Original paper

Adherence to recommendations in the diagnosis of urinary tract infection: a multicenter study

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Abstract

Introduction: pediatric urinary tract infection (UTI) should be diagnosed based on the presence of compatible symptoms and a positive urine culture with adequate sample collection, but diagnostic errors are common.

Objective: to analyze the inappropriate diagnosis of UTI based on the 2019 Spanish guideline recommendations.

Material and methods: we conducted a multicenter, prospective and observational study in Spain between October 2019 and December 2020. A total of 206 primary care pediatricians documented episodes of suspected UTI in their caseloads.

Results: of the 1506 submitted episodes, 1402 were considered valid for analysis: 1212 (86.4%) were appropriately diagnosed and 190 (13.6%) inappropriately diagnosed ($p<0.001$). The reasons diagnosis was considered inappropriate were: use of samples collected with inadequate technique for urine culture (37.4%), diagnosis without urine culture (31.6%), incorrect interpretation of colony counts (26.8%) and underdiagnosis (4.2%). The use of urine collection bags in children aged less than 2 years, particularly in primary care compared with hospital emergency departments (66.7% *vs.* 21.7%; $p=0.005$), and the lack of urine culture in children aged 6 years or older compared with those aged 2 to 5 years (33.9% *vs.* 66.1%; $p=0.015$) were associated with a higher frequency of inappropriate diagnosis. Hematuria (4.7% *vs.* 11.1%; $p=0.001$), weight loss (2.4% *vs.* 5.8%; $p=0.016$), and detection of leukocyte esterase (42.8% *vs.* 53.6%; $p=0.009$) were also associated with a higher frequency of inappropriate diagnosis. Follow-up urine cultures were more frequent in the group of inappropriately diagnosed episodes (39.0% *vs.* 26.5%; $p=0.002$), a group that also accounted for 23.6% of antibiotic prescribing.

Conclusions: the diagnostic approach did not adhere to the 2019 recommendations in 13.6% of suspected UTI episodes, resulting in a percentage of inappropriate antibiotic prescribing of 23.6%. These findings underscore the need to reinforce evidence-based practices, particularly regarding urine sample collection, microbiological confirmation and interpretation of culture results.

Key words:
- Antibacterial agents
- Diagnostic errors
- Guideline adherence
- Overtreatment
- Urinary tract infections
- Urine culture
- Urine specimen collection

Adherencia a las recomendaciones en el diagnóstico de la infección urinaria: estudio multicéntrico

Resumen

Introducción: la infección del tracto urinario (ITU) pediátrica debe diagnosticarse cuando existen síntomas compatibles y un urocultivo positivo obtenido mediante una técnica adecuada, aunque los errores diagnósticos son frecuentes.

Objetivo: analizar la inadecuación diagnóstica en ITU, según las recomendaciones del documento español del 2019.

Material y métodos: estudio observacional, prospectivo y multicéntrico, realizado en España entre octubre de 2019 y diciembre de 2020, en el que 206 pediatras de Atención Primaria (AP) registraron episodios de sospecha de ITU en sus pacientes.

Resultados: de 1506 registros, 1402 fueron válidos: 1212 (86,4%) diagnósticos adecuados y 190 (13,6%) inadecuados (p <0,001). Causas de inadecuación: urocultivo de muestra inadecuada (37,4%), diagnóstico sin urocultivo (31,6%), interpretación inadecuada del recuento de UFC/mL (26,8%) e infradiagnóstico (4,2%).

El uso de bolsa colectora para urocultivo en <2 años, especialmente en AP frente a urgencias hospitalarias (66,7% *vs.* 21,7%; p = 0,005), y ausencia de urocultivo en ≥6 años frente a ≥2-5 años (33,9% *vs.* 66,1%; p = 0,015), se asociaron a mayor inadecuación.

Hematuria (4,7% *vs.* 11,1%; p = 0,001), pérdida de peso (2,4% *vs.* 5,8%; p = 0,016) y esterasa leucocitaria positiva (42,8% *vs.* 53,6%; p = 0,009) se asociaron con mayor probabilidad de errores diagnósticos.

En los inadecuadamente diagnosticados, los urocultivos de control fueron significativamente más frecuentes (39,0% *vs.* 26,5%; p = 0,002) y concentraron el 23,6% de las prescripciones antibióticas.

Conclusiones: el 13,6% de las sospechas de ITU no cumplieron las recomendaciones, generando un 23,6% de tratamientos antibióticos innecesarios. Hallazgos que subrayan la importancia de reforzar prácticas basadas en la evidencia, particularmente en la obtención de muestras, confirmación microbiológica e interpretación de aislamientos.

Palabras clave:
- Adherencia a guías clínicas
- Agentes antibacterianos
- Errores diagnósticos
- Infecciones del tracto urinario
- Obtención de muestras de orina
- Sobretratamiento
- Urocultivo

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INTRODUCTION

Urinary tract infection (UTI) in the pediatric age group poses a clinical, diagnostic and therapeutic challenge, particularly in the primary care (PC) setting (PC).[1]

Its definition requires the combination of two key elements: the presence of compatible symptoms and confirmation by a positive urine culture. This must be performed on a urine sample collected using adequate technique to minimize the risk of contamination and ensure the validity of the result.[1-3]

From an epidemiological perspective, the prevalence of UTIs varies considerably according to age and sex. In infants aged less than one year, it is higher in boys (3.7%) compared to girls (2%). This trend is reversed in school-aged children, with a prevalence of 3% in girls and 1% in boys.[4] here are also risk factors (RFs) that increase susceptibility to UTIs, including bladder and bowel dysfunction, congenital abnormalities of the urinary system such as vesicoureteral reflux and, in boys, phimosis.[5,6]

Diagnosis in children younger than two years is particularly complicated due to the nonspecificity of symptoms (fever without source, irritability, vomiting) and the difficulty in obtaining adequate urine samples, which often requires invasive methods[1,5,6] Although the urine dipstick test (UDT) is useful for screening, urine culture is required for definitive diagnosis.[1,6-9]

An adequate approach to diagnosis is of the essence. On one hand, a high level of suspicion and early antibiotherapy are key for reducing the risk of renal scarring, especially in febrile infants.[1,10] Overdiagnosis leads to prescribing of unnecessary antibiotherapy, which promotes the development of bacterial drug resistance, and performance of diagnostic tests that place an additional burden on the patient and the health care system.[11,12] Moreover, the variation between clinical guidelines results in substantial heterogeneity in the diagnostic approach.[1,13-15]

We conducted a study with the primary objective of assessing the appropriateness of the diagnostic approach to episodes of suspected ITU in pediatric care in Spain in reference to the *Recommendations on the Diagnosis and Treatment of Urinary Tract Infection* of 2019[3] and the *Clinical Practice Guideline on Urinary Tract Infection in the Pediatric Population* of 2011[2], which was the current guideline in Spain at the time the new recommendations were published.

As a secondary objective, we sought to identify the most frequent errors in the diagnostic process and measure the impact of these inappropriate practices in terms of the use of antibiotics and the performance of a follow-up urine culture ($UC_{f/u}$).

MATERIAL AND METHODS

Nationwide multicenter, prospective and observational study conducted from October 2019 to December 2020.

The study universe consisted of children aged 0 to 15 years with manifestations suggestive of UTI (**Table 1**), managed in different care settings and followed up in PC pediatrics clinics. A total of 206 PC pediatricians selected at random and practicing throughout Spain (with representation of 16 autonomous communities) collaborated on a voluntary basis and documented the episodes of suspected ITU in their caseloads.

The exclusion criteria were: episode of UTI for which follow-up was not possible, case outside the caseload of the provider, lack of informed consent.

We collected anonymized data for providers, patients and episodes by means of an online form. Each collaborating pediatrician entered the data on the clinical characteristics and management of the episodes. Providers were also asked to confirm or rule out the initial suspected diagnosis of UIT based on their clinical judgment and the available test results.

Subsequently, the research team classified each episode as "appropriately diagnosed episode" (ADE) if it met the microbiological criteria of the 2019 recommendations (**Table 1**) along with compatible symptoms[3] (**Table 1**) or "inappropriately

Table 1. Criteria for definition of clinically significant bacteriuria based on the *Recommendations on the Diagnosis and Management of Urinary Tract Infection* document of 2019[3] and clinical manifestations associated with urinary tract infection in children[6]

Collection technique		**Colony count (UFC/mL)**		
Suprapubic aspiration		Any		
Urinary catheterization		≥10 000		
Clean catch urine		≥100 000. Considerer 10 000-50 000 if there is a high probability of urinary tract infection (fever + pyuria/bacteriuria or in patients with renal disease)		
Clinical manifestations				
Age groups		**More frequent ← → Less frequent**		
Age < 3 months		Fever	Loss of appetite	Abdominal pain
		Vomiting	Failure to thrive	Jaundice
		Lethargy		Hematuria
		Irritability		Foul-smelling urine
Age > 3 months	Preverbal (<2 years)	Fever	Abdominal or flank pain	Lethargy, irritability
			Vomiting	Hematuria, foul-smelling urine
			Loss of appetite	Failure to thrive
	Verbal (>2 years)	Frequent voiding	Failure to thrive	Fever
		Disuria	Changes in continence	Malaise, vomiting
			Abdominal or flank pain	Hematuria, foul-smelling and/or cloudy urine

CFU: colony-forming units.

diagnosed episode" (IDE) otherwise. Inappropriately diagnosed episodes were further classified into four subgroups for more detailed analysis (**Figure 1**):

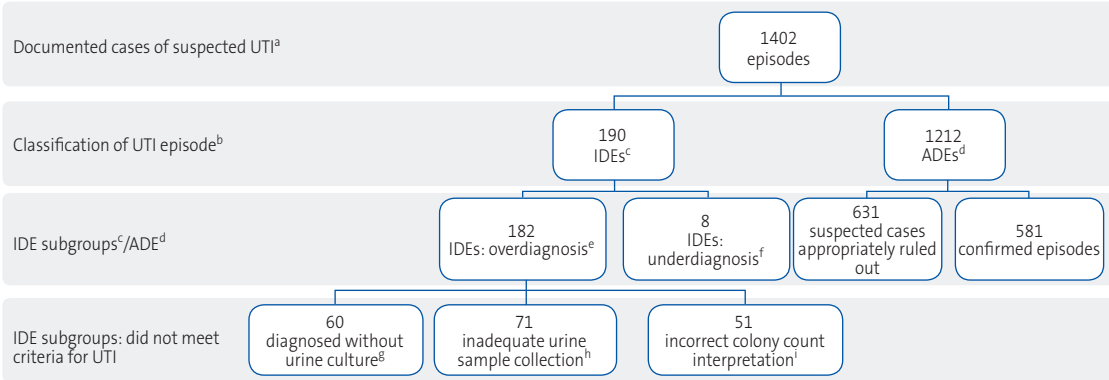
- Episodes with inadequate sample collection: urine collected in a bag in an incontinent child.
- Episodes diagnosed without urine culture: diagnosis based on clinical manifestations, with or without urinalysis (conventional urinalysis or UDT), without microbiological confirmation.
- Episodes with inadequate interpretations of colony counts: the interpretation of the concentration of colony forming units (CFU/mL) did not meet the criteria for significant bacteriuria according to the specimen collection method.
- Underdiagnosis: cases that met the criteria for UTI but were not confirmed as such by the collaborating pediatrician.

We analyzed different variables: demographic and professional characteristics of pediatricians, clinical and demographic characteristics of patients, characteristics of UTI episodes and their temporal distribution to assess the potential impact of the COVID-19 pandemic on inappropriate diagnosis. We also analyzed the ordering of $UC_{f/u}$ and the use of antibiotherapy in IDEs. We compared IDEs and IDE subgroups with ADEs for those variables found to be statistically significant and to have an impact in the study.

The study was approved by the Ethics Committee of the Hospital Universitario de Fuenlabrada, Madrid, (APR 19/03). Patients were included after obtaining informed consent from the parents/legal guardians and assent from patients aged more than 12 years.

The statistical analysis was carried out with the software JASP 0.19.3, summarizing continuous variables as mean or median with the corresponding dispersion statistic (standard deviation or interquartile range). Categorical variables were expressed as absolute frequencies and percentages. We made comparisons by means of the χ^2 test and Fisher exact test (dichotomous variables). We calculated odds ratios (ORs) with the corresponding

Figure 1. Flow chart of the study



[a]UTI: urinary tract infection.

[b]The researchers applied the criteria recommended in the 2019 Spanish guideline[3] to assess the appropriateness of diagnosis: clinical manifestations, risk factors, urinalysis results and urine culture results.

[c]IDE: inappropriately diagnosed episode on account of not meeting one or more of the criteria.

[d]ADE: appropriately diagnosed episode based on meeting the criteria to either confirm or rule out UTI.

[e]IDE (OVERDIAGNOSIS): UTI episodes diagnosed by participating pediatricians in which diagnosis did not adhere to the criteria established in the 2019 guideline.[3]

[f]IDE (UNDERDIAGNOSIS): episodes that met the criteria for UTI but not diagnosed as UTI by participating pediatricians.

[g]EPISODES DIAGNOSED WITHOUT URINE CULTURE: diagnosis based solely on clinical and/or laboratory criteria (dipstick or conventional urinalysis).

[h]EPISODES WITH INADEQUATE SAMPLE COLLECTION: urine culture was performed, but using specimens obtained from a urine collection bag in incontinent children.

[i]EPISODES WITH INCORRECT INTERPRETATION OF COLONY COUNTS: urine culture was performed, but the interpretation of colony counts (CFU/mL) did not adhere to the criteria established in the 2019 guideline.[3]

95% confidence interval (95 CI) and *p* values for the Fisher exact test in the analysis of the association between variables.

RESULTS

We obtained a total of 1506 episode records, of which 1402 were considered valid for analysis (Figure 1). Of these total, 190 (13.6%) were classified as IDEs and 1212 (86.4%) as ADEs (p <0.001).

The distribution of the reason for classifying an episode as an IDE was as follows (Table 2.1): use of an inadequate specimen, the most frequent error, due to collection in a urine bag (37.4%); following in frequency, diagnosis without urine culture (31.6%), incorrect interpretation of the colony count (26.8%) and, less frequently, underdiagnosis (4.2%).

Factors associated with inappropriate diagnostic practices

Analysis by provider-related characteristics and care setting (Table 2.1)

Male providers, and particularly those with more than 20 years' experience, reported a significantly higher proportion of IDEs (95% *vs.* 71%; p 0.034; OR: 6.44; 95 CI: 1.18 to 4.18; p = 0.034) and of diagnosis without urine culture (OR: 2.14; 95 CI: 1.18 to 4.18; p = 0.013) (Table 2.2).

As regards the care setting (Table 2.1), inappropriate diagnosis was significantly less frequent in routine PC (rPC) compared to urgent primary care (uPC) services (OR: 0.32; 95 CI: 0.21 to 0.50; p <0.001) (Table 2.3).

In the separate analysis of episodes in patients without bladder control, the frequency of inappropriate diagnosis was greater in rPCs compared to hospital-based emergency departments (hEDs) on account of episodes with inadequate urine

Table 2.1. Association of inappropriate diagnosis with provider-related and care setting characteristics

	ADE	IDE	*p*	IDE (inadequate specimen)[a]	*p*	IDE (no urine culture)	*p*	IDE (colony count)[b]	*p*
Episodes, N (%)	1212 (86.4)	190 (13.6)	**<0.001**	71 (37.4)		60 (31.6)		51 (26.8)	
Sex[c]									
Female	1139 (94.1)	170 (89.5)	**0.026**			53 (88.3)	0.092	40 (78.4)	**<0.001**
Male	72 (5.9)	20 (10.5)				7 (11.7)		11 (21.6)	
Female[d]	251 (57.8)			40 (56.3)	**<0.001**				
Male[d]	183 (42.2)			31 (46.7)					
Geographical setting									
Rural care setting	324 (26.7)	52 (27.37)	0.860	20 (28.2)	0.235	21 (35.0)	0.160	8 (15.7)	0.079
Urban care setting	888 (73.3)	138 (72.63)		51 (71.8)		39 (65.0)		43 (84.3)	
Work experience									
>20 years	758 (62.6)	125 (65.8)	0.314*	43 (84.3)	0.904*	47 (78.3)	**0.043***	30 (58.8)	0.076*
11-20 years	312 (25.8)	49 (25.8)		20 (28.2)		8 (13.3)		19 (37.2)	
<11 years	141(11.7)	16 (8.4)		8 (11.3)		5 (8.3)		2 (4.0)	
>20 years (male providers)	44 (71.0)	18 (94.7)	**0.034**						
<11 years (male providers)	18 (29.0)	1 (5.3)							
Setting where uti was suspected									
Episodes in rPC	827 (91.0)	119 (76.3)	**<0.001**			32 (54.2)	**<0.001**	30 (66.2)	**<0.001**
Episodes en uPC	82 (9.0)	37 (23.7)				27 (45.8)		14 (31.8)	
Episodes in incontinent Pts in rPC	254 (94.1)	2 (3.69)		54 (96.4)	0.748				
Episodes in incontinent Pts in uPC	16 (5.9)								
Episodes in rPC	827 (73.2)	119 (77.8)	0.241			32 (97.0)	**<0.001**	30 (61.1)	0.347
Episodes in hED	303 (26.8)	34 (22.2)				1 (3.0)		7 (18.9)	
Episodes in incontinent Pts in rPC	254 (60.6)			54 (66.7)	**0.005**				
Episodes in incontinent Pts in hED	165 (39.4)			15 (21.7)					

ADE: appropriately diagnosed episode; **hED:** hospital-based emergency department; **IDE:** inappropriately diagnosed episode; **Pt:** patient; **rPC:** routine primary care; **uPC:** urgent primary care. *P* value obtained in χ^2 test. [a]IDE due to inadequate sample collection. [b]IDE due to incorrect interpretation of colony count (CFU/mL). [c]Sex not documented in one episode. [d]Limited to the group of providers (male and female) who documented episodes in incontinent patients.

specimens (OR: 2.32; 95 CI: 1.29 to 4.40; $p = 0.005$) (Table 2.3).

The proportion of inappropriate diagnosis due to failure to do the lack of urine culture was significantly greater among episodes suspected in the uPC *vs*. the rPC setting (OR: 8.51; 95 CI: 4.86 to 14.90; $p = 0.0001$) (Table 2.3).

When it came to IDEs on account of incorrect interpretation of colony counts, the proportion was lower in the group of episodes suspected in the rPC *vs*. the uPC setting (OR: 0.21; 95 CI: 0.11 to 0.43; $p = 0.0001$) (Table 2.3).

Analysis by patient- and episode-related characteristics (Table 3)

Inappropriate diagnosis due to inadequate urine specimens was associated with a younger mean age while inappropriate diagnosis due to lack of urine culture was associated with older age.

Inappropriate diagnosis was most frequent among children aged less than 24 months. In 14% of episodes in incontinent children in whom UTI was ruled out, the reason for IDE classification was an inadequate specimen (71 out of 505; Table 4). On the other hand, diagnosis without urine culture was more common in children aged 6 years or

Table 2.2. Odds ratios for IDE/ADE in relation to provider characteristics

Variable	OR	LCL95	UCL95	*p*
Provider sex	0.54	0.32	0.92	0.026
Work setting: rural / urban	0.91	0.30	2.53	1.000
Caseload: < 1000 patients / ≥ 1000 patients	1.11	0.81	1.51	0.523
Work experience: >20 years / <11 years	1.22	0.71	2.25	0.581
Work experience (male providers): >20 years / <11 years	6.44	1.17	163.03	0.034
Work experience (IDE due to no urine culture): >20 years / <20 years	2.14	1.18	4.18	0.013

IDE/ADE: inappropriately diagnosed episodes/appropriately diagnosed episodes; **LCL95:** upper bound of 95% confidence interval; **UCL95:** upper bound of 95% confidence interval.

Table 2.3. Odds ratios for IDE/ADE based on care setting

Variable		OR	LCL95	UCL95	*p*
IDE/ADE	rPC/uPC	0.32	0.21	0.50	**0.0001**
	hED/rPC	1.28	0.86	1.94	0.241
Incontinent patients: inadequate specimen/ADE	rPC / uPC	1.60	0.43	11.20	0.748
	rPC/hED	2.32	1.29	4.40	**0.005**
No urine culture/ADE	uPC/ rPC	8.51	4.86	14.90	**0.0001**
	rPC/hED	10.28	2.22	243.39	**0.0001**
Wrong colony count interpretation/ADE	rPC/uPC	0.21	0.11	0.43	**0.0001**
	rPC/hED	1.54	0.71	3.90	0.347

hED: hospital-based emergency department; **IDE/ADE:** inappropriately diagnosed episodes/appropriately diagnosed episodes; **LCL95:** lower bound of 95% confidence interval; **rPC**: routine primary care; **uPC**: urgent primary care; **UCL95:** upper bound of 95% confidence interval.

Table 3. Patient-related characteristics in the total episodes documented by participating providers

	ADE	IDE	*p*	IDE (inadequate specimen)[a]	*p*	IDE (no urine culture)	*p*	IDE (colony count)[b]	*p*
Episodes, *n* (%)	1212 (86.4)	190 (13.6)	**<.001**	71 (37.4)		60 (31.6)		51 (26.8)	
Patient age									
Mean (SD) (years)	4.7 (3.9)	5.7 (3.0)		0.8 (0.6)		7.5(3.3)		6.1 (4.4)	
Median (IQR) (years)	3.9 (6.3)	6.9 (4.4)		0.7 (0.6)		7.8 (3.5)		4.7 (6.1)	
<24 months	400 (33.0)	78 (41.0)	**0.032**	68 (95.8)	0.337	1 (1.7)	**<0.001**	9 (17.6)	**0.022**
≥24 months	812 (67.0)	112 (59.0)		3 (4.2)		59 (98.3)		42 (82.4)	
2-5 years	414 (50.9)	45 (40.2)	**0.034**			20 (33.9)	**0.015**	19 (45.2)	0.528
≥6 years	398 (49.0)	67 (59.8)				39 (66.1)		23 (54.8)	
2-5 years (female)	334 (50.2)					18 (34.0)	**0.031**		
≥6 years (female)	331 (49.8)					35 (66.0)			
Patient sex[c]									
Female	886 (73.2)	140 (73.7)	0.930			53 (88.3)	**0.010**	40 (78.4)	0.518
Male	324 (26.8)	50 (26.3)				7 (11.7)		11 (21.6)	
Incontinent female Pts	251 (57.8)			40 (56.3)	0.897				
Incontinent male Pts	183 (42.2)			31 (43.7)					
Incontinence									
Yes[d]	435 (36.6)	83 (43.7)	0.052	71 (100)		4 (6.7)	**<0.001**	8 (15.7)	**0.002**
No	768 (63. 4)	107 (56.3)		-		56 (93.3)		43 (84.3)	
Episode number									
1st episode	1059 (87.3	153 (80.5)	**0.016**			51 (85.0)	0.553	43 (84.3)	0.519
≥2nd episode	153 (12.6)	37 (19.5)				9 (15.0)		8 (15.7)	
1st episode in incontinent Pt	388 (89.2)			54 (76.1)	**0.004**				
≥2nd episode in incontinent Pt	47 (10.8)			17 (23.9)					

ADE: appropriately diagnosed episode; **IDE:** inappropriately diagnosed episode; **Pt:** patient. [a]IDE due to inadequate sample collection. [b]IDE due to incorrect interpretation of colony count (CFU/mL). [c]Sex not documented in two episodes. [d]Total number of incontinent patients: 506.

older compared to those aged 2 to 5 years, a difference that was statistically significant (66.1% *vs*. 33.9%; $p = 0.015$) (Table 3).

We also found a significantly higher proportion of first episodes in the ADE group (87.3% *vs*. 80.5%) and of successive episodes in the IDE group (19.5% *vs*. 12.6%; $p = 0.016$) (Table 3).

Presence of risk factors

Overall, the presence of RFs was not associated with inappropriate diagnosis (37.6% *vs*. 41.6%; $p = 0.297$). However, bladder dysfunction was significantly associated with a lower probability and hypercalciuria with a higher probability of IDE (Table 4).

Analysis based on clinical presentation and performance of urinalysis

Hematuria (4.7% *vs*. 11.1%; p 0.001), weight loss (2.4% *vs*. 5.8%; $p = 0.016$), urinary frequency (27.9% *vs*. 48.3%; $p < 0.001$), dysuria (48.6% *vs*. 90%; $p < 0.001$) and urgency (13.2% *vs*. 25.5%; $p = 0.008$) were associated with inappropriate diagnosis. On the contrary, fever higher than 38 °C was significantly less frequent in cases of inappropriate diagnosis due to an inadequate specimen in incontinent patients (42.3% *vs*. 59.5%; $p = 0.009$) and episodes diagnosed without urine culture (25.3% *vs*. 5%; $p < 0.001$) (Table 5).

In respect of UDT results, we ought to highlight that the presence in urine of leukocyte esterase (LE) in absence of nitrites was significantly associated with an increased probability of diagnosis without urine culture (42.8% *vs*. 58.8%; $p = 0.030$). When both parameters (LE and nitrites) were negative, the probability of inappropriate diagnosis decreased (32.5% *vs*. 15.1%; $p < 0.001$) (Table 6).

Underdiagnosis

We identified 8 cases of missed diagnosis in continent children (Figure 1). The reasons included disregarding the possibility of polymicrobial infection in samples with two isolates (eg: *Proteus* spp. + *Klebsiella* spp.), the clinical significance of isolates such as *E. faecalis* o *S. saprophyticus* despite compatible symptoms or colony counts that were actually significant in patients with underlying renal disease.

Table 4. Patient incontinence and risk factors for the total documented episodes

Risk factors *n* (%)	ADE	IDE	*p*	IDE (inadequate specimen)[a]	*p*	IDE (no urine culture)	*p*	IDE (colony count)[b]	*p*
Yes	455 (37.6)	79 (41.6)	0.297			20 (33.3)	0.585	30 (58.8)	0.659
Yes, in incontinent Pts with nonpathological results[c]	263 (60.5)			40 (56.3)	0.517				
Labial adhesions (girls)	19 (1.7)	2 (1.4)	0.756					2 (5.0)	0.229
Phimosis (boys)	102 (31.5)	16 (32.0)	1.000					4 (36.4)	0.747
Phimosis in incontinent boys[d]	82 (44.8)			12 (38.7)	0.560				
Previous UTI	253 (20.9)	50 (26.3)	0.107			17 (28.3)	0.194	13 (25.5)	0.482
Previous UTI in incontinent Pt[c]	63 (14.5)			15 (21.1)	0.160				
VUR	50 (4.1)	6 (3.2)	0.690					1 (2.0)	0.719
VUR in incontinent Pt[c]	23 (5.3)			4 (5.6)	0.782				
Other RM	54 (4.5)	9 (4.7)	0.851			1 (1.7)	0.513	1 (2.0)	0.165
Other RM in incontinent Pt[c]	37 (8.5)			7 (9.9)	0.653				
Bladder dysfunction	40 (3.3)	1 (0.5)	**0.034**						
Constipation-encopresis	90 (7.4)	10 (5.3)	0.362			3 (5.0)	0.618	2 (3.9)	0.578
Constipation-encopresis in incontinent Pt[c]	13 (3.0)			2 (2.8)	1.000				
Hypercalciuria	3 (0.3)	3 (1.6)	**0.036**			2 (3.3)	**0.020**	1 (2.0)	0.152

ADE: appropriately diagnosed episode; **IDE:** inappropriately diagnosed episode; **Pt:** patient; **RM:** renal malformation; **UTI:** urinary tract infection; **VUR:** vesicoureteral reflux. [1]IDE due to inadequate sample collection. [2]IDE due to incorrect interpretation of colony count (CFU/mL). [3]Incontinent patients with nonpathological results in ADE group: 435. [4]Incontinent boys in ADE group: 183.vesicoureteral. [a]EID por muestra recogida incorrectamente. [b]EID por interpretación inadecuada del recuento de UFC/mL. [c]EAD en incontinentes no patológicos: 435. [d]EAD niños (hombres) incontinentes: 183.

Table 5. Clinical characteristics of documented episodes

Clinical manifestations, *n* (%)	ADE	IDE	*p*	IDE (inadequate specimen)[a]	*p*	IDE (no urine culture)	*p*	IDE (colony count)[b]	*p*
Fever >38 °C	376 (31.0) 259 (59.5)[c]	48 (25.3)	0.126	30 (42.3)[c]	**0.009**	3 (5.0)	**<0.001**	11 (21.6)	0.166
Dysuria	589 (48.6) 39 (9.0)[c]	94 (49.5)	0.876	5 (7.0)[c]	0.820	54 (90.0)	**<0.001**	31 (60.8)	0.115
Urinary frequency	321 (26.5)	53 (27.9)	0.724			29 (48.3)	**<0.001**	19 (37.3)	0.106
Urinary urgency	145 (12.0)	25 (13.2)	0.633			11 (18.3)	0.156	13 (25.5)	**0.008**
Changes in urine color, odor	106 (8.8) 34 (7.8)[c]	14 (7.4)	0.675	7 (9.9)[c]	0.491	3 (5.0)	0.476	4 (7.8)	1.000
Nycturia	65 (5.4)	8 (4.2)	0.601			4 (6.7)	0.562	4 (7.8)	0.356
Hematuria	57 (4.7) 6 (1.4)	21 (11.1)	**0.001**	1 (1.4)[c]	1.000	9 (15.0)	**0.003**	10 (19.6)	**<0.001**
Polyuria	38 (3.1)	6 (3.2)	1.000			2 (3.3)	0.713	3 (5.9)	0.227
Irritability	151 (12.5) 126 (29.0)[c]	24 (12.6)	0.906	19 (26.8)[c]	0.778	3 (5.0)	0.103	2 (3.9)	0.078
Loss of appetite	131 (10.8) 105 (24.1)[c]	28 (14.7)	0.139	23 (32.4)[c]	0.143			4 (7.8)	0.646
Vomiting	115 (9.5) 70 (16.1)[c]	14 (7.4)	0.418	9 (12.7)[c]	0.597			5 (9.8)	0.811
Weight loss	29 (2.4) 26 (6.0)[c]	11 (5.8)	**0.016**	10 (14.1)[c]	**0.022**			1 (2.0)	1.000
Abdominal pain	176 (14.5) 15 (3.4)[c]	15 (7.9)	**0.012**	2 (2.8)[c]	1.000	6 (10.0)	0.449	4 (7.8)	0.222
Lumbar pain	26 (2.1)	4 (2.1)	1.000			1 (1.7)	1.000	3 (5.9)	0.108
Costovertebral angle tenderness (+)	15 (1.2)	2 (1.1)	1.000						

ADE: appropriately diagnosed episode; **IDE:** inappropriately diagnosed episode; **UTI:** urinary tract infection. [a]IDE due to inadequate sample collection. [b]IDE due to incorrect interpretation of colony count (CFU/mL). [c]Episodes in incontinent patients with nonpathological results; ADE in incontinent patients with nonpathological results: 435.

Analysis in relation to the pandemic (Table 7)

We also assessed the impact of the COVID-19 pandemic on inappropriate diagnosis. We found a higher proportion of IDEs in relation to ADEs during the pandemic (44.7% *vs*. 35.6%; $p = 0.019$) compared to the preceding months.

Analysis of management immediately after diagnosis

We considered the ordering of $UC_{f/u}$, which was more frequent in IDEs compared to ADEs (39% *vs*. 26.5%; $p = 0.002$) (Table 8). Furthermore, in 42.3% of IDEs in which culture was performed, the turna-

Table 6. Results of urinalysis and association with inappropriate diagnosis

Dipstick/conventional *n* (%)	ADE	IDE	*p*	IDE (inadequate specimen)[a]	*p*	IDE (no urine culture)	*p*	IDE (colony count)[b]	*p*
Yes, performed	1146 (94.6)	166 (87.3)	**<0.001**			51 (100)		47 (92.2)	0.524
Yes, performed in incontinent Pts[c]	417 (54.3)			60 (84.5)	**0.001**				
N +/LE+	217 (18.9)	43 (25.9)	**0.038**			15 (29.4)	0.071	7 (14.9)	0.572
N +/LE+ in incontinent Pts[c]	73 (17.5)			19 (31.7)	**0.014**				
N +/LE−	66 (5.8)	9 (5.4)	1.000			3 (5.9)	1.000	2 (4.3)	1.000
N +/LE- in incontinent Pts[c]	26 (6.2)			4 (6.7)	0.781				
LE +/N−	491 (42.8)	89 (53.6)	**0.009**			30 (58.8)	**0.030**	29 (61.7)	**0.015**
LE +/N- in incontinent Pts[c]	162 (38.8)			25 (41.7)	0.674				
N −/LE−	372 (32.5)	25 (15.1)	**<0.001**			3 (5.9)	**<0.001**	9 (19.1)	0.057
N −/LE− in incontinent Pts[c]	156 (15.1)			12 (20.0)	0.009				

ADE: appropriately diagnosed episode; **IDE:** inappropriately diagnosed episode; **LE**: leukocyte esterase; **N**: nitrite. [a]IDE due to inadequate sample collection. [b]IDE due to incorrect interpretation of colony count (CFU/mL). [c]Episodes in incontinent patients with nonpathological results; number of incontinent patients with nonpathological results in ADE group: 435

Table 7. Impact of pandemic on inappropriate diagnosis

Impact of pandemic *n* (%)	ADE	IDE	*p*	IDE (inadequate specimen)[1]a	*p*	IDE (no urine culture)	*p*	IDE (colony count)[b]	*p*
During pandemic	431 (35.6)	85 (44.7)	**0.019**			28 (46.7)	0.098	19 (37.3)	0.882
Before pandemic	781 (64.4)	105 (55.3)				32 (53.3)		32 (62.7)	
During pandemic, incontinent patients	164 (37.7)[c]			37 (52.1)	0.116				
Before pandemic, incontinent patients	271 (62.3)[c]			34 (47.9)					

EAD: episodios con diagnóstico adecuado; **EID**: episodios con diagnóstico inadecuado. [a]EID por muestra recogida incorrectamente. [b]EID por interpretación inadecuada del recuento de UFC/mL. [c]Número total de incontinentes no patológicos en EAD: 435.

Table 8. Association between follow-up culture and inappropriate diagnosis

Follow-up culture, *n* (%)	ADE	IDE	*p*	IDE (inadequate specimen)[a]	*p*	IDE (no urine culture)	*p*	IDE (colony count)[b]	*p*
Not performed	425 (73.5)	111 (61.0)	**0.002**			34 (66.7)	0.324	33 (64.7)	0.190
Performed	153 (26.5)	71 (39.0)				17 (33.3)		18 (35.3)	
Performed in incontinent Pt	164 (80.4)[c]			35 (49.3)	**<0.001**				
Not performed in incontinent Pt	40 (19.6)[c]			36 (50.7)					

ADE: appropriately diagnosed episode; **IDE:** inappropriately diagnosed episode. [a]IDE due to inadequate sample collection. [b]IDE due to incorrect interpretation of colony count (CFU/mL). [c]Number of incontinent patients with nonpathological results in ADE group: 435

round time exceeded 72 hours. Of the total prescriptions for antibiotics, 23.6% (*n* = 180) were made in IDEs. Empirical treatment was initiated immediately once UTI was suspected in 80% of cases and had a mean duration of 7.9 ± 2 days. There were no significant differences in duration between IDEs and ADEs (**Table 9**).

DISCUSSION

Among the relevant findings of the study, we ought to highlight that in 13.6% of diagnosed episodes of UTI, the diagnostic approach did not adhere to the 2019 recommendations[2,3] and that nearly one fourth (23.6 %) of prescribed antibiotherapy regimens were unnecessary. This reflects suboptimal adherence to current clinical practice guidelines (CPGs),[3,16] although the frequency of inadequate adherence was lower compared to the figures reported in other studies (53-75%), including studies conducted exclusively in emergency care settings and those that included cases managed at the primary care level.[11,12,17-19] The inclusion of PC pediatricians in our case series, which allowed longitudinal follow-up of the patients, could have contributed to the greater adherence.

Table 9. Urine culture turnaround time and antibiotherapy in inappropriately diagnosed episodes

UC turnaround time[a]	
Episodes with UC results in <48 hours	4 (3.1%)
Episodes with UC results in 48-72 horas	43 (33.1%)
Episodes with UC results in >72 horas	55 (42.3%)
Episodes with unknown turnaround time	28 (21.5%)
EPISODES WITH ABX	
Total IDEs managed with ABx	182 (23.6%)[b]
Initiation of ABx	
Immediately	147 (80.8%)
Following day	6 (3.3%)
2 days	7 (3.8%)
3 days	3 (1.6%)
>3 days	16 (8.8%)
Not documented	3 (1.6%)
DURATION (DAYS) OF ABX (mean ± SD)	
Duration in IDEs[c]	7.9 ± 2.0
Duration in ADEs[c]	6.7 ± 3.1

ABx: antibiotherapy; **ADE:** appropriately diagnosed episode; **IDE:** inappropriately diagnosed episode; **UC**: urine culture. [a]Number of IDEs with UC: 130. [b]Total ABx prescriptions: 772 (76.4% in ADEs). [c]No significant differences in duration between IDEs and ADEs.

We found that work experience was associated with significantly lower adherence to recommendations (**Tables 2.1** and **2.2**). This association is a widely recognized phenomenon in the medical literature. More experienced professionals may be more reluctant to implement new guidelines, particularly if they consider them unclear or inconsistent. These factors may encourage the persistence of previous recommendations, which are deeply ingrained.[16,20]

The analysis by care setting revealed a higher frequency of inappropriate diagnosis when UTI was suspected in uPC compared to rPC settings. In the latter setting, there was a higher proportion of diagnosis without urine culture and failure to adhere to recommended colony count cut-offs. In the uPC setting, care is usually provided by physicians primarily trained to care for the adult population, which is conducive to the implementation of protocols for adult management and therefore inappropriate diagnosis in pediatric patients.[21]

However, in our study, the collaborating provider was tasked with making a final diagnosis after evaluating the test results, confirming or ruling out the suspicion. Some errors persisted through this process, probably due to favorable outcomes or because treatment had already been completed. Similarly, studies on misdiagnosis following UTI suspicion showed that in more than half of the cases, antibiotherapy was not discontinued despite ruling out UTI, even based on negative urine culture results.[17]

In a more detailed analysis of the common errors in diagnosis, two practices stood out:

The first one was the persisting use of urine collection bags for sample collection in incontinent patients (14% 71/506; **Table 3**). There is ample evidence of the high false-positive rate associated with this sample collection method, which, according to some systematic reviews may be as high as 35-45%[22] or even exceed 50%.[3] Although bags continue to be used to collect urine samples in the PC setting and even in hospital-based emergency departments due to the simplicity of the method, [23] this practice should be limited to initial screening in low-acuity cases.[4,24,25] The fact that 22% of cases of inappropriate diagnosis due to an inadequate sample in incontinent patients occurred in hEDs (**Table 2.1**) is particularly relevant, given that the human and material resources available in this care setting allow for the use of appropriate specimen collection techniques.[19,23]

The second one was diagnosis of UTI without performance of urine culture (**Table 3**). In one third of IDEs, UTI was diagnosed solely based on clinical manifestations with or without urinalysis. The UDT is a useful tool to guide diagnosis and rule out UTI with substantial confidence in pediatric patients, especially those aged more than 3 months.[9,26] However, the specificity of leukocyte esterase is low (78%),[7,27-30] so its detection can give rise to false positives in patients presenting with manifestations such as fever, dehydration or vulvovaginitis.[6] Furthermore, the omission of urine culture chiefly affected patients aged 6 years or older. The high frequency of lower urinary tract symptoms or prepubertal vulvovaginitis in girls, conditions with clinical manifestations that overlap those of UTI, may lead to misinterpretation of these symptoms as indicative of a UTI.[17,31] In consequence, microbiological confirmation is required in most common clinical scenarios.[1,29,30]

The interpretation of clinical factors, together with age, contributes relevant information that is associated with lower adherence to recommendations. In this regard, fever was associated with a higher frequency of appropriate diagnosis, probably because it raises the level of suspicion of a serious bacterial infection, such as pyelonephritis, which promotes more rigorous management and greater adherence to CPGs.[16,32] In contrast, less specific symptoms, such as weight loss or hematuria, acted as confounding factors, increasing the frequency of inappropriate diagnosis[1,3,30] (**Tables 1** and **3**).

Determining whether the presence of RFs could have encouraged greater adherence to recommendations is relevant, as RFs can increase the risk or severity of UTI (**Table 4**). We observed that, overall, the presence of RFs did not significantly change management. Specifically, only bladder dysfunction

was associated with more rigorous management, a practice recommended in CPGs because it bladder dysfunction is strongly associated with recurrent infection and kidney injury.[1,5,6,33] Hypercalciuria, while infrequent, was associated with a greater probability of inappropriate diagnosis. While hypercalciuria is recognized as a RF for recurrent UTI (up to 20%),[34,35] it also can be a source of confusion in the diagnostic process, especially if adherence is suboptimal and appropriate microbiological confirmation is not pursued. Its impact on urinary symptoms and the interpretation of urinalysis findings can promote diagnostic error in the aforementioned situations.[34]

Another relevant finding was the increased frequency of inappropriate management in successive episodes of UTI compared to first episodes, independently of other risk factors, even when CPGs provided clear recommendations for such scenarios.[2,3,5] Current evidence suggests that the tendency toward the inadequate management of additional UTI episodes is mainly due to the habits and fast, reflexive decision-making processes of providers rather than patient-related factors, which favors the repetition of specific medical errors.[36]

These findings have significant implications. On the one hand, urine culture turnaround times exceeding 72 hours in almost half of the IDEs may have promoted continuation of unnecessary treatment. Faster turnaround would facilitate changes to management and help avoid antibiotic overuse.[12,29] On the other hand, our findings highlight the impact of inappropriate diagnosis on antibiotic prescribing. Of the total antibiotic prescriptions, 23.6% were made and maintained in patients without a confirmed diagnosis (as defined by CPGs), which not only exposes children to adverse drug effects but also contributes to the serious problem of bacterial drug resistance.[36-38] However, our analysis of the management of UTI by PC pediatricians reveals a lower frequency of inappropriate treatment compared to other studies, mostly conducted in emergency care settings, which have reported rates of antibiotic overuse of 36 to 59%.[12,18]

In addition, we found evidence of inappropriate use of follow-up culture, especially in IDEs, but a fourth of them were ordered in ADEs, despite all CPGs discouraging this practice.[2,3,5] Routine performance of $UC_{f/u}$ can trigger the performance of a series of additional unnecessary tests and treatments, increasing the costs and burden for the health care system.[1,5,16,37,38]

The main strengths of the study are its prospective design, the large number of records included in the analysis and its national scope, which provide a comprehensive perspective of diagnostic practices in pediatric UTI in Spain. Among the limitations, it should be noted that participation was voluntary and uneven across regions, which precluded the proportional and homogeneous representation of all autonomous communities in the country.

CONCLUSIONS

This study allowed the identification of the most prevalent errors in the diagnosis of pediatric UTIs in everyday clinical practice in Spain: (1) performance of urine culture with samples obtained using urine collection bags in incontinent patients; (2) omission of urine culture in patients with a positive UDT, especially those positive for LE; (3) incorrect interpretation of colony counts without taking into account the sample collection method; (4) diagnosis of UTI based on nonspecific signs and symptoms without performance of urine culture for confirmation or with performance of culture using an inadequate sample[1,2,6] and (5) the lack of an individualized evaluation in atypical UTI cases.[37,39]

The frequency of errors in the diagnosis of suspected UTI was small, which was indicative of high-quality care delivery by participating pediatricians.[16,18] Nevertheless, we believe that coordinated educational interventions targeting different care settings are still needed to correct some practices and promote adherence to CPGs[1,13,15,28,38] in order to improve care quality and patient safety.[20,36]

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare in relation to the preparation and publication of this article.

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AUTHORSHIP

Author contributions: drafting the manuscript (JAA y MEMH), statistical analysis (RJA), study design, coordination with collaborators, literature search and final review of manuscript (all authors).

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ABBREVIATIONS

ABX: antibiotherapy • **ADE**: appropriately diagnosed urinary tract infection episodes • **CFU**: colony-forming units • **CPG**: clinical practice guideline • **hED**: hospital-based emergency department • **IDE**: inappropriately diagnosed urinary tract infection episode • **IQR**: interquartile range • **LE**: leukocyte esterase • **OR**: odds ratio • **PC**: primary care • **RF**: risk factor • **RM**: renal malformation • **rPC**: routine primary care • **SD**: standard deviation • $UC_{f/u}$: follow-up urine culture • **UDT**: urine dipstick test • **uPC**: urgent primary care • **UC**: urine culture • **UTI**: urinary tract infection • **VUR**: vesicoureteral reflux • **95 CI**: 95% confidence interval.

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