Impact of a Statewide Antimicrobial Stewardship Collaborative to Improve Antibiotic Use for Inpatient Urinary Tract Infections and Skin and Soft Tissue Infections

December 2017



Colorado Hospital Association Acute Care Antimicrobial Stewardship Collaborative

FINAL REPORT

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Executive Summary

In May 2015, Colorado Hospital Association (CHA), noting the coming mandates for establishing hospital antimicrobial stewardship (AMS) programs, launched a statewide collaborative to engage hospitals in AMS. The overarching goal of the two-year collaborative was to engage as many Colorado hospitals as possible in AMS and, going beyond establishing the core elements of AMS programs, asking hospitals to focus on two specific syndromes commonly associated with overprescribing: urinary tract infections (UTIs) and skin and soft tissue infections (SSTIs) (e.g., cellulitis).

CHA led the development of a community-based steering committee of academic and community partners with relevant expertise in medicine and pharmacy. The committee developed treatment guidelines and a data collection strategy. Each hospital formed a multi-disciplinary team to implement UTI- and SSTI-specific AMS interventions tailored to the hospital's needs and resources. CHA provided education and support to the teams, including evidence-based diagnosis and prescribing guidelines, annual in-person meetings, monthly webinars, twice-monthly coaching newsletters and access to local and national AMS experts. Each hospital was asked to submit retrospective data on the management of 80 cases of UTI and SSTI during 2014 (i.e., baseline period) and 20 cases each quarter after the intervention was started in October 2015. During the intervention, quarterly summaries with individual hospital performance data and benchmarking to peer hospitals were disseminated to each team. The steering committee selected the following specific goals:

- Reduce median treatment duration by 20 percent for UTIs and SSTIs;
- 2. Increase the proportion of UTIs meeting the Infectious Diseases Society of America (IDSA) definition by 15 percent;
- **3.** Reduce fluoroquinolone (FQ) use by 30 percent for UTIs; and,
- **4.** Reduce broad-spectrum gram-negative antibiotics by 30 percent for SSTIs.

Twenty-six acute care hospitals (inpatient bed range of 15 - 567) participated in the collaborative; all hospitals participated in the UTI intervention and 17 participated in the SSTI intervention. Data were submitted for 1,530 UTI and 722 SSTI cases during the baseline period and for 2,530 UTI and 1,030 SSTI cases during the intervention. In pre-post analysis, these data demonstrated:

- Among UTI cases, the proportion meeting clinical criteria for UTI increased from 51 percent to 54 percent (p=0.10), and the use of FQs declined from 49 percent to 41 percent (p<0.0001).
- Among SSTI cases, the proportion treated with broad-spectrum gram-negative antibiotics declined from 61 percent to 53 percent (p=0.001), and the median duration of therapy decreased from 11 days to 10 days (p<0.0001).
- Interrupted time series analyses demonstrated robust results for UTI. The trend in exposure to FQs for UTIs decreased significantly from baseline to the intervention (p = .03).
- The change in trends for the SSTI outcomes did not reach statistical significance.

In summary, a statewide AMS collaborative facilitating syndrome-specific guidelines for UTI and SSTI is a feasible approach to engage a large number of hospitals in antimicrobial stewardship. Collaborative aims were partially met for UTI and SSTI prescribing. Many lessons were learned, particularly about the support required for rural and critical access hospitals. Future collaborative work should include investigation of implementation and maintenance strategies for AMS.

Background and Significance

Combating the increasing prevalence of antibiotic-resistant bacteria has become a national priority.¹⁻³ Judicious use of antibiotics, or antimicrobial stewardship, is a key component of efforts to limit the emergence of antimicrobial resistance in hospitals.^{2,3} Infectious diseases societies and the Centers for Disease Control and Prevention (CDC) therefore advocate for programs to promote antimicrobial stewardship in all hospitals.^{1,4} Recent studies suggest that over half of hospitals have a formal antimicrobial stewardship program or are developing one;^{5,6} however, additional efforts to engage all hospitals in antimicrobial stewardship activities are necessary.³

Within hospitals, approximately one-half to two-thirds of patients are exposed to antibiotics.^{7,8} Common infections such as pneumonia, UTI and SSTI account for over half of such antibiotic exposure.⁷ Unfortunately, a significant amount of antibiotic use in hospitals is either suboptimal or unnecessary.⁹ UTI and SSTI are specific conditions where a substantial amount of antibiotic use has been demonstrated to be unnecessary.¹⁰⁻¹³ Antimicrobial stewardship interventions targeted toward these infections therefore have great potential to reduce antibiotic use in hospitals.

In September 2014, CHA, along with local experts, began to organize a statewide quality improvement (QI) initiative designed to assist Colorado hospitals with improving antibiotic use for patients hospitalized with UTIs and SSTIs. The intent of the initiative was to disseminate evidencebased prescribing guidelines for these infections and help hospitals promote uptake of the guidelines by providers. This antimicrobial stewardship collaborative, formally launched in May 2015, involved 26 hospitals across Colorado, making it one of the largest, single antimicrobial stewardship initiatives to-date in the United States. This project therefore has significant importance to national antimicrobial stewardship efforts and can serve as a model for how antimicrobial stewardship can be more widely scaled up across hospitals. The purpose of this report is to summarize the objectives, methods, results and lessons learned during this QI initiative.

Objectives

The CHA antimicrobial stewardship collaborative's primary objective was to disseminate evidence and strategies for antimicrobial stewardship and to assist hospitals in embedding strategies into daily clinical practice. A syndrome-specific approach was used to focus activities on proper prescribing of antimicrobials for UTIs and SSTIs.

CHA established the following specific aims and goals:

AIM:

To determine the effect of a statewide antimicrobial stewardship initiative on antibiotic prescribing for patients hospitalized with UTI.

Goals:

- 15 percent increase in proportion of cases treated for UTI that met the clinical definition for UTI
- 20 percent reduction from baseline in median duration of treatment
- 30 percent reduction in proportion of patients exposed to a FQ

AIM:

To determine the effect of a statewide antimicrobial stewardship initiative on antibiotic prescribing for patients hospitalized with SSTI.

Goals:

- 20 percent reduction from baseline in median duration of treatment
- 10 percent reduction in proportion of patients exposed to an antibiotic with broad-spectrum gram-negative activity

Methods

Leadership

Teri Hulett, RN, infection preventionist; and Sarah Hodgson, project manager; directed by Nancy Griffith, then CHA director of quality improvement and patient safety, were the primary architects of the project. They assembled a steering committee of key stakeholders and subject matter experts from CHA member hospitals, including infectious diseases (ID) physicians, ID pharmacists, a Colorado Department of Public Health and Environment (CDPHE) liaison, Telligen (Colorado's Quality Improvement Network-Quality Improvement Organization (QIN-QIO)) liaisons, a Colorado Health Care Association (a member association of nursing homes) representative, a geriatrician, a hospitalist and a biostatistician. For a complete list of steering committee members see **Appendix 1**.

The steering committee met quarterly for the duration of the project. Two physician subject matter experts from the University of Colorado School of Medicine faculty – Dr. Heidi Wald and Dr. Tim Jenkins – were retained to provide clinical expertise for the UTI and SSTI components of the project, respectively.

Planning Phase (October 2014 – May 2015)

During the planning phase, CHA convened the steering committee, chose a project focus, developed syndromespecific guidelines, defined goals, developed a data collection strategy, solicited interest, recruited hospitals and planned a symposium.

As the initial component of the initiative, local experts developed evidence-based guidelines for the diagnosis and treatment of UTIs and SSTIs. It was felt that specific prescribing guidelines would be most actionable for the facilities. UTI and SSTI were selected because they are among the most common indications for antibiotics in hospitals and because local clinical experts on these topics were available to participate. The guidelines were based on national guidelines and current literature and were vetted by the entire steering committee, including several rounds of revision. Treatment regimens for UTI and SSTI were designed to provide sufficient flexibility to allow for differences in local resistance patterns and differing formularies. The guidelines are found in *Appendices 2 and 3*.

The steering committee selected outcome measures relevant to the guidelines and developed goals informed by the biomedical literature. Data collection was an important part of the collaborative so that improvements could be documented. Primary chart review was selected, despite the obvious burden on participating sites. Data collection tools were developed by subject matter experts.

Recruitment

Facility recruitment was carried out by the Association through several modalities. The primary modality was an email to key stakeholders at each acute care member facility; this was usually the head of the AMS program. The recruitment information was included in the CHA daily e-newsletter – *HealthBEAT Today* – and was announced at the Quality Professional Council and Clinical Excellence Council. Finally, in-person meetings were an additional opportunity to encourage participation. The kickoff meeting was held in May 2015, and all member acute care facilities were invited to attend.

Participants: Acute Care Facilities Across Colorado

This QI initiative was open to all CHA member hospitals. Participation was voluntary and required a motivated team leader and documentation of support from hospital leadership. No financial support was provided to hospitals. Twenty-six facilities actively participated for the entire length of the collaborative, representing a mix of academic and community hospitals and hospitals of all sizes, including critical access hospitals:

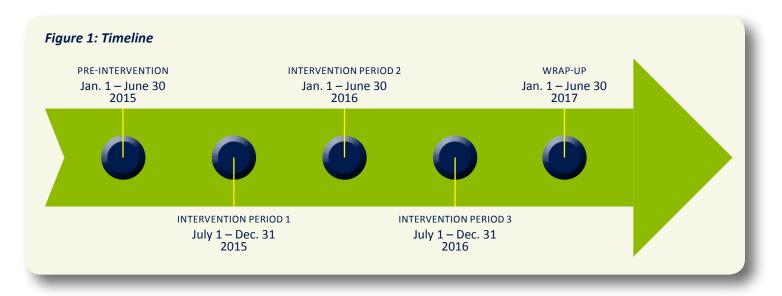
- Aspen Valley Hospital
- Delta County Memorial Hospital
- Denver Health
- Good Samaritan Medical Center
- Grand River Hospital District
- Heart of the Rockies Regional Medical Center
- Longmont United Hospital
- Lutheran Medical Center
- Memorial Hospital
- Montrose Memorial Hospital
- Mt. San Rafael Hospital
- Poudre Valley Hospital
- Prowers Medical Center
- Rio Grande Hospital
- Rose Medical Center
- San Luis Valley Health Regional Medical Center
- Sky Ridge Medical Center
- Southwest Health System Hospital
- Spanish Peaks Regional Health Center
- St. Mary's Hospital and Medical Center
- Swedish Medical Center
- University of Colorado Hospital
- Vail Valley Medical Center
- Valley View Hospital
- Yampa Valley Medical Center
- Yuma District Hospital

Hospital participation was remarkably robust. One hospital did not complete the final data collection period but is included in the earlier data collection periods.

$Methods \ {\rm continued}$

Timeline and Interventions

A project timeline appears in *Figure 1* below and describes the activities in each project period.



Pre-Intervention Period (January – June, 2015)

At each hospital, teams were formed that served to champion the intervention to improve antibiotic use. One individual was designated as the team lead and was typically a pharmacist. Additional team members generally included at least one physician. Other members included infection preventionists, microbiologists, quality officers, nurses and hospital executives.

Based on a pre-intervention assessment via survey, the hospitals selected one of two tracks: beginner or advanced.

- The beginner track was intended for hospitals without any formal antimicrobial stewardship program in place. Fifteen hospitals selected the beginner track.
- The advanced track was intended for hospitals with existing antimicrobial stewardship programs looking for assistance to move their program forward, more actively engage facility leadership or take antimicrobial stewardship outside their hospital into the community (e.g., clinics, long-term or post-acute care facilities). Eleven hospitals selected the advanced track.

During the pre-intervention period, teams completed retrospective baseline data collection for the period of Jan. 1 - Dec. 31, 2014 using a sampling methodology of 20 cases of each diagnosis (UTI or SSTI) per quarter, for a total of 80 cases of each diagnosis. Data collection tools can be found in **Appendix 4**, and the complete strategy can be found in **Appendix 7**.

Hospital teams also used this period to decide on an intervention approach.

Intervention Period (July 2015 – December 2016)

Each participating hospital had the option to implement an intervention aimed at improving antibiotic use for UTIs, SSTIs or both. Of the 26 hospitals, 17 opted to implement interventions for both UTIs and SSTIs and nine hospitals opted to focus only on UTIs. The intervention period was viewed as three six-month periods for the purposes of organizing data collection and reporting. To facilitate effective dissemination of the guidelines and to promote use by providers, CHA used a modification of the Institute for Healthcare Improvement's Breakthrough (collaborative) Series. In so doing, it provided many resources to each hospital's team:

- Educational offerings
 - Monthly webinars (Appendix 5)
 - Regional meetings
 - Three statewide meetings
- Technical support
 - Prescribing guidelines for UTI and SSTI; diagnosis guidelines for UTI (*Appendices 2 and 3*)
 - Site visits
 - Coaching calls
 - Peer mentorship
 - Access to regional and national experts
- QI support
 - Team recruitment tools and advice
 - Team readiness checklist
 - QI methods webinars
 - Implementation survey
- Data reports
 - Data collection support
 - Quarterly reports: hospital, regional and statewide levels
- Marketing and communications
 - Bi-weekly newsletter
 - Internal informational posters

A sample hospital-level data report can be found in *Appendix 6.*

Wrap-Up (January – June 2017)

Following the final data collection period, hospital-based teams submitted their final quarterly data, received final quarterly reports and final project reports. The steering committee held a final summit with national speakers and prepared an academic publication, presentations and this report. Considerable time was dedicated to identifying the next phase of collaborative activities.

Data Collection

Data collection comprised a significant portion of the work at individual hospitals. Data collection forms for UTI and SSTI cases were developed for this project by members of the steering committee *(Appendix 4)*. A Research Electronic Data Capture (REDCap) account was obtained from Vanderbilt University to facilitate data entry and the development of a unified, HIPAA-compliant, limited data set for the purposes of feedback and benchmarking reports. Each site had a REDCap login and only had access to their data. The project's experienced clinical data analyst was not able to access direct patient identifiers from individual cases.

In the baseline data collection period, sites were asked to provide 80 cases for each of UTI and/or SSTI during the 12-month period between Jan. 1 – Dec. 31, 2014. Nine hospitals did not participate in the SSTI intervention and did not provide SSTI data. During the 18-month intervention, sites were asked to provide 20 cases per quarter for each of UTI and SSTI. Details of how to abstract the cases was left to the site. Sites were free to identify the first 20 cases each quarter or select 20 cases at random each quarter. Cases were initially identified using selected International Classification of Diseases (ICD)-9 version codes for UTI and SSTI. On Oct. 1, 2015, hospitals made the mandated switch to using the ICD-10 codes. All UTI and SSTI diagnosis codes were cross-walked to the ICD-10 for use in the remainder of the data collection.

This was a QI collaborative. Results were analyzed formally for dissemination with oversite from the Colorado Multiple Institutional Review Board (COMIRB). The full protocol, including data collection procedures, outcome measure definitions, population and analysis, appears in *Appendix 7*.

Measures

The main outcome measures for the UTI intervention were:

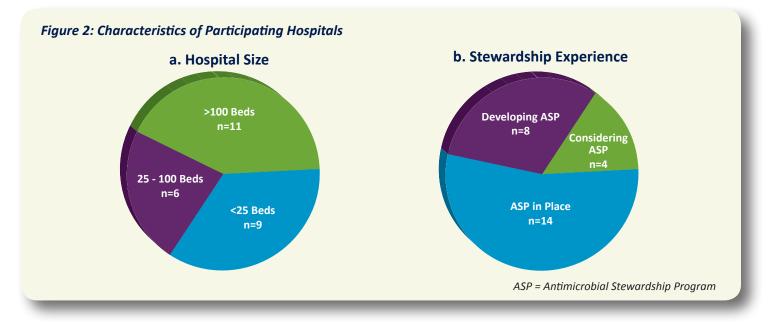
- Change in the proportion of cases treated for UTI that met IDSA definition for UTI (i.e., symptomatic UTI)
- Change in the median duration of treatment
- Change in the proportion of patients exposed to a FQ

The main outcome measures for the SSTI intervention were: • Change in median duration of treatment

 Change in proportion of patients exposed to antibiotics with a broad-spectrum gram-negative activity, defined as FQs, carbapenems, 2nd-5th generation cephalosporins, beta-lactam/beta-lactamase inhibitor combinations, aminoglycosides, tigecycline and colistin

Results

Twenty-six acute care hospitals (inpatient bed range 15–567) participated in the collaborative. Seventeen sites implemented both UTI and SSTI interventions. Nine implemented UTI interventions only. Characteristics of participating hospitals appear in *Figures 2a and b.*



Characteristics of UTI and SSTI Cases

Data were submitted for 1,530 UTI and 722 SSTI cases during the baseline period; data were submitted for 2,530 UTI and 1,030 SSTI cases during the intervention. *Tables 1 and 2* compare the baseline and intervention characteristics of UTI and SSTI cases, respectively.

Table 1: UTI Case Characteristics

	Baseline N = 1530	Intervention N = 2530
Age, median (IQR)	76 (62-85)	74 (60-84)
Female	1,078 (70)	1,759 (70)
Infection type		
Complicated cystitis	1,371 (83)	2,119 (76)
Pyelonephritis	76 (5)	227 (8)
Simple cystitis	83 (5)	184 (8)
Diabetes mellitus	400 (26)	
Long-term care facility resident	253 (17)	386 (15)
Fever (≥38.0°C)	413 (27)	892 (36)
Leukocytosis (≥12,000mm³)	863 (57)	1,458 (58)

Table 2: SSTI Case Characteristics

	Baseline N = 1530	Intervention N = 1030
Age, median (IQR)	60 (45-75)	60 (45-75)
Male	393 (54)	564 (55)
Infection type		
Non-purulent cellulitis	530 (73)	719 (70)
Wound infection/purulent cellulitis	134 (19)	211 (20)
Abscess	58 (8)	100 (10)
Diabetes mellitus	216 (30)	312 (30)
Fever (≥38.0°C)	152 (21)	203 (20)
Leukocytosis (≥12,000mm³)	409 (57)	509 (51)

Pre-Post Outcomes

UTI Outcomes:

- Use of FQs declined from 49 percent to 41 percent (p<0.0001)
- The proportion meeting clinical criteria for UTI increased from 51 percent to 54 percent (p=0.10)
- The median duration of therapy did not change, likely because it was within the goal range at baseline (Table 3)

Table 3: UTI Pre-post Outcomes % Baseline Intervention Outcome p Value N = 1530 N = 2530 Change Cases treated with a fluoroquinolone, n (%) 745 (49%) 1,030 (41%) -16 < 0.0001 Cases meeting IDSA definition of UTI, n (%) 6 0.10 786 (51%) 1,367 (54%) Duration of therapy, median (IQR) 6 (3-10) 0.32 6 (3-9) 0

Results continued

SSTI Outcomes:

- The proportion treated with antibiotics with broad-spectrum gram-negative activity declined from 61 percent to 53 percent (p=0.001)
- The median duration of therapy decreased from 11 days to 10 days (p<0.0001) (Table 4)

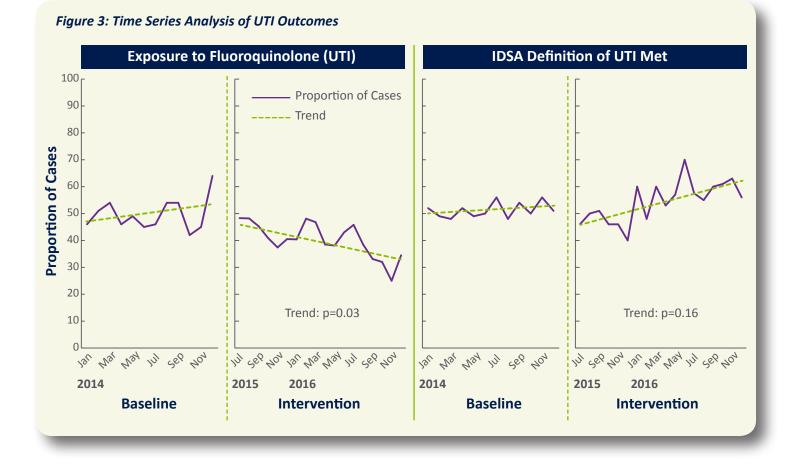
Table 4: SSTI Pre-post Outcomes				
Outcome	Baseline N = 722	Intervention N = 1030	% Change	p Value
Exposure to antibiotics with broad-spectrum gram-negative activity, n (%)	440 (61%)	551 (53%)	-13	0.001
Duration of therapy, median (IQR)	11 (8-13)	10 (8-13)	-9	0.03
Exposure to combination therapy, n (%)	368 (51%)	472 (46%)	-10	0.02

These results were significant and directionally in-line with initial predictions, although the achieved percent change was generally half of what was hypothesized. In the case of duration of therapy for UTI, however, the baseline result was already at goal, and thus no change was noted.

Time-Series Analysis

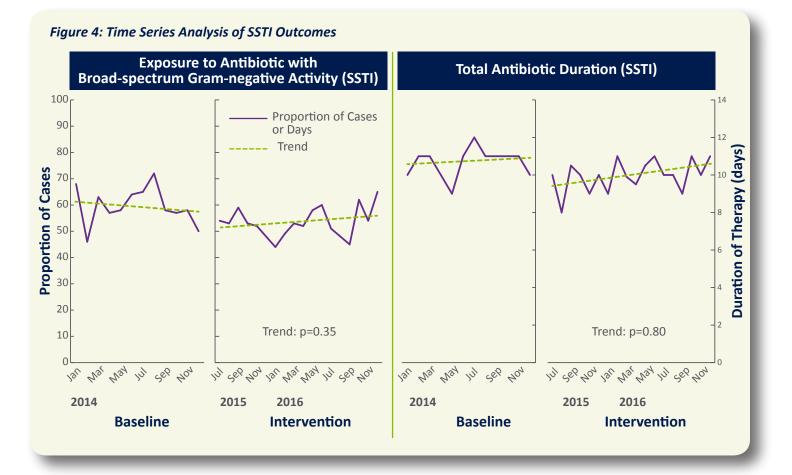
CHA subjected the results to a more rigorous time-series analysis, which allows the detection of trends given sufficient repeated measurements over time.

Figure 3 shows the time series analysis for two of the three outcomes for UTI; median duration of therapy is not shown. The results from the time series support the results of the pre-post analysis. Namely, that exposure to FQ significantly decreased over the course of the project and the proportion of cases meeting the IDSA definition of UTI increased over the course of the project, but this increase did not reach statistical significance.



$Results \ {\tt continued}$

Figure 4 shows the time series analysis for the SSTI outcomes. The results from the time series are not as robust as the pre-post analysis. Neither trend achieved statistical significance. Namely, for both outcomes, exposure to antibiotics with broad-spectrum gram-negative activity and median duration of therapy, there was an initial decline seen, but the decline did not appear to be maintained over the course of the project.



Comments from Participating Sites:

"This has been very helpful to jumpstart our efforts. To succeed, I feel that our facility needs continued access to experts such as ID physicians and ID pharmacists."

"Our participation in the CHA collaborative has helped us take a big step forward to a formal antimicrobial stewardship program."

Lessons Learned

In this large collaborative effort, many lessons were learned.

- 1. Engagement: There were high levels of engagement by the partnering organizations and the members of the steering committee. There was outstanding engagement of participating hospitals, particularly at the outset and ongoing desire to do more collectively. Many sites credit this work as pivotal for developing their stewardship programs.
- 2. Diversity: Smaller hospitals, specifically critical access hospitals, have different needs than larger, urban hospitals. Specifically, these hospitals differ in size and resources. In Colorado, few will have the content matter expertise that a full time ID pharmacist or ID physician would bring. Medical staffs are small and non-physician providers may be more common. Further, resources for data collection and data analysis are limited. Thus, creative approaches to fulfilling the core elements of AMS and implementing solutions are needed. On the other hand, with fewer parties involved, it is possible that some changes are easier to make in critical access hospitals than larger hospitals. While this collaborative was initially conceived as having two cohorts - those with beginner AMS programs and those with advanced AMS programs – this division may have been less important when creating a cohort of critical access hospitals, which are a sizeable proportion of Colorado hospitals.
- **3. Burden:** Many of the participating hospitals struggled with dedicating the needed resources to the manual data abstraction. Some hospitals chose not to participate at all based on that commitment. An electronic health record data extract, rather than a chart review process, may decrease burden, but would also require additional information technology (IT) resources.

- 4. Teamwork: Antimicrobial stewardship teams were primarily led by ID pharmacists or ID physicians at participating hospitals. Teams led by pharmacists can struggle to obtain physician buy-in if they do not have a strong physician champion. As an example, a physician champion may be more effective in trying to change provider behaviors around diagnostic pathways, such as sending urine testing in patients without UTI symptoms. Further, pharmacists tend to be skilled in feedback and academic detailing, but less familiar with QI methodologies. Thus, in future collaborative work, CHA would recommend the inclusion of a QI specialist on each project team.
- 5. Methodology: To change long-standing behaviors and embed those changes in workflow, it is helpful to have team members with expertise in QI methods. Further, there should be equal education time spent on subject matter and QI methodologies. Finally, methods of sustaining gains should be a focus to avoid the results demonstrated by the SSTI intervention.
- 6. Implementation: CHA periodically surveyed facilities, beginning at the one-year mark, to understand the barriers and facilitators for implementing the interventions. This practice should be expanded in future implementation projects. In this project, CHA was unable to ascertain the adherence of the facilities to the interventions, namely how the guidelines for UTI and SSTI were disseminated and implemented. Further, CHA had little information on their acceptability to frontline providers. Nonetheless, the Association believes that syndrome-specific guidelines are a potentially highimpact approach.
- **7. Communication:** The role of frequent communication is critical to internal and external stakeholders. A marketing plan can be enhanced with more templated materials for sites, listservs and check-in calls.

Next Steps

CHA and the steering committee have disseminated this work through presentations at IDWeek (Oct. 7, 2017) and for the Maryland Department of Health. A manuscript is being prepared for publication, with one or more additional manuscripts to follow.

CHA is supportive of the spread of this work to other state hospital associations, to help jumpstart stewardship programs in areas where there is little stewardship experience or many small independent hospitals. Finally, CHA, its partners and the steering committee are developing next steps for its current collaborative. Work may focus on development of additional syndromespecific guidelines and the use of mobile applications for dissemination of this guidance. There is continued enthusiasm in the state for collaborative work on antimicrobial stewardship.

Conclusions

A statewide AMS collaborative facilitating syndrome-specific interventions for UTI and SSTI is a feasible approach to engage a large number of hospitals in antimicrobial stewardship. This approach was particularly impactful in supporting smaller hospitals and those new to AMS. Collaborative aims were partially met for UTI and SSTI prescribing. Future work should include investigation of implementation and maintenance strategies for AMS.

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Appendix 1 – Steering Committee Members

Bryan Knepper, MPH Infection Prevention/Statistical Analysis Denver Health

Chris Czaja, MD, MPH (Infectious Diseases) Antimicrobial Stewardship Medical Epidemiologist Healthcare-Associated Infections Program Colorado Department of Public Health and Environment

Gerry Barber, RPh, MPH, FASHP

Coordinator: Pharmacy and Therapeutics, Clinical Pharmacy Co-Chair: Pharmacy and Therapeutics Committee University of Colorado Hospital

Greg Gahm, MD (Geriatrician) Colorado Medical Directors Association

Heidi Wald, MD, MSPH (Geriatrician, Hospitalist)

Associate Professor of Medicine University of Colorado School of Medicine Physician Liaison Colorado Hospital Association

Jeff DesJardin, MD (Infectious Diseases) Western Infectious Disease Consultants, P.C.

John Hammer, MD (Infectious Diseases) Denver Infectious Disease Consultants, PLLC

Kati Shihadeh, PharmD

Clinical Pharmacist – Infectious Diseases Denver Health

Marc Meyer, RPh, BPharm, CIC, FAPIC

Pharmacy Practice, Infection Prevention and Antibiotic Stewardship Southwest Memorial Hospital

Sarah Hodgson

Project Manager Colorado Hospital Association

Stacy Volk, PharmD

Clinical Pharmacy – Infectious Diseases Lutheran Medical Center

Teri Hulett, RN, BSN, CIC, FAPIC

Infection Prevention Consultant Colorado Hospital Association

Tim Jenkins, MD (Infectious Diseases)

Director, Antimicrobial Stewardship Program Denver Health

Wendy Bamberg, MD (Infectious Diseases) Medical Epidemiologist Healthcare-Associated Infections Program Manager

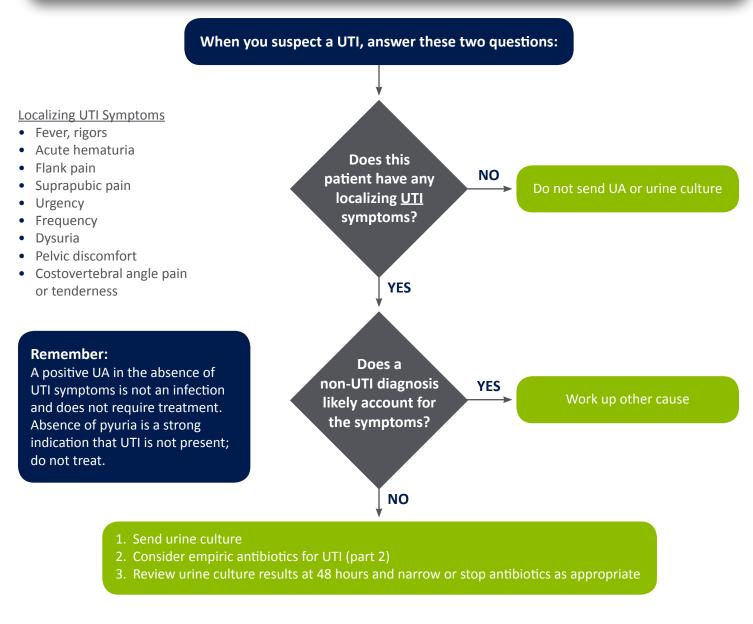
Colorado Department of Public Health and Environment

Appendix 2 – UTI Guidelines

Guideline for the Diagnosis and Management of Adults Hospitalized with UTI (Part 1)

4 key concepts to optimize diagnosis of UTI in hospitalized patients:

- 1) Most UTIs present with fever and/or symptoms localizing to the urinary tract.
- 2) Antibiotics are not recommended to treat colonization of the urinary tract (asymptomatic bacteriuria), except in pregnancy and invasive genitourinary procedures.
- 3) Urinalysis and urine culture have poor test characteristics in older patients and patients with indwelling urinary catheters they should not be sent unless symptoms are present.
- 4) Alteration in mental status (delirium) is neither sensitive nor specific for UTI. Thus, delirium without other localizing symptoms is unlikely to be a UTI.



This is intended as a guide for evidence-based decision making and should not replace clinical judgment.

REFERENCES: Trautner BW, Grigoryan L, Petersen NJ, et al. JAMA Intern Med. Published online May 26, 2015; IDSA Guideline for ABU 2005; IDSA Guideline for CAUTI 2009

Guideline for the Diagnosis and Management of Adults Hospitalized with UTI (Part 2)

Key concepts to optimize antibiotic use when managing UTI in hospitalized patients:

- 1) Obtain urine culture prior to initiating antimicrobial therapy.
- 2) Fluoroquinolones and trimethoprim-sulfamethoxazole are not routinely recommended as empiric therapy due to increasing bacterial resistance to these agents.
- 3) For patients with an appropriate clinical response, the recommended treatment duration for complicated cystitis, pyelonephritis or CAUTI is 5 - 7 days.

Guideline applicable to patients with: Uncomplicated cystitis, complicated cystitis, pyelonephritis, catheter-associated UTI (CAUTI). NOT applicable to: Prostatitis, pregnancy, bacteremia, renal transplant, persistent urinary tract obstruction, renal/perinephric abscess, percutaneous nephrostomy tubes and other clinical scenarios requiring specialized management.

Uncomplicated Cystitis

Uncomplicated cystitis, defined as a bladder infection in a healthy, nonpregnant woman <65 years old without evidence of upper urinary tract involvement, obstruction, anatomic abnormalities or recent instrumentation

Common pathogens: E. coli, Klebsiella, Proteus, S. saphrophyticus .

Initial antibiotic selection

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- Nitrofurantoin 100mg PO BID x 5 days (contraindicated if creatinine clearance <60mL/min) OR
- Fosfomycin 3gm PO x 1 dose OR
- Trimethoprim-sulfamethoxazole DS 1 • tab PO BID x 3 days (if local resistance in *E. coli* is <15%)

Target antibiotic selection to microbiologic data when available

Treatment duration: as noted in initial antibiotic selection section above

Complicated Cystitis

Complicated cystitis, defined as any bladder infection not meeting all criteria for uncomplicated cystitis (including any

male) OR Pyelonephritis OR **Catheter-associated UTI* AND**

Low Risk for Antibiotic-Resistant Organism (absence of risk factors to right)

Common pathogens: E. coli, Enterococcus, Klebsiella, other gram-negative bacilli

Empiric therapy depends on local antimicrobial susceptibilities and formulary. Options may include:

Ceftriaxone

+

•

• If severe PCN allergy: Ciprofloxacin OR Levofloxacin

Empiric therapy should be narrowed or stopped at 48 hours depending on culture results.

Transition to oral therapy: Target antibiotic selection to microbiologic data when available. For empiric therapy, consider:

- If ceftriaxone used as inpatient: oral 2nd- or 3rd-generation cephalosporin OR
- Fosfomycin (only if no pyelonephritis) • OR
- Ciprofloxacin OR levofloxacin • +

Treatment duration for patients with an appropriate clinical response: 5-7 days

Complicated Cystitis – High Risk for Antibiotic-Resistant Organism

Complicated cystitis OR Pyelonephritis OR Catheter-associated UTI* AND High Risk for Antibiotic-Resistant Organism, defined as hospitalization for >3 days or prior colonization/infection with an antibioticresistant organism OR Severe sepsis, hemodynamic instability or shock ¥

Common pathogens: E. coli, Pseudomonas aeruginosa, Enterobacter, Enterococcus, other gram-negative bacilli

Empiric therapy depends on local antimicrobial susceptibilities and formulary. Options may include:

Cefepime or Ceftazidime ٠

•

- Piperacillin-Tazobactam
- Carbapenem (if suspicion for extended-spectrum beta-lactamase (ESBL)-producing organism)
- If severe PCN allergy: Ciprofloxacin OR levofloxacin

Empiric therapy should be narrowed or stopped at 48 hours depending on culture results.

¥

•

Transition to oral therapy: Target antibiotic selection to microbiologic data when available. For empiric therapy, consider:

Ciprofloxacin OR levofloxacin OR Fosfomycin (3 doses) (only if no pyelonephritis)

Treatment duration for patients with an appropriate clinical response: 5-7 days

This is intended as a guide for evidence-based decision-making and should not replace clinical judgment. Patient and clinical characteristics, local antimicrobial susceptibility patterns, allergies, and formulary must be considered in treatment decisions.

REFERENCES: Trautner BW et al. JAMA Intern Med. 2015;175:1120; IDSA Guideline for Acute Uncomplicated Cystitis/Pyelonephritis .CID 2011;52:e103; IDSA Guideline for Catheter-Associated Urinary Tract Infection. CID 2010; 50:625; IDSA Guideline for Asymptomactic Bacteriuria. CID 2005;40:643

Appendix 2 – UTI Guidelines continued

Dosing Table for Adults Hospitalized with UTI (Part 3)

Antimicrobial	Recommended Dose
Cefdinir	300 mg PO BID
Cefepime	2 g IV Q12H
Cefixime	400 mg PO once daily
Cefpodoxime	200 mg PO BID
Ceftazidime	1 g IV Q8H
Ceftriaxone	1 g IV Q24H
Cefuroxime	500 mg PO BID
Ciprofloxacin	400 mg IV Q12H or 500 mg PO BID (reserve for severe PCN allergy)
Ertapenem	1 g IV Q24H
Fosfomycin	Uncomplicated UTI: 3 g PO x 1 dose Complicated UTI: 3 g PO Q48H x 3 doses (avoid for pyelonephritis)
Imipenem-cilastatin	500 mg IV Q6H
Levofloxacin	750 mg IV/PO Q24H (reserve for severe PCN allergy)
Meropenem	500 mg IV Q8H
Nitrofurantoin	100 mg PO BID x 5 days (uncomplicated UTI only)
Piperacillin-tazobactam	3.375 g IV Q6H
Trimethoprim-sulfamethoxazole	1 DS tab PO BID

Doses are based on normal renal function, adjust dose as appropriate; always assess for antibiotic allergies and drug interactions

Appendix 3 – SSTI Guideline

Management of Adults Hospitalized with Skin and Soft Tissue Infection

3 key concepts to optimize antibiotic use in the management of skin infections:

- 1) Most skin infections are caused by *Staphylococcus aureus* and streptococci antibiotics should be targeted toward these gram-positive pathogens.
- 2) Antibiotics with a broad spectrum of gram-negative activity are NOT recommended and in most cases, should be avoided.
- 3) For patients with an appropriate clinical response, the recommended treatment duration is 5-7 days. Longer treatment durations are generally unnecessary.

Guideline applicable to patients with: cellulitis, erysipelas, cutaneous abscess or wound infection. Guideline NOT applicable to clinical scenarios requiring specialized management, including but not limited to: suspected or confirmed necrotizing or deep tissue infection, diabetic foot infection, infected ulcers, surgical site infection, animal/human bites, undrained abscesses, periorbital/orbital/perineal infections, critical illness, bloodstream infection, pregnancy.

Non-purulent Cellulitis

Common pathogens

β-hemolytic streptococci and MSSA

+

Initial antibiotic selection

Recommended: Cefazolin 2gm IV Q8H*

If severe β -lactam allergy or history of MRSA: Vancomycin 15 mg/kg IV Q12H* or refer to institutional vancomycin protocol or Clindamycin 600-900mg IV Q8H

♦

Transition to oral therapy

Cefazolin→Cephalexin 500mg PO Q6H* <u>or</u> Dicloxacillin 500mg PO Q6H*

Vancomycin, clindamycin→TMP-SMX DS 1 tab PO BID (2 tabs if >80kg)* <u>or</u> Clindamycin 300-450mg PO TID

♦

Treatment duration for patients with an appropriate clinical response: 5-7 days

Abscess, Wound Infection or Purulent Cellulitis

Common pathogens MRSA, MSSA and streptococci

¥

Drain abscesses and send purulence for culture

Initial antibiotic selection

Recommended: Vancomycin 15 mg/kg IV Q12H* or refer to institutional vancomycin protocol

If vancomycin allergy: Linezolid 600mg IV or PO Q12H or Daptomycin 4mg/kg IV Q24H*



Transition to oral therapy

Vancomycin, linezolid, or daptomycin→ TMP-SMX DS 1 tab PO BID (2 tabs if >80kg)* <u>or</u> Doxycycline 100mg PO BID

Linezolid 600mg PO BID is an alternative but \$\$\$

Target antibiotic selection to microbiologic data when available

. ↓

Treatment duration for patients with adequate abscess drainage (if applicable) and an appropriate clinical response: 5-7 days

*Antibiotic doses based on normal renal function, adjust as appropriate; always assess for antibiotic allergies and drug interactions

This is intended as a guide for evidence-based decision-making and should not replace clinical judgment.

REFERENCES: Practice Guidelines for the Diagnosis and Management of Skin and Soft Tissue Infections: 2014 Update by the Infectious Diseases Society of America *Clin Infect Dis* 2014; 52:285-92; *NEJM* 2015;372:1093; *Arch Int Med* 2011;171:1072

Appendix 4 – Data Collection Tools

UTI Data Collection Tool – Please print all responses to help with legibility

Hospital Name:			Patient Age:	
Sex: 🛛 M 🗳 F	Admission Date:	Discharge Date:		
Antibiotic Allergies:				None

 Primary or Secondary Diagnosis Any of the Following N30.00 Acute cystitis without hematuria N30.01 Acute cystitis with hematuria A56.01 Chlamydial cystitis and urethritis N30.80 Other cystitis without hematuria N30.81 Other cystitis with hematuria N30.90 Cystitis, unspecified without hematuria N30.91 Cystitis, unspecified with hematuria N39.0 Urinary tract infection, site not specified N11.9 Chronic tubule-interstitial nephritis, unspecified as acute or chronic 	 <18 years of age Pregnancy Urologic or gynecologic surgery/procedure during current hospitalization Renal transplant Percutaneous nephrostomy Discharge antibiotic/duration unknown 		
 N13.6 Pyonephrosis Comorbid Conditions Diabetes mellitus Genitourinary tract abnormality Prior/recurrent UTI Dementia Immunosuppressed (see data dictionary) History of MDRO infection (see data dictionary) HIV infection 	Yes 	No - - - - -	Not Documented
Hospital Location/Service Admitted via: ED Outpatient Clinic Transfer fr Is the patient a resident of a long-term care facility (LTCF) Level of care at time of UTI diagnosis: ICU Non-I Primary Service at Time of UTI Diagnosis Medicine/Hospitalist ENT Surgery Podiate General Surgery OB/GYN Other	? 🗖 No [ICU		mit <a>Other Plastic Surgery

Initial Clinical/Laboratory Data: Hig	hest Value within 72 hours	Before or After Time of UTI	Diagnosis	
Highest body temperature:	Not O	btained		
Serum WBC:				
Serum Creatinine:		btained		
Serum Lactate:		btained		
1. Urinalysis I Not obtained Bacteria I Micro not dor	,	erase 🔲 Positive nitrite	□ WBC \geq 5 cells/hpf	
2. Urine Culture (culture closest in	time to UTI diagnosis)			
Date of urine culture:		🛛 Negative 🗳 Not c	btained	
Results of urine culture:				
l	1000-10,000 cfu/mL	10,000-100,000 cfu/mL	□ >100,000 cfu/mL	
Organism Name				
II	1000-10,000 cfu/mL	□ 10,000-100,000 cfu/mL	□ >100,000 cfu/mL	
Organism Name III. Organism Name	□ 1000-10,000 cfu/mL	□ 10,000-100,000 cfu/mL	□ >100,000 cfu/mL	
3. Blood Cultures (cultures closest	in time to UTI diagnosis the	at were obtained within 72 ho	ours before or after time	
of UTI diagnosis)				
Date of blood culture:		Not obtained		
		No Growth		

Clinical Findings

1. Did the patient have any of the following signs or symptoms within 72 hours before or after UTI diagnosis:

	Yes	No	Not Documented
Urgency			
Frequency			
Dysuria			
Suprapubic Tenderness			
Costovertebral angle pain or tenderness			
Delirium or other alteration in mental status			

2. Did the patient have an indwelling urinary catheter in place at time of UTI diagnosis OR did the patient have an indwelling urinary catheter in place for >2 calendar days that was removed the day of or the day before the event?

🛛 Yes 🗳 No

Appendix 4 – Data Collection Tools continued

Treatment

Did the patient receive any antibiotic thought to be prescribed for the current infection prior to presentation? Yes No Unkown

Record all antibiotics related to UTI episode that were administered in the ED, hospital, or prescribed at discharge

Antibiotics	Route (PO or IV)	Date Started	Date Stopped	Given in ED?	Initial Regimen Prescribed by Admitting Provider?	Prescribed in Response to Culture Results?
				🛛 Yes 🖵 No	🛛 Yes 🖵 No	🗅 Yes 🗅 No
				🛛 Yes 🖵 No	🛛 Yes 🖵 No	🗅 Yes 🗅 No
				🗅 Yes 🕒 No	🛛 Yes 🗖 No	🗅 Yes 🗅 No
				🗅 Yes 🕒 No	🛛 Yes 🖵 No	🗅 Yes 🕒 No
				🗅 Yes 🕒 No	🛛 Yes 🗖 No	🗅 Yes 🗅 No
				🗅 Yes 🕒 No	🛛 Yes 🖵 No	🗅 Yes 🕒 No
				🗅 Yes 🕒 No	🛛 Yes 🖵 No	🗅 Yes 🕒 No
				🗅 Yes 🕒 No	🛛 Yes 🖵 No	🗅 Yes 🗅 No
				🛛 Yes 🖵 No	🛛 Yes 🖵 No	🗅 Yes 🗅 No
Discharge Antibiotics	Route (PO or IV)	Prescribed Duration (Days)				

Was infecting pathogen(s) susceptible to the initial antibiotic regimen prescribed based on lab susceptibility report? Yes No No susceptibilities available N/A (no positive culture)

Final diagnosis documented by treating pro			
(select single answer most consistent with medi	ical reco	ra aocur	nentation)
UTI or cystitis – not otherwise specified			
UTI or cystitis – simple			
UTI or cystitis – complicated			
Pyelonephritis			
Urosepsis			
Urinary source bacteremia			
Catheter-associated UTI (CA-UTI)			
Other			
	C 11		
Medical record documentation of any of the	ne follo	wing du	ring current hospitalization
Sepsis	🗖 Yes	🗖 No	
Severe Sepsis	🗅 Yes	🗖 No	
Septic Shock	🗅 Yes	🗖 No	
C. difficile infection	🗅 Yes	🗖 No	If yes, date

🛛 Yes 🖵 No

Follow-up:

□ Additional bacterial infection present?

Was the patient re-hospitalized at same facility within 30 days after discharge? If yes, was the hospitalization potentially related to urinary tract infection? Yes No

Appendix 4 – Data Collection Tools continued

SSTI Data Collection Tool – Please print all responses to help with legibility

Hospital Name:	Patient Age:	
Sex: 🛛 M 🗳 F Admission Date:	Discharge Date:	
Antibiotic Allergies:		None
Primary ICD-10 diagnosis (select only one)	Exclusion Criteria	
**See Excel Spreadsheet and Data Dictionary for list of	Infected ulcer (diabetic, decubitus, stasis)	
ICD-10 Inclusion Codes	Bone, joint, muscle, tendon involvement	

- Necrotizing fasciitis/soft tissue infection
- Perineal infection
- □ Surgical site infection
- □ Tooth or odontogenic space infection
- **U** Human or animal bite
- Periorbital or orbital cellulitis/abscess
- <18 years of age</p>
- □ Discharge antibiotic/duration unknown

**See Excel Spreadsheet and Data Dictionary for list of associated ICD-10 Exclusion Codes

Anatomical location of infection (If more than one site, check all that apply)

Lower extremity					
Involves foot?	🖵 Yes 📮 No				
Upper extremity					
Involves hand?	🗖 Yes 📮 No				
Trunk (chest/abdon	nen/back/axilla)				
Head/neck					
Involves face?	🗅 Yes 📮 No				
Buttock					
Inguinal/groin					
Comorbid Condition	15	Yes	No	Not Documented	
Diabetes mellitus					
Injection drug use					
HIV infection					
History of skin infection	n				

Hospital Location/Service

Admitted via:	🗖 ED	Outpatient of the second se	clinic 🛛 🖵	Transfer from other facility	Direct admit	Other:
Level of care at	time of	admission:	Non-ICU			

Primary Service at Time of Admission

History of MRSA colonization or infection

Immunosuppressed (see data dictionary for definition)

Medicine/Hospitali	st	🔲 ENT :	Surge	ry 🗖	Podiatry	Orthopedic Surgery	Plastic Surgery	
General Surgery		OB/GYN		Other_		 		

Initial clinical/laboratory data: highest value within 24 hours of presentation

- Highest body temperature: _____
- Serum WBC: ______
- Serum CRP: ______ Serum Creatinine: ______ not obtained
- Serum Lactate: ______ not obtained

Dhycical Evam

Physical Exam
Purulence (e.g., abscess, pus, purulent drainage, exudate) noted in ED exam:
Purulence (e.g., abscess, pus, purulent drainage, exudate) noted in initial H&P:
Traumatic wound (e.g., laceration, abrasion, skin tear) noted: Yes No
Initial Microbiology
□ Surface culture (e.g., wound, drainage) performed □ Yes □ No □ Date
If yes: In No growth In Image And Image And American Structures (no susceptibility) Image Structures Coag-neg Staph
Anaerobes Other:
Abscess culture (pus or tissue) performed Yes INO Date
If yes: 🔲 No growth 🖾 MRSA 🖾 MSSA 🖾 S. aureus (no susceptibility) 🚨 Streptococcus 🚨 Coag-neg Staph
🗅 Anaerobes 📮 Other:
Non-abscess tissue culture performed Yes No Date
If yes: 🔲 No growth 🖾 MRSA 🖾 MSSA 🗔 S. aureus (no susceptibility) 🗔 Streptococcus 🗔 Coag-neg Staph
Anaerobes Other:
Aspirate of bullae, tissue or other I Yes I No Date
If yes: No growth MRSA MSSA S. aureus (no susceptibility) Streptococcus Coag-neg Staph
Anaerobes Other:
□ Blood culture performed □ Yes □ No □ Date
If yes: 🔲 No growth 🖾 MRSA 🖾 MSSA 🖾 S. aureus (no susceptibility) 🖾 Streptococcus 🗔 Coag-neg Staph
Anaerobes Other:

not obtained

not obtained

Treatment

Did the patient receive any antibiotic *thought to be prescribed for the current infection* prior to presentation? Yes 🗋 No Unknown

Procedures performed for current infection:

- □ Bedside incision and drainage or debridement □ Yes □ No □ Unknown
- □ Operative incision and drainage or debridement □ Yes □ No □ Unknown

Appendix 4 – Data Collection Tools continued

Record all antibiotics administered in the ED, hospital or prescribed at discharge

Antibiotics	Route (PO or IV)	Date Started	Date Stopped	Given in ED?	Initial Regimen Prescribed by Admitting Provider?	Prescribed in Response to Culture Results?
				🗅 Yes 📮 No	🗅 Yes 📮 No	🗅 Yes 📮 No
				🗅 Yes 📮 No	🗅 Yes 📮 No	🗅 Yes 📮 No
				🗅 Yes 📮 No	🗅 Yes 📮 No	🗅 Yes 📮 No
				🗅 Yes 📮 No	🛛 Yes 🖵 No	🗅 Yes 📮 No
				🗅 Yes 📮 No	🗅 Yes 🕒 No	🗅 Yes 🗅 No
				🗅 Yes 🕒 No	🗅 Yes 🕒 No	🗅 Yes 🗅 No
				🗅 Yes 🕒 No	🗅 Yes 🕒 No	🗅 Yes 🗅 No
				🗅 Yes 📮 No	🛛 Yes 🖵 No	🗅 Yes 🗅 No
				🗅 Yes 🕒 No	🛛 Yes 🖵 No	🗅 Yes 🗅 No
Discharge Antibiotics	Route (PO or IV)	Prescribed Duration (Days)				

Was infecting pathogen(s) susceptible to the initial antibiotic regimen prescribed based on lab susceptibility report? Yes No No susceptibilities available N/A (no positive culture)

Final diagnosis documented by treating provider in discharge summary or progress notes

(select single answer most consistent with medical record documentation)

- Cellulitis or erysipelas (no mention of abscess)
- □ Abscess (no mention of cellulitis) (e.g., skin abscess, cutaneous abscess, subcutaneous abscess, shooter's abscess, carbuncle, furuncle)
- □ Abscess with cellulitis OR cellulitis with abscess

Wound infection

Medical record documentation of any of the following during current hospitalization

Sepsis	🗖 Yes 📮 No	
Severe Sepsis	🗖 Yes 📮 No	
Septic Shock	🛛 Yes 🗳 No	
C. difficile infection	🗖 Yes 📮 No	If yes, date
Additional bacterial infection present?	🛛 Yes 🗳 No	

Follow-up

Was the patient re-hospitalized at same facility within 30 days after discharge?

❑ Yes❑ No❑ Unknown❑ Yes❑ No

Appendix 5 – Webinars

Торіс	Presenter	Date
Kick-off	Teri Hulett, RN; Sarah Hodgson	May 2015
Data Webinar	Teri Hulett, RN; Sarah Hodgson	May 2015
Interventions Part 1	Teri Hulett, RN; Sarah Hodgson	June 2015
AMS in Resource Limited Settings	Arjun Srinivasan, MD; Marc Meyer, RPh	July 2015
Interventions Part 2	Steering committee members	August 2015
Evidence-based Diagnosis of UTI	Heidi Wald, MD, MSPH	October 2015
Barriers and Successes in Implementation – Coaching	Teri Hulett, RN; Sarah Hodgson	November 2015
Screening for UTI and Other Practices to Avoid	Barbara Trautner, MD, PhD	December 2015
SSTI – Using Data to Drive Change	Tim Jenkins, MD, MSPH	February 2016
Managing CDI and An Overview of AMS	Teri Hulett, RN; Gerry Barber, PharmD	March 2016
UTI Using Data to Drive Change	Heidi Wald, MD, MSPH	March 2016
Debunking Common Myths	Steering committee members	April 2016
Antibiotic Prescribing – Is it risky to Choose Wisely?	Teri Hulett, RN; Heidi Wald, MD, MSPH	July 2016
CMS Rule Changes	John Hammer, MD	August 2016
Good Nursing is Good Stewardship and Good Stewardship is Good Nursing	Rita Olans, DPN, RN	September 2016
AMS and Sepsis	Jeff DesJardin, MD	October 2016
Implementing a Public Health Approach to Antimicrobial Stewardship in Colorado	Chris Czaja, MD, MPH	January 2017
Colorado's Statewide AMS Collaborative: Facilitating Syndrome-specific Interventions for Skin and Urinary Tract infections	Steering committee members	February 2017
CHA AMS Challenges and Potential Solutions	Teri Hulett, RN	March 2017
Rational Antimicrobial Use in CAP	Lakshmi Chauhan, MD	April 2017

Appendix 6 – Sample Data Report

Antimicrobial Stewardship Collaborative Quarterly Data Summary Reporting Period: January 1, 2016—March 31, 2016

Report: UTI Data Summary

In this report you will find a summary of quarterly UTI data for January through March, 2016. We analyzed demographics and comorbid conditions, clinical findings, laboratory values, culture results, antimicrobial treatment, and important outcome data.

For most sites, UTI cases have been classified in 3 categories: uncomplicated UTI, complicated UTI (CAUTI, urosepsis, UTI unspecified, complicated UTI, and urinary source bacteremia), and pyelonephritis. Sites with cases classified as Other have this category added.

Please feel free to contact us with any questions or comments!

Your Quarterly Data at a Glance – Q1 2016

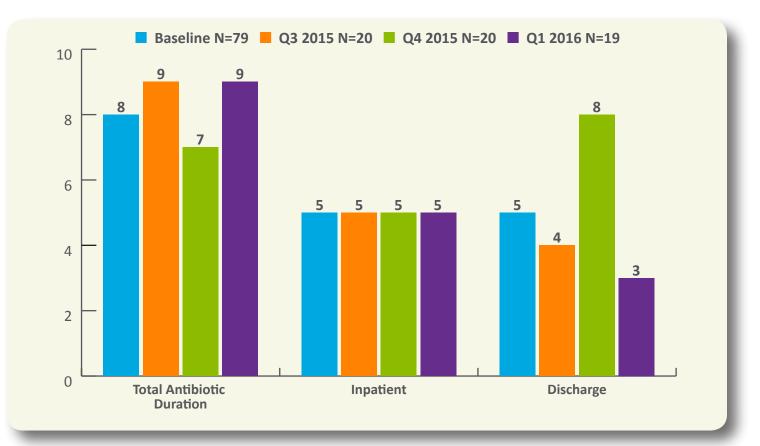
Demographics And Comorbidities – Number of Patients or Median*						
	Uncomplicated UTI	Complicated UTI	Pyelonephritis	Total		
Ν	0	18	1	19		
Median Age	-	60	52	60		
Female	-	9	1	10		
Diabetes	-	4	0	4		
LTAC/SNF Resident	-	0	0	0		
ICU Admission	-	3	0	3		
Fever	-	7	0	7		
Leukocytosis	-	11	1	12		
Other signs/symptoms	-	13	1	14		
Alteration of mental status	-	2	0	2		
Positive Urine Culture/Obtained	-	15/18	1/1	16/19		
E. coli	-	4	1	5		
Other gram-negative organisms	-	2	0	2		
Gram-positive organisms	-	3	0	3		
Positive blood culture	-	1/8	1/1	2/9		

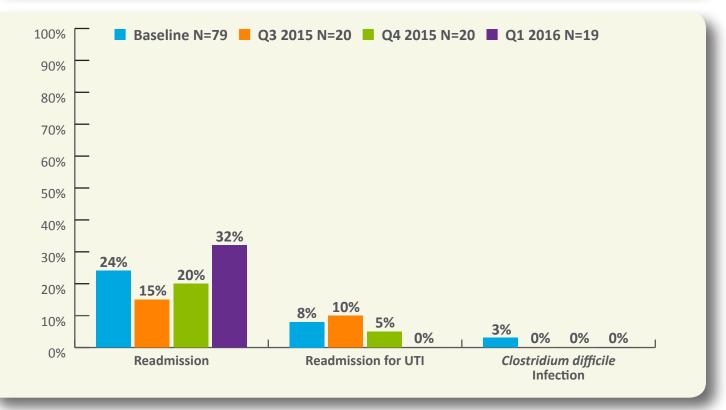
Appendix 6 – Sample Data Report continued

Culture and Antimicrobial Treatment Data – Q1 2016

	Your Site	Sites Like Yours	All Sites
N	19	97	405
Empiric Antibiotics			
Combination Therapy	21%	13%	18%
Fluoroquinolone	16%	26%	26%
Higher-generation IV Cephalosporin	74%	61%	60%
IV Beta-Lactam/Beta-Lactamase Inhibitor	16%	13%	11%
IV Vancomycin	32%	14%	12%
Initial Regimen			
Combination Therapy	32%	20%	19%
Fluoroquinolone	21%	23%	24%
Higher-generation IV Cephalosporin	68%	54%	47%
IV Beta-Lactam/Beta-Lactamase Inhibitor	5%	7%	7%
IV Vancomycin	37%	12%	10%
Inpatient Antibiotics after Culture			
Combination Therapy	0%	2%	1%
Fluoroquinolone	11%	5%	11%
Higher-generation IV Cephalosporin	5%	4%	6%
IV Beta-Lactam/Beta-Lactamase Inhibitor	0%	1%	3%
IV Vancomycin	5%	1%	1%
Discharge Antibiotics			
Combination Therapy	0%	2%	4%
Fluoroquinolone	21%	15%	26%
Cephalexin	0%	7%	7%
Trimethoprim-sulfamethoxazole	0%	3%	4%
Any Discharge Antibiotic	47%	57%	61%
Total Antibiotic Duration, Median Days	9	9	9
Inpatient Duration, Median Days	5	5	5
Discharge, Median Days	3	5	6

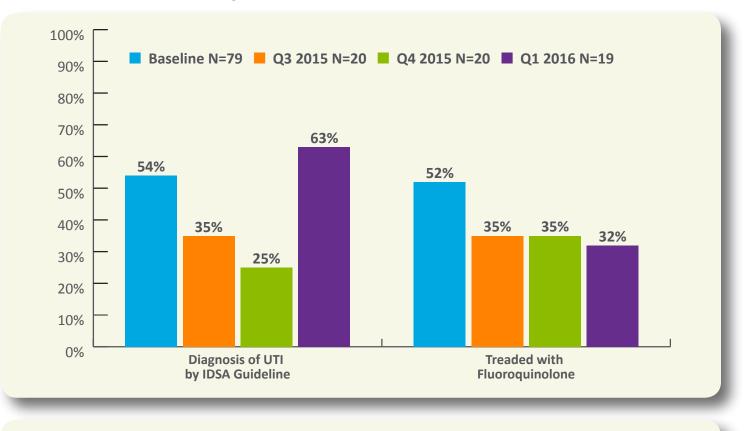
Outcomes and Collaborative Targets

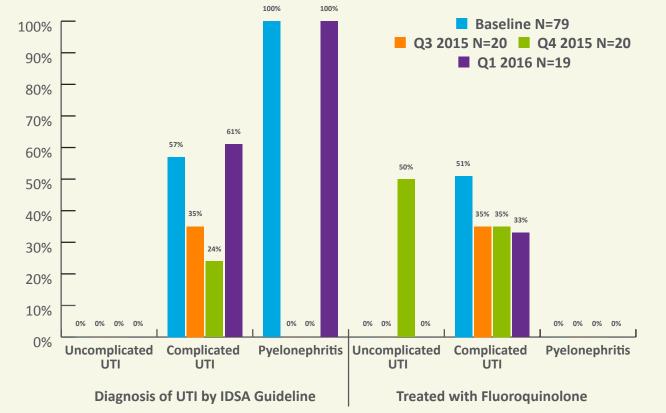




Appendix 6 – Sample Data Report continued

Outcomes and Collaborative Targets





Appendix 7 – Technical Description of the Quantitative Evaluation

(Excerpted as-is from human subjects' research protocol)

This quality improvement initiative is intended for adults (≥18 years old) hospitalized with SSTIs, including cellulitis, cutaneous abscess, or wound infection, or UTIs, including uncomplicated cystitis, complicated cystitis, and pyelonephritis. It is not intended to address the management of complex infections; therefore, the prescribing guidelines specifically state that they are not applicable to clinical scenarios requiring specialized management. For SSTIs, this includes patients with suspected or confirmed necrotizing or deep tissue infection, diabetic foot infection, infected ulcers, surgical site infection, animal or human bites, undrained abscesses, periorbital/orbital/perineal infections, critical illness, bloodstream infection or pregnancy. For UTIs, this includes patients with prostatitis, pregnancy, bloodstream infections, renal transplant, persistent urinary tract obstruction, renal or perinephric abscess or percutaneous nephrostomy tubes.

Study Design

To evaluate the effect of this statewide quality improvement initiative on diagnosis and treatment practices for SSTIs and UTIs, CHA will use a retrospective, pre-intervention post-intervention study design.

Source of data

For the proposed study, CHA will use data that will have been entered into a secure REDCap database as part of the CHA quality improvement initiative. The following is a description of the process for how the data is collected:

In order to assess for intended changes in diagnosis and treatment patterns, each site is collecting data through retrospective chart reviews of a random sample of cases that occurred during a baseline pre-intervention period and during the intervention.

- The pre-intervention period is Jan. 1, 2014 Dec. 31, 2014
- The intervention period is July 1, 2015 Dec. 31, 2016
- Cases are identified using ICD-9 codes, as follows: (These codes have been mapped to the corresponding ICD-10 codes as of Oct. 1, 2015.)

SSTI

Inclusion ICD-9 codes: patients discharged from the hospital with a primary ICD-9 diagnosis of any of the following:

- 680.* carbuncle and furuncle
- 681.* cellulitis and abscess of finger and toe
- 682.* other cellulitis and abscess
- 035. erysipelas
- 686.9 other local infections of skin and subcutaneous tissue

Exclusion ICD-9 codes: cases with any of the following secondary ICD-9 codes during the hospitalization are excluded:

- 707.* chronic ulcer
- 730.* osteomyelitis
- 728.0 infective myositis
- 040.0 gas gangrene
- 785.4 gangrene
- 728.86 necrotizing fasciitis
- 998.* postoperative infection
- 683. acute lymphadenitis
- 376.01 orbital cellulitis
- 478.* retropharyngeal/parapharyngeal abscess
- 522.5 periapical abscess without sinus (dental abscess)
- 528.3 cellulitis and abscess (Ludwig's angina)
- E906.* animal bite
- E928.3 human bite
- E968.7 human bite
- 705.83 hidradentitis suppurativa

Appendix 7 – Technical Description of the Quantitative Evaluation continued

UTI

Inclusion ICD-9 codes: patients discharged from the hospital with a primary or secondary ICD-9 diagnosis of any of the following:

- 595.0 Acute cystitis
- 595.4 Cystitis in disease classified elsewhere
- 595.89 Other specified types of cystitis/surgical procedure
- 595.9 Unspecified cystitis
- 599.0 Urinary tract infection not specified elsewhere
- 590.8 Pyelonephritis

Exclusion ICD-9 codes: cases with any of the following primary or secondary ICD-9 codes during the hospitalization should be excluded:

- 590.2 renal and perinephric abscess
- 590.3 pyeloureteritis cystica
- 595.1 chronic interstitial cystitis
- 595.2 other chronic cystitis
- 597.* urethritis, not sexually transmitted, and urethral syndrome
- 597.0 urethral abscess

At each hospital, eligible patients identified by the ICD-9 search are manually reviewed by a team member from that hospital. For cases meeting the appropriate criteria, clinical, laboratory, microbiological, and treatment data are collected retrospectively using a standardized data collection tool.

All data for this quality improvement initiative are collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at Vanderbilt University. REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. Each hospital is asked to submit 80 cases from the pre-intervention period and 20 cases per quarter during the intervention. Data collection and data entry for the pre-intervention period is complete, and quarterly data collection during the intervention period is ongoing. Throughout the intervention, CHA will analyze the guarterly data for individual hospitals and in aggregate. These data will be fed back to each hospital so that the teams can gauge their hospital's progress with the main outcomes of the initiative and use the data to drive further change.

In summary, a REDCap database containing clinical data from cases of inpatient SSTIs and UTIs has been developed for the purposes of this quality improvement initiative. In this Institutional Review Board proposal, CHA is requesting only to systematically analyze the data within this REDCap database for the purposes of publication.

Outcome Measures

Given the distinct management of SSTIs and UTIs, the goals of the statewide antibiotic stewardship intervention differ for the two conditions. These goals will be the main outcomes used for this research proposal.

The main outcome measures for the SSTI intervention are:

- Change in mean duration of treatment
- Change in proportion of patients exposed to antibiotics with a broad-spectrum of gram-negative activity, defined as fluoroquinolones, carbapenems, 2nd-5th generation cephalosporins, beta-lactam/beta-lactamase inhibitor combinations, aminoglycosides, tigecycline, and colistin

The main outcome measures for the UTI intervention are:

- Change in the proportion of cases treated for UTI that meet the Infectious Diseases Society of America definition for UTI (i.e., symptomatic UTI)
- Change in the mean duration of treatment
- Change in the proportion of patients exposed to a fluoroquinolone

A secondary outcome is the rate of *Clostridium difficile* infection at the participating hospitals.

In addition to the main outcome measures above, given the large amount of data obtained over the course of this initiative, CHA proposes to perform descriptive and exploratory analyses. For example, we will describe the epidemiology and treatment of SSTIs and UTIs in Colorado hospitals, including the specific types of infections, diagnostic practices, common pathogens and their antimicrobial susceptibilities, and antibiotic prescribing patterns. CHA will also evaluate factors associated with adherence to recommended prescribing practices.

Regulatory

As the goal of these efforts is the improvement of local performance with respect to evidence-based standard of care, the individual sites are engaged in quality improvement, and not human subjects research. Data are provided to CHA via a secure and HIPAA-compliant web-based platform (REDCap) for the purposes of tracking prescribing practices over time during the initiative and benchmarking to peer institutions in aggregate. Data (as described below) consist of a limited data set (dates of service) with no direct identifiers (such as name, medical record number, social security number, date of birth, etc.). Data is identified by hospital for this purpose. Data is provided under a letter of commitment signed by each hospital's chief executive or proxy.

In this research proposal, CHA will analyze the REDCap data resulting from this quality improvement initiative in order to describe the epidemiology of UTI and SSTI in Colorado hospitals, describe current practice in treatment of UTI and SSTI in Colorado Hospitals, and evaluate the outcomes of the collaborative. This data set contains only a very limited data set of protected health information (dates of service) and no direct patient identifiers. While hospitals are identified in the data set, they will not be identified in any publication resulting from this work.

Given all data collection, entry, and storage are performed as part of the ongoing CHA quality improvement initiative, this proposal to systematically analyze the data does not pose any physical risk to patients. The only risk to patients would be the potential for loss of confidentiality of protected health information. However, the use of a limited data set containing only dates of service and no direct identifiers greatly limits that risk. During the course of the data analysis set forth in this proposal, each hospital will be given a study number and a crosswalk file will be created so that hospitals will not be identifiable directly from the primary data set. Thus, CHA will be able to protect the identity of individual hospitals in the collaborative. Because the number of hospitals is small, care will be taken to report results in aggregate so that individual hospitals cannot be identified from descriptive data.



7335 East Orchard Road Greenwood Village, Colorado 80111-2512 www.cha.com



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