The Fungus Conundrum

PEP WEBINAR JUNE 2019
GUEST SPEAKERS; CYNTHIA CERNAK, DPM AND GARY REES
Our first guest speaker

DR. CYNTHIA CERNAK
Let me introduce myself

I AM...

- A mother & grandmother
- A musician
- An educator & advocate
- A community activist
- An Animal lover
- A podiatrist

I AM...

- Cynthia R. Cemak, DPM
- FACFAS, FABPS, FACFAOM
- Board Certified by ABPS, ABPOPPM,
- Member AENS
- Founding member of the Institute of Peripheral Nerve Surgery
- Practicing Physician at Weill Foot and Ankle Institute, Kenosha, WI
Surgery is fun but fungus pays the bills
Most say “for coverage of mycotic nail debridement, mycological confirmation is expected for patients whose debridement is prescribed absent of concomitant pharmacological therapy.”
Bill what you did, Chart what you bill, AND Sign your Notes

Remember, if you did not use anesthesia during any procedure that would normally require it, this needs to be documented:

- **Example**: Patient is neuropathic, patient is on Coumadin, patient refused local anesthesia, etc.

Document the patient’s tolerance for the procedure and post-operative instructions.
Medical Documentation For Biopsy

- Medical necessity audits are increasing
  - laboratories often need to send physician medical records
- Document medical necessity for performing biopsy
  - pain, color change, rapid growing, suspicion of malignancy
- Description of lesion or condition
  - location, size, shape, color
- Procedure note for biopsy
  - document laboratory test ordered
- Confirm review of laboratory report
  - did diagnosis change, what action is being taken
“Onychomycosis is a fungal infection of the nail that is often recalcitrant to treatment and PRONE to relapse”

She used molecular methods to test 8816 clinically suspicious toenails

Results showed approximately 50% to contain both fungi and bacteria with T. RUBRUM showing the highest content in about 40% of the samples.

All the remaining 50% 34% had bacteria species, and 16% had NEITHER.

She concluded that the clinical significance of her results are currently unknown.
Polymerase Chain Reaction (PCR); DNA testing

**Information provided by BakoDx regarding Onychodystrophy DNA Testing**

BakoDx optimizes cost using a proprietary reflex testing workflow that identifies the relevant agents of disease. Not all genus/species are treated the same.

DNA testing helps you to determine the safest and most effective oral and topical treatment for your patient.
Initial DNA Screening for the Presence of a

- Dermatophyte
  - T. rubrum Complex
  - T. mentagrophytes Complex
  - Epidermophyton spp
  - Microsporum spp
- Saprophyte
  - Acremonium spp
  - Aspergillus spp
  - Fusarium spp
  - Scopulariopsis spp
- Yeast
  - Candida albicans
  - Candida parapsilosis Complex
  - Candida guilliermondii Complex
  - Malassezia spp*
  - Trichosporon spp*
  - Cryptococcus spp*
  - Candida tropicalis
- Pseudomonas aeruginosa

Dry Sample
(Nail cannot be placed in formalin)

Reflex

No Further Testing

Pseudomonas aeruginosa*
Benefits of DNA Testing

- **Targeted Technology.** Knowing the genus/species of the causative agent with 99.9% analytical specificity allows for targeted therapy.¹

- **Accurate.** Correlates highly with gold standard histology with 86% sensitivity, while providing identification of genus/species.¹

- **Timely.** Rapid results in 24-48 hours mean the right treatment, right away.

- **Cost Effective.** Quick identification of genus/species supports informed treatment decisions that can more quickly lead to effective outcomes.²

- **Required.** Many payors require precise identification of fungal species for preauthorization of anti-fungal Rx.

- **Covered.** Bako’s onychodystrophy DNA test is covered by Medicare and most insurance plans.
Diagnosing/Confirming Proof of 110.1

PAS and C&S of nail clippings have a 90% success rate in diagnosing 110.1.

If you prescribe oral meds you must confirm proof of onychomycosis.

When billing for 110.1 either a secondary infection due to 110.1 or limited ambulation and clinical proof of 110.1.

You can perform a KOH in the office to confirm proof of onychomycosis.
Treating with oral and topical medications

If using Lamisil you need to do ASA and LFTs plus provide your patient with a detailed handout regarding medication and potential risks.

Remind your patients NOT TO DRINK ALCOHOL WITH THIS MEDICATION.

Ketoconazole needs to be under occlusion.
We studied almost 2000 nails ... 827 that were clinically dystrophic.

- Our studies showed *T. Rubrum* also in about 30% of patients but MRSA was isolated more than all fungal species combined.
- **Thank you to Dr. Erin Kline for all her hard work in heading up our research team**
What looks like a fungus and smells like a fungus does not always hold true...

- Therefore
  - ALL TOENAILS SHOULD BE SUBMITTED FOR ANALYSIS
  - MEDICAL HISTORY REVIEWED
  - DO VASCULAR TESTING AS ADJUNCT

As you now look at toenails and newly pigmented stripes closer, think “always biopsy”

**Aggressive melanomas are seen often in sleep apnea patients**
Treatment Thoughts; Debridement alone is not an adequate treatment.

Topical options: Jublia/Kerydin, Tolcylen, Compound medications

Oral options: Lamisil - only indicated for T. rubrum

Adjunct options: Foot soaks

Shoe sanitizer
Broad spectrum anti-fungal and anti-bacterial for skin
When past treatments have been unsuccessful

The nail is a significant barrier.

Medication didn't get to the nail bed—which is where the infection was thought to be.

Early medications for this problem were not adequate.

You may be treating the wrong organism(s).
Patients with Dystrophic Toenails

ALL toenails should be submitted for analysis.

Medical history should be reviewed.

Adjunct testing should be performed (i.e. PADnet).
16s rRNA Analysis – Isolated Organisms

- Bacteria: 47%
- Fungus + Bacteria: 48%
- Fungus: 2%
- Inconclusive: 3%
Commonly Pathogenic Organisms

• Dermatophytes (80-90%)
  • Epidermophyton floccosum
  • Microsporum species
  • Trichophyton interdigitale
  • Trichophyton mentagrophytes
  • Trichophyton rubrum
  • Trichophyton tonsurans

• Yeast (2-11%)
  • Candida albicans
  • Candida guilliermondii
  • Candida parapsilosis

• Non-dermatophytic mold
  • Acremonium species
  • Aspergillus species
  • Alternaria species
  • Cladosporum carrionii
  • Fusarium species
  • Geotrichoum candidum
  • Lasiodiplodia theobromae
  • Onychocola species
  • Scopulariopsis species
  • Scytalidium species

## What we think we know

<table>
<thead>
<tr>
<th>Classification</th>
<th>Clinical Features</th>
<th>Causative Organism</th>
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</thead>
<tbody>
<tr>
<td>Distal and lateral subungual</td>
<td>Starts distal or lateral Spreads to the nail bed</td>
<td>E. Floccosum</td>
</tr>
<tr>
<td></td>
<td></td>
<td>T. mentag</td>
</tr>
<tr>
<td></td>
<td></td>
<td>T. rubrum</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C. Albicans</td>
</tr>
<tr>
<td>Endoxy subungual</td>
<td>Nail is ‘milky white’ Indentations, lamellar splitting No hyperkeratosis or onycholysis</td>
<td>T. soudanense</td>
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<tr>
<td>Proximal subungual</td>
<td>Debris proximally Onycholysis and white color that spreads proximally</td>
<td>T. rubrum</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C. Albicans</td>
</tr>
<tr>
<td>Superficial (white)</td>
<td>Powder like patches Transverse ridges</td>
<td>T. Mentag</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acremonium</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Scytalidium</td>
</tr>
<tr>
<td>Total dystrophic</td>
<td>Complete destruction from long standing infection</td>
<td>?</td>
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</tbody>
</table>

### What we think we know

<table>
<thead>
<tr>
<th>Type of Disease</th>
<th>Causitive Organisms</th>
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<tbody>
<tr>
<td>• Distal/lateral onychomycosis</td>
<td>• Trichophyton rubrum</td>
</tr>
<tr>
<td>• Total dystrophic</td>
<td>• Trichophyton mentagrol</td>
</tr>
<tr>
<td>• Proximal onychomycosis</td>
<td>• Epidermophyton</td>
</tr>
<tr>
<td>• Superficial white onychomycosis</td>
<td>• Microsporum</td>
</tr>
<tr>
<td></td>
<td>• Candida albicans</td>
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</table>
Foot Soaks

Secrets of the Mona Lisa revealed.
Before Soaks
One month using Soaks
One month using soaks
Our next guest speaker

GARY REES
Gary Rees is a Health Care Consultant living in Houston Texas with his wife of 17 years and 2 of his 4 children (two in college).

He got his start in 2007 and has founded two companies in the healthcare space that reached 100 million in revenue within 24 months of inception. Currently he is VP of operations with PAS Research, a full service CRO based in Tampa Fl., and the owner of Become The Pharmacy which has over 200 clinics participating in their program.

Gary is a huge advocate of feeding children globally and his family devotes much of their time and resources serving in that field.
Become The Pharmacy

Out of Office Pharmacy Dispensing Program

- Set Up and Credentialing
- Adjudication
- Customer Service
- Refills
- Patient Convenience
- Revenue for the Clinic
Program At A Glance

Prescriber orders prescription

Pharmacy fills prescription and ships

Rx faxed to Pharmacy

Patient receives medication at home or clinic
Behind the Scenes

Our staff completes the dispense and adjudicates for payment

Leased space where physician owned medications are stored

Pharmacy Tech fills the script

Staff reviews clinic’s schedule and pre-certifies patients for topicals... then faxes list to clinic for the next day

Medications are packaged and readied for shipment
Become the Pharmacy Advantage

01 Prior Pre-certification of patient medication eligibility
02 Management of inventory
03 Management of Account Receivables
04 State Reporting
05 Credential clinic(s) with RX PBMs
06 Formulary Development and Support
07 Regional Manager Account Support
08 24 Hour Technical Support
09 Dedicated Client Service Personnel
10 On-Call Pharmacist
### Financials

33 scripts filled 2/1/19-2/15/19 One Prescriber

<table>
<thead>
<tr>
<th>Rx Number</th>
<th>Prescribed Item</th>
<th>Primary</th>
<th>Acquisition Cost</th>
<th>Net to Prescriber</th>
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$9,200.89

AVG 4-6 refills per patient
Moving Forward

Create custom script pad and use for 60-90 days as we complete the credentialing process and determine the best prescription based on patient needs and insurance coverage.

Agreement

Licences

Use Custom Script Pad

We credential your clinic with PBMs and your state

60 – 90 days to your Profits!
FAQs...

- **Which insurances pay?** ALL PPO AND MEDICARE. NO HMO NO MEDICAID OR TRICARE
- **How much will patient pay?** CAPPED AT $50 PER PRESCRIPTION. MOST PAY $0-20
- **What is in for me?** AFTER CREDENTIALING . 50% AFTER C O G S. AVG IS 200 PLUS PER APPROVED PATIENT.
  
  **WE DO NOT PAY ON MEDICARE THUS AVOIDING STARK LAW VIOLATIONS**

- **IS THIS COMPOUNDING?** NO. WE USE SINGLE DIGIT NDC TO ACCOMPLISH THE SAME THING IN COMBINATION
- **Cost to Physician?** Simple structure ZERO OUT OF POCKET COST
- **What states are you NOT operating in at this time?** TX UT MA NY KY NJ SC AL MS
Over 120 Doctors are currently LIVE in this program and every practice who contributes prescriptions is in profit.

Contact Gary Rees for details about the pharmacy program:

Gary@becomethepharmacy.com 888-585-0760

**Not available in Utah/Texas/New York/New Jersey/Alabama/South Carolina/Massachusetts or Mississippi**

For information regarding clinical studies contact Dr. Cemak: dr.cemak@gmail.com
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