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Author manuscript

*J Am Acad Dermatol.* Author manuscript; available in PMC 2023 December 04.

Published in final edited form as:

*J Am Acad Dermatol.* 2023 March ; 88(3): 683–686. doi:10.1016/j.jaad.2022.06.1201.

## Opportunities to improve guideline adherence for the diagnosis and treatment of onychomycosis: Analysis of commercial insurance claims data, United States

Jeremy A. W. Gold, MD<sup>a</sup>, Karen Wu, DVM<sup>a,b</sup>, Brendan R. Jackson, MD<sup>a</sup>, Kaitlin Benedict, MPH<sup>a</sup>

<sup>a</sup>Mycotic Diseases Branch, Centers for Disease Control and Prevention, Atlanta, Georgia

<sup>b</sup>Epidemic Intelligence Service, Centers for Disease Control and Prevention, Atlanta, Georgia.

### Keywords

antifungal drug resistance; antifungal stewardship; ciclopirox; dermatophyte; direct microscopy; onychomycosis; efinaconazole; epidemiology; fluconazole; griseofulvin; histopathology; itraconazole; ketoconazole; nail debridement; polymerase chain reaction; tavaborole; terbinafine; tinea unguium; treatment

### To the Editor:

Onychomycosis, a fungal nail infection most frequently caused by dermatophytes, is an underrecognized public health problem, particularly given the global emergence of terbinafine resistance.<sup>1,2</sup> We estimated onychomycosis prevalence, described risk factors, and assessed adherence to American Academy of Dermatology (AAD) guidelines that recommend confirmatory testing (eg, direct microscopy, histopathology, fungal culture) before prescribing oral antifungal therapy.<sup>3</sup>

We analyzed IBM MarketScan Commercial and Medicare Supplemental databases. We used International Classification of Diseases, 10th Revision, codes to identify onychomycosis patients and underlying conditions; we used Current Procedural Terminology codes to identify onychomycosis-related tests and procedures (Supplementary Table I, available via Mendeley at <https://doi.org/10.17632/33j7s646j7.1>). We calculated disease prevalence among all outpatients seen during 2018. We assessed underlying conditions and diagnostic and treatment practices in an analytic cohort; this cohort included outpatients diagnosed with onychomycosis during 2018 who had continuous insurance enrollment 365 days before and

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Correspondence and reprint requests to: Jeremy A. W. Gold, MD, Mycotic Diseases Branch, Centers for Disease Control and Prevention, 1600 Clifton Rd Northeast, MS 24-10, Atlanta, GA 30329, [jgold@cdc.gov](mailto:jgold@cdc.gov).

Conflicts of interest  
None disclosed.

IRB approval status: Not required.

*Disclaimer: The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the CDC. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy (for example, 45 CFR, part 46, 21 CFR, part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq).*

after incident diagnosis date and no onychomycosis diagnosis during the 365 days before their 2018 incident diagnosis.

During 2018, among 21,298,716 outpatients, onychomycosis prevalence was 1.6% overall and 12.7% among patients aged  $\geq 65$  years. In the analytic cohort ( $n = 121,386$ ), male gender (age-adjusted odds ratio [aOR] = 1.03, 95% confidence interval [CI]: 1.02–1.04) and nonrural residence (aOR = 1.34, 95% CI: 1.31–1.37) were associated with onychomycosis (Table I). Common underlying conditions included diabetes (23.0%), immunosuppressive conditions (21.8%), and non-unguim tinea (12.6%).

Most patients were initially diagnosed by podiatrists ( $n = 62,177$ , 51.2%), followed by general practitioners ( $n = 28,223$ , 23.3%) and dermatologists ( $n = 15,910$ , 13.1%) (Table II). Across specialties, confirmatory laboratory testing was infrequent (15.3%); 12.0% of patients received a histopathology test, 2.8% a fungal culture, 2.1% direct microscopy, and 2.1% fungal polymerase chain reaction; 0.5% received antifungal susceptibility testing. Patients seen by dermatologists more frequently received confirmatory testing (31.0%) than those seen by podiatrists (16.9%) or general practitioners (5.2%). Overall, of the 18,128 patients prescribed an oral antifungal drug (most frequently terbinafine [88.2%]), 1756 (9.7%) received confirmatory diagnostic testing.

We found a lower onychomycosis prevalence (1.6%) than previous European and North American studies (2% to 14%),<sup>4</sup> potentially reflecting underreporting, lack of clinical nail examination and testing, or differences in study design. Compared with other oral antifungals, terbinafine was more commonly prescribed, likely because it is of low cost and generally covered by health insurance without a requirement for laboratory testing. Compared with an urban academic medical center,<sup>5</sup> patients in our study less frequently received confirmatory diagnostic testing (15.3% vs 39.3%), possibly because fewer providers in our study were dermatologists (13.1% vs 62.1%) and practices at an academic institution likely differ from other settings.

Despite the limitations inherent to administrative data, including potential disease misclassification and undercoding, our study provides an update regarding US onychomycosis epidemiology and a concerning assessment of adherence to AAD guidelines for onychomycosis diagnosis and treatment. Confirming the diagnosis of onychomycosis with laboratory testing is important for ensuring appropriate therapy and avoiding unnecessary antifungal exposure. In the era of antifungal-resistant dermatophytosis, a renewed, cross-specialty emphasis on guideline-based onychomycosis treatment is needed, emphasizing antifungal stewardship to preserve available treatment options.

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Table 1.

Demographic features and underlying medical conditions associated with onychomycosis patients ( $n = 121,386$ ) in a large, commercially insured population—United States, 2018

Characteristic	<i>n</i>	%	aOR (95% CI)*
Age (years), median (IQR)	56	(45–63)	NA
Gender			
Male	56,231	46.3	1.03 (1.02–1.04)
Female	65,155	53.7	Referent
Urban-rural classification			
Nonrural	110,371	90.9	1.34 (1.31–1.37)
Rural	10,847	8.9	Referent
Unknown/missing <sup>†</sup>	168	0.1	NA
US census region of primary beneficiary's residence			
Northeast	37,091	30.6	1.47 (1.45–1.50)
South	47,593	39.2	1.04 (1.02–1.05)
West	13,933	11.5	1.01 (0.99–1.03)
Midwest	22,529	18.6	Referent
Unknown/missing <sup>†</sup>	240	0.2	NA
Underlying conditions			
Tinea (non-unguitum)	15,237	12.6	13.46 (13.21–13.72)
Tinea pedis	13,292	11.0	26.75 (26.18–27.33)
Tinea manuum	231	0.2	15.43 (13.31–17.88)
Psoriasis	2514	2.1	1.58 (1.52–1.65)
Hallux valgus	5373	4.4	5.26 (5.11–6.42)
Overweight or obesity	21,883	18.0	1.64 (1.61–1.66)
Diabetes	27,910	23.0	2.03 (2.00–2.05)
Immunosuppressive conditions	26,461	21.8	1.56 (1.54–1.58)
Cancer	21,141	17.4	1.54 (1.52–1.57)
Immune-mediated inflammatory disease	6153	5.1	1.48 (1.44–1.52)
HIV	499	0.4	1.57 (1.44–1.72)
Solid organ or stem cell transplantation	513	0.4	1.69 (1.55–1.85)

Characteristic	<i>n</i>	%	aOR (95% CI) <sup>*</sup>
Chronic venous insufficiency	3505	2.9	2.58 (2.49–2.67)
Peripheral arterial disease	5248	4.3	3.64 (3.53–3.75)
Tobacco use/nicotine dependence	6120	5.0	1.13 (1.10–1.16)

<sup>a</sup>*aOR*, Age-adjusted odds ratio; *CI*, confidence interval; *IQR*, interquartile range; *NA*, not applicable.

<sup>\*</sup> Age-adjusted odds ratios were calculated by comparing patients diagnosed with onychomycosis versus patients not diagnosed with onychomycosis during 2018. Among the 121,386 patients diagnosed with onychomycosis, 2.6% were aged <18 years, 8.8% were aged 18–34 years, 12.6% were aged 35–44 years, 22.2% were aged 45–54 years, 31.2% were aged 55–64 years, and 22.6% were aged 65 years. Among the 10,732,239 patients without onychomycosis, 23.6% were aged <18 years, 19.8% were aged 18–34 years, 15.1% were aged 35–44 years, 19.0% were aged 45–54 years, 18.4% were aged 55–64 years, and 4.1% were aged 65 years.

<sup>†</sup> These missing data were excluded from aOR calculations.

Diagnostic and treatment practices by provider type for patients with onychomycosis in a large, commercially insured population—United States, 2018

Table II.

Characteristic*	Overall (N = 121,386)		Dermatologist (n = 15,910)		Podiatrist (n = 62,177)		General practitioner (n = 28,223)		Other or unknown† (n = 15,076)		P-value‡
	N	%	n	%	n	%	n	%	N	%	
Diagnostic testing	18,579	15.3	4939	31.0	10,537	16.9	1469	5.2	1634	10.8	<.0001
Histopathology	14,602	12.0	4046	25.4	8866	14.3	609	2.2	1081	7.2	
Fungal culture	3361	2.8	779	4.9	1590	2.6	608	2.2	384	2.5	
Direct microscopy	2513	2.1	700	4.4	1171	1.9	375	1.3	267	1.8	
Polymerase chain reaction	2496	2.1	47	0.3	2243	3.6	89	0.3	117	0.8	
Antifungal susceptibility testing	564	0.5	72	0.5	274	0.4	131	0.5	87	0.6	
Prescription antifungal drugs	29,833	24.6	5153	32.4	7571	12.2	12,226	43.3	4883	32.4	<.0001
Topical	12,392	10.2	3115	19.6	3904	6.3	3576	12.7	1797	11.9	<.0001
Ciclopirox	9725	8.0	2043	12.8	2963	4.8	3216	11.4	1503	10.0	
Efinaconazole	2282	1.9	930	5.8	750	1.2	341	1.2	261	1.7	
Tavaborole	444	0.4	171	1.1	209	0.3	26	0.1	38	0.3	
Oral	18,128	14.9	2204	13.9	3897	6.3	8845	31.3	3182	21.1	<.0001
Terbinafine	15,985	13.2	1692	10.6	3522	5.7	8004	28.4	2767	18.4	
Fluconazole	1691	1.4	469	2.9	316	0.5	578	2.0	328	2.2	
Itraconazole	272	0.2	30	0.2	40	0.1	144	0.5	58	0.4	
Griseofulvin	184	0.2	12	0.1	26	0.0	119	0.4	27	0.2	
Ketoconazole	102	0.1	11	0.1	5	0.0	59	0.2	27	0.2	
Posaconazole	2	0.0	0	0.0	1	0.0	0	0.0	1	0.0	
Both oral and topical antifungal therapy	687	0.6	166	1.0	230	0.4	195	0.7	96	0.6	<.0001
Prescribing and testing practices											
Prescribed oral antifungal therapy without a confirmatory test	16,372	13.5	1561	9.8	3346	5.4	8516	30.2	2949	19.6	<.0001
Prescribed topical antifungal therapy without a confirmatory test§	10,454	8.6	2215	13.9	3191	5.1	3435	12.2	1613	10.7	<.0001
Nonpharmaceutical therapies											
Nail debridement	24,839	20.5	105	0.7	22,937	36.9	466	1.7	1331	8.8	<.0001
Nail avulsion or excision	4998	4.1	54	0.3	4172	6.7	350	1.2	422	2.8	<.0001
Photodynamic therapy	18	0.0	12	0.1	5	0.0	1	0.0	0	0.0	

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\* Patients could receive more than 1 type of diagnostic test and more than 1 type of treatment. Diagnostic tests were considered onychomycosis related if they were documented within 7 days before, on, or after the incident onychomycosis visit date. Antifungal drug prescriptions and non-pharmaceutical therapies were considered onychomycosis related if they were documented within 0–7 days after the incident onychomycosis visit date. In total, 57.3% of onychomycosis patients had 1 visit for onychomycosis, 20.4% had 2 visits, 9.4% had 3 visits, and 12.9% of patients had 4 visits.

† Provider type was missing for 1229 patients; otherwise, the most common provider type visited on the incident diagnosis date among these patients included physician assistants (specialty unknown) ( $n = 1742$ ) and nurse practitioners (specialty unknown) ( $n = 1733$ ).

‡  $P$ -values were calculated using  $\chi^2$  tests to compare practices among provider types.

§ Overall, 8369 of 9725 (86.1%) patients were prescribed ciclopirox, 1805 of 2282 (79.1%) patients were prescribed efinaconazole, and 322 of 444 (72.5%) were prescribed tavaborole without receiving a confirmatory diagnostic test.