In 2019, the FDA issued guidance on drug development for Shionogi (Consultant) descriptive comparison, we present the efficacy of ciprofloxacin 250 mg BID, 3d vs logical intent-to-treat population in accordance with the 2019 FDA guidance. For data were used to re-analyze clinical and microbiological outcomes in the microbio versus norfloxacin 400 mg BID, 3d was reported in a 2002 publication. Patient-level guidance.

original publications versus recent analyses conducted in accordance with the FDA guidance.

Session: P-81. UTIs

Background. Urinary tract infections (UTIs) and asymptomatic bacteria (AB) are common in patients with neurogenic bladder (NB) but differentiating between the two is challenging because laboratory tests cannot distinguish AB from UTI. This diagnostic uncertainty can lead to antibiotic overuse. Characterization of patient-reported symptoms from large cohorts of patients with NB can inform interventions to improve appropriate UTI diagnosis and management.

Methods. Retrospective cohort study of 1,797 adults with NB due to spinal cord injury/disorder (SCI/D), multiple sclerosis (MS), and/or Parkinson’s Disease (PD) accounted for 568 patients with UTI encounters (via ICD10) at 4 Veterans Affairs (VA) medical centers between 2017-2018. Demographic and clinical data were collected from national VA datasets. Medical record review was performed on a random sample of 198 encounters. Chi-square/Fisher’s exact test were used to compare symptoms by patient and encounter characteristics.

Results. Among the 198 encounters (mean age=65 years), 33% of patients had SCI/D, 29% PD, 20% MS, and 17% had more than one disease. Most encounters were for men (88%) in inpatient or long-term care settings (62%). 76% of patients used bladder catheters; most indwelling (n=92). Fever was the most frequent symptom (30%), followed by change in urine odor, color, and/or consistency (26%) and lethargy/malaise (21%). Only 38% of encounters had a urinary tract-specific symptom recorded (e.g., dysuria); 81% had non-specific symptoms (e.g., fever, lethargy). 64% of encounters were deemed an appropriate UTI diagnosis. Characteristics in red in Figure 1 were significantly associated with non-specific symptoms (p<0.05).

Patient and encounter characteristics found to be significantly associated with non-specific symptoms, p<0.05.

Conclusion. Symptoms not specific to the urinary tract are the most frequently reported symptoms in patients with NB and encounters with a UTI diagnosis. Change in urine odor/color were reported often; however, guidelines recommend against using these for UTI diagnosis. Providers should ensure that alternate sources of non-specific symptoms are evaluated prior to attributing them to UTI. Antibiotic stewardship interventions targeted to physical medicine and rehabilitation (PM&R) and primary care providers in inpatient settings may improve UTI diagnosis in patients with NB.

Disclosures. Charlesnika T. Evans, PhD, MPH, BioK+ (Consultant)

1433. Impact of 2019 US Food and Drug Administration (FDA) Guidance on Developing Drugs for Urinary Tract Infection (UTI) on the Perceived Efficacy of Antibiotics for the Treatment of Uncomplicated UTI (uUTI)

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Session: P-81. UTIs

Background. In 2019, the FDA issued guidance on drug development for treatment of UTIs. To explore the impact of this guidance, we compared clinical and microbiological outcomes of the fluoroquinolones norfloxacin and ciprofloxacin and the β-lactams pivmecillinam and sulopenem for treatment of uUTIs from original publications versus recent analyses conducted in accordance with the FDA guidance.

Methods. The efficacy of pivmecillinam 400 mg twice daily (BID), 3 days (3d) versus norfloxacin 400 mg BID, 3d was reported in a 2002 publication. Patient-level data were used to re-analyze clinical and microbiological outcomes in the microbiological intent-to-treat population in accordance with the 2019 FDA guidance. For descriptive comparison, we present the efficacy of ciprofloxacin 250 mg BID, 3d vs sulopenem 500 mg BID, 5d in the 2020 SURE-1 trial (also conducted in accordance with FDA guidance) alongside historical efficacy data for ciprofloxacin.

Results. Re-analysis of data from the trial of pivmecillinam and norfloxacin showed microbiological responses for pivmecillinam and norfloxacin of 64% and 79%, respectively. Microbiological responses were higher, 75% for pivmecillinam and 91% for norfloxacin, in the original analysis. For clinical response, re-analysis showed 75% for pivmecillinam and 88% for norfloxacin, while historical data were 82% and 88%, respectively. In the SURE-1 trial, the microbiological response of patients assessed at Day 12 was 76.6% for sulopenem and 79.1% for ciprofloxacin. In a 2002 publication, bacterial eradication at 4 to 11 days after treatment was 93.7% for ciprofloxacin 250 mg, a higher response rate than that reported in SURE-1. For clinical response, rates were 78.7% for ciprofloxacin in SURE-1 and 92.7% for the historical ciprofloxacin data.

Conclusion. When assessed in accordance with the 2019 FDA guidance, clinical and microbiological efficacy of both fluoroquinolones and β-lactam antibiotics appears lower than has been published in the past. Healthcare providers should be aware that newer antibiotics may appear to have a lower efficacy than older antibiotics due to the application of more stringent definitions in the FDA guidance.

Disclosures. Anne Santerre Henriksen, MS, Advanz (Consultant) Shionogi (Consultant) UTILITY Therapeutics (Consultant) Lindsay Nicolle, MD, Entos (Consultant) GSK (Consultant) Iterum (Consultant) Utility Therapeutics (Consultant) Anita F. Das, PhD, Adagio Therapies, Inc. (Consultant)
Table 2. Primary outcomes of uncomplicated UTI outpatients during January 1, 2013–December 31, 2018, stratified by any switch in AB use during 12-month follow-up

| Overall | No Switch | AB Switch * | p-value |
|---------|-----------|-------------|---------|
| Symptom relief | 70% | 75% | 0.866 |
| Clearing infection | 78% | 80% | 0.866 |
| Prevent recurrence | 55% | 60% | 0.125 |
| Education of preventing infection | 50% | 50% | 0.866 |
| Carrying out antibiotic stewardship | 52% | 52% | 0.866 |

*Statistically significant value (p < 0.05)

AB: antibiotics; ED: emergency department; HRU: healthcare resource use; SD: standard deviation; UTI: urinary tract infection

**Conclusion.** US females with uUTI who switched AB had more rUTI cases and increased overall costs and HRU compared with those who did not switch AB, suggesting an unmet need for improved prescribing practices.

**Disclosures.** Rena Moon, MD, Premier Applied Sciences, Premier Inc. (Employee) Alen Marijam, MSc, GlaxoSmithKline plc. (Employee, Shareholder) Fanny S. Mitrani-Gold, MPH, GlaxoSmithKline plc. (Employee, Shareholder) Daniel C. Gibbons, PhD, GlaxoSmithKline plc. (Employee, Shareholder) Alex Kartashov, PhD, Premier Applied Sciences, Premier Inc. (Employee) Ning Rosenthal, MD, Premier Applied Sciences, Premier Inc. (Employee, Shareholder) Ashish V. Joshi, PhD, GlaxoSmithKline plc. (Employee, Shareholder)

1435. Unmet Needs in Uncomplicated Urinary Tract Infection in the United States and Germany: A Physician Survey

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**Session:** P-81. UTIs

**Background.** Uncomplicated urinary tract infections (uUTI) are one of the most common bacterial infections in women. Understanding unmet needs of physicians in diverse healthcare systems is important for developing novel uUTI treatment (tx).

**Methods.** A cross-sectional survey of physicians in the US and Germany (DE). Physicians were recruited via specialist panel and the survey was piloted (1 US, 1 DE physician) prior to recruitment. Primary objectives were understanding physician tx goals, management approaches, and prescribing patterns for uUTI. Secondary objectives included understanding perceptions of uUTI impact on patients and awareness of antibiotic (AB) resistance. Descriptive statistics were used for analysis. See Table for inclusion/exclusion criteria.

**Table. Physician inclusion and exclusion criteria**

| Inclusion | Exclusion |
|-----------|----------|
| Actively managing uUTI patients | Qualified before 1990 |
| Minimum uUTI caseload of 10 patients a month | |
| Responsible for making treatment decisions for uUTI patients under their care | US only - state government employee or Pharmacy & Therapeutic Committee members licensed to practice medicine or reside in Illinois, Massachusetts, Minnesota or Vermont |
| A resident of US or DE | |
| Any of primary care physicians, urologists, gynecologists, or emergency physicians | |
| Infectious disease specialists (US only) | |
| Able to read English (US) or German (DE) | |
| Provided informed consent to participate | |

Physicians were recruited via specialist panel

**Results.** Overall, 300 physicians (200 US, 100 DE) were surveyed. Symptom relief was in the top 3 (of 5) most important outcomes for ≥ 90% of physicians (US and DE); clearing infection was a top 3 outcome for 85% of US and 60% of DE physicians (Fig. 1). Physicians estimated ≥ 20% of patients do not achieve complete relief from initial AB tx. Generally, urinalysis, dip stick, and symptom review were most commonly used in diagnosis, with culture and AB susceptibility tests mostly used to aid tx decisions (Fig. 2). For first-line AB, US physicians reported trimethoprim-sulfamethoxazole (TMP-SMX; 76%) and nitrofurantoin (57%) as most prescribed; in DE, fosfomycin (61%) and TMP-SMX (50%) were prescribed most. In both countries, ciprofloxacin (US 51%, DE 45%) was most prescribed after ≥ 2 tx failures. On a scale of “very poor” (1) to “exceptional” (7) for tx and management of uUTI, 58% of US physicians gave TMP-SMX a 6 or 7, and 62% of DE physicians gave fosfomycin a 6 or 7. More than 33% of physicians believed patients’ quality of life was greatly impacted by 1 tx failure, rising to 60% of physicians for 2 tx failures, and 73% for ≥ 3 tx failures. Most physicians (72% US, 63% DE) agreed that development of AB resistance was serious (Fig. 3), but fewer (56% US, 46% DE) were confident in their knowledge of AB resistance.

**Figure 1.** Treatment goal considered in the top 3 most important goals by physicians for managing patients with uUTI

**Figure 2.** Use of diagnosis (A) and treatment decision (B) aids

**Figure 3.** Physicians’ opinions on antibiotic resistance

**Conclusion.** Symptom relief was the primary uUTI tx goal for physicians. Physicians recognized that patients are greatly impacted by tx failure and AB resistance is a serious problem, but many were not confident or had insufficient information on AB resistance.

**Disclosures.** Megan O’Brien, BA, Adelphi Real World (Employee, Employee of Adelphi Real World, which received funding from GlaxoSmithKline plc. to conduct this study) Alen Marijam, MSc, GlaxoSmithKline plc. (Employee, Shareholder)

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