Outpatient Update on Dermatology for the Internist

Daniel J. Sheehan, MD
Associate Professor of Dermatology
Georgia Regents University
Conflicts of Interest

• I have none.
Agenda

• Cost considerations
• Inflammatory conditions
• Infectious conditions
• Neoplastic conditions
Case Illustration - Cost Problem

- Patient with contact dermatitis (poison ivy) comes to your office
- Patient has health insurance and prescription drug coverage
- You prescribe a strong topical steroid - generic clobetasol cream
- Patient calls back saying his cost, after insurance coverage, is $540
ARS. Case Illustration - Cost Problem

What do you do?

A. Ask him to pay the $540?  2%
B. Prescribe another weaker generic steroid you know is less likely to work (but might also not be “covered”)?  17%
C. Use a “name brand” strong topical steroid from a mail pharmacy for $75?  23%
D. Prescribe systemic steroids (which you think will be much cheaper) even though you may have safety concerns about them and the dermatitis may not justify the systemic therapy?  57%
Cost of Medications – Paradigm Shifting

• Old paradigm:
  • Generic medications are affordable and “covered” by insurance.

• New paradigm:
  • Generic medications are very expensive and often not “covered.”
  • Cost of doxycycline generic increased “6000%” in one year
    • $0.06 per pill to $3.65 per pill

Cost of Medications

• Illustration of new paradigm

• Me: prescription written for desonide cream

• Insurance company: “we have reviewed your request for desonide 0.05% cream... and we denied your request.”
Cost of Medications

• I routinely see similar issues with other “generics”:
  • Topical clindamycin
  • Topical steroids
  • Topical antimicrobials (permethrin)

• Problems:
  • Patient does not get better
  • My staff spends lots of time churning the paperwork
Cost of Medications Going up – Why?

• “Soaring prices cause dermatologist to rethink common therapies”
  • Drug manufacturer “industry consolidation”
  • Supply disruptions, production lapses (“FDA crackdowns”)
  • Pharmacies risk “substantial losses”

https://www.aad.org/dw/monthly/2015/may/gargantuan-growing-generic-prices
Cost of Medications

• “Bernie Sanders is unleashing a plan to make prescription drugs cheaper”
  • “generic drug prices have nearly quadrupled in the last five years”
  • He wants rebates paid back to the federal government by the manufacturers

http://www.vox.com/2015/5/19/8624879/sanders-prescription-drug-prices
Cost of Medications

In regards to health insurance companies:

“Imagine being in an industry where you can charge people for a service, and then after they have paid you, you decide that you’re not going to provide that service. Unfortunately, there is a lack of control over what the insurance companies are able to do because there is a lot of fine print. Our patients end up being the losers.”

Mark Lebwohl, MD (President of the AAD)

Dermatology World (www.aad.org/dw)

June 2015
How do we work through these issues?

• “Traveler, there is no way; the way is made by traveling. By traveling you make the way, and after passing you look back and see the way which will never again be traveled. Traveler, there is no way; only your wake in the waters of the sea.”

• Antonio Machado, Spanish poet, quoted by my mentor Omar Sangueza, MD in the American Journal of Dermatopathology
My Approach to Prescription Medications

• I ask myself:
  • Is there some way to help the patient without Rx medication?
  • Do I want the patient to get better?
My Response

• Work with what you have
  • Some insurers: free reign to prescribe what you feel is best for the patient
  • Others: very few choices

• Empower the patient
  • GoodRx
  • “App” for smartphone
My Response

• Get creative
  • Look for low cost suppliers of medications
    • One pharmaceutical supplier
    • $25 for cash-paying patients for:
      • Doxycycline hyclate
      • Sodium sulfacetamide 8%
      • Benzoyl peroxide foam or wash
      • Metronidazole 0.75% gel
My Response

• Shop around
  • Metronidazole topical (self-pay prices)
    • $25 (0.75% gel from a pharmacy in Arizona)
    • $50 (1% gel from a pharmacy in New York)
    • $75 (1% cream from a pharmacy in Pennsylvania)
My Response

• Shop around
  • Tretinoin (self-pay prices)
    • $50 (0.0025% gel with clindamycin phosphate 1.2% from a pharmacy in Pennsylvania)
My Response

• Get creative
  • Look for free medications
    • Ciprofloxacin, sulfa, amoxicillin
  • Grocery retailers
Acne

• Traditional therapies
  • Topicals
    • Tretinoin
    • Clindamycin
  • Oral meds
    • Doxycycline
    • Minocycline
    • Sulfamethoxazole
    • Isotretinoin

• Newer medications
  • Topical dapsone
Acne

• Dapsone 5% gel
• FDA approved for the topical treatment of acne vulgaris
• Safety concern: what about hemolysis in patients who are G6PD deficient? Peripheral neuropathy?
  • No evidence of clinically relevant hemolysis or anemia in these patients
  • Combining it with trimethoprim/sulfamethoxazole may increase risk of hemolysis in patients with G6PD deficiency
  • No evidence of peripheral neuropath in clinical trials
  • Most common adverse reaction was peeling, erythema at application site
Rosacea

• Pathogenesis
  • Molecular pathways (cathelicidins, TLR2, “vanilloids”)
  • Demodex mites (activate toll-like receptors)

• Traditional therapies
  • Topicals
    • Metronidazole
    • Clindamycin

• Oral meds
  • Doxycycline (inhibit cathelicidins, block MMP synthesis)
  • Minocycline
  • Isotretinoin (interfere with neutrophil function)

• Newer topicals
  • Ivermectin
  • Brimonidine

_Cohen DE. Dermatology Focus. Spring 2015. 34(1): 7-10_
Rosacea

- **Ivermectin 1% cream**
  - Indicated for adults with inflammatory rosacea lesions
  - Use once daily
  - Mechanism:
    - Kills Demodex folliculorum mites
    - Anti-inflammatory effects (inhibits production of TNF-alpha and IL-1beta)
  - Concerns: cost, irritation

Scheinfeld N. 1% Ivermectin cream for the treatment of rosacea. SKINmed. 2015;13:222-224.
Rosacea

• Brimonidine 0.33% topical gel
  • First FDA-approved topical treatment for the facial erythema of rosacea
  • Results last up to 12 hours
  • Concerns: cost, irritation, possible lowering of blood pressure
Atopic Dermatitis

• Pathogenesis
  • Filaggrin gene (FLG)
  • Loss of function mutations
  • Causes epidermal barrier defects (not fully understood)

Atopic Dermatitis

• Non-prescription methods
  • Dilute bleach baths (supported in 2 studies)
    • Blocks NFkB-dependent genes in keratinocytes
    • Decreases disease severity score by 35-45% after 6 weeks
  • “wet wraps”

• Topical therapies
  • Corticosteroids
  • Pimecrolimus
  • Tacrolimus

Psoriasis
Psoriasis
Psoriasis

• New medications
• Secukinumab
• IL-17A antagonist (subcutaneous injection)
• Indicated for moderate to severe plaque psoriasis in patients who are candidates for systemic therapy or phototherapy
• Concern: cost
• Safety concerns
  • increased risks of minor infections (URI, candidiasis) in clinical trials
  • Need TB screen prior to therapy
  • Can exacerbate Crohn’s disease
  • Rare anaphylaxis or urticaria
  • Should not receive live vaccinations
Psoriasis

• Apremilast
  • Oral medication
  • PDE-4 inhibitor (inhibits degradation of cyclic adenosine monophosphate)
  • Indicated for moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
  • Concern: cost
  • Safety concerns: diarrhea, nausea, weight loss, depression

Dermatophytosis
Dermatophytosis
• Traditional topical therapies
  • Ciclopirox
• Traditional oral medications
  • Terbinafine
  • Itraconazole
Dermatophytosis

• New topical therapy
• Luliconazole 1% cream
  • Indicated for interdigital tinea pedis, tinea cruris, and tinea corporis
  • To be applied once daily for two weeks
Onychomycosis

• Traditional topical therapies
  • Ciclopirox nail lacquer
    • Was only topical agent FDA approved for more than a decade
    • Inhibits microbial metabolism

• Traditional oral medications
  • Terbinafine
    • Inhibits ergosterol synthesis

Onychomycosis

• New topical therapies
• Tavaborole 5% topical solution
  • FDA-approved for the treatment of onychomycosis of the toenails (July 2014)
  • Boron-containing compound (oxaboroles)
  • Protein synthesis inhibitor targeting fungal tRNA synthetase
  • Better able to penetrate nails than ciclopirox
  • Perhaps fungi are less “resistant” to it
  • May be good choice for those that have failed traditional agents

Onychomycosis

- Efinaconazole 10% solution
  - Indicated for the topical treatment of onychomycosis of the toenails
  - Once daily for 48 weeks using a brush applicator
Onychomycosis

• Other “old school” methods
  • Dilute vinegar water soaks
  • Dilute bleach water soaks
Scabies

- Infestation with *Sarcoptes scabiei*
- Estimates - it affects 300 million people worldwide per year
- Often very difficult to diagnosis
- Treatment compliance is often not good
- Treatment failures with permethrin cream are being seen
- Future directions for treatment?

Genital Warts (Condyloma Acuminata)

• HPV infection

• Traditional therapy
  • Cryosurgery
  • Topical imiquimod cream

• Newer topical therapy
  • Sinecatechins ointment 15%
  • Indicated for external genital and perianal warts (TID)
  • First botanical drug approved for prescription use in the U.S.
  • Mechanism of action “unknown”
Basal Cell Carcinoma
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Basal Cell Carcinoma

- Most common cancer in US
- 3 million cases per year
- All skin types
- Incidence doubling every 25 yrs
- Face is most common site

ASDS Currents. July-August 2015. (asds.net)
Basal Cell Carcinoma

• Why the increasing incidence?
• Our behavior in the sun is changing
• Percent of skin exposed in Men’s swimwear
  • 1900-1910: 23%
  • 1910-1930: 47%
  • 1940-2000: 89%

Basal Cell Carcinoma Treatment

- **Topical therapies**
  - 5-fluorouracil
  - Imiquimod
- **Radiation therapy**
- **Surgery**
  - Electrodeexcision and curettage
  - Cryosurgery
  - Excision
  - Mohs surgery
    - **Substantial cost saving (mean costs)**
      - Traditional excision in ambulatory surgical center 90% more expensive than Mohs
      - Traditional excision in hospital operating room 368% more expensive than Mohs

*ASDS Currents. July-August 2015. (asds.net)*
Basal Cell Carcinoma Treatment

- New chemotherapy
  - Vismodegib
    - FDA approved for the treatment of locally advanced or metastatic basal cell carcinoma
    - Oral small molecule inhibitor of the Hh pathway
    - Inhibits a G-protein coupled receptor called smoothened (SMO)
    - Concerns: cost, hair loss, loss of taste, weight loss, muscle spasms, fetotoxic, teratogenic

Basal Cell Carcinoma Treatment

• New chemotherapy
  • Vismodegib
Actinic Keratoses

• Ingenol mebutate
  • FDA approved for treatment of actinic keratoses
• FDA warning in August 2015 about severe allergic reactions and shingles associated with the use of this medicine
  • Throat tightness, difficulty breathing, swelling of the lips or tongue
  • Eye injuries – be careful with contact lenses
  • Avoid the mouth and lips
Melanoma
Melanoma
Melanoma Diagnosis

• New diagnostic testing
  • FISH
    • Neosite FISH analysis for ambiguous melanocytic lesions
    • Diagnostic discrimination between nevi and melanoma
    • Done on paraffin-embedded tissue
    • Sensitivity 86%
    • Specificity 90%
    • http://www.neogenomics.com/neosite-melanoma.htm
Melanoma Staging

• Is Sentinel Lymph Node biopsy helpful?
• “German trial argues against complete nodal dissection for SLN-positive melanoma”
  • A randomized, phase III trial in 483 patients with stage III melanoma and micrometastases in their sentinel nodes
  • Patients who did and did not undergo complete lymph node dissection were statistically indistinguishable with respect to distant metastases–free survival, recurrence-free survival, and melanoma-specific survival

Melanoma Treatment

- New chemotherapies for advanced melanoma
- RAF inhibitors
  - Vemurafenib
  - Dabrafenib
- MEK inhibitors
  - Trametinib
- Anti-CTLA-4 antibody
  - Ipilimumab

Questions?

My email
djs8582@yahoo.com

My office number
706-364-3223
Evaluation

- Please take < 90 seconds to evaluate this session.
- Time permitting, speaker will take questions following evaluation.
- Responses are not displayed and are important in maintaining high quality education.
The overall performance of the speaker:

1. Poor
2. Fair
3. Average
4. Good
5. Excellent

- Poor: 0%
- Fair: 0%
- Average: 4%
- Good: 19%
- Excellent: 77%
How well were the learning objectives met?

1. Poor
2. Fair
3. Average
4. Good
5. Excellent
Did speaker present a balanced view of therapeutic options?

1. Yes
2. No
3. N/A
How useful will this session be in your practice?

1. Poor
2. Fair
3. Average
4. Good
5. Excellent

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As a result of this program, do you intend to change your patient care?

1. Yes
2. No
Thank you!