Please note: These studies may involve findings that exceed the claims currently cleared by the FDA for the product. Bravida Medical is not intending to make performance claims about its product. The intent is to disseminate the scientific literature on these products. We encourage you to read these studies to understand the strengths and limitations of the data. For some claims, Bravida is seeking to broaden the indications with the FDA in the future using data, such as these studies, to provide the substantiation.

Decreasing Utilization of Indwelling Urinary Catheters Using Creative Strategies

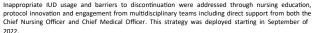
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Background

- · Indwelling urinary catheters (IUD) comes with high risk of Catheter Associated Urinary Tract Infections (CAUTIs) leading to increased morbidity, mortality, length of stay, readmission, and cost of care.
- · An estimated 70% of CAUTI are preventable using known strategies with the cornerstone of prevention being early IUD removal.
- Delay of discontinuation for IUDs is frequent despite available alternative external collection devices (ECDs) due to concern for urinary leakage which can result in incontinence associated pressure injury and inaccurate output measurement.
- · Standardized utilization ratio (SUR) reports the ratio of the number of observed device days and the number of predicted device days and is used nationally for tracking IUD use.
- · SUR is used as a quality improvement measure by hospitals to gauge progress and compare with local, state, and national standards.



Nursing education tackled:

- Inappropriate IUD usage
- Barriers to IUD discontinuation
- · Use and expectations of the new protocol · Proper use and maintenance of the new
- device with continued support from nursing education and infection
- Figure 2: Images of the new ECD (A) and tube securement device (B) chosen for unit stocking prevention during deployment and beyond as part of this intervention, images from www.

Targeted process change for IUD insertion, maintenance and discontinuation:

- Nurse-driven ILID removal
- 2-person insertion checklist

- · Compliance audit by nursing leadership including daily device meetings to review every IUD with unit staff

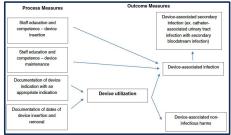


Figure 3: Abrantes-Figueiredo et. al. (2018) outlines how process change and device utilization change outcomes associated with device related infection

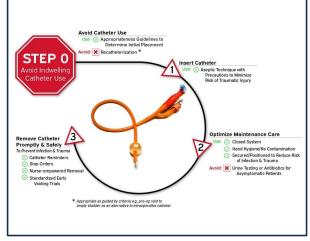


Figure 1: Steps to decrease risk of CAUTI as outlined by Patel PK, et al. (2023).

• Analysis of variance (ANOVA) revealed a statistically significant reduction in IUD SUR following implementation of the intervention (p<0.001) with mean SUR ratios falling from 0.74 to 0.52 pre and post intervention, respectively (Figure 5).

Results

Evidence Based Process Improvement Strategy

· Additionally, the hospital reported only one CAUTI in the seven months following implementation compared to four in just three months prior.

А

- · Hospital supply data of stocked units for devices used (Figure 4) pre and post intervention.
- New devices were not stocked prior to the intervention yet stocking levels post intervention far exceed levels for the devices used pre intervention, indicating much higher usage for patient care.

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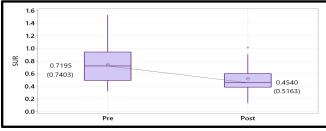


Figure 4: SUR pre and post implementation. median (mean)

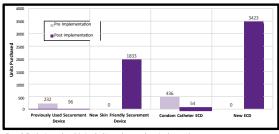


Figure 5: Total units purchased during the 21 months pre and post implementation.

Problem Identified

When a rise in CAUTI was identified, Christus Santa Rosa Hospital - Westover Hills decided to reduce CAUTI through focused reduction of SUR using a nurse-led innovative prevention protocol. Evidence suggests that reducing IUD use when possible, using good aseptic technique for insertion when an IUD is necessary, improving maintenance care and removing IUDs as early as is safe will lead to a decrease in CAUTI. This intervention utilized these evidence-based strategies along with employment of a new ECD that promised improved patient adherence, improved patient mobility and reduced leakage which is often a concern related to incontinence associated pressure injury and inaccurate output measurement. Also introduced was a new tube securement device intended to keep both the IUD and ECD in place during use.

- Decreasing IUD standardized utilization ratio is an important step towards reducing risk of CAUTI. · By reducing the use of IUD through standardized insertion guidelines, new securement device, clear expectations regarding removal, the availability of an easy to use and reliable alternative ECD and top-down accountability.
- · Patient outcomes improve when nurses are empowered to implement practice changes that consider the demands of nursing workflow, provide adequate education, and utilize effective and usable devices

Acknowledgement

Thank you to Leonardo Aguirre, Supply Chain Specialist at Christus Santa Rosa Health System for his contributions to this project related to supply chain data and process

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Clinical Implications

