



## Complete Summary

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### GUIDELINE TITLE

Recommendations for the management of onychomycosis in adults.

### BIBLIOGRAPHIC SOURCE(S)

University of Texas at Austin, School of Nursing, Family Nurse Practitioner Program. Recommendations for the management of onychomycosis in adults. Austin (TX): University of Texas at Austin, School of Nursing; 2003 May. 16 p. [38 references]

### GUIDELINE STATUS

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT

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## SCOPE

### DISEASE/CONDITION(S)

Onychomycosis

### GUIDELINE CATEGORY

Diagnosis  
Management  
Prevention  
Treatment

### CLINICAL SPECIALTY

Family Practice  
Internal Medicine  
Podiatry

## **INTENDED USERS**

Advanced Practice Nurses  
Physician Assistants  
Physicians

## **GUIDELINE OBJECTIVE(S)**

To supply health care providers with current evidenced-based practice guidelines in reference to diagnosis and management of onychomycosis in adult patients

## **TARGET POPULATION**

Adults (>18 years of age) diagnosed with or with symptoms suggestive of onychomycosis

## **INTERVENTIONS AND PRACTICES CONSIDERED**

### **Diagnosis**

1. Subjective Assessment
  - History of present illness (onset, duration, morphology of nail, predisposing factors, and prior treatments and outcomes)
  - Past medical history
  - Family medical history
  - Personal/social history
2. Objective Assessment
  - Physical exam (general appearance; vital signs, height and weight; general skin assessment, nail examination: color, texture, nail base angle, ridging, beading, pitting, peeling and/or crumbling, nail plate firmness and adherence to nail bed, and presence of odor)
  - Diagnostic tests as indicated: microscopy, Wood's lamp exam, fungal culture (if considering long term treatment), and skin/nail biopsy

### **Management/Prevention/Treatment**

1. Interventions to prevent onychomycosis (e.g., properly fitting shoes; wearing flip-flops or shower shoes when using community baths and showers; washing feet daily with soap and water; wearing hosiery made of synthetic materials to allow airflow; supplying manicurist with own pedicure/manicure tools)
2. Pharmacological therapy to treat onychomycosis
  - A. Combination therapy for severe onychomycosis
    - 5% amorolfine [Loceryl\*] in combination with terbinafine [Lamasil]
    - 5% amorolfine [Loceryl\*] in combination with itraconazole [Sporanox]

- B. Nail lacquer monotherapy for mild to moderate onychomycosis
  - Amorolfine [Loceryl\*] Nail Lacquer, 5% Topical Solution
  - Ciclopirox [Penlac] Nail Lacquer, 8% Topical Solution
  - 40% Urea [Carmol 40], 40% Urea Keratolytic Topical Solution
- C. Oral monotherapy for mild to moderate onychomycosis
  - Terbinafine [Lamasil]
  - Itraconazole [Sporanox]
  - Fluconazole [Diflucan]
- 3. Follow-up (laboratory evaluations; nails cut and filed)
- 4. Referral to podiatrist as indicated

\*Not currently available in the United States

## **MAJOR OUTCOMES CONSIDERED**

- Mycological and clinical cure
- Adverse effects of medications

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Hand-searches of Published Literature (Primary Sources)  
 Hand-searches of Published Literature (Secondary Sources)  
 Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

Searches were performed via Electronic databases including Medline, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and PubMed. Additional resources were found using bibliographies of relevant articles and brochures.

### **NUMBER OF SOURCE DOCUMENTS**

Not stated

### **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Weighting According to a Rating Scheme (Scheme Given)

### **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

#### **Quality of Evidence**

**I.** Evidence obtained from at least one properly randomized controlled trial.

**II-1.** Evidence obtained from well-designed controlled trials without randomization.

**II-2.** Evidence obtained from well-designed cohort or case-controlled analytic studies, preferably from more than one center or research group.

**II-3.** Evidence obtained from multiple time series with or without intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could be regarded as this type of evidence.

**III.** Opinions of respected authorities based on clinical experience descriptive studies and case reports or reports of expert committees.

*Adapted from: United States Department of Health and Human Services (U.S. DHHS), Office of Public Health & Science. U.S. Preventive Services Task Force, (1996). Guideline to Clinical Preventive Services, (2<sup>nd</sup> ed.), Alexandria, VA: International Medical Publishing, Inc.*

## **METHODS USED TO ANALYZE THE EVIDENCE**

Review of Published Meta-Analyses  
Systematic Review

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus  
Informal Consensus

## **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Not stated

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

### **Strength of Recommendation**

- A. There is good evidence to support the recommendation that the treatment be specifically considered in the management of onychomycosis.
- B. There is fair evidence to support the recommendation that the treatment be specifically considered in the management of onychomycosis.
- C. There is insufficient evidence to recommend for or against the inclusion of the treatment in the management of onychomycosis, but recommendations may be made on other grounds.
- D. There is fair evidence to support the recommendation that the treatment be excluded from consideration in the management of onychomycosis.
- E. There is good evidence to support the recommendation that the treatment be excluded from consideration in the management of onychomycosis.

## **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## **METHOD OF GUIDELINE VALIDATION**

External Peer Review  
Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

A group of Family Nurse Practitioner students developed a draft which was submitted to the University of Texas at Austin nursing faculty for review. Revisions were made after recommendations were received. An outside specialist in Podiatry provided final external review.

## **RECOMMENDATIONS**

### **MAJOR RECOMMENDATIONS**

Definitions for the grades of the evidence (I, II-1, II-2, II-3, III) and the strength of the recommendations (A-E) are repeated at the end of the Major Recommendations field.

1. Complete a comprehensive history of presenting symptoms with particular attention to history of onset, duration, morphology of nail, predisposing factors, and prior treatments and outcomes.
2. The physical examination should include the degree of severity: nail color, texture, nail base angle, plate firmness and adherence to the nail bed. In addition, examine the nail for ridging, beading, pitting, peeling/crumbling, and presence of odor. Severe onychomycosis is defined as >80% of nail surface and/or matrix involvement of at least one toenail (excluding the fifth metatarsal).
3. Diagnostic tests indicated for diagnosis of onychomycosis include microscopy, Wood's lamp examination, skin/nail biopsy, and fungal culture (if considering long term oral therapy). Differential diagnoses include lichen planus, psoriasis, myxoid cyst, yellow nail syndrome, peripheral vascular disease, and trauma.
4. Lifestyle modifications may aid in the prevention of onychomycosis. Modifications consist of wearing properly fitting shoes, using shower shoes in community showers, washing feet daily with soap and water, wearing hosiery made of synthetic materials, and supplying manicurist with personal pedicure/manicure tools (**strength of recommendation B; quality of evidence III**).
5. 5% amorolfine (Loceryl)\* applied once weekly for 15 months in combination with terbinafine (Lamasil) 250mg orally every day for 12 weeks is strongly supported as the most effective means of mycological and clinical cure for severe dermatophyte onychomycosis. In addition, studies indicate combination therapy to be the most cost-effective means of treatment as

- compared to monotherapy. (**strength of recommendation A; quality of evidence I**).
6. 5% amorolfine (Loceryl) applied once weekly for 24 weeks in combination with itraconazole (Sporanox) 200mg orally every day for 12 weeks is strongly supported as the most effective means of mycological and clinical cure for severe non-dermatophyte onychomycosis. This combination was also shown to be a more cost-effective treatment as compared to monotherapy. (**strength of recommendation A; quality of evidence I**).
  7. Multiple randomized, controlled studies support the use of nail lacquers for effective treatment of mild to moderate onychomycosis. 5% amorolfine (Loceryl) applied once or twice weekly for six months for fingernails and nine to twelve months for toenails (**strength of recommendation A; quality of evidence I**) or 8% ciclopirox (Penlac) applied daily for 48 weeks with monthly clinical removal of unattached nail (**strength of recommendation A; quality of evidence I**).
  8. Respected authorities recommend 40% Urea (Carmol 40), 40% Urea Keratolytic topical solution applied 1 to 2 times a day until complete chemical avulsion of nail is achieved. Indicated for moderate to severe nail involvement. Recommended for persons >18 years of age (**strength of recommendation C; quality of evidence III**). There is evidence to support the use of Carmol 40 as a preparatory agent to avulse the nail and leave the nail bed more permeable to treatment with a topical antifungal (**strength of recommendation B, quality of evidence I**).
  9. Oral antifungals as monotherapy have been strongly supported for the treatment of moderate to severe onychomycosis. Terbinafine (Lamasil) 250mg orally every day for 6 weeks for fingernails and 12 to 16 weeks for toenails has been shown to be the most effective treatment of dermatophyte infection (**strength of recommendation A; quality of evidence I**). Itraconazole (Sporanox) 200mg orally every day for 12 weeks or pulse therapy (400mg PO qd x one week q four weeks for 12-16 weeks) has been shown to be the most effective treatment of non-dermatophyte infection, with greater efficacy in favor of pulse therapy (**strength of recommendation A; quality of evidence I**). Fluconazole (Diflucan) 150mg once weekly for 24 weeks demonstrated lower efficacy in clinical and mycological cure of non-dermatophyte infections (**strength of recommendation A; quality of evidence I**).
  10. Complete blood count and liver function tests should be monitored prior to, during, and at the end of treatment with oral antifungals. When using nail lacquer treatment, nails should be cut and filed monthly by a healthcare professional.
  11. Referral should be made to a podiatrist for severe and relapsing cases.

\* 5% amorolfine (Loceryl) is not available in the United States at this time.

## **Definitions:**

### **Strength of Recommendation**

- A. There is good evidence to support the recommendation that the treatment be specifically considered in the management of onychomycosis.
- B. There is fair evidence to support the recommendation that the treatment be specifically considered in the management of onychomycosis.

- C. There is insufficient evidence to recommend for or against the inclusion of the treatment in the management of onychomycosis, but recommendations may be made on other grounds.
- D. There is fair evidence to support the recommendation that the treatment be excluded from consideration in the management of onychomycosis.
- E. There is good evidence to support the recommendation that the treatment be excluded from consideration in the management of onychomycosis.

### **Quality of Evidence**

**I.** Evidence obtained from at least one properly randomized controlled trial.

**II-1.** Evidence obtained from well-designed controlled trials without randomization.

**II-2.** Evidence obtained from well-designed cohort or case-controlled analytic studies, preferably from more than one center or research group.

**II-3.** Evidence obtained from multiple time series with or without intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could be regarded as this type of evidence.

**III.** Opinions of respected authorities based on clinical experience descriptive studies and case reports or reports of expert committees.

*Adapted from: U.S. DHHS, Office of Public Health & Science. U.S. Preventive Services Task Force, (1996). Guideline to Clinical Preventive Services, (2<sup>nd</sup> ed.), Alexandria, VA: International Medical Publishing, Inc.*

### **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of evidence is identified and graded for selected recommendations (see "Major Recommendations").

## **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

### **POTENTIAL BENEFITS**

- Appropriate diagnosis and management of onychomycosis in the adult population
- Mycological and clinical cure for onychomycosis

### **POTENTIAL HARMS**

### **Adverse effects of medications for onychomycosis:**

- Antifungal Nail Lacquers:
  - Loceryl: The most common side effect of Loceryl is a transient burning sensation at the application site.
- Oral Antifungal Agents:
  - Terbinafine (Lamisil): The most frequent side effects of Lamisil are headache, gastrointestinal disturbance (diarrhea and/or dyspepsia), rash, and elevated liver enzymes ( $\geq 2x$  the upper limit of normal).
  - Itraconazole (Sporanox): The most frequent side effects of Sporanox include increased liver function tests, skin rash, high triglycerides, and gastrointestinal effects (nausea, bloating, and diarrhea).
  - Ketoconazole (Diflucan): The most common side effects are headache, skin rash, and/or gastrointestinal (GI) disturbance (nausea, vomiting, diarrhea, and/or abdominal pain).

### **Subgroups Most Likely to Experience Harms:**

Oral antifungals should be avoided in patients with hepatic and liver insufficiency as well as pregnant or nursing mothers.

## **CONTRAINDICATIONS**

### **CONTRAINDICATIONS**

Contraindications to specific medications to treat onychomycosis:

- Loceryl is contraindicated during pregnancy and/or lactation.
- Terbinafine (Lamisil): known drug-drug interactions with cyclosporine, warfarin, rifampin, and/or cimetidine
- Itraconazole (Sporanox): Sporanox has known drug-drug interactions with the following categories of medications: antiarrhythmics, anticonvulsants, antimycobacterials, antineoplastics, antipsychotics, benzodiazepines, calcium channel blockers, H2 blockers, GI motility agents, statins, immunosuppressants, macrolide antibiotics, non-nucleoside reverse transcriptase inhibitors, oral hypoglycemic agents, amphotericin B, and/or protease inhibitors
- Ketoconazole (Diflucan): Drug-drug interactions have been noted with the following medications: oral hypoglycemics, coumadin-type anticoagulants, phenytoin, cyclosporine, rifampin, theophylline, terfenadine, cisapride, astemizole, rifabutin, tacrolimus, and alcohol.

## **QUALIFYING STATEMENTS**

### **QUALIFYING STATEMENTS**

Five percent (5%) amorolfine (Loceryl) is not available in the United States at this time.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Getting Better  
Staying Healthy

### IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

University of Texas at Austin, School of Nursing, Family Nurse Practitioner Program. Recommendations for the management of onychomycosis in adults. Austin (TX): University of Texas at Austin, School of Nursing; 2003 May. 16 p. [38 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2003 May

### GUIDELINE DEVELOPER(S)

University of Texas at Austin School of Nursing, Family Nurse Practitioner Program  
- Academic Institution

### SOURCE(S) OF FUNDING

Not stated

### GUIDELINE COMMITTEE

Practice Guidelines Committee

## **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

*Authors:* Louise Feuge, RN, MSN, FNP; Megan Passe, RN, MSN, FNP; Janie Rios, RN, MSN, FNP

## **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Not stated

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: None available

Print copies: Available from the University of Texas at Austin, School of Nursing.  
1700 Red River, Austin, Texas, 78701-1499

## **AVAILABILITY OF COMPANION DOCUMENTS**

None available

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This NGC summary was completed by ECRI on April 5, 2004. The information was verified by the guideline developer on May 18, 2004.

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