Nikhil Seval, PGY-1

CRR, IRB Protocol

Supply Room Standardization For Optimized Utilization of Foley Catheters

A. Study Purpose and Rationale

The current economic climate of the healthcare industry has placed focus on cost lowering measures, increasing efficiency, and reducing duplication in services, all with the and goal of delivering both quality and affordable healthcare to patients. Notably, the New York Presbyterian system operates in a high competition market specializing in tertiary care with relatively high morbidity patients, making cost saving measures all the more important. As compared against peer institutions within the NYC metro area, NYP's average expenses per adjusted discharge are 400 dollars higher for the 2009 year, and similarly so when NYP is compared to other honor roll hospitals. (1) NYP Milstein has higher expenses per patient stay compared to Cornell, MSCHONY and The Allen. Despite preliminary cost saving measures, the expense per patient stay for Milstein went up $.12 from fiscal year 2012 to 2013 (2).

As such, the HERCULES project was initiated at NYP to evaluate for low budget cost saving measures. Proper supply utilization is one of the target focuses of the HERCULES project and internal evaluations suggest that improper supply stocking is partly causative. A recent survey of supply rooms across the hospital for central line supplies showed highly differential inventory, with some floors being completely devoid of certain items and others being replete (3). Improper use of more expensive kits for procedures was also identified as a source of increased cost. Improper use of Foley Catheterization kits instead of a straight catherization kits when performing a straight catheterization is one particular identified problem.

Urethral catheterization is a common nursing procedure, which is performed for a variety of reasons: from diagnostic (fluid status quantification, end organ evaluation in critical patients) to treatment based (bladder decompression in urinary retention). An indwelling Foley is comprised of a urethral catheter with an inflatable balloon on the tip of the device that is deployed to retain the distal tip in position in the bladder. In general indwelling and especially prolonged catheter use is associated with bactiuria and UTI development (4). In certain clinical situations it is wiser to use straight catheterization, which employs a similar catheter sans balloon which is inserted and removed immediately after bladder decompression. Clean (non-sterile) technique for intermittent catheterization is safe with lower complication rates compared with indwelling urethral or suprapubic catheterization (5). Notably a straight catheterization kit costs $1.49, and a Foley catheterization kit costs $22.37 (6). Due to reasons such as expediency, poor clean supply room inventory and inadequate organizational standardization, nursing staff will sometimes use a Foley catheter kit for purposes of a straight catheterization. As such, there can be significant losses from improper utilization, which likely occurs in other realms of equipment use such as IV kits.

This study aims to provide organizational standardization to the clean supply rooms on medical floors to optimize inventory replacement, decrease time to locate equipment, and cause familiarity amongst staff between all floors of common equipment. We hypothesize that said changes will result in overall improved utilization of proper equipment, specifically via measurement in reduction of the improper use Foley catheterization kits.

B. Study Design and Statistical Analysis

This is a prospective interventional nonrandomized study. The study participants will be the patients admitted to the ward service on given studied floors (6GS/6GN and 7GS/7GN, see further exclusion/inclusion criteria below). Two metrics will be measured: improper Foley Catheter incidence per month, and combined Foley catheter plus straight catheter budget. The clean supply rooms on both floors will remain unstandardized for a run-in period of 4 months to evaluate for trends of differential catheter use over time. Data will be gathered post intervention for 2 weeks, with an estimated group size of 400 patient charts (200 per group). 6GN/GS will be the intervention floor and 7GS/GN will be the control floor.

Sample Size and Power

At alpha = .05 and power = .90, 193 patients are needed in each sample, considering:

- an average of 400 patients per month per combined floor (GS+GN floors)
- approximately 40% of patients receiving urethral catheterization of any type
- 40% of these patients receiving straight catheterization (as opposed to indwelling)
- 40% improper utilization of Foleys during straight cath procedures
- estimated percent reduction of 90% through intervention

Chi squared analysis will be used to evaluate difference in improper Foley use in the intervention and control arm.

C. Study Procedure

This study will require patient chart examination to determine which type of catheterization is used on patients. Patients will be queried within the corresponding studied floors initially based on CPT coding of catheterization placement. These patients will be undifferentiated in the type of device placed and the context of whether this device was meant to be indwelling or not. A blinded reviewer will then review the charts of this abstracted data list and conduct chart review of Nursing Charts for these patients. The type of device used (Foley versus straight) and the context of device placement (indwelling versus intermittent) will be documented.

D. Study Drugs

No study drugs will be used

E. Medical Device

The medical equipment in this study are considered 'nonsignificant risk' per the FDA and are commonly used in standard of care treatment. No additional medical devices will be used.

F. Study Questionnaires

No study questionnaires will be used

G. Study Subjects

The study population will consist of medical patients admitted to the 'ward' services on the floors of 6 Garden South/North and 7 Garden South/North who have received some type of catheterization while inpatient. This study will be open to all men and women who meet the inclusion criteria regardless of race or ethnicity.

H. Recruitment of Subjects

Inclusion

Chart documentation of catheterization procedure

Age 18-75

Exclusion

Surgical patients

I. Confidentiality of Study Data

Patient data that is abstracted from the database will be devoid of patient identifiers in order to maintanc HIPAA compliance. Deidentified patient data will be assigned patient codes for identification within the study. All data will be stored and transferred on encrypted devices.

J. Potential Conflict of Interest

There are no conflicts of interest in this analysis.

K. Location of Study

Two general medical or 'ward', floors of New York Presbyterian hospital and their corresponding clean supply rooms, namely 6 Garden South and North, and 7 Garden South and North.

L. Potential Risks

As the intervention in this study is not directly involving patient care, there are no additional risks in this study.

M. Potential Benefits

There are no anticipated direct benefits from participation in this study due to similar patient care goals of using differing catheter kits for straight catherizations.

N. Alternative Therapies

There will be no alternative therapies.

O. Compensation to Subjects

There are no compensation to subjects.

P. Costs to Subjects

There are no costs to subjects.

Q. Minors as Research Subjects

No minors will be studied.

R. Radiation or Radioactive substances

There will be no radiation or radioactive substances used in this study.

References

1. A Report on Reform of Medicaid's Inpatient Rate Setting Methodology and Payment Levels. The New York State Department of Health, Commissioner Richard F. Daines, M.D. February 2009.

2. HERCULES Supply Utilization, "Overall Census Patient Day Expense Trending" chart. Kaiser and Halik. January 7, 2014.

3. Bundle Kit Supply Inventory. Unpublished. Cunningham et al. January 2014.

4. Nosocomial infections in U.S. hospitals, 1975-1976: estimated frequency by selected characteristics of patients.Haley RW, Hooton TM, Culver DH, Stanley RC, Emori TG, Hardison CD, Quade D, Shachtman RH, Schaberg DR, Shah BV, Schatz GD Am J Med. 1981;70(4):947.

5. Di Benedetto P. Clean intermittent self-catheterization in neuro-urology. Eur J Phys Rehabil Med 2011; 47:651

6. Epidemiology of urinary tract infections: incidence, morbidity, and economic costs. Foxman et al. The American Journal of Medicine. Volume 113 (1), 8 July 2002, 5–13.