Innovative Microbiome friendly skin care formulation reduces nosocomial associated CAUTI rates when used for insertion and maintenance of urinary catheters.

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Introduction

Soap and water based products have been considered the standard of care for urinary catheter maintenance for centuries (CDC recommendation).

Potent skin antiseptics (PSA) have replaced soap and water to prevent certain Hospital Acquired Infections such as CLABSI and SSI.
Safety concerns of potent drugs on mucous membranes leave few options relative soap, which has therefore remained the standard of care.

PSA have resulted in significant improvements in CLABSI and other HAI's
Unfortunately, CAUTI have increased and remains the number one infection in healthcare.

The CDC sponsored CUSP study sought to determine the effectiveness of soap and water cleansing in reducing CAUTI in 600+ hospitals
Only a 1% reduction in ICU setting and 14% reduction on general medical floors was observed[10].

Suggests soap and water care may be beneficial in reducing macroscopic debris and prepare the perineum for application of other agents that may be additive in their effect on reducing CAUTI.

Less than expected results from all products and methodology point to the need for quality improvement oversight and implementation for evidenced based practice guidelines including comprehensive education across all departments [11- 14]

Methods

10 hospitals were queried for their outcome data regarding CAUTIs.
- Implemented the skin care system protocol for an >20 months
- Demonstrated excellent quality in providing confirmed data for the 40+ month period

These institutions applied the protocol in a variety of care settings:
High-risk neurological, cardiovascular and trauma intensive care units.

Many patients were incontinent of urine, feces or both in these settings. was used in all of its available forms: foam, spray or moisture-impregnated cloths.

Clinical protocol:
- Prior to insertion of a catheter, apply to the meatus and surrounding tissue to establish a zone of inhibition
- Then reapply the product 3x / d and after each incident of fecal incontinence as a maintenance intervention.

Hospitals were asked to provide insertion and maintenance details on utilization, pre-and post- implementation CAUTI rates as reported to the National Healthcare Safety Network.

Post implementation results were then compared to an extended pre-implementation period with analogous patient populations.

CAUTI were reported per 1,000 catheter days consistent with the CDC reporting nomenclature and AHRQ [9]

Proposed mechanism of action: Reduction in the pH
Optimization of the stratum corneum of the skin, urethral meatus and vaginal mucosa.
Stratum corneum can function at maximal immune and barrier capacity.
Normal dermal microbiome is preserved reducing the presence of more virulent bacteria, fungi or viruses.

Results

Ten hospitals provided both pre- and post-intervention data.
80% of the hospitals complied with recommended clinical protocols.

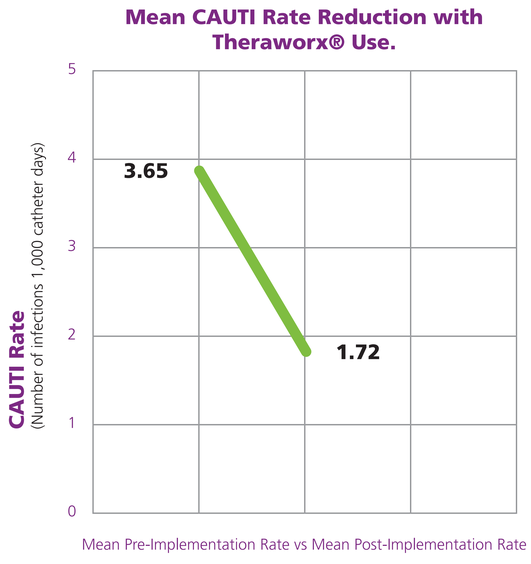
Average pre-intervention period: 22.9 months.
Average post-intervention period: 14.0 months.

8 / 8 hospitals reported markedly reduced CAUTI rate.
Reductions ranged from: 22.47% (UHS-San Antonio in San Antonio, Tex.) to 100% (Centennial Hospital in Frisco, Texas and Peace Health St. Joseph Medical Center, in Bellingham, Washington)

Mean pre-intervention CAUTI rate for the eight compliant hospitals:
3.65 / 1,000 catheter days.
Mean post-intervention CAUTI rate for the eight compliant hospitals:
1.72 / 1,000 catheter days
Reduction of 1.93 / 1,000 catheter days (52.88%)

Review of the 2 hospitals that did not consistently follow protocol revealed troubling data.
- Institution #1: No change in CAUTI rate
- Institution #2: 30.31% increase in CAUTI rate

Site	CAUTI Rate Pre-Intervention Period (per 1,000 catheter days)	Pre-Intervention Period Start Date	Pre-Intervention Period End Date	Pre-Intervention Period in Months	CAUTI Rates Post-Theraworx® Intervention (per 1,000 catheter days)	Post-Theraworx® Intervention Start Date	End Date of Theraworx® Intervention Data	Post-Theraworx® Intervention Period in Months	Percent Change
University Hospital (San Antonio, TX)	3.16	1 / 2015	3 / 2015	2	2.45	4 / 2015	6 / 2016	14	-22.47%
Baylor Scott & White Medical Center – Centennial (Frisco, TX)	1.84	11 / 2013	10 / 2015	23	0	11 / 2015	6 / 2016	7	-100.00%
South Miami Hospital / Baptist Health South Florida (South Miami, TX)	3.04	1 / 2013	12 / 2014	23	0.51	12 / 2014	6 / 2016	18	-83.22%
First Health Moore Regional (Pinehurst, NC)	1.25	1 / 2012	12 / 2013	23	0.65	1 / 2014	12 / 2015	23	-48.00%
Mercy Hospital Springfield (Springfield, MO)	2.34	8 / 2013	7 / 2015	23	1.4	8 / 2015	7 / 2016	11	-40.17%
St. Joseph Medical Center (Towson, MD)	3.34	7 / 2013	10 / 2015	27	0	12 / 2015	6 / 2016	5	-100.00%
Little Company of Mary Hospital (Evergreen Park, IL)	2.93	1 / 2012	12 / 2014	35	1.17	1 / 2015	9 / 2016	20	-60.07%
Regional Medical Center at Memphis, (Memphis, TN)	11.3	N / A	N / A	-	7.55	N / A	N / A	-	-33.19%
Large Florida University Hospital (NONCOMPLIANT SITE)	2.87	1 / 2015	8 / 2015	7	3.74	10 / 2015	9 / 2016	11	30.31%
Large Kansas City hospital (NONCOMPLIANT SITE)	1.2	1 / 2013	5 / 2015	28	1.2	5 / 2015	1 / 2016	8	0.00%
Total for compliant sites	**3.65**			**22.9**	**1.72**			**14**	**-52.88%**



Discussion

The skin care system (Avadim Technologies, Asheville, NC), is a **non-toxic topical skin and mucosal membrane application that was associated with a significant reduction in CAUTIs** over a period of 20 months or more of implementation at hospitals, across the United States, in a myriad of high risk ICU patient care settings.

Upon implementation of the protocol, **CAUTI rates decreased between 22.47% and 100%** in 8 / 10 institutions which remained compliant with design protocol, representing a mean decrease in CAUTIs of >53%.

2 noncompliant sites were the only sites that did not achieve a substantial improvement in their CAUTI rates and, in one instance, CAUTI rates actually increased.

This paradigm shift is an exciting approach to the prevention of infections and additional attempts at the reduction of the further development of multi-drug resistant organisms by reducing antibiotic use.

Conclusions

Results of this aggregated data set suggest that **patients at hospitals with CAUTIs may benefit from use of skin formulation at catheter insertion and for catheter maintenance.**

This approach **may be especially appropriate for institutions that are failing to meet their own, or national, CAUTI benchmarks** and suffering financial penalties for these critical HAIs.

We encourage institutions to consider including the protocol into their CAUTI clinical pathway to potentially achieve additional reduction in their CAUTI rates.