

Abstract citation ID: ofac492.1861

2243. Patient Perceptions of Treatment Success in Uncomplicated Urinary Tract Infection

Claire L. Trennery, MSc¹; Susan Martin, MSPH²; Katherine Kosa, MSc²; Lydia Demetriou, MSc¹; Ashish V. Joshi, PhD¹; ¹GlaxoSmithKline plc., Brentford, England, United Kingdom; ²RTI Health Solutions, Ann Arbor, Michigan

Session: 242. UTIs

Saturday, October 22, 2022: 12:15 PM

Background. Regulatory guidance for developing uncomplicated urinary tract infection (uUTI) treatments requires endpoints assessing uUTI symptom resolution present at trial entry. The meaningfulness of this endpoint and definition of treatment success is rarely explored with patient-experience data (PED), and there is a paucity of PED in the literature.

Methods. This cross-sectional interview study included English- and Spanish-speaking women aged ≥ 12 years with confirmed uUTI diagnosis within 14 days of screening. Interviews were recorded, transcribed and analyzed using qualitative methods. Participants were asked questions to elicit spontaneous and probed

reports of uUTI symptoms and how these impacted health-related quality of life. Participants provided descriptions of symptom resolution, treatment success and evaluated a 4-point scale assessing dysuria, urinary frequency, urinary urgency and suprapubic pain. They were asked if the scale contents captured their uUTI experience, including assessing meaningful treatment effect.

Results. Overall, 30 participants were included, mean age 40 (range: 12–61) years. Urgency was the most common symptom reported (n=29, Table 1), and nearly all (n=29) participants reported their recent uUTI affected mood/emotions (Table 2). Participants reported the relevance of symptoms and the meaning of the points on the scale (Table 3). At interview, 24 participants scored each symptom as “none” and reported this was meaningful/important. Most participants (n=27) said they would not consider treatment successful if they still experienced ≥ 1 symptom by the end of the treatment period; however, almost half (n=14) agreed that with severe symptoms, the smallest meaningful improvement would be moving from severe to moderate. A limitation of this study is that participants were not asked about underlying symptoms between episodes of uUTI.

Table 1. Patient-reported uUTI symptoms (N=30)

Symptom	Total, n (%)	Spontaneous, n	Probed, n
Urgency of urination	29 (96.7)	14	15
Unable to empty bladder completely (pass only small amounts of urine)	26 (86.7)	14	12
Frequency of urination	25 (83.3)	15	10
Pain or burning when passing urine	24 (80.0)	18	6
Pain or uncomfortable pressure in lower abdomen/pelvic area	24 (80.0)	17	7
Odor*	7 (23.3)	7	—
Discolored urine*	4 (13.3)	4	—
Urethral pain (constant)*	2 (6.7)	2	—
Urethral discharge*	1 (3.3)	1	—
Fatigue*	1 (3.3)	1	—
Headache*	1 (3.3)	1	—
Incontinence*	1 (3.3)	1	—
Nausea*	1 (3.3)	1	—

*The symptom was not probed during the interview but was spontaneously reported by the participant(s).

Abbreviation: uUTI, uncomplicated urinary tract infection.

Table 2. Patient-reported impacts of uUTI (N=30)

Impact	Total, n (%)	Spontaneous, n	Probed, n
Mood or emotions	29 (96.7)	6	23
Social activities or relationships	22 (73.3)	9	13
Daily activities*†	21 (70.0)	20	1
Work or school	20 (67.7)	10	10
Physical activities*‡	9 (30.0)	9	—
Loss of appetite*	2 (6.7)	2	—
Sleep*	2 (6.7)	2	—
Intimate relationships (N=25)§	18 (72.0)	4	14

*The impact was not systematically probed during the interview but was spontaneously reported by the participant; †daily activities included cleaning, shopping, caring for children, exercising, or playing sports; ‡physical activities included walking, hiking, playing sports, exercising, and going to the gym; §adolescents (n=5) were not asked about intimate relationships.

Abbreviation: uUTI, uncomplicated urinary tract infection.

Table 3. Sample of quotations from patient interviews

Context	Quotation
Effect on mood/emotions of most recent uUTI	<i>It can make me feel sad if I go out with my friends, and I want to socially drink, I can't because I'll be on antibiotics. Those are like the main emotions as well as frustrated.</i>
	<i>...I was getting so aggravated that I wanted to cry because of the pain, and it's not normal for me to just sit all day, and I wanted to go to work, to my new job, and I couldn't go.</i>
	<i>Just a little bit irritable when you feel bad. I get a little bit cranky, and when it affects my sleep, I get even crankier.</i>
Interpretation of the points on the scale	<i>I guess I would consider mild to be just tolerable. I mean you feel things, but it doesn't prevent you from doing your normal everyday activities. Essentially moderate is now affecting you to the point where you don't want to carry out things that you normally do every day. Severe symptoms, essentially, you're in so much pain and frustration, you can't do anything.</i>
	<i>Mild: I think that means that it's probably not at the point where you feel like you need to go in and have treatment. Symptoms are minimal. It's probably in the back of your mind because the symptoms aren't so straight in your face. So, for moderate, I'd say that at this point, it's impacting your life. You're probably thinking about it a little more, maybe even looking into possible treatments or finding a way to quickly get it treated. Severe: At this point, you're probably already sitting at the doctor's office because it's not tolerable, and you really want to get it treated.</i>
	<i>...I would say mild for example would be if I don't need to see the doctor. Moderate would be if this does not get better, I will go to the doctor. Severe would be that I definitely need to be checked by the doctor.</i>
The meaningfulness/importance of symptom improvement to none on the scale	<i>Very important. This week has been pretty busy...I have had a ton of stuff to go to and so I probably would have just had another week like the week before last when I just wanted to stay home and cancel my plans and just heal if I still were feeling the symptoms.</i>
	<i>Because it doesn't affect my day-to-day life and considering my own past of having frequent UTIs, it doesn't make me feel anxious that I have to accommodate my future plans to fit my UTI.</i>
	<i>Absolutely 100% because I feel normal. I don't have any issues with thinking that I have UTI or discomfort.</i>

Abbreviations: UTI, urinary tract infection; uUTI, uncomplicated urinary tract infection.

Conclusion. Participants reported numerous impacts of uUTI. Definitions of symptom resolution and treatment success should be established with PED, with complete symptom resolution considered the most valued. The regulatory definition relevance of symptom resolution for uUTI and the content validity of a scale to assess symptom resolution was confirmed by participants.

Disclosures. Claire L. Trennery, MSc, GlaxoSmithKline plc.: Employee and shareholder|GlaxoSmithKline plc.: GlaxoSmithKline plc.-sponsored study 217370 Susan Martin, MSPH, GlaxoSmithKline plc.: GlaxoSmithKline plc.-sponsored study 217370|RTI Health Solutions: Employee of RTI Health Solutions which received funding from GlaxoSmithKline plc. to conduct this study Katherine Kosa, MSc, GlaxoSmithKline plc.: GlaxoSmithKline plc.-sponsored study 217370|RTI Health Solutions: Employee of RTI Health Solutions which received funding from GlaxoSmithKline plc. to conduct this study Lydia Demetriou, MSc, GlaxoSmithKline plc.: Employee and shareholder|GlaxoSmithKline plc.: GlaxoSmithKline plc.-sponsored study 217370 Ashish V. Joshi, PhD, GlaxoSmithKline plc.: Employee and shareholder|GlaxoSmithKline plc.: GlaxoSmithKline plc.-sponsored study.