (ZeptoMetrix #0810024CF)
Host Cell Line: HCT-8 (ATCC #CCL-244)
Volume Plated per Well: 1.0 mL

Dilution (- Log10)	Virus Control			Test			NTC	NC	CTC	CC
	1 minute	30 minutes	60 minutes	1 minute	30 minutes	60 minutes				
										0000
-2	NT	NT	NT	CT	CT	CT	CT	NT	++++	
-3	++++	++++	++++	++++	++++	+++0	++++	++++	0000	
-4	++++	++++	++++	+++0	++00	0000	++++	++++	0000	
-5	++++	++++	++++	0000	0000	0000	+00+	+++0	NT	N/A
-6	00++	+000	0000	0000	0000	0000	++00	000+	NT	
-7	0000	0000	0000	0000	0000	0000	0000	0000	NT	
$TCID_{50}$ (log_{10})	6.00	5.75	5.50	4.25	4.00	3.25	5.50	5.50	2.50	
Log_{10} Reduction	N/A			**1.75**	**1.75**	**2.25**	N/A			
Percent Reduction				**98.22**	**98.22**	**99.44**				

Forearm Controlled Application Test For Evaluating the Relative Mildness and Skin Moisturization Effectiveness of Two Products

The purpose of this Forearm Controlled Application Technique (FCAT) evaluation was to determine the relative mildness and skin moisturizing effect of two cleansing test products. Visual evaluations and skin measurements were performed with non-invasive instrument evaluations during the test period.

In this Study, 27 subjects between the ages of 18 and 65 years completed testing. Visual evaluation were performed prior to enrollment in the study, to assure that subjects complied with the inclusion criteria that included appropriate inner are dryness and erythema levels. Upon completion of the 5-day conditioning period, the subjects underwent a 5-day treatment period with production application taking place twice daily. The product applications were performed on the lower inner forearms on each subject, randomly applying one test material per arm. Visual evaluations and measurements using Corneometer, Skicon, and Trans-epidermal Water Loss (TEWL) instrumentation were performed daily prior to the 1st and 2nd product applications on each of the 5 test days and again 2 to 3 hours after the 2nd product application on the fifth day.

Non-Inferiority Evaluation - The test product (Theraworx®) achieved a non-inferiority status compared to the comparator product (Hibiclens®) in all of the evaluations: Corneometer, SkiCon, TEWameter, Visual Erythema and Visual Dryness.

Non-Superiority Evaluation - For the Corneometer, SkiCon and TEWameter readings the test product (Theraworx®) was superior to the comparator product (Hibiclens®).

Equivalence Evaluation - For the Corneometer, SkiCon and TEWameter readings the test product (Theraworx®) to the control product (Hibiclens®)

Table 34. Descriptive Statistics Non-Superiority Test – Tewameter Readings

Variable	*N*	Mean	StDev	SE Mean
Test Product	277	3.0848	3.2925	0.19783
CHG Comparator	277	2.8314	2.7395	0.16461

Table 35. Difference: Mean (Test Product) – Mean (CHG Comparator)

Difference	SE	95% Upper Bound	Upper Limit
0.2534	0.25735	0.67747	0.2

The upper bound is not less than0.2. Cannot claim Mean (Test Product) – Mean (CHG Comparator) <0.2.

Table 36. Non-Superiority Test Non-Superiority Test – Tewameter Readings

Null hypothesis:	Mean (Test Product) – Mean (CHG Comparator) ≥ 0.2	Superior
Alternative hypothesis:	Mean (Test Product) – Mean (CHG Comparator) < 0.2	Non-Superior
α level:	0.05	

Degrees of Freedom	*T*-Value	*P*-Value
534	0.20761	0.582

The ***P*-Value** is >0.05. Cannot claim Mean (Test Product) – Mean (CHG Comparator) <0.2.
The test product is superior to the comparator product (Hibiclens®).

Theraworx® v. Chlorhexidine Gluconate Bathing and Peri-operative Skin Cleansing Study

Principal Investigator: Roger Huckfeldt, MD
Co-Investigators: Phillip Finley MS, Cindy Lowe MS, Keela Davis MS, Kara Childers MS

In a simulated patient decolonization comparative study, 30 healthy volunteers avoided bathing for 24 hours and were then randomized into two groups. The two groups were then observed as they utilized two bathing protocols. The first group performed a ten minute shower using CHG, following my a focused CHG scrub of four specific body areas, the sub-clavicular space, midline abdomen, groin and patellar area. The second group underwent a one minute scrub of the same four areas using a single Theraworx® impregnated cloth per area. After the chlorhexidine shower or Theraworx® scrub the subjects were clothed in freshly laundered surgical clothing and placed in a monitored room. Skin cultures using a standardized tube/scrub method were obtained prior to randomization as a baseline and again at two and six hours post intervention. Serial dilutions and agar plating were performed immediately and incubated for 48 hours. Colony counting was then performed and log reduction from pre-intervention counts performed. The Theraworx® product demonstrated a statistically better log reduction vs. CHG in three of four body areas, at the two hour cultures, and a statistically better log reduction vs. CHG in two of four body areas, at the four hour cultures.

Two Hour Cultures

1. Subclavicular space: Theraworx® showed a statistical difference at p=0.083 in greater log reduction of bacteria as compared to chlorhexidine gluconate.
2. Midline: No statistical difference observed (p=0.103).
3. Groin: Theraworx® showed a statistical difference at p=0.078 in greater log reduction of bacteria as compared to chlorhexidine gluconate.
4. Knee: Theraworx® showed a statistical difference at p<0.001in greater log reduction of bacteria as compared to chlorhexidine gluconate.

Six Hour Cultures

1. Subclavicular space: No statistical difference observed (p=0.172)
2. Midline: Theraworx® showed a statistical difference at p=0.062 in greater log reduction of bacteria as compared to chorhexidine gluconate
3. Groin: No statistical significance observed (p=0.371)
4. Knee: Theraworx® showed a statistical difference at p<0.003 in greater log reduction of bacteria as compared to chlorhexidine gluconate.

NTI Abstracts-2020 National Teaching-Institute Evidence-Based Solutions Abstracts
Journal of Critical Care Nursing: American Association of Critical-Care Nurses
doi:https://doi.org/10.4037/ccn2020670
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Change Has Arrived: Antimicrobial Bathing and CLABSI

Patricia Sung, Mary Virgallito, Theresa Murphy, Raffi Boghossian, Rose Young;
University of Southern California, Verdugo Hills Hospital, Glendale, California

Purpose: Persistent central catheter–associate bloodstream infections (CLABSIs) occurred each quarter from 2014 to 2016 in our 12-bed intensive care unit (ICU), prompting an infection prevention (IP) assessment in November 2016. Low compliance with the bathing protocol was identified as a gap in practice. Staff surveys indicated confusion about chlorhexidine (CHG) application and dissatisfaction with effects on patients' skin. A topical immune health system was introduced to replace CHG bathing products in an effort to improve staff satisfaction, raise compliance, and reduce CLABSI rates.

Evaluation/Outcome: Pre -implementation assessment identified gaps in practice. Staff indicated CHG was "too sticky," and "too complicated; patients don't like it." In July 2019, a questionnaire was
administered to ICU nurses after the change to the new antimicrobial bathing product. Of 20 responses received from nurses, all stated they like the product. In response to an open-ended question asking why staff and/or patients like the product, 4 nurses (20%) cited the ease of use, and 7 (35%) cited the protective effects on the patients' skin. A random sample audit of patient bathing compliance before (5 of 10) and after (10 of 10) implementation identified a statistically significant difference (P = .02).
The ICU achieved a rate of 0 CLABSI in February 2018 and has remained at zero through April 2020.

***Statistical Significance in ICU Bathing Compliance after implementing Theraworx Protect at (P= .02)**

***CLABSI Rate since converting to Theraworx Protect from CHG 2% has remained at zero since February 2018**

NTI Abstracts-2020 National Teaching-Institute Evidence-Based Solutions Abstracts
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Closing the Gap: Targeting CAUTIs With a Novel Approach to Perineal Care

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St. Joseph Medical Center, Towson, Maryland

Purpose: Persistent catheter-associated urinary tract infections (CAUTIs) occurred in University of Maryland St. Joseph Medical Center's 28-bed critical care unit despite a robust prevention bundle. Root-cause analyses identified poor compliance with perineal and urinary catheter care as a gap in evidence-based practice. A change from applying soap and water with a washcloth from a basin to a topical immune health system wipe–based product was implemented to standardize process, improve compliance, and eliminate CAUTIs.

Summary: Despite continuous efforts to reduce infections, patients in the medical-surgical intensive care unit (MSICU) continued to have CAUTIs. Although a 44% reduction from fiscal year (FY)14 to FY15 was achieved, 1 infection was still too many. Root-cause analyses were performed on each CAUTI to identify a potential reason for the infection. Compliance with perineal and urinary catheter care was identified as a potential root cause and an opportunity to improve. In November 2015, the MSICU implemented a new process for managing bowel incontinence and enhancing perineal and urinary catheter care. These interventions included baby wipes for incontinence care and a topical immune health system wipe for perineal and urinary catheter care. The topical immune health system is used during the following situations: before and after insertion of a urinary catheter; to clean every 6 hours, or every 4 hours for catheters indwelling longer than 5 days, patients with urinary catheters; as a final cleaning step for any incontinence events; as a final cleaning step during the daily CHG bath; and before straight catheterization. With this new practice, perineal and urinary catheter care increased from once per day to up to 6 times per day, based on the duration of the catheter. Frontline staff were involved in the solution and implementation processes.

Evaluation/Outcome: Staff satisfaction was very high with the new standard of care. Staff survey results were notable for ease of use (100%), preference over previous practice (97%), and catheter care being worth the extra step (100%). Compliance with perineal care also improved. After implementation, the MSICU celebrated 351 days without a CAUTI. The success has continued: the unit recently celebrated 365 days CAUTI free. Our standardized infection ratio also decreased by 49% from before to after implementation of the new interventions. It is important to acknowledge that this success is not the result of a single intervention but rather multiple interventions designed to reduce CAUTIs.

100% Staff Satisfaction

Improved Compliance

365 continuous Days Zero CAUTI

Reduction in Standardized Infection Ratio by 49%

Effects of Education and Improved Foley Catheter Care on Nurses' Knowledge and Catheter Associated Urinary Tract Infections

Urinary tract infection are the most common Hospital acquired infection, accounting for 40% of nosocomial infections annually. Approximately 70- 80% of UTIs are caused by indwelling foley catheters, and 56-89% of adults in critical care areas have foley catheters. The risk for catheter associated urinary tract infection (CAUTI) increases every day that the catheter is present; therefore, reducing the duration of catheterization and improving foley catheter care will result in lower infection rates. Additionally, the use of (Theraworx®) wipes and Theraworx® foam cleanser during foley insertion and for routine care have demonstrated reduced CAUTI rates in clinical studies. Furthermore, in the 3 months after staff education and implementation of Theraworx® there were 1667 catheter days, and the CAUTI rate was 0/1000 catheter days in the critical care areas. The previous year in the corresponding months there were 1728 catheter days, with a CAUTI rate of 2.3/1000 catheter days.

Effects of Education and Improved Foley Catheter Care on Nurses' Knowledge and Catheter Associated Urinary Tract Infections

FirstHealth OF THE CAROLINAS

Gloria Walters MSN, RN-BC, CCRN
Jayne Lee BSN, MPH, RN, CIC
Leona Riddle BSN, RN

Background

Urinary tract infections are the most common hospital-acquired infection, accounting for 40% of nosocomial infections annually. Approximately 70- 80% of UTIs are caused by indwelling foley catheters, and 56-89% of adults in critical care areas have foley catheters. The risk for catheter associated urinary tract infection (CAUTI) increases every day that the catheter is present; therefore, reducing the duration of catheterization and improving foley catheter care will result in lower infection rates.

Additionally, the use of silver impregnated (TheraworxTM) wipes and TheraworxTM foam cleanser during foley insertion and for routine care have demonstrated reduced CAUTI rates in clinical studies.

The purpose of this study was to determine whether nurses' knowledge about foley catheter management increased after additional education and whether CAUTI rates were reduced after implementation of catheter care with TheraworxTM products.

Research Questions

1. Did nurses' test scores measuring their knowledge of catheter care improve after additional education?
2. Did CAUTI rates decrease after implementation of focused nursing education and the use of a new product for catheter insertion and care (TheraworxTM)?

Methods

A convenience sample of nursing staff was recruited from the critical care areas. A pre-test was administered and was comprised of questions pertaining to knowledge of foley catheter management and care. Following the pre-test, educational sessions were provided to reemphasize correct catheter insertion and maintenance both at Skills Fairs and at other times on the critical care units. Additionally, the use of TheraworxTM wipes and foam cleanser was implemented as a best practice with both foley insertion and routine catheter care. After staff education and implementation of the use of the wipes and foam cleanser for three months, a post-test was administered to the staff in the critical care areas.

Results

93 participants completed the pre-test, with a mean score of 68.60 (*SD*=12.73). 38 participants completed the post-test, with a mean score of 73.18 (*SD*=8.73). However, only 19 individuals completed both the pre-test and the post-test. Mann-Whitney U Test for the difference between the mean scores of the pre- and post-test for all participants was statistically significant (*Z*=-2.15, *p*=0.031). Wilcoxon Signed Rank Test for those that completed both the pre-and post-tests was also statistically significant (*Z*=-2.797, *p*=0.005).

Furthermore, in the 3 months after staff education and implementation of TheraworxTM there were 1667 catheter days, and the CAUTI rate was 0/1000 catheter days in the critical care areas. The previous year in the corresponding months there were 1728 catheter days, with a CAUTI rate of 2.3/1000 catheter days.

Conclusion

Education about best practices for foley catheter insertion and care increased nurses' knowledge. Increased knowledge and the implementation of the TheraworxTM products reduced CAUTIs in the critical care areas. Future research should evaluate whether these findings can be replicated in other settings.

Preventing Chronic Urinary Tract Infections from Urinary and Fecal Incontinence: The Impact of Theraworx®

Urinary and fecal incontinence are common syndromes which can lead to significant morbidity, such as urinary tract infection.[1] It has been reported that over half of patients residing in long-term care facilities have urinary incontinence and nearly half have fecal incontinence.[2] Proper management of urinary and fecal incontinence can be costly due to nursing time,[3] but is critical to prevent urinary tract infection. Current management typically includes rapid cleansing with soap and water, however these interventions may be limited in effectiveness due to poor bactericidal activity of soap and water.

Peterson Healthcare initiated Theraworx® and its patented protocol in the recurrent UTI population who were also fecal and urine incontinent. The 16 site year long evaluation showed a significant reduction in monthly UTI rates. Previous to Theraworx® intervention these 16 sites averaged (27) infections per month for a full 12 months. After implementation of Theraworx® these same sites averaged 6.3 infections per month.

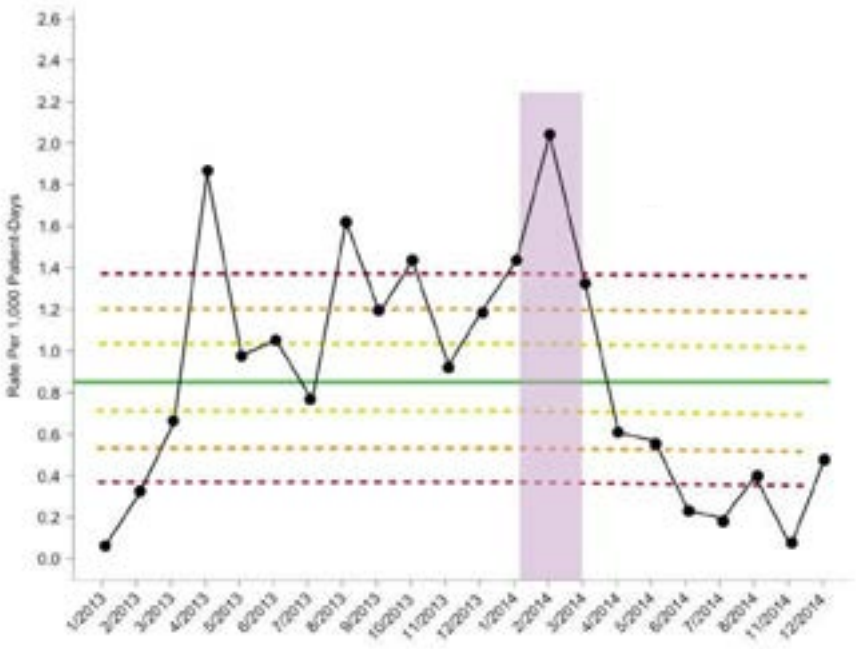

Figure 1. Chrnoic Urinary Tract Infection Rate Jan 2013–Dec 2014

1. THaab F. Chapter 1: The conditions of neurogenic detrusor overactivity and overactive bladder. Neurourol Urodyn. 2014 Jul;33 Suppl 3:S2-5. doi: 10.1002/nau.22636.
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3. Borrie MJ, Davidson HA. Incontinence in institutions: costs and contributing factors. CMAJ. 1992;147(3):322-328.

Quality Intervention: Sutter Healthcare- CAUTI Intervention- Cost and Efficacy Comparison

Assessing the Efficacy and Cost-Effectiveness of Theraworx Protect to Existing Regimens and Products- a 120- day Intervention: Emergency Department, ICU, SDU, Neuro

Sutter Health Infectious Disease: Jeffery Silvers, MD

Sutter Health Infection Prevention:

Background

Sutter Health, one of the leading health IDN's in the country sought to compare the effectiveness, acceptability and cost-effective of Theraworx Protect to standard practices for the sole purpose to ease nursing demands, improve supply chain redundancies without compromising efficacy. These quality driven interventional studies are driven primarily for either cost or efficiency related challenges combined with the need to ever improve infection prevention outcomes.

Method

The system Tracked Efficacy: 1. Photo record of moisture associated skin damage (MASD) pre and post intervention 2. Track usage of antifungal medications 3. Track rate of catheter associated urinary tract infections (CAUTI's)Assess Sutter System CAUTI trends With attention to the potential effects of other policy interventions Relative to products used.

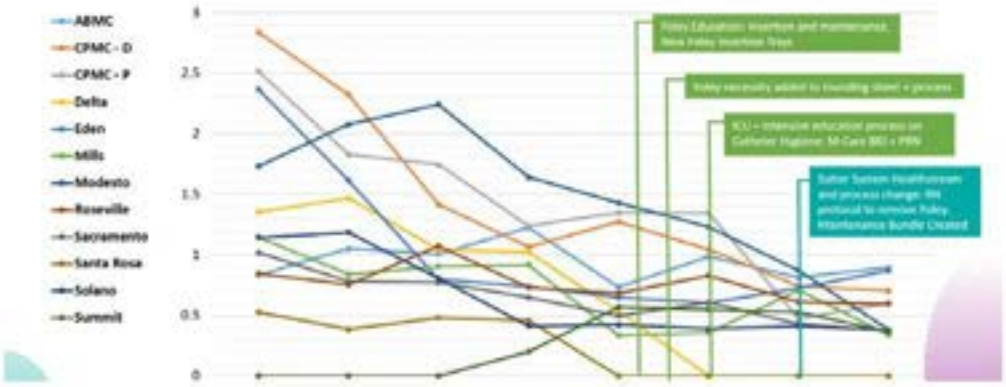
The system tracked Cost: 1. Track unit census, and acuity/dependency of patient population for relevant time frames Track usage of linen: washcloths and towels 2. Track usage and costs of Theraworx during trial period 3. Track usage and costs of replaced products, antifungals and linens

The System Tracked Patient and Clinic Satisfaction: 1. Survey of clinicians who use Theraworx 2. Monitor product appropriation to o ther units 3. Survey of capable patients who have used Theraworx

Sutter Health Eden Medical Center

12 Month Rolling CAUTI SIR By Facility

Theraworx



Non-ICU - Total Body Bathing + Decolonization				
Product	Application - Detail	Price	Sub-Total	Difference
Sage/ Comfort Bath Care Application - 8 cloths	Total body application	$ 2.30		
Dimethicone Skin Protectant Barrier cream	Routine perineum care - 3 apps/ day @ $0.23 ea	$ 0.69		
Band/ other glycol based wipe	Routine perineum care - 3 addtl apps/ day @ $1.25 ea	$ 3.75		
Sage/Band System – cost per routine day			$ 6.74	
Theraworx Bathing/ Barrier System - 8 cloths	Total body application	$ 4.07		
Theraworx Spray Application	Routine perineum care - 3 addtl apps/ day @ $0.09 ea	$ 0.27		
Theraworx System – cost per routine day			$ 4.34	
Difference per routine day				$ (2.40)
ICU - Total Body Bathing + Decolonization				
Product	Application - Detail	Price	Sub-Total	Difference
Sage/ other CHG Cloth Application - 6 cloths	Body application - **NOT** face and perineum	$ 5.52		
Glycol based wipe	Face and perineum care	$ 1.25		
Dimethicone Skin Protectant Barrier cream	Routine perineum care - 3 apps/ day @ $0.23 ea	$ 0.69		
Band/ other glycol based wipe	Routine perineum care - 3 addtl apps/ day @ $1.25 ea	$ 3.75		
Sage/CHG System – cost per routine day			$ 11.21	
Theraworx ICU Bathing/ Barrier System - 8 cloth	Total body application – including face and perineum	$ 4.07		
Theraworx Spray Application	Routine perineum care - 3 addtl apps/ day @ $0.09 ea	$ 0.27		
Theraworx System – cost per routine day			$ 4.34	
Difference per routine day				$ (6.87)

American Healthcare Association (AHCA)
Spring Session 2017

Equipping Clinicians With Advanced Care Options Leads To Reductions In Urinary Tract Infections

Nexion Health and Rehab implemented a QAPI[1] and RCA (Quality Assurance and Performance Improvement) and (Root Cause Analysis) program to reduce the incidence of UTI's (Urinary Tract Infections) in the "recurrent UTI population" who were fecally and urine incontinent and ventilator dependent, all of which are of the highest acuity populations in long term care. The QAPI initiatied Theraworx® as a daily intervention. Nexion reduced their average # of new UTI cultures 53% over the 6 month implementation plan.

Improvement Steps We utilized:
• QAPI: Root Cause Analysis (RCA), Performance Improvement Plans and Validation;
• The expanded AHCA QIs;
• and the Baldrige Performance Excellence Framework
to meet measurable targets in line with the three key priorities: (initially) improvements in organizational success and (long term goal of) short-stay/post-acute care impact for readmissions.

Additionally, we employed a trainer for Theraworx® application and implementation. We continued to track the # of new Cultured UTIs per month from May (month of implementation) though October.

"In the critical battle against hospital acquired conditions, you now have an innovative new alternative—a simple, inexpensive, total body safe alternative— Theraworx® Technology, from Avadim Technologies, Inc. Theraworx, a new paradigm for skin hygiene, working to optimize the natural antimicrobial action of the skin's acidic mantle, preserving the low pH of the stratum corneum, the outer layer of the epidermis. Theraworx, working to preserve rather than degrade the skin's permeability barrier, allowing the skin to do its job in preventing water loss and avoiding dryness. Theraworx, a non-toxic product, safe for use around mucous membranes, including the perineum.

Now, for the first time, you have a product that is safe for use in Foley catheter insertion and care, safe for use in establishing a zone of inhibition for urine and fecal incontinence, safe for use in full-body bathing for a wide age and range of patient populations. Broad spectrum, non-drying, and available in a wide range of delivery systems, including an eight cloth full body bathing system that includes cloths for face and perineum..."
Source: theraworx.com

Theraworx® TECHNOLOGY nexion

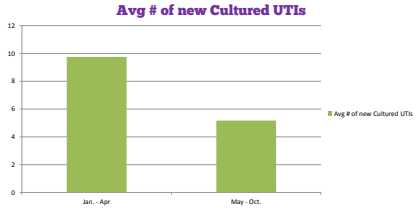
Meadowview Health & Rehab Center

Equipping Clinicians with Advanced Care Options Leads to Reduction in UTIs: Theraworx® Works Wonders

Goal: Meadowview Health and Rehab Center, a Nexion Affiliate and Ventilator Dependent Skilled Nursing Facility recognized a negative trend in # of new Cultured UTIs in the early part of 2016.

Upon the completion of a RCA, it was determined that there was not a significant concern with care or proper pericare. After consulting with the facility support team including its Certified Wound Care Specialist it was determined that Meadowview would trial a new an upcoming product-Theraworx®.

Avg # of new Cultured UTIs



Staff Involved Corporate Clinical Nurse, Physicians, Direct Care Staff, Director of Nursing and Operations.

Resources Theraworx® product and consultants were the necessary additional resources. We also allocated additional time of our Corporate Clinical Nurse and Certified Wound Care Specialist to aide in the process of being responsive to the Theraworx® team.

Challenges Meadowview's operator, Nexion Health, is very committed to a strict process in regards to best practices and care in order to ensure consistency among its affiliates. Reassuring Meadowview that is was "approved" to venture from its formulary was challenging at first but a rewarding and well needed reminder to be flexible when it makes sense.

SUCCESS We met and exceeded our goal to reduce the average # of new cultured UTIs by 50%. We reduced the average # of new cultured UTIs by 53%.

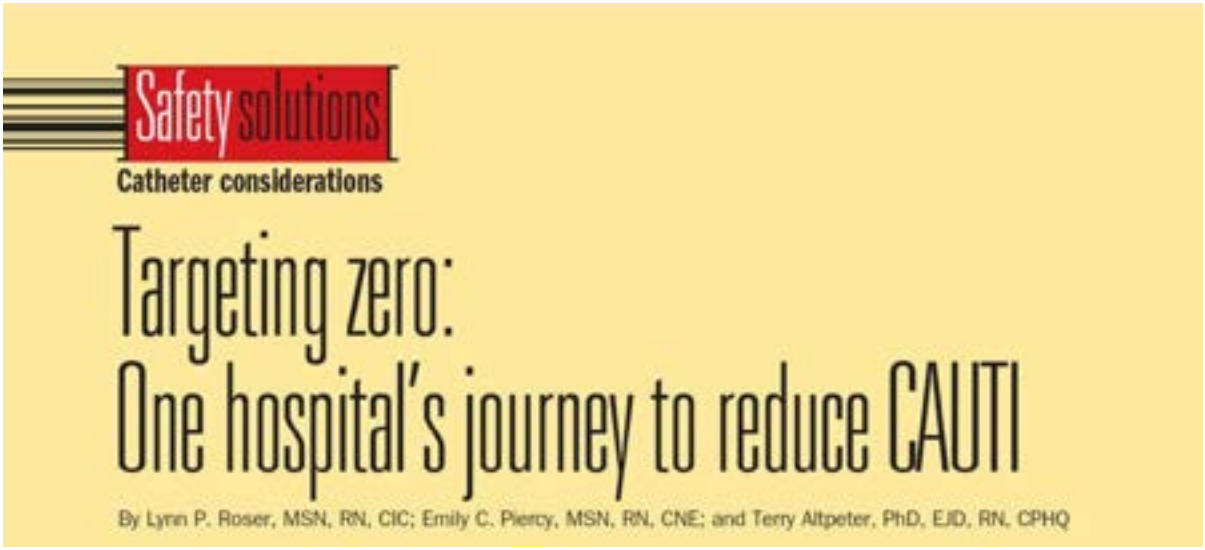
Plan to Sustain Improvement We will not vary from our commitment to the QAPI process. We will ensure that our staff have continued training, adequate supplies and understand the bigger picture of what the ultimate goals are-customer satisfaction through improved quality of care and quality of life with a long term goal of reducing hospital readmissions.

Business Outcomes We care for a very delicate and many times very sick population at our Meadowview facility. Our stakeholders are very pleased with our ability to consistently evaluate ourselves, look for opportunities for improvement especially in clinical outcomes and quality of care. Reducing UTIs impacts our operations through staff efficiencies, stakeholder satisfaction and quality measures. Our willingness to try new and innovative products and taking the steps to validate their impact also makes us a leader in our community.

Journal of Nursing Management
18–20
December 2014

Targeting ZERO: One hospital's journey to reduce CAUTI

Baptist Health Lexington, a 383-bed Magnet® recognized community hospital, reduced catheter associated urinary tract infection (CAUTI) rates in all critical care environments by a minimum of 60% during 2013. Given the acuity level of patients in CCUs, the incidence of CAUTIs was higher in that population than those in other areas of the hospital. For this reason, ICU patients were targeted for the implementation of a performance improvement (PI) project targeted to reduce the rate of CAUTIs. The ICU nurses identified an antimicrobial bundle (composed of three cleansing products- Theraworx® Foam, Theraworx® Spray and Theraworx® Impregnated Towels) that works as an effective barrier against a broad array of Gram-positive and negative organisms potentially leading to CAUTI. Data collected from the ICU's revealed further decline in CAUTI over all previous interventions.



Annals of Infectious Disease and Epidemiology-Published: 25 Nov, 2016

Non-Toxic Skin Formulation Promotes Healing of Dermatitis and Skin Injuries That Are Prone To Infection in Long-Term Care Facility Residents

Janalynn Miller, FNP-C, GNP, CWCN-AP1,2* and Joseph F Renzulli1*
1Department of Urology, University Urological Associates, USA
2Extended Care Specialists, Inc

Elderly patients in long-term care facilities (LTCFs) often exhibit skin disorders caused by multiple factors, including aging skin and co-morbidities such as obesity, diabetes, dementia, and urinary and fecal incontinence. Conditions common at LTCFs can also exacerbate skin disorders. Finally, skin conditions such as fungal dermatitis, incontinence-associated dermatitis, moisture-associated skin damage, pressure injuries, and venous ulcers often occur in bodily creases, making it difficult for clinicians to assess the areas, particularly in obese patients. Standard remedies can be ineffective if they congeal in body folds, or aggravate moisture-relateddermatitis and skin injury if they contain a moisture or zinc additive. Cleansing agents used to clean patients with fecal incontinence can dry out the skin, making the patient more infection-prone. If the patient has fungal dermatitis, dryness can impede or prevent resolution. The two cases discussed herein demonstrate these issues and show how a novel skin care formulation used in place of standard approaches addressed the problems. The formulation is intended to restore the skin's normal pH level to support the natural antimicrobial action of the skin's outer layer, maintain the skin's permeability barrier to prevent moisture loss, reduce the bio-burden of potentially infectious skin flora, and moisturize dry skin. In the first case, a Stage 2 pressure injury closed and fungal dermatitis resolved after treatment with the formulation and Diflucan. In the second case, a venous ulcer improved markedly after treatment with the formulation following a year in which standard treatments produced no results.

Sacral Pressure Injury Case #1

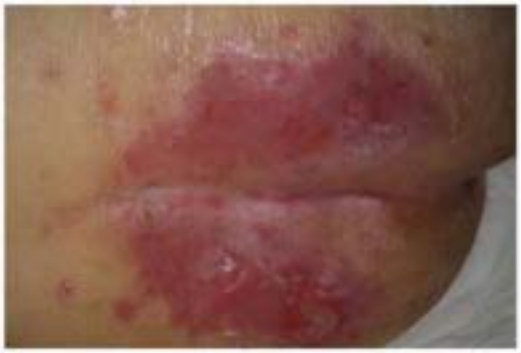


Figure 1: Stage 2 Pressure injury on left buttock and fungal dermatitis on bilateral buttock prior to treatment with skin care formulation and Diflucan. Length=1.8 cm, width=1.8 cm, depth=<0.1 cm.

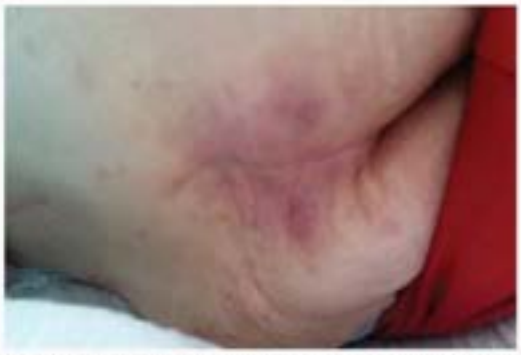


Figure 2: Less than two weeks after treatment with skin formulation began, pressure injury had closed and fungal dermatitis had resolved.

Refractory Venous Ulcer Case #2

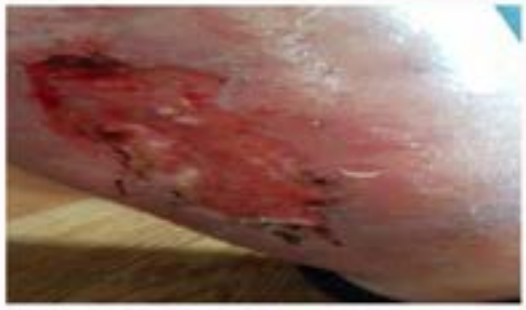


Figure 3: Venous ulcer prior to treatment with skin care formulation. Length = 12 cm, width = 3.5 cm, depth = 0.1 cm, wound bed tissue type = 90 % pink granular with islands of epithelialization and 10 % yellow slough. Wound edges exhibited dried serous drainage.

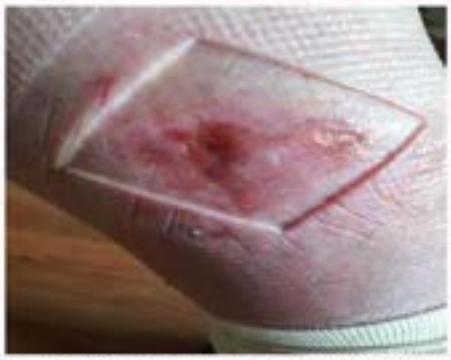


Figure 5: After six months of treatment with the skin care formulation, the wound had improved markedly. It measured approximately 0.1 cm by 0.2 cm with 100% red granular wound bed tissue type.

Independent Laboratory Study: ATS Labs Protocol # SJC01051614.EXVO

Ex-Vivo Antibacterial Evaluation of Topical Products Using a Vitro-Skin® Model- Vancomycin Resistant Enterococcus faeca/is - VRE (ATCC 51575) Matthew Sathe, B.S. Senior Microbiologist

Background

Enterococci are an emerging pathogen in hospitalized patients [1]. These pathogens ubiquitously occur in the hospital environment and show a high tenacity on inanimate surfaces [2,3,4]. As a result, enterococcal infections emerge with a rising frequency. Additionally, enterococci have the ability of acquiring resistances to multiple antimicrobial agents and the capacity to transfer resistances to other pathogens via mobile genetic elements [5,6,7]. For this reason the prevalence of vancomycin resistant enterococci (VRE) has increased intensively [1]. Vancomycin resistance is associated with enhanced mortality, e.g. among patients with enterococcal blood stream infections [8]. Within hospital settings prevention of VRE transmission is therefore a major objective.

Method

A film of the test organism dried onto a 1" x 1" demarcated area of 1.5" x 1.5" rehydrated Vitro-Skin® carriers was treated by wiping each carrier over and back twice with a saturated towelette for a total of 4 passes. Following treatment and exposure, each carrier was neutralized and assayed for survivors. Appropriate culture purity, neutralizer sterility, carrier sterility, population and neutralization confirmation controls were performed. Percent and Log10 reductions were determined for the test based on the test population control results.

Results

Theraworx Technology Lot 141291, ready to use, demonstrated a >99.99% (>4.80 log10) reduction of Vancomycin Resistant Enterococcus faecalis - VRE (ATCC 51575) following a 15-minute exposure time when tested at ambient temperature (20.90°C).

TABLE 3: POPULATION CONTROL RESULTS

Test Organism	Carrier #	CFU/Carrier	Log_{10} of CFU/Carrier	Average Log_{10}	Geometric Mean (CFU/Carrier)
Vancomycin Resistant *Enterococcus faecalis* - VRE (ATCC 51575)	1	1.3×10^6	6.11	6.10	1.26×10^6
	2	1.2×10^6	6.08		

CFU = Colony Forming Unit

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7. Gawryszewska I, Zabicka D, Hryniewicz W, Sadowy E. Linezolid-resistant enterococci in polish hospitals: species, clonality and determinants of linezolid resistance. Eur J Clin Microbiol Infect Dis. 2017;36:1279–86.
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Executive Summary

Ebola Virus disease has been rapidly spreading through Western Africa since 2013. Several cases have been exported to industrialized nations, but person-to-person spread outside of Western Africa has been limited. The extreme contagiousness of the virus, coupled with the high mortality related to infection increases the need for novel interventions for preventing the spread of this virus.

Transmitted through blood and body fluids, Ebola Virus transmission can be limited through prevention of contact with these fluids. The difference between the transmission of Ebola Virus and other bloodborne pathogens such as HIV and Hepatitis B or C, lies in the very low infectious dose of this virus. The infectious dose is the number of viral particles it takes to cause an infection in a host. For Ebola Virus, the infectious dose is one virus. Where millions of virus are present in even small amounts of body fluids, it is clear that transmission prevention can be very difficult.

Due to the transmission route of this virus, one possible intervention for prevention of transmission may be skin antisepsis - killing of the virus on the skin in order to limit contact. Due to this possibility, Avadim Technologies collaborated with the Texas Biomedical Research Institute to study the efficacy of Theraworx, a novel silver-based skin antiseptic, against Ebola Virus on simulated human skin.

The research study was conducted as follows: First, two human skin analogs were placed in a high containment (Biosafety Level 4) laboratory at Texas Biomedical Research Institute. A standardized amount of Ebola Virus was placed on each skin surface. After 5 minutes of drying time, one of the areas was sprayed with a salt water solution, while the other area was sprayed with Theraworx. The salt water solution served as a control, as the salt water has no killing activity against the Ebola Virus. After 5 minutes, the skin surfaces were swabbed and the amount of Ebola Virus left on each skin surface was defined in terms of plaque forming units (PFU).

The skin surface sprayed with the saline solution had 200,000 PFUs left, while the Theraworx treated surface had 18,000 PFUs left. This is a 91% reduction in Ebola Virus on the human skin analog using Theraworx compared to no active treatment.

These results suggest that Theraworx has the ability to kill the Ebola Virus rapidly on human skin. It is possible that using this product on an infected person, or even on a caregiver may help to prevent the transmission of this deadly virus.

Appendix

Avadim HEALTH

Discovering
New Ways to Care

I am delighted to enthusiastically endorse the unique technology of Theraworx, from Avadim Technologies, Inc. . Our laboratory at the University of California San Francisco and the San Francisco Veterans Administration Hospital is actively studying the origins, functions and clinical implications of the skin's 'acid mantle'. Long thought to originate from exogenous sebaceous gland-derived free fatty acids, we showed that four endogenous mechanisms contribute to the strikingly low, pH of normal stratum corneum (the degradation of phospholipids to free fatty acids; the deimination of filaggrin-derived amino acids into polycarboxylic acids; the sodium-proton antiporter type 1; and melanin granule extrusion). Because of differences in their subcellular location, each of these mechanisms regulate different critical functions of the skin. The key functions of the cutaneous acid mantle include: 1) epidermal permeability barrier homeostasis; 2) stratum corneum integrity and cohesion; 3) antimicrobial defense; and 4) antiflammatory activity. Please find attached a recent review article which briefly summarizes our research findings and its clinical implications. Note: this review article follow in the reference documents, no. , pp)

This spectrum of activities in normal skin suggests broad applications for pH-related technology in clinical arenas ranging from infection control to prevention and treatment of inflamed skin. These benefits form the basis for Avadim's unique, pH-dependent technology. We have evaluated the impact of Avadim's Theraworx technology in normal human and hairless mouse skin, and found that topical applications indeed reduces the surface pH of the skin significantly; i.e., from an average of 5.5 to 4.5-5 (note that pH is an exponential function, and this decline translates into a 5-10-fold increase in the proton concentration within the stratum corneum. We have also compared the Theraworx product to Hibiclens in normal hairless mouse skin, and found that the latter does not achieve a comparable reduction in pH, and that it was more drying than the former.

These findings imply that the pH-dependent technology embodied in Theraworx products should provide superior benefits for antimicrobial defense (note that pathogenic flora, like *S. aureus* and *S. pyogenes* grow avidly at a high pH, while the cutaneous normal flora prefer a low pH); enhanced permeability bsarrier function; optimal cutaneous integrity and cohesion; and decreased propensity to develop inflammation. Based upon these studies, I believe that Avadim's novel pH-dependent technology, as embodied in Theraworx formulations, is very worthy of recognition in the form of a Breakthrough Technology Award. Please let me know, if you would like further information about our work in the pH arena, or our pre-clinical studies with the Theraworx formulations.

Sincerely,

Peter M. Elias, MD
VA Medical Center/UCSF
4150 Clement Street
Dermatology MS 190
San Francisco, CA 94121
ph: 415-750-2092

Patient Bathing Instructions

Theraworx® PROTECT

hcp.theraworx.com

TO USE:

Cleanse with either side of cloth. Use all eight (8) cloths for a full bath (see diagram). Allow to air dry.

Store between 32° and 120° Fahrenheit

Theraworx Protect is safe for use on the skin including the most sensitive areas. It should be applied all over the body, including the face, groin area and genitals.

DO NOT FLUSH • DO NOT MICROWAVE.

Theraworx Protect
Application System
(8 towels per pouch)
Order# **HX-8808**

Theraworx Protect
Application System
Fragrance Free
(8 towels per pouch)
Order# **HX-8808FF**

MICROBIOME COMPLIANT

Theraworx® PROTECT

US Patent Number 14/629,320

Patented Urinary Health Protocol

Prior to foley insertion make sure you follow facility cleansing protocol:

2 CLOTH APPLICATION SYSTEM:

INSERTION:

1 **Urinary Tract Care Prior To Catheter Insertion**

- Use 1st cloth BEFORE opening the urinary catheter tray.
- Unfold 1st cloth completely, apply to urethral opening and perineal area. Apply front to back for women and in concentric circles around the glans penis for men. Fold and use for 2nd application as needed.

DO NOT FLUSH • DO NOT RINSE • DRY TIME 30 SECONDS

2 **Insert Foley in Accordance With Facility Protocol**

3 **Urinary Catheter Care Post Insertion**

- Apply 2nd cloth of Theraworx Protect AFTER insertion is completed. Apply around the meatus and catheter.
- Apply front to back for women and in concentric circles around glans penis for men.
- Next, fold same cloth in half and apply from the umbilicus to mid-thigh, creating a **Zone of Protection** (see picture).

DO NOT FLUSH • DO NOT RINSE • DRY TIME 30 SECONDS

Specialty Care Pack
(2 wipes per pouch)
Order# **SCP-8802**

Specialty Care Pack
Fragrance Free
(2 wipes per pouch)
Order# **SCP-8802FF**

MAINTENANCE and INCONTINENCE:

Urinary Catheter Maintenance and Perineum Care: Frequency Q12 Hours

- Continue to use cloths for routine catheter care every 12 hours as well as after each incontinent episode.
- Unfold 1st cloth completely, apply to urethral opening and perineal area. Apply front to back for women and in concentric circles around the glans penis for men. Fold and use for 2nd application as needed.
- Apply the 2nd cloth to all areas from the umbilicus to the mid-thigh, creating a **Zone of Protection** (Include all skin folds and rectal area).

MICROBIOME COMPLIANT

hcp.theraworx.com

Cleans.

Supports.

Protects.

Theraworx® PROTECT

Patient Pre-Surgical Bathing

Using Theraworx Protect 8-Pack Towels

You will be sent home with a purple and white package that has eight (8) cloths of **Theraworx Protect.** The night before your surgery, please take a shower and wash your hair as you normally do. Towel dry completely and apply Theraworx Protect as indicated:

☐ **Total body cleansing:**
Cleanse with **Theraworx Protect** using either side of cloth, scrub for a duration of **ONE MINUTE.** Follow these instructions for each area indicated on diagram utilizing all eight (8) cloths. Do not rinse. Allow to air dry.

☐ **Targeted skin cleansing:**
Apply (2 to 4) cloths and scrub for **ONE MINUTE** on and around area being operated on (see diagram below for body area). Do not rinse. Allow to air dry.

Cloth 1
Scrub on face, neck, chest and upper abdomen to the umbilical (belly button) area. ***It is safe to use around the eyes and mouth.***

Cloth 2
Scrub right arm and armpit, hand and fingers

Cloth 3
Scrub left arm and armpit, hand and fingers

Cloth 4
Scrub right leg, including behind the knee, feet and toes

Cloth 5
Scrub left leg, including behind the knee, feet and toes

Cloth 6
Scrub back area. You may need a helper!

Cloth 7
Scrub both buttocks, ending with the rectal area

Cloth 8
Start at the area where you urinate, scrub around that area and covering the entire genital area. Turn the cloth over and scrub from the lower abdomen from the umbilical area (belly button) to the mid thighs.

DO NOT MICROWAVE. DO NOT FLUSH.
Dispose cloths in household trash.

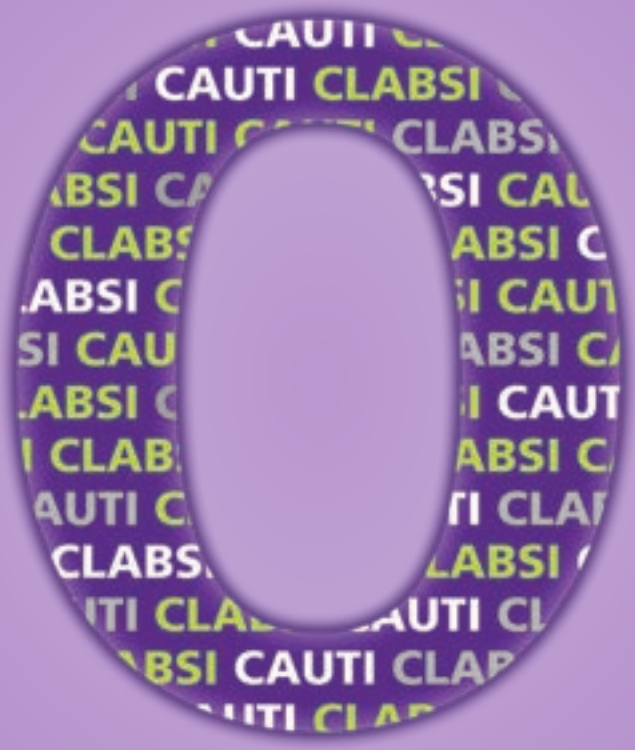
MICROBIOME COMPLIANT

When clean is not enough.

Avadim Technologies Inc. • 81 Thompson Street • Asheville, NC 28803 • 877.677.2723 • **theraworxprotect.com**

Does not contain antiseptic drugs

ATI18-003



Mission: Zero

P E D I A T R I C S

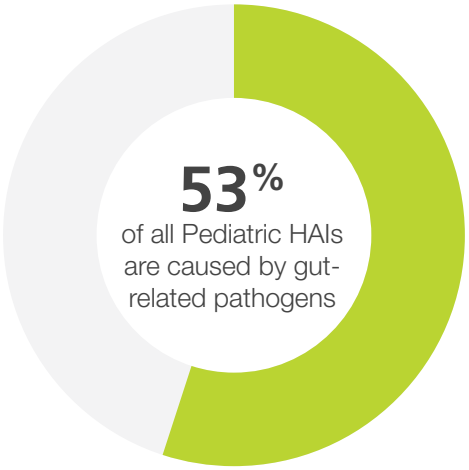
To Help Reduce And Eliminate HAIs, Including Catheter-Associated Urinary Tract Infections (**CAUTI)** And Central Line-Associated Blood Stream Infections (**CLABSI**) As A Part Of Your Infection Control Bundle

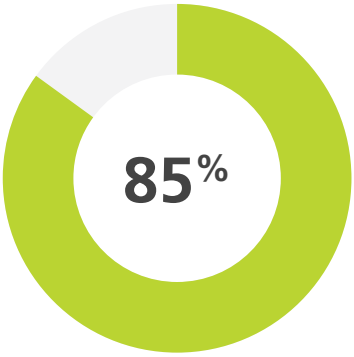
Theraworx®
PROTECT

Here Is What We Know: Pediatric HAIs

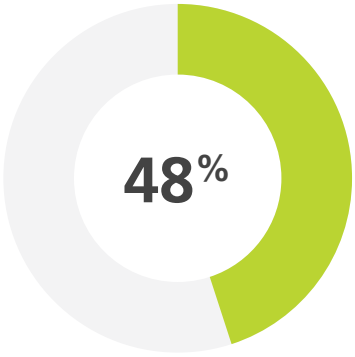
The CDC implicates **15 pathogens that account for over 88%** of healthcare-associated infections (**HAIs**)[1]. Of these opportunistic pathogens, **9 are considered gut-related.**

Gut Related Pathogens Are A Significant Cause of HAIs

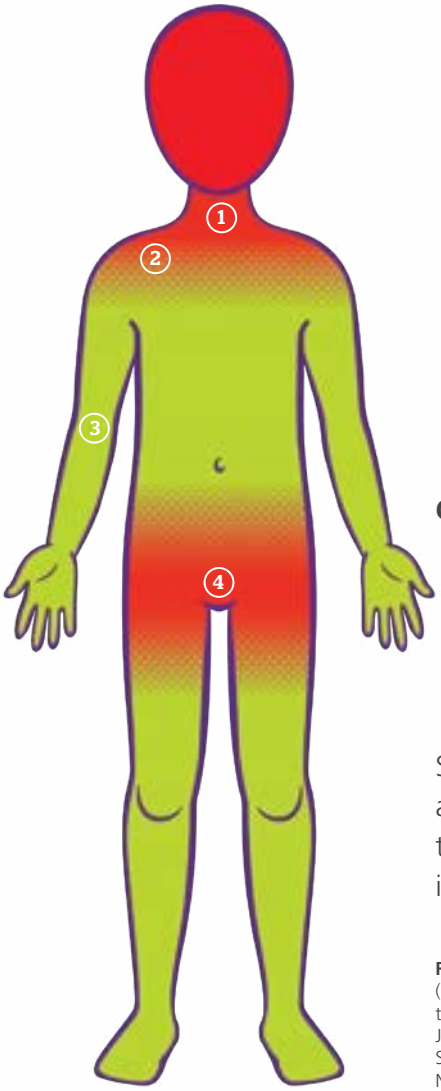




CAUTI



CLABSI



Gaps In Protection

CHG Bathing is not Recommended for Pediatrics under 2 months and Hematology / Oncology patients.

Most Hospitals decolonize Pediatric Patients over 2 months with Chlorhexidine Gluconate (CHG) but do not address perineum decolonization (red area) to address gut-related pathogens because of efficacy and safety concerns with CHG.

Pediatric ICU Patients that cannot use CHG: Around 10% of ICU patients cannot use CHG due to anaphylactic history, allergies and sensitivities, contraindications such as psoriasis, eczema, Stevens-Johnson syndrome, Graft vs Host disease, non-intact skin, patient refusals, and other reasons.

Current Practice leaves gaps in care which can lead to infection in:

1. Tracheotomy tube
2. Central venous catheter
3. PICC line
4. Urinary catheter
5. Surgical sites

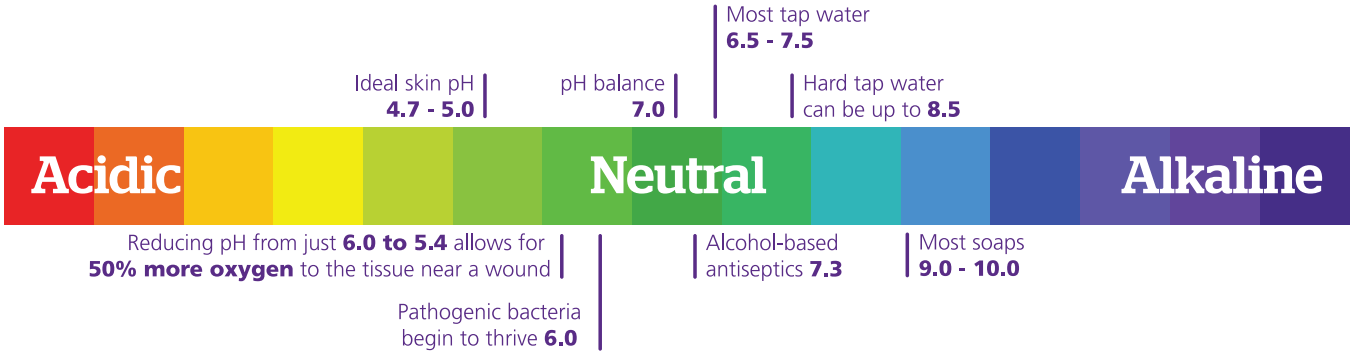
Soap and water or equivalent wipes do not decolonize the perineum and can strip away the skin's natural antimicrobial barrier and defensive functions. Most products that can decolonize the skin are either contraindicated for use in the perineum and in mucosa or lack safety and efficacy data.

References:
(1) Antimicrobial-resistant pathogens associated with pediatric healthcare-associated infections: Summary of data reported to the National Healthcare Safety Network, 2015–2017. Lindsey M. Weiner-Lastinger MPH , Sheila Abner PhD, Andrea L. Benin MD, Jonathan R. Edwards MStat, Alexander J. Kallen MD, MPH, Maria Karlsson PhD, Shelley S. Magill MD, PhD, Daniel Pollock MD, Isaac See MD, Minn M. Soe MBBS, MPH, Maroya S. Walters PhD and Margaret A. Dudeck MPH. Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia

A Clear Solution: pH Matters

Healthy skin (mucosa) thrives in an optimal low pH environment. It competes successfully for nutrition and space on the skin surface, protecting against invasion by pathogens and resulting infections.

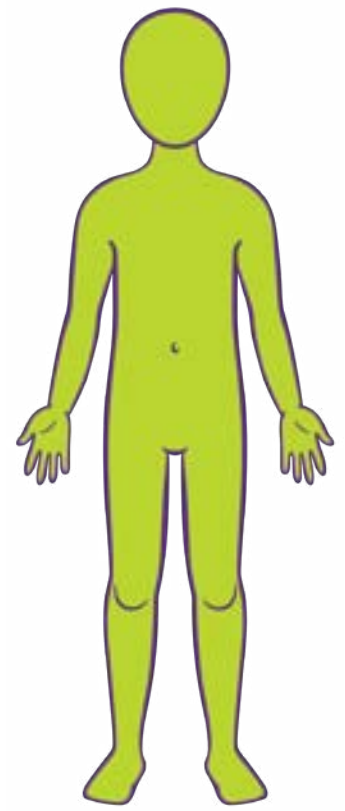
When pH rises, the normal healthy microbiome suffers, and pathogenic bacteria capitalizes on the change in pH.



Four Systems Supported By Theraworx Protect

An ideal acidic skin pH creates a hostile environment to pathogens, while supporting skin integrity and proper skin function. Theraworx Protect's unique low pH formulation **supports 4 systems** that are critical to driving quality and safety **while helping to reduce hurt and harm.**

pH Acidic Systems	Surfactant Systems	Barrier Systems	Preservative Systems
Key ingredient: Citrus Paradisi (Grapefruit Seed Extract)	**Key ingredient:** Cocamidopropyl Betaine	**Key ingredients:** Dimethicone, Allantoin	**Key ingredient:** Colloidal Silver



Theraworx Protect provides advanced total body and perineum care, trusted by hospitals and health care settings as a part of their infection control bundles.

Theraworx Protect Addresses the Gaps

- Advanced perineum care
- One step to total body and perineum protection–reducing time and human error
- Safe for use on compromised skin
- Low-pH formulation supports the skin's natural antimicrobial barrier and defensive functions
- Improve quality and safety while helping to reduce hurt and harm
- Contains NO CHG or antiseptic drugs
- Skin Friendly including ingredients that hydrate, nourish, and protect the skin
- Used by leading pediatric hospitals since 2015

01-101
Theraworx U-Pak

HXC-08Z
7.1 fl oz Foam

HXC-04Z
3.4 fl oz Foam

HXS-02Z
1.7 fl oz Pump Spray

Choose from several products to meet your care setting needs.

SCP-8802FF
2-Pack Fragrance Free Towels

SCP-8802
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HX-8808FF
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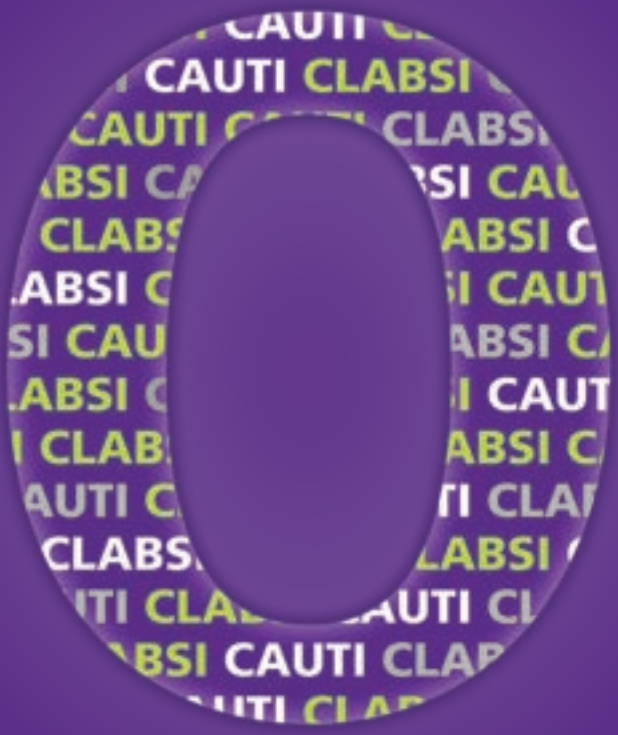
Learn about Theraworx Protect's clinical data, visit
hcp.theraworxprotect.com/learn

SCAN ME



Mission: Zero

To Help Reduce And Eliminate HAIs, Including Catheter-Associated Urinary Tract Infections (**CAUTI)** And Central Line-Associated Blood Stream Infections (**CLABSI**) As A Part Of Your Infection Control Bundle

Theraworx®
PROTECT

Here Is What We Know

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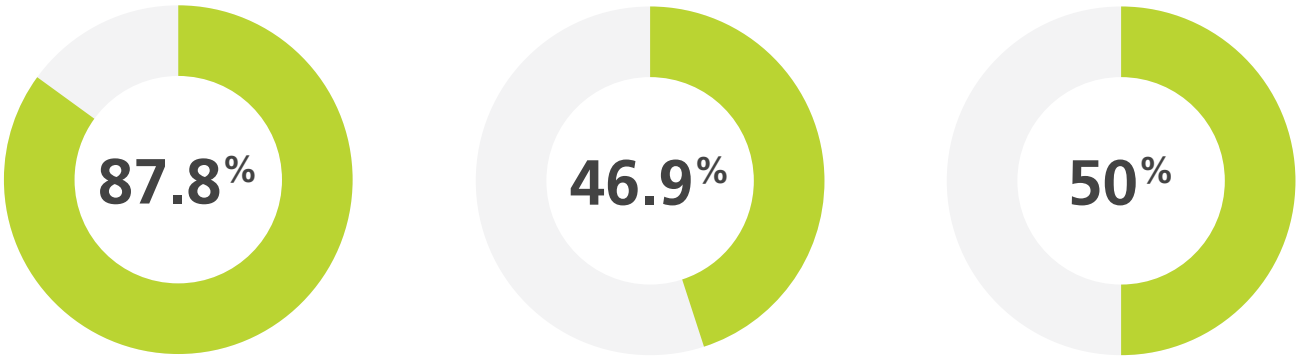
Gut Related Pathogens Are A Significant Cause of HAIs



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Current Practice Does Not Address Gut Related Pathogens In The Perineum, Which Can Lead To Infections In:

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(1) Dudeck MA et al., Antimicrobial-resistant pathogens associated with adult healthcare-associated infections; Summary of data reported to the National Healthcare Safety Network, 2015-2017. Infection Control and Hospital Epidemiology (2020), 41, 1-18. Doi:10.1017/ice.2019.296

(2) https://www.jointcommission.org/-/media/tjc/documents/resources/hai/clabsi_monographpdf.pdf

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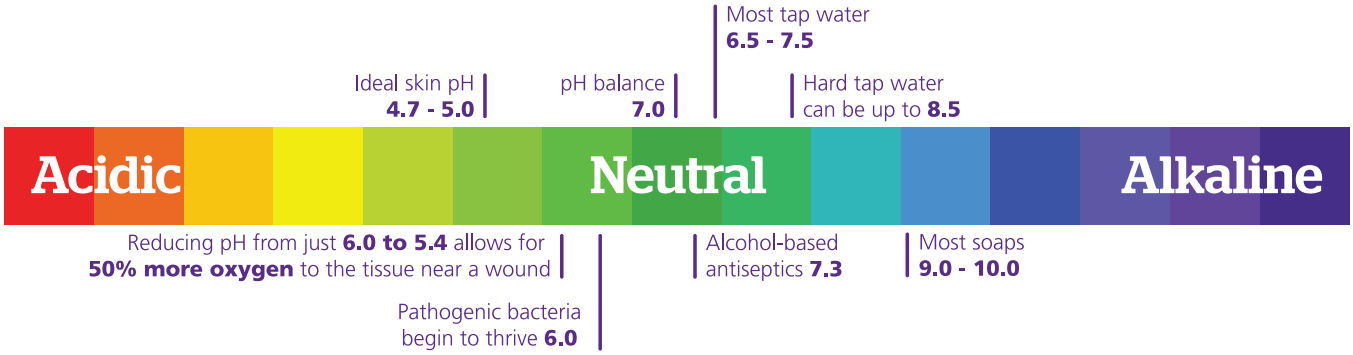

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- Cost effective
- No contraindications

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