

## **Standardizing Treatment by Establishing a Pathway (STEP) for Urinary Tract Infections**

### **1. BACKGROUND:**

Urinary Tract Infections (UTIs) are one of the most common reasons for admission to the general pediatrics floor. Many hospitals have standardized pathways for treatment and management of patients with UTI with the goal to improve outcomes, decrease length of stay, and follow the most current evidence-based practice.<sup>1-3; 6-7</sup> At CHONY, there is no standard treatment of UTI and there is frequently dissent on how to appropriately treat (type, form, and duration of antibiotics), as well as what type of imaging, subspecialty referral, and follow up is required.<sup>4,5</sup>

### **2. RESEARCH AIM AND STUDY HYPOTHESIS**

#### Overall Aim:

To design a CHONY-specific UTI pathway with the goals of reducing variability in management of UTI, decreasing length of stay, and standardizing follow up (both imaging and urologic).

#### Specific Aims:

The first phase of our project would be three-fold and will enable us to understand current practices and outcomes at CHONY:

1. Conducting a retrospective data from the past 12-24 months on the management of UTI in the inpatient setting at CHONY.
2. Conducting a survey of CHONY inpatient attending physicians on current management preferences (separate IRB request for survey administration will be submitted)
3. Reviewing the current guidelines/evidence, as well as reviewing pathways at established children's hospitals.

The second phase of the project would be developing and rolling out a pathway and using a QI/PDSA approach to improve adherence. We're specifically interested in the following outcomes:

- Decrease variability in first antibiotic choice and length/utility of IV treatment
- Decrease variability/create standard for imaging (ultrasound, VCUG, etc)
- Decrease variability/create standard for urology consultation/follow-up
- Decreasing LOS/costs

### **3. STUDY DESIGN:**

This will be a retrospective observational study with up to 250 pediatric charts from the Clinical Data warehouse. Charts will be manually reviewed in order to:

1. Identify all patients with the positive urine culture admitted to the general pediatrics service on the CHONY hospital floor (4T, 5T, 6T, 8C).
2. Extract data of these patients consisting of but, not limited to, laboratory data, admission and discharge dates, medications, imaging, and subspecialty evaluation.

This study is a retrospective chart review without treatment intervention; up to 250 pediatric patients will be reviewed. This IRB requests access to a previously acquired database on demographic data, length of admission, antibiotics use and positive urine cultures. The database is located in the Clinical Data Warehouse and will be provided by Dr. Philip Zachariah upon

approval from IRB. Dr. Philip Zachariah is an Infectious Disease attending and head of Antibiotic Stewardship program at CHONY. This will enable the study to review AllScripts data (supplied by Dr. Zachariah) from admissions in the past 24 months to examine management of UTI and assess length of stay, duration of IV therapy, whether antibiotic choices were either proper empiric coverage or in accordance with available culture sensitivities, and what proportion of patients were appropriately referred for ultrasound 4-6 weeks after admission. Patient records will be also be manually reviewed and entered into a database by investigators (Christina Sanders Manice, Francesca Kingery, or Philip Zachariah) or PI (Dr. Sumeet Banker) for demographic data (sex, age), outcomes (type of antibiotic treatment (form and type), length of treatment, and whether imaging was performed during hospitalization.) This information will be de-identified and entered into a spreadsheet using Microsoft Excel (Microsoft Corp., Redmond, Wash.) and will be stored on an onsite password protected server, in a folder on the MC domain created by an onsite IT employee, only accessible to investigators and PI of this study. No PII or PHI will be present on the excel sheet, and each subject will have a corresponding “subject number” which will correlate to a list of MRNs, which will only be accessible by the PI and Study Investigators and it will be stored. Any data with PHI will have additional password protection.

#### **4. STATISTICAL PROCEDURES:**

This will be a retrospective observational study with up to 250 pediatric charts from the Clinical Data warehouse. Charts will be manually reviewed in order to:

3. Identify all patients with the positive urine culture admitted to the general pediatrics service on the CHONY hospital floor (4T, 5T, 6T, 8C).
4. Extract data of these patients consisting of but, not limited to, laboratory data, admission and discharge dates, medications, imaging, and subspecialty evaluation.

Descriptive statistical analysis will be performed to estimate the proportion and compute exact confidence intervals. We will explore for possible risk factors associated with admission for urinary tract infection. We will determine mean duration of IV therapy and differences between age group and gender. Here will estimate odds ratios and their confidence intervals and perform Chi-Squared tests or Fisher’s exact tests as appropriate.

Power analysis:

- Pre-intervention analysis:
  - Group 2: Estimated 240 cases of children admitted with Urinary Tract Infection (UTI) over 24 months at CHONY
- Post-pathway implementation analysis (future separate IRB)
  - Group 1: Estimated 60 cases of UTI in 6 months of analysis following pathway implementation

Example power analysis using unpaired t-test for duration of IV therapy:

- Group 1: N = 60
- Group 2: N =240
- Group2/Group1 ratio: 4
- Standard Deviation: 24 hours
- Unpaired T-test: you can show a difference of size: 9.7 hours

#### **5. CONFIDENTIALITY OF STUDY DATA**

The information (without direct identifiers) will be stored on an encrypted, password protected, server, only by pre-authorized users with MC (Medical Center) domain and password. Patient data will be identified patient number and age with no patient name, date of birth, or other identifying data. The database will only be stored on this password-protected server, with password protected individual files with user restricted access only by the PIs and research team.

#### **6. STUDY PROCEDURES:**

No procedures will be performed for this study.

#### **6. EXISTING DATA:**

Data will be used from 7/12015- 7/1/2017

#### **8. MEDICAL DEVICE**

No medical devices will be used for this study.

#### **9. STUDY DRUGS**

No drugs will be given for this study.

#### **10. STUDY QUESTIONNAIRES**

No questionnaires will be used for this study.

#### **11: STUDY SUBJECTS**

This is a retrospective study looking at routinely collected clinical data, which will be used to examine current practices at Columbia Children's Hospital of New York. We will be reviewing management of UTI in all patients admitted to the hospital floor with positive urine culture, thus 1 day to 18 years will be included. Thus given the nature of the retrospective review for pediatric urinary tract infection management guideline, charts from neonates, children, and adolescents will be reviewed.

#### **12. RECRUITMENT OF SUBJECTS**

No study subjects will be recruited for this study

#### **13. POTENTIAL CONFLICT OF INTEREST**

None to disclose.

#### **14. LOCATION OF STUDY**

CHONY 4 Tower, CHONY 5T, CHONY 6T, CHONY 8 Central

#### **15. POTENTIAL RISKS**

The primary risk associated with this retrospective study is potential dissemination or “leak” of database information. However, the database will be password protected and stored on protected server, with password protected individual files with user restricted access only by the PIs and research investigators. Data will be de-identified of patient’s name, birth-date, social security number, or address limiting the consequences of an information leak.

#### **16. POTENTIAL BENEFITS**

There are no direct benefits to research subjects from participating in this observational study. However, the information obtained from this study will serve a basis of better understanding of the management practice of pediatric patients with Urinary Tract Infections at CHONY. The outcome of this descriptive study will enable us to help inform providers on the best evidenced based practice for management of UTI and help us standardize this treatment.

#### **17. ALTERNATIVE THERAPIES**

Not applicable.

#### **18. COMPENSATION TO SUBJECTS**

Not applicable.

#### **19. COSTS TO SUBJECTS**

Not applicable.

#### **20. MINORS AS RESEARCH SUBJECTS**

This study will be minimal risk because it is a retrospective study of patients who have already undergone standard clinical care. Thus, the research does not involve any risk (potential for physical, emotional, social or similar harm). No new patients will be enrolled in this study and no new tests or treatments will be investigated. The study will involve only collection of existing, routinely collected clinical data, no direct subject contact is necessary.

#### **21. RADIATION OR RADIOACTIVE SUBSTANCES**

Not applicable.

#### **22: RESOURCES**

1. Schroeder AR. UTI and Faulty Gold Standards. *Pediatrics*. 2017;139(3).
2. La Scola C, De Mutiis C, Hewitt IK, et al. Different guidelines for imaging after first UTI in febrile infants: yield, cost, and radiation. *Pediatrics*. 2013;131(3):e665-671.
3. Subcommittee on Urinary Tract Infection SCoQI, Management, Roberts KB. Urinary tract infection: clinical practice guideline for the diagnosis and management of the initial UTI in febrile infants and children 2 to 24 months. *Pediatrics*. 2011;128(3):595-610.
4. Montini G, Tullus K, Hewitt I. Febrile urinary tract infections in children. *N Engl J Med*. 2011;365(3):239-250.
5. Schroeder AR, Abidari JM, Kirpekar R, et al. Impact of a more restrictive approach to urinary tract imaging after febrile urinary tract infection. *Arch Pediatr Adolesc Med*. 2011;165(11):1027-1032.
6. Seattle Children's Hospital, Taxier R, Austin E, Caglar D, Crowell C, Fenstermacher S, Grady R, Klee K, Leu MG, Otto R, Rooholamini S. 2015 April. Urinary Tract Infections (UTI) Pathway. <<http://www.seattlechildrens.org/pdf/UTI-pathway.pdf>>
7. Children's Hospital of Philadelphia, K. Shaw, MD, N. Plachter, CRNP, J. Lavelle, MD, T. Kolon, MD, M. Carr, MD, R. Keren, MD, R. Patel, MD, M. Dunne, MD, J. Kim, MD, J. Gerber, MD, M. Pradhan, MD, K. Ota, MD, C. Jacobstein MD, K. McGowan, PhD, T. Metjian,

PharmD. 2014 August. Pathway for the Evaluation and Treatment of Children with Febrile UTI.  
≤ <http://www.chop.edu/clinical-pathway/urinary-tract-infection-uti-febrile-clinical-pathway> ≥