Table 1. Cohort assignment for high-risk cohorts and controls

High-risk condition	Case definition	Control definition
T2D	Patients with uUTI and a diagnosis of controlled T2D (uncomplicated) in the baseline period	Patients with uUTI and without diagnosis of T2D (controlled or uncontrolled) at any time during the study period
CKD	Patients with uUTI and a diagnosis of mild/moderate CKD in the baseline period	Patients with uUTI and without diagnosis of CKD, ESRD, or dialysis at any time during the study period
rUTI	Patients with ≥ 2 uUTI diagnoses (3 total including index uUTI diagnosis) during 6 months prior to index date, or ≥ 2 (3 total including index episode) in 12 months prior to index date	Patients with uUTI and with no UTI episodes prior to the index date
ELD	Patients with uUTI ≥ 65 years of age on index date	Patients with uUTI 12 to < 65 years of age on index date
PMP	Patients with uUTI ≥ 50 years of age on index date	Patients with uUTI 12 to < 50 years of age on index date

High-risk cohorts were not mutually exclusive (patients could be included in > 1 cohort).

CKD, chronic kidney disease; ELD, elderly; PMP, postmenopausal; rUTI, recurrent urinary tract infection; T2D, type 2 diabetes; uUTI, uncomplicated urinary tract infection

Results. Of 339,100 patients with uUTI, case/control cohorts comprised T2D, n=15,423/n=77,115; CKD, n=1041/n=5205; rUTI, n=7937/n=39,685; ELD, n=23,666/n=118,330; and PMP, n=105,608/n=211,216 patients. HRU trends across cohorts varied. During 1-year followup, outpatient visits were significantly different for cases versus controls in the T2D, rUTI, and PMP cohorts ($p \leq 0.0079$), with higher case than control values in the rUTI and PMP cohorts; pharmacy claims were significantly higher for rUTI, ELD, and PMP cases, and inpatient visits were significantly higher for ELD and PMP cases, versus controls (all $p < 0.0001$; Table 2). Adjusted total uUTI-related costs (emergency room + outpatient + pharmacy) were significantly different ($p < 0.0001$) for cases versus controls at index episode and during follow-up in all cohorts except CKD: case values were higher than controls at index episode and during follow-up in the T2D cohort, and during follow-up in the rUTI and ELD cohorts (Table 3).

Table 2. uUTI-related HRU* for cases versus controls according to high-risk cohort

HRU	T2D			CKD			rUTI			ELD			PMP		
	Case n=15,423	Control n=77,115	p-value	Case n=1041	Control n=5025	p-value	Case n=7937	Control n=39,685	p-value	Case n=23,666	Control n=118,330	p-value	Case n=105,608	Control n=211,216	p-value
During index uUTI episode															
ER visits	0.10	0.09	**0.0001†**	0.10	0.10	ns	0.07	0.11	**< 0.0001†**	0.12	0.11	ns	0.09	0.13	**< 0.0001**
OP visits	1.02	1.04	**0.0267†**	1.02	1.02	ns	1.12	1.02	**< 0.0001†**	0.97	1.04	**< 0.0001†**	1.04	1.02	**< 0.0001**
Pharmacy claims	1.13	1.15	**0.0316†**	1.12	1.16	ns	1.19	1.13	**< 0.0001†**	1.16	1.13	**0.0002†**	1.14	1.12	**< 0.0001**
During 1-year follow-up period															
IP visits	0.00	0.00	ns	0.00	0.01	ns	0.00	0.00	ns	0.01	0.00	**< 0.0001†**	0.00	0.00	**< 0.0001**
ER visits	0.12	0.11	**0.0004†**	0.12	0.12	ns	0.12	0.14	**< 0.0001†**	0.14	0.14	ns	0.11	0.15	**< 0.0001**
OP visits	1.34	1.37	**0.0079†**	1.35	1.42	ns	1.96	1.33	**< 0.0001†**	1.35	1.34	ns	1.36	1.31	**< 0.0001**
Pharmacy claims	1.42	1.44	**0.0192†**	1.41	1.50	**0.0213†**	1.94	1.40	**< 0.0001†**	1.50	1.40	**< 0.0001†**	1.42	1.38	**< 0.0001**

Multivariate analysis was performed via generalized linear modeling. All models were adjusted by cohort, baseline Charlson Comorbidity Index score, and baseline all-cause HRU (inpatient, ER, outpatient, pharmacy). High-risk cohorts were not mutually exclusive (patients could be included in > 1 cohort).

*HRU outcomes examined included all-cause and uUTI-related office visits, hospitalizations, prescriptions, and ER visits; †Statistically significant difference ($p < 0.05$).

CKD, chronic kidney disease; ELD, elderly; ER, emergency room; HRU, healthcare resource use; IP, inpatient; ns, not significant; OP, outpatient; PMP, postmenopausal; rUTI, recurrent urinary tract infection; T2D, type 2 diabetes; UTI, urinary tract infection; uUTI, uncomplicated urinary tract infection.

Table 3. uUTI-related costs* for cases versus controls according to high-risk cohort

Costs, $	T2D			CKD			rUTI			ELD			PMP		
	Case n=15,423	Control n=77,115	p-value	Case n=1041	Control n=5025	p-value	Case n=7937	Control n=39,685	p-value	Case n=23,666	Control n=118,330	p-value	Case n=105,608	Control n=211,216	p-value
During index UTI episode															
ER	91	71	**< 0.0001‡**	118	102	ns	46	83	**< 0.0001‡**	132	77	**< 0.0001‡**	71	89	**< 0.0001‡**
OP	153	149	**0.0113†**	191	169	**0.0048†**	142	159	**< 0.0001‡**	183	153	**< 0.0001‡**	150	159	**< 0.0001‡**
Pharmacy	12	13	**< 0.0001‡**	11	14	**< 0.0001‡**	18	13	**< 0.0001‡**	14	13	**< 0.0001‡**	13	13	**< 0.0001‡**
Total[a] (≤ 99th percentile by cohort)	177	164	**< 0.0001‡**	195	185	ns	159	183	**< 0.0001‡**	205	282	**< 0.0001‡**	166	193	**< 0.0001‡**
During 1-year follow-up period															
ER	110	83	**< 0.0001‡**	162	123	ns	166	91	**< 0.0001‡**	166	91	**< 0.0001‡**	85	104	**< 0.0001‡**
OP	193	194	ns	223	235	ns	253	200	**< 0.0001‡**	249	192	**< 0.0001‡**	192	197	**< 0.0001‡**
Pharmacy	16	17	**< 0.0001‡**	15	19	**< 0.0001**	29	16	**< 0.0001‡**	18	16	**< 0.0001‡**	16	16	ns
Total[a] (≤ 99th percentile by cohort)	232	215	**< 0.0001‡**	270	269	ns	287	236	**< 0.0001‡**	307	230	**< 0.0001‡**	217	243	**< 0.0001‡**

Multivariate analysis was performed via generalized linear modeling. All models were adjusted by cohort, baseline Charlson Comorbidity Index score, and baseline all-cause HRU (inpatient, ER, outpatient, pharmacy). High-risk cohorts were not mutually exclusive (patients could be included in > 1 cohort).

*Costs included direct costs associated with all-cause and uUTI-related office visits, hospitalizations, prescriptions, and ER visits, and indirect costs such as workplace absenteeism, short-term disability days, and total productivity loss; †Includes IP, emergency room, OP, and pharmacy costs; ‡Statistically significant difference ($p < 0.05$).

CKD, chronic kidney disease; ELD, elderly; ER, emergency room; HRU, healthcare resource use; IP, inpatient; ns, not significant; OP, outpatient; PMP, postmenopausal; rUTI, recurrent urinary tract infection; T2D, type 2 diabetes; UTI, urinary tract infection; uUTI, uncomplicated urinary tract infection.

Conclusion. Females in some high-risk case cohorts had higher uUTI-related HRU and costs versus controls. Further studies of relationships between comorbidities and uUTI burden are needed.

Disclosures. **Madison T. Preib, MPH**, **STATinMED Research** (Employee, Former employee of STATinMED Research, which received funding from GlaxoSmithKline plc. to conduct this study) **Alen Marijam, MSc**, **GlaxoSmithKline plc.** (Employee, Shareholder) **Fanny S. Mitrani-Gold, MPH**, **GlaxoSmithKline plc.** (Employee, Shareholder) **Daniel C. Gibbons, PhD**, **GlaxoSmithKline plc.** (Employee, Shareholder) **Xiaoxi Sun, MA**, **STATinMED Research** (Employee, Employee of STATinMED Research, which received funding from GlaxoSmithKline plc. to conduct this study) **Christopher Adams, MPH**, **STATinMED Research** (Employee, Employee of STATinMED Research, which received funding from GlaxoSmithKline plc. to conduct this study) **Ashish V. Joshi, PhD**, **GlaxoSmithKline plc.** (Employee, Shareholder)

1430. Descriptive Epidemiology of Emergency Department Visits with cUTI in the US, 2012-2018

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Session: P-81. UTIs

Background. Urinary tract infections (UTI) represent a substantial burden to the healthcare system. In the early 2000s annual UTI admissions numbered 100,000, and these infections resulted in over 1 million emergency department (ED) visits. While only a fraction of total UTI volume, the estimated cost of complicated (cUTI) to the healthcare system exceeded $3.5 billion. We set out to evaluate the contemporary burden of cUTI in the US in terms of ED visits annually.

Methods. We conducted a retrospective multicenter cohort study within the National Emergency Department (NEDS) database, a 20-percent stratified sample of all US hospital-based EDs, from 2012-2018, to explore characteristics of patients discharged with a cUTI diagnosis. We applied a previously published algorithm to identify cUTI using administrative coding. We applied survey methods to develop national estimates.

Results. Among 3,010,997 ED visits with cUTI, 43.3% were female, and 59.0% were age 65 years or older. Commensurately, Medicare was the primary payor in 62.8% of the visits. The majority of the patients (59.1%) presented to metropolitan teaching hospitals, and plurality were in the Southern US (39.6%). There was a narrow range in the visits' seasonal variation, from 6.4% occurring in February to 7.9% in October. cUTI was the principal diagnosis in 48.5% of all cUTI visits. In the remaining 51.5%, sepsis was the most common principal diagnosis (33.9%), but severe sepsis and septic shock codes each appeared in 4.9%. Of all cUTI ED visits, 21.4% had catheter-associated UTI. While only 19.8% had a code for pyelonephritis, 2,050,548 (68.1%) were admitted to the hospital. Mortality in the ED was 0.02%.

Conclusion. During the seven-year span, there were over 3 million ED visits for cUTI. Although fewer than 1 in 10 patients met criteria for severe sepsis/septic shock, approximately 2/3rds of cUTI patients presenting to the ED were subsequently hospitalized.

Disclosures. **Marya Zilberberg, MD, MPH**, **Cleveland Clinic** (Consultant)**J&J** (Shareholder)**Lungpacer** (Consultant, Grant/Research Support)**Merck** (Grant/Research Support)**scPharma** (Consultant)**Sedana** (Consultant, Grant/Research Support)**Spero** (Grant/Research Support) **Brian Nathanson, PhD**, **Lungpacer** (Grant/Research Support)**Merck** (Grant/Research Support)**Spero** (Grant/Research Support) **Kate Sulham, MPH**, **Spero Therapeutics** (Consultant) **Andrew F. Shorr, MD, MPH, MBA**, **Merck** (Consultant)

1431. Evaluating Physician Decision Making in Inpatient Antibiotic Prescription for Suspected Urinary Tract Infection

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Session: P-81. UTIs

Background. Physicians are constantly asked to evaluate inpatients for possible antibiotic treatment. As part of antibiotic stewardship it is imperative to understand the decision-making process behind a physician's choice to prescribe antibiotics appropriately in an inpatient setting. Fuzzy Trace Theory (FTT) suggests that physicians use one of two methods in medical decision making; verbatim, employing a comprehensive risk benefit analysis, and gist, considering a bottom line analysis.

Methods. Seventy-six hospitalists at Weill Cornell Medicine in Manhattan, New York received a survey with two reminders to evaluate their decision-making process. Five basic demographic questions regarding participant gender, race, background, age, and years in practice were asked. A clinical vignette describing an inpatient with a possible urinary tract infection (UTI) was followed with statements framing hypothetical antibiotic prescription. A seven point Likert scale with response choices from Strongly Disagree scored as one to Strongly Agree scored as seven was used to assess degree of participant agreement with each statement. Questions were presented in a random order to eliminate possible effects of questions clusters or question order.

Results. Twenty-six hospitalists completed the survey. Consistent with previous literature, the hospitalists surveyed displayed a gist interpretation of the risks and benefits of antibiotics, with a mean Likert scale score of 5.54 agreeing that there are benefits to antibiotic prescription, and a mean Likert scale score of 6.04, agreeing that there are risks to antibiotic prescription. . However, the clinicians surveyed ultimately found antibiotics to be a necessary risk given the possible benefit of improving patient health. The hospitalists surveyed also did not view antibiotic prescription to be a product of pressure from patient families, agreeing by a mean Likert scale score of 5.08 that the patient's family will trust their physician to prescribe antibiotics if needed.

Conclusion. These findings suggest that physician education to reduce overprescribing of antibiotics should underscore possible antibiotic risk, despite potential benefit.

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1432. Patient-Reported Urinary Tract Infection Symptoms Among Veterans with Neurogenic Bladder

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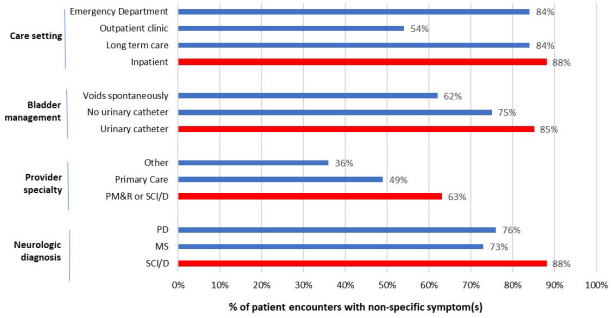
Session: P-81. UTIs

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 diagnosis. 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).

Figure 1. Significant patient and encounter characteristics associated with non-specific symtoms



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 BV** (Consultant)**UTILITY Therapeutics** (Consultant) **Lindsay Nicolle, MD**, **Entos** (Consultant)**GSK** (Consultant)**Iterum** (Consultant)**Utility Therapeutics** (Consultant) **Anita F. Das, PhD**, **Adagio Therapeutics, Inc.** (Consultant)

1434. Treatment Patterns, Healthcare Resource Use, and Associated Costs in Females with Uncomplicated Urinary Tract Infection in the United States

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Session: P-81. UTIs

Background. Urinary tract infections (UTIs) disproportionately affect women and are a substantial burden on healthcare systems. We assessed the effect of antibiotic (AB) switching on UTI recurrence, healthcare resource use (HRU), and related costs among adolescent and adult females in the US with uncomplicated UTIs (uUTIs).

Methods. This retrospective cohort study used US Optum claims data (United Healthcare, January 1, 2013–December 31, 2018). Eligible patients were females ≥ 12 years of age with an acute uUTI diagnosis at outpatient or emergency department (ED) visit (index date) and an oral AB prescription within ± 5 days of index. Patients with recurrent UTIs (rUTIs), defined as 2 UTI diagnoses (including index) in 6 months or ≥ 3 UTI diagnoses (including index) in 12 months, were included; those with complicated UTI were excluded. Patients were assigned to two groups: AB switch (≥ 2 filled prescriptions of different AB within 28 days post index [uUTI episode]) and no AB switch.

Results. In 5870 eligible patients (mean age 44.5 years; 76.6% White), ciprofloxacin (CIP; 38.6%), nitrofurantoin (NFT; 31.4%), and trimethoprim-sulfamethoxazole (TMP-SMX; 25.6%) were the most commonly prescribed first-line ABs at index, and 567 (9.7%) patients switched AB. CIP was switched to NFT and TMP-SMX in 2.0% and 1.7% of patients, respectively. NFT was switched to CIP and TMP-SMX in 2.6% and 1.5% of patients, respectively. TMP-SMX was switched to CIP and NFT in 3.0% and 2.4% of patients, respectively. During index visit, the AB switch group had higher mean ambulatory care and pharmacy claims (both p < 0.001), and higher total mean HRU costs ($2186.4) per patient compared with the no switch group ($1508.8; p = 0.011). More patients had rUTI in the AB switch group (18.9%) versus the no switch group (14.2%; p < 0.001), and more had ED visits in the AB switch group than the no switch group (p < 0.0001) (Table 1). During follow-up, the AB switch group had a higher mean number of uUTI episodes per patient (p < 0.001; Table 1), and more patients had UTI-related ED visits (10.8%) compared with the no switch group (7.7%; p = 0.010; Table 2).

Table 1. Primary outcomes of uncomplicated UTI outpatients during January 1, 2013–December 31, 2018, stratified by any switch in AB use during index episode

	Overall	Subgroup		p-value
	N=5870	AB Switch n=567	No AB Switch n=5303	
Overall outcomes of uncomplicated UTI				
28-day risk of UTI-related hospitalization, n (%)	2 (0.03)	1 (0.2)	1 (0.02)	0.183
Mean (SD) number of uncomplicated UTI episodes	1.3 (0.7)	1.4 (0.9)	1.3 (0.7)	**< 0.001***
Proportion of recurrent UTI, n (%)	861 (14.7)	107 (18.9)	754 (14.2)	**< 0.001***
HRU during index uncomplicated UTI episode				
Proportion of inpatient visits, n (%)	2 (0.03)	1 (0.2)	1 (0.02)	0.183
Mean (SD) number of inpatient visits	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)	N/A
Mean (SD) inpatient length of stay, days	1.5 (0.7)	1.0 (0.0)	2.0 (0.0)	N/A
Proportion of ED visits, n (%)	732 (12.5)	98 (17.3)	634 (12.0)	**< 0.001***
Mean (SD) number of ED claims	5.6 (9.1)	6.1 (7.6)	5.5 (9.3)	0.527
Proportion of ambulatory care visits, n (%)	5856 (99.8)	565 (99.6)	5291 (99.8)	0.638
Mean (SD) number of ambulatory care claims	7.1 (7.4)	10.1 (9.6)	6.8 (7.1)	**< 0.001***
Mean (SD) number of pharmacy claims	2.9 (2.4)	4.6 (2.7)	2.8 (2.3)	**< 0.001***
Mean (SD) outpatient ED visit charges, $	3411.6 (7610.1)	4861.1 (5630.5)	3187.6 (7851.5)	**0.042***
Mean (SD) ambulatory care visit charges, $	1023.2 (4848.1)	1154.9 (3771.3)	1009.2 (4949.3)	0.497
Mean (SD) pharmacy visit charges, $	125.9 (984.9)	179.3 (324.2)	120.1 (1030.9)	0.174
Mean (SD) total charges during index uncomplicated UTI episode, $	1574.3 (6071.8)	2186.4 (5335.8)	1508.8 (6142.2)	**0.011***

Continuous variables compared using Student's T-test, and categorical variables compared using chi-square or Fisher's exact test. The denominator for the mean TOTAL cost is all patients. For patients who did not have follow-up visits, the cost was set to 0. For all other cost variables, the cost was set to missing if the patient did not incur any cost.

*Statistically significant value (p < 0.05).

AB, antibiotic; ED, emergency department; HRU, healthcare resource use; N/A, not applicable; SD, standard deviation; UTI, urinary tract infection