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JDPA

Journal of Dermatology for Physician Assistants

Official Journal of the Society of Dermatology Physician Assistants

HELP YOUR PATIENT PUT HER

BEST SELFIE FORWARD

Experience

ALTRENO™ lotion

the **first** and **only** acne treatment that provides the proven efficacy of tretinoin in a hydrating **lotion**.[1,2]

Model shown is for illustrative purposes only.

See tolerability and efficacy results at ALTRENOHCP.com.

INDICATION

ALTRENO™ (tretinoin) lotion, 0.05% is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

IMPORTANT SAFETY INFORMATION

ALTRENO is for topical use only. Not for ophthalmic, oral, or intravaginal use.

Skin Irritation: Patients using ALTRENO may experience application site dryness, pain, erythema, irritation, and exfoliation. Depending upon the severity of these adverse reactions, instruct patients to use a moisturizer, reduce the frequency of the application of ALTRENO, or discontinue use. Avoid application of ALTRENO to eczematous or sunburned skin.

Ultraviolet Light and Environmental Exposure: Minimize unprotected exposure to ultraviolet light, including sunlight and sunlamps. Warn patients with frequent sun exposure and those with inherent sensitivity to sunlight to exercise caution. Use sunscreen and protective clothing over treated areas when exposure cannot be avoided.

Fish Allergies: ALTRENO contains soluble fish proteins. Use with caution in patients with known sensitivity or allergy to fish. Advise patients to contact their healthcare provider if they develop pruritus or urticaria.

Adverse Reactions: The most common adverse reactions in clinical trials were application site dryness (4%), pain (3%), erythema (2%), irritation (1%) and exfoliation (1%).

Nursing Women: It is not known whether topical administration of tretinoin could result in sufficient systemic absorption to produce detectable concentrations in human milk. The developmental health benefits of breastfeeding should be considered along with the mother's clinical need for ALTRENO and any potential adverse effects on the breastfed child from ALTRENO.

To report SUSPECTED ADVERSE REACTIONS, contact Customer Service at 1-800-321-4576 or the FDA at 1-800-FDA-1088 or fda.gov/medwatch.

Please see Brief Summary of Prescribing Information on preceding pages.

References: 1. Altreno lotion [package insert]. Bridgewater, NJ: Ortho Dermatologics a division of Bausch Health Companies, Bridgewater, NJ 08807 USA. **2.** Data on file. Ortho Dermatologics a division of Bausch Health Companies, Bridgewater, NJ 08807 USA.

Altreno™
(tretinoin) Lotion, 0.05%

Ortho | Dermatologics

BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use ALTRENO safely and effectively. See full prescribing information for ALTRENO.

ALTRENO™ (tretinoin) lotion, for topical use
Initial U.S. Approval: 1973

INDICATIONS AND USAGE

ALTRENO™ (tretinoin) lotion, 0.05% is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Skin Irritation

Patients using ALTRENO may experience application site dryness, pain, erythema, irritation, and exfoliation. Depending upon the severity of these adverse reactions, instruct patients to use a moisturizer, reduce the frequency of the application of ALTRENO, or discontinue use. Avoid application of ALTRENO to eczematous or sunburned skin.

Ultraviolet Light and Environmental Exposure

Minimize unprotected exposure to ultraviolet light including sunlight and sunlamps during the use of ALTRENO. Warn patients who normally experience high levels of sun exposure and those with inherent sensitivity to sun to exercise caution. Use sunscreen products and protective clothing over treated areas when sun exposure cannot be avoided.

Fish Allergies

ALTRENO contains soluble fish proteins. Use with caution in patients with known sensitivity or allergy to fish. Advise patients to contact their healthcare provider if they develop pruritus or urticaria.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In 2 randomized, double-blind, vehicle-controlled trials, subjects age 9 years and older applied ALTRENO or vehicle once daily for 12 weeks. The majority of subjects were White (74%) and female (55%). Approximately 47% were Hispanic/Latino and 45% were younger than 18 years of age. Adverse reactions reported by ≥1% of subjects treated with ALTRENO and more frequently than vehicle are summarized in Table 1.

Table 1: Adverse Reactions Reported by ≥1% of Subjects Treated with ALTRENO and More Frequently than Vehicle

Adverse Reactions n (%)		
	ALTRENO N=767	Vehicle N=783
Application site dryness	29 (4)	1 (<1)
Application site pain[1]	25 (3)	3 (<1)
Application site erythema	12 (2)	1 (<1)
Application site irritation	7 (1)	1 (<1)
Application site exfoliation	6 (1)	3 (<1)

[1]Application site pain defined as application site stinging, burning or pain.

Skin irritation was evaluated by active assessment of erythema, scaling, hypopigmentation, hyperpigmentation, itching, burning and stinging. The percentage of subjects who were assessed to have these signs and symptoms at any post baseline visit are summarized in Table 2.

Table 2: Application Site Tolerability Reactions at Any Post Baseline Visit

	ALTRENO N=760 Mild/Mod/Severe	Vehicle N=782 Mild/Mod/Severe
Erythema	51%	44%
Scaling	49%	30%
Hypopigmentation	12%	10%
Hyperpigmentation	35%	35%
Itching	35%	28%
Burning	30%	14%
Stinging	21%	8%

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Available data from published observational studies of topical tretinoin in pregnant women have not established a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. There are no data on ALTRENO use in pregnant women. The systemic levels following topical administration are lower than with administration of oral tretinoin; however, absorption of this product may result in fetal exposure. There are reports of major birth defects similar to those seen in infants exposed to oral retinoids, but these case reports do not establish a pattern or association with tretinoin-related embryopathy *(see Data)*.

Animal reproduction studies have not been conducted with ALTRENO. Topical administration of tretinoin in a different formulation to pregnant rats during organogenesis was associated with malformations (craniofacial abnormalities [hydrocephaly], asymmetrical thyroids, variations in ossification, and increased supernumerary ribs) at doses up to 0.5 mg tretinoin/kg/day, approximately 2 times the maximum recommended human dose (MRHD) based on body surface area (BSA) comparison and assuming 100% absorption. Oral administration of tretinoin to pregnant cynomolgus monkeys during organogenesis was associated with malformations at 10 mg/kg/day (approximately 100 times the MRHD based on BSA comparison and assuming 100% absorption) *(see Data)*.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of major birth defects, loss, and other adverse outcomes. The background risk in the U.S. general population of major birth defects is 2 to 4% and of miscarriage is 15 to 20% of clinically recognized pregnancies.

Data

Human Data

While available studies cannot definitively establish the absence of risk, published data from multiple prospective controlled observational studies on the use of topical tretinoin products during pregnancy have

not identified an association with topical tretinoin and major birth defects or miscarriage. The available studies have methodologic limitations, including small sample size and in some cases, lack of physical exam by an expert in birth defects. There are published case reports of infants exposed to topical tretinoin during the first trimester that describe major birth defects similar to those seen in infants exposed to oral retinoids; however, no pattern of malformations has been identified and no causal association has been established in these cases. The significance of these spontaneous reports in terms of risk to the fetus is not known.

Animal Data

Tretinoin in a 0.05% gel formulation was topically administered to pregnant rats during organogenesis at doses of 0.1, 0.3 and 1 g/kg/day (0.05, 0.15, 0.5 mg tretinoin/kg/day). Possible tretinoin malformations (craniofacial abnormalities [hydrocephaly], asymmetrical thyroids, variations in ossification, and increased supernumerary ribs) were observed at maternal doses of 0.5 mg tretinoin/kg/day (approximately 2 times the MRHD based on BSA comparison and assuming 100% absorption). These findings were not observed in control animals. Other maternal and reproductive parameters in tretinoin-treated animals were not different from control. For purposes of comparison of the animal exposure to human exposure, the MRHD is defined as 4 g of ALTRENO applied daily to a 60-kg person.

Other topical tretinoin embryofetal development studies have generated equivocal results. There is evidence for malformations (shortened or kinked tail) after topical administration of tretinoin to pregnant Wistar rats during organogenesis at doses greater than 1 mg/kg/day (approximately 5 times the MRHD based on BSA comparison and assuming 100% absorption). Anomalies (humerus: short 13%, bent 6%, os parietal incompletely ossified 14%) have also been reported when 10 mg/kg/day (approximately 50 times the MRHD based on BSA comparison and assuming 100% absorption) was topically applied to pregnant rats during organogenesis. Supernumerary ribs have been a consistent finding in rat fetuses when pregnant rats were treated topically or orally with retinoids.

Oral administration of tretinoin during organogenesis has been shown to induce malformations in rats, mice, rabbits, hamsters, and nonhuman primates. Fetal malformations were observed when tretinoin was orally administered to pregnant Wistar rats during organogenesis at doses greater than 1 mg/kg/day (approximately 5 times the MRHD based on BSA comparison). In the cynomolgus monkey, fetal malformations were reported when an oral dose of 10 mg/kg/day was administered to pregnant monkeys during organogenesis (approximately 100 times the MRHD based on BSA comparison). No fetal malformations were observed at an oral dose of 5 mg/kg/day (approximately 50 times the MRHD based on BSA comparison). Increased skeletal variations were observed at all doses in this study and dose-related increases in embryo lethality and abortion were reported in this study. Similar results have also been reported in pigtail macaques.

Oral tretinoin has been shown to be fetotoxic in rats when administered at doses 10 times the MRHD based on BSA comparison. Topical tretinoin has been shown to be fetotoxic in rabbits when administered at doses 4 times the MRHD based on BSA comparison.

Lactation

Risk Summary

There are no data on the presence of tretinoin or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. It is not known whether topical administration of tretinoin could result in sufficient systemic absorption to produce detectable concentrations in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ALTRENO and any potential adverse effects on the breastfed child from ALTRENO.

Pediatric Use

Safety and effectiveness of ALTRENO for the topical treatment of acne vulgaris have been established in pediatric patients age 9 years to less than 17 years based on evidence from two multicenter, randomized, double-blind, parallel-group, vehicle-controlled, 12-week trials and an open-label pharmacokinetic study. A total of 318 pediatric subjects aged 9 to less than 17 years received ALTRENO in the clinical studies [see *Clinical Pharmacology* and *Clinical Studies* in full Prescribing Information].

The safety and effectiveness of ALTRENO in pediatric patients below the age of 9 years have not been established.

Geriatric Use

Clinical trials of ALTRENO did not include any subjects age 65 years and older to determine whether they respond differently from younger subjects.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

A 2-year dermal mouse carcinogenicity study was conducted with topical administration of 0.005%, 0.025% and 0.05% of a tretinoin gel formulation. Although no drug-related tumors were observed in surviving animals, the irritating nature of the drug product precluded daily dosing, confounding data interpretation and reducing the biological significance of these results.

Studies in hairless albino mice with a different formulation suggest that concurrent exposure to tretinoin may enhance the tumorigenic potential of carcinogenic doses of UVB and UVA light from a solar simulator. This effect was confirmed in a later study in pigmented mice, and dark pigmentation did not overcome the enhancement of photocarcinogenesis by 0.05% tretinoin. Although the significance of these studies to humans is not clear, patients should minimize exposure to sunlight or artificial ultraviolet irradiation sources.

The genotoxic potential of tretinoin was evaluated in an in vitro bacterial reversion test, an in vitro chromosomal aberration assay in human lymphocytes and an in vivo rat micronucleus assay. All tests were negative.

In dermal fertility studies of another tretinoin formulation in rats, slight (not statistically significant) decreases in sperm count and motility were seen at 0.5 mg/kg/day (approximately 2 times the MRHD based on BSA comparison and assuming 100% absorption), and slight (not statistically significant) increases in the number and percent of nonviable embryos in females treated with 0.25 mg/kg/day and above (approximately the MRHD based on BSA comparison and assuming 100% absorption) were observed.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Distributed by:
Ortho Dermatologics, a division of Bausch Health US, LLC.
Bridgewater, NJ 08807 USA

U.S. Patent Number: 6,517,847

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JDPA Journal of Dermatology for Physician Assistants

EDITORIAL MISSION: The JDPA is the official clinical journal of the Society of Dermatology Physician Assistants. The mission of the JDPA is to improve dermatological patient care by publishing the most innovative, timely, practice-proven educational information available for the physician assistant profession.

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To read the JDPA publication's Ethics and Malpractice Statement, please visit https://jdpa.org/how-to-write-for-the-jdpa/

KEEP CURRENT WITH THE SDPA:

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Making Connections

Having been involved with the SDPA as a member and volunteer behind the scenes for many years, I have seen leaders come and go, policies adapted, initiatives introduced, and several changes embraced while others fleeting. Through all of these changes, one area that has remained constant is the importance and value of networking with fellow dermatology PAs. Initially, this process of networking and connecting with fellow SDPA members has been done at conferences and leadership retreats. Some of the connections have turned into long-standing friendships, some of which have even extended to include families of fellow SDPA members. These conferences and retreats have always been something I look forward to – reconnecting with cherished colleagues. My family also looks forward to reconnecting with those SDPA families they have met and continue to see on a yearly basis at conferences. Despite living in different states, our children have grown up knowing one another, and look forward to reconnecting with their conference friends.

Technology has made it possible to extend the time of these connections to not simply being when we are face to face at conferences. The use of conference calls, email, texting, and various apps makes it easier to stay connected and in touch in between the face-to-face meetings. I have seen this carry over and include not only connections being maintained with those SDPA friends and colleagues I have met face to face- but also to include those I have yet to meet. I have had the opportunity to be connected with fellow SDPA members through a mutual contact when I have needed to find a good quality healthcare provider to recommend a patient to when he/she is relocating to another state. Initially, it seemed as though making these connections online/virtually took away some of the valued personal element of meeting fellow PAs at conferences. However, as time has gone on I have realized the importance of us connecting and uniting via technology to further strengthen the unity of our dermatology PA profession. This layer of networking and connecting with one another through technology makes it possible to achieve tasks that in the past we would have had to wait to tackle once or twice a year at conferences.

An excellent example of the positive application of this type of connecting is the recently launched program called, SDPA Connect – an online forum for SDPA members to connect with one another and offer advice relating to anything that is on your mind right now. This is a forum for new and veteran PAs to share their experiences, opinions, support, and knowledge with one another. While there is nothing quite like traveling to a beautiful destination and spending time connecting and learning with fellow SDPA members at a conference, Connect is providing a platform to fill in the gaps in those in between times. I look forward to continuing to meet fellow SDPA members in person at conferences and virtually through Connect. This truly is an exciting time to be a dermatology PA.

Travis Hayden, MPAS, PA-C
JDPA Editor in Chief
editor@jdpa.org

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CALENDAR OF EVENTS

2019

NOVEMBER
SDPA 17th Annual Fall Dermatology Conference
November 21–24, 2019
The Westin Kierland Resort & Spa
Scottsdale, AZ

2020

MARCH
AAD Annual Meeting
March 20–24, 2020
Denver, CO

MAY
SDPA Annual Summer Dermatology Conference
May 13–17, 2020
Hyatt Regency Denver at Colorado Convention Center
Denver, CO

AUGUST
AAD Summer Meeting
August 13–16, 2020
Seattle, Washington

OCTOBER
SDPA Annual Fall Dermatology Conference
October 29–November 1, 2020
InterContinental Miami
Miami, Florida

Empower. Educate. Advance.
The Future of Dermatology

FROM THE SDPA
NEWS & CURRENT AFFAIRS

Greetings Colleagues,

Let me start by saying that I was honored to be elected President of the SDPA, in which my term began at the beginning of July. As I progress through my presidential year, I am looking forward to working with my fellow dermatology PAs and SDPA Board members. I know that it takes a village to be successful and understand that I could not be in this position if it wasn't for the team. It is the team that moves things forward, whether it be in our offices or in our careers and profession.

I started my term with our SDPA leadership retreat in Charleston, SC. We emphasized positivity, success, and teamwork. Along with serving, these are the pillars of my term that I hope to utilize and move our Society forward.

I am lucky to have such a great team in all aspects of my life. From my family, to the Society and most importantly in my career, every one of my team members has played a crucial role in my life.

As for my career, my team begins with my two collaborating physicians who support my endeavors and leadership goals and dreams. My physicians are accommodating with my schedule so that I have the ability to serve my fellow dermatology PAs in my new role.

Alongside these great physicians, I am also surrounded by three brilliant dermatology PAs. Each and every day these ladies allow me to share patient cases, challenging diagnoses, and simply their friendship. My office staff has also been supportive and encouraging. My first day as President, I was welcomed with a decorated desk with confetti and balloons congratulating me on my accomplishment.

I also have the honor to work with such an incredible team of dermatology PAs on the SDPA Board of Directors and Committee Chairs who are dedicated to the success of our membership. We are extremely proud and excited to bring to our members this year the launch of the Leadership Academy to encourage other SDPA members to share their talents with our team.

As President Reagan once said, "There is no limit to the amount of good you can do if you don't care who gets the credit". So, I encourage each of you to appreciate the individuals surrounding and supporting you every day. The majority of us could not provide the exceptional patient care if we did not have our team members of physicians, PAs, nurses, and office staff to work along our side.

Speaking of teamwork, the SDPA has teamed up with the AAPA over the years to help educate members on legislative affairs affecting the PA profession. The SDPA has also teamed up with its state affiliate chapters to promote the dermatology PA profession. It is this teamwork that will drive our profession forward within this ever-changing healthcare market. We are all PAs and as David Mittman, President of AAPA stated, "We are all family."

In closing, the SDPA is celebrating twenty-five years as an association. This great accomplishment could not have been achieved without the teamwork and efforts from our fellow dermatology PA volunteers and leaders. I encourage our members to continue to work hard and work together as a team to continue to move our profession and association forward. Thank you to ALL my team members for your support and allowing me to be your President. Let's continue to build our team for another twenty-five years.

Best,

Gina D. Mangin

Gina Mangin, MPAS, PA-C
President SDPA
Diplomate SDPA

Dermatology Market Watch

MyPaTH Story Booth Opportunity

PaTH Network University of Pittsburgh UPMC

MyPaTH StoryBooth

Many people do not understand the challenges that individuals with ichthyosis or other related skin types face; we hope that the Story Booth project can help combat that problem by amplifying the voices of individuals and families who are dealing with ichthyosis. Stories are conveniently collected over the phone and take about 45 minutes to complete.

The PaTH Clinical Data Research Network is conducting a research study and wants to know about patients' experiences with health and illness. By sharing these stories with researchers, we hope to focus research on topics that are of importance to patients and likely to improve health and health care. Using MyPaTH Story Booth patients can record a conversation to share with researchers. We'd love to hear your point of view.

How: Share your story by phone

Who: If you are 18 years or older and able to read and understand English you may be eligible

Phone: 412-864-3025

Email: mystory@pitt.edu

Facebook: MyPaTH Story Booth

Twitter: @ThePaTHNetwork

Story Booth stories can...

1. Draw attention to people's experiences as patients or caregivers in the health care setting and/or help people learn more about ichthyosis or other related skin types.
2. Give a voice to people who are under-represented or under-served by the research community
3. Inspire research projects that try to improve the way health care is delivered
4. Support FIRST's advocacy missions *(we share stories back to partnering community groups when storytellers indicate an interest in doing so)*

Our project is funded by the Patient-Centered Outcomes Research Institute to develop an online searchable story archive that empowers patients and aims to foster more patient-centered healthcare. We hope you will consider partnering with us! For more information about participating in MyPaTH Story Booth, email mystory@pitt.edu

Please visit the following website to listen to participant's stories: http://pathnetwork.org/Community/story_booth.html

What Do You Want To Read About In The JDPA?

We're interested in knowing what kind of articles SDPA members would be interested in reading more about in order to help improve their practice of dermatology.

Share your content ideas today.
Email them to editor@jdpa.org

JDPA
Journal of Dermatology for Physician Assistants

Once-daily

Seysara®

(sarecycline) tablets

Not an actual patient, results may vary.

INTRODUCING SEYSARA, A NOVEL ORAL TETRACYCLINE DEVELOPED SPECIFICALLY FOR MODERATE TO SEVERE ACNE PATIENTS AS YOUNG AS 9.[1]

For more information, visit SEYSARA.com

***STUDY DESIGN:** The safety and efficacy of SEYSARA was assessed in two identically designed, 12-week, multicenter, randomized, double-blind, placebo-controlled trials. In both studies, SEYSARA was administered orally once-daily for 12 weeks as 60 mg, 100 mg, or 150 mg tablets, based on patient weight.

***STUDY RESULTS:** Mean absolute reduction (co-primary endpoint) was 15.3 in study 1 (SC1401) and 15.5 in study 2 (SC1402) vs 10.2 and 11.1 in the placebo groups at Week 12, respectively. 21.9% of ITT patients in study 1 and 22.6% of ITT patients in study 2 achieved IGA success (co-primary endpoint; defined as ≥2-point improvement from baseline in IGA scale for inflammatory lesions of acne, and a score of 0 [clear] or 1 [almost clear]) at Week 12 vs 10.5% and 15.3% of patients with placebo, respectively (p<.0001 for study 1 and p=.0038 for study 2).

INDICATIONS AND USAGE

SEYSARA (sarecycline) tablet, is indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.

Limitations of Use: Efficacy of SEYSARA beyond 12 weeks and safety beyond 12 months have not been established. SEYSARA has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, SEYSARA should be used only as indicated.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

SEYSARA is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.

WARNINGS AND PRECAUTIONS

- The use of SEYSARA during **tooth development** (second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown).
- ***Clostridium difficile* associated diarrhea (CDAD)** has been reported with nearly all antibacterial agents, and may range in severity from mild diarrhea to fatal colitis. If *Clostridium difficile* Associated Diarrhea (antibiotic associated colitis) occurs, discontinue SEYSARA.

WHAT DO I SAY TO PATIENTS FRUSTRATED WITH ACNE?

I SEYSARA®

TOUGH ON ACNE.

- Significant inflammatory lesion count reduction at Week 12, and as early as Week 3[1,*]

EASY ON PATIENTS.

- Convenient once-daily dosing, with 3 weight-based strengths; with or without food[1]

— With a demonstrated safety profile[1] —

- **Central nervous system side effects,** including light-headedness, dizziness or vertigo, have been reported with tetracycline use. Patients who experience these symptoms should be cautioned about driving vehicles or using hazardous machinery. These symptoms may disappear during therapy and may disappear when the drug is discontinued.
- **Intracranial hypertension** in adults and adolescents has been associated with the use of tetracyclines. Clinical manifestations include headache, blurred vision and papilledema. Although signs and symptoms of intracranial hypertension resolve after discontinuation of treatment, the possibility for sequelae such as visual loss that may be permanent or severe exists. Concomitant use of isotretinoin and SEYSARA should be avoided because isotretinoin, a systemic retinoid, is also known to cause intracranial hypertension.
- **Photosensitivity** manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using SEYSARA.
- **Bacterial resistance** to tetracyclines may develop in patients using SEYSARA. Because of the potential for drug-resistant bacteria to develop during the use of SEYSARA, it should only be used as indicated.
- As with other antibiotic preparations, use of SEYSARA may result in overgrowth of non-susceptible organisms, including fungi. If **superinfection** occurs, SEYSARA should be discontinued and appropriate therapy instituted.

ADVERSE REACTIONS

Most common adverse reaction (incidence ≥ 1%) is nausea.

PLEASE TURN THE PAGE FOR BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION.

IGA, investigator's global assessment; reflects the investigator's overall general assessment of the quantity and quality of inflammatory lesions (range 0-4 with 0 being clear and 4 being severe).

ITT, intent-to-treat.

Reference:
1. SEYSARA [package insert]. Exton, PA: Almirall, LLC, 2018.

USSEY0311c 05-2019

almirall

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION FOR SEYSARA® (sarecycline)

This brief summary does not include all the information needed to use SEYSARA safely and effectively. See full Prescribing Information for SEYSARA (sarecycline) tablets for oral use.

INDICATIONS AND USAGE

SEYSARA® (sarecycline) tablet, is indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.

Limitations of Use: Efficacy of SEYSARA beyond 12 weeks and safety beyond 12 months have not been established. SEYSARA has not been evaluated in the treatment of infections.

To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, SEYSARA should be used only as indicated *[see Warnings and Precautions]*.

CONTRAINDICATIONS

SEYSARA is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.

WARNINGS AND PRECAUTIONS

Teratogenic Effects

- SEYSARA, like other tetracyclines, can cause fetal harm when administered to a pregnant woman. If SEYSARA is used during pregnancy or if the patient becomes pregnant while taking SEYSARA, the patient should be informed of the potential hazard to the fetus and treatment should be stopped immediately.
- The use of drugs of the tetracycline-class during tooth development (second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). This adverse reaction is more common during long-term use of these drugs, but has been observed following repeated short-term courses. Enamel hypoplasia has also been reported.
- All tetracyclines form a stable calcium complex in any bone-forming tissue. A decrease in fibula growth rate has been observed in premature human infants given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was shown to be reversible when the drug was discontinued. Results of animal studies indicate that tetracyclines cross the placenta, are found in fetal tissues, and can cause retardation of skeletal development on the developing fetus. Evidence of embryotoxicity has been noted in animals treated with SEYSARA during pregnancy in association with maternal toxicity *[see Use in Specific Populations]*.

***Clostridium difficile* Associated Diarrhea (Antibiotic Associated Colitis)**

Clostridium difficile associated diarrhea (CDAD) has been reported with nearly all antibacterial agents, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to potential overgrowth of *C. difficile.*

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* should be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

Central Nervous System Effects

Central nervous system side effects including light-headedness, dizziness or vertigo have been reported with tetracycline use. Patients who experience these symptoms should be cautioned about driving vehicles or using hazardous machinery. These symptoms may disappear during therapy and may disappear when the drug is discontinued.

Intracranial Hypertension

Intracranial hypertension in adults and adolescents has been associated with the use of tetracyclines. Clinical manifestations include headache, blurred vision and papilledema. Although signs and symptoms of intracranial hypertension resolve after discontinuation of treatment, the possibility for sequelae such as visual loss that may be permanent or severe exists. Women of childbearing age who are overweight have a greater risk for developing intracranial hypertension. Patients should be questioned for visual disturbances prior to initiation of treatment with tetracyclines. Concomitant use of isotretinoin and SEYSARA should be avoided because isotretinoin, a systemic retinoid, is also known to cause intracranial hypertension *[see Drug Interactions]*. If visual disturbance occurs during treatment, patients should be checked for papilledema.

Photosensitivity

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using SEYSARA. If patients need to be outdoors while using SEYSARA, they should wear loose-fitting clothes that protect skin from sun exposure and discuss other sun protection measures with their physician.

Development of Drug Resistant Bacteria

Bacterial resistance to tetracyclines may develop in patients using SEYSARA. Because of the potential for drug-resistant bacteria to develop during the use of SEYSARA, it should only be used as indicated.

Superinfection/Potential for Microbial Overgrowth

As with other antibiotic preparations, use of SEYSARA may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, SEYSARA should be discontinued and appropriate therapy instituted.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

A total of 1064 subjects and 1069 subjects with moderate to severe acne vulgaris were treated with SEYSARA and placebo, respectively, for 12 weeks in 3 controlled clinical trials. The only adverse drug reaction that was reported in at least 1% of subjects was nausea, SEYSARA (3.1%) versus placebo (2.0%).

The following additional adverse drug reactions occurred in less than 1% of female SEYSARA subjects: vulvovaginal mycotic infection (0.8%) and vulvovaginal candidiasis (0.6%).

DRUG INTERACTIONS

Effect of Other Drugs on SEYSARA

Oral Retinoids: Tetracyclines may cause increased intracranial pressure as do oral retinoids, including isotretinoin and acitretin *[see Warnings and Precautions]*. Avoid coadministration of SEYSARA with oral retinoids.

Antacids and Iron Preparations: Coadministration with antacids containing aluminum, calcium or magnesium, bismuth subsalicylate, and iron-containing preparations may impair absorption of SEYSARA, similar to other tetracyclines, which may decrease its efficacy. Separate dosing of SEYSARA from antacids containing aluminum, calcium or magnesium, bismuth subsalicylate, and iron-containing preparations.

Effect of SEYSARA on Other Drugs

Penicillin: Similar to other tetracyclines, SEYSARA may interfere with the bactericidal action of penicillin. Avoid coadministration of SEYSARA with penicillin.

Anticoagulants: Similar to other tetracyclines, SEYSARA may depress plasma prothrombin activity, which may increase the risk of bleeding in patients who are on anticoagulant therapy. Decrease anticoagulant dosage when coadministered with SEYSARA as appropriate.

P-Glycoprotein (P-gp) Substrates: Concomitant use of SEYSARA may increase concentrations of concomitantly administered P-gp substrates (e.g. digoxin). Monitor for toxicities of drugs that are P-gp substrates and may require dosage reduction when given concurrently with SEYSARA.

Oral Hormonal Contraceptives: There is no clinically significant effect of SEYSARA on the efficacy of oral contraceptives containing ethinyl estradiol and norethindrone acetate.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary: SEYSARA, like tetracycline class drugs, may cause fetal harm, permanent discoloration of teeth, and reversible inhibition of bone growth when administered during pregnancy *[see Warnings and Precautions and Use in Specific Populations]*. The limited available human data are not sufficient to inform a drug-associated risk for birth defects or miscarriage. Tetracyclines are known to cross the placental barrier; therefore, SEYSARA may be transmitted from the mother to the developing fetus. In animal reproduction studies, sarecycline induced skeletal malformations in fetuses when orally administered to pregnant rats during the period of organogenesis at a dose 1.4 times the maximum recommended human dose (MRHD) of 150 mg/day (based on AUC comparison). When dosing with sarecycline continued through the period of lactation, decreases in offspring survival, offspring body weight, and implantation sites and viable embryos in offspring females occurred at a dose 3 times the MRHD (based on AUC comparison). The potential risk to the fetus outweighs the potential benefit to the mother from SEYSARA use during pregnancy; therefore, pregnant patients should discontinue SEYSARA as soon as pregnancy is recognized.

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Lactation

Risk Summary: Tetracyclines are excreted in human milk. Because of the potential for serious adverse reactions on bone and tooth development in nursing infants from tetracycline-class antibiotics, advise a woman that breastfeeding is not recommended with SEYSARA therapy *[see Warnings and Precautions]*.

Females and Males of Reproductive Potential

Infertility: Avoid using SEYSARA in males who are attempting to conceive a child. In a fertility study in rats, sarecycline adversely affected spermatogenesis when orally administered to male rats at a dose 8 times the MRHD (based on AUC comparison).

Pediatric Use

The safety and effectiveness of SEYSARA have been established in pediatric patients 9 years of age and older for the treatment of moderate to severe inflammatory lesions of non-nodular acne vulgaris.

Safety and effectiveness of SEYSARA in pediatric patients below the age of 9 years has not been established. Use of tetracycline-class antibiotics below the age of 8 is not recommended due to the potential for tooth discoloration *[see Warnings and Precautions]*.

Geriatric Use

Clinical studies of SEYSARA did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

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Certification Review

All Those Things Inside the Skin You Might Have Forgotten

By James A. Van Rhee, MS, PA-C

Are you recertifying soon? Start your board review early. Each issue of the JDPA features one board question accompanied by a brief explanation of the answer along with any pertinent test taking tips. Best of luck!

QUESTION: A 30-year-old female, with a past history of polycystic ovarian syndrome, presents with 16 pound weight gain and rounding of her face. No signs of easy bruising, thinning of the skin, buffalo hump or purple striae. Physical examination is normal except for the rounding of the face. Admission labs are noted below.

WBC count	6.9 x 109/L		ACTH	<5.0 pg/mL
Hemoglobin	15.5 g/dL		Sodium	144 mEq/L
Hematocrit	45%		Potassium	4.0 mEq/L
Platelet count	191 x 109/L		BUN	10 mg/dL
Cortisol 8AM	14.3 µg/dL		Creatinine	0.7 mg/dL
Cortisol 10PM	14.6 µg/dL			

Which of the following laboratory results would be most helpful in confirming the most likely diagnosis for this patient?

A. Elevated plasma aldosterone and renin

B. Elevated urine metanephrine and VMA

C. Elevated plasma ACTH and negative cosyntropin stimulation test

D. Elevated urine free cortisol and negative dexamethasone suppression test

EXPLANATION: Cushing's syndrome results from prolonged, inappropriate exposure to excessive amounts of circulating free cortisol. Endogenous Cushing's syndrome can be ACTH dependent or independent. Presenting symptoms include fat redistribution and muscle wasting. An elevated cortisol is typically noted with loss of circadian rhythm. To confirm the diagnosis an elevated urine free cortisol and negative dexamethasone suppression test are noted. Addison's disease reveals hyperkalemia and hypoglycemia. Further laboratory testing that can aid in the diagnosis includes an elevated ACTH level and negative cosyntropin stimulation test. Elevated plasma aldosterone and renin are noted in primary aldosteronism or Conn syndrome. Elevated urine metanephrine and VMA are noted in pheochromocytoma.

The correct answer is D.

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OPTIONAL WORKSHOPS AVAILABLE!

Dermatology PAs in the Screening of Psoriasis Comorbidities

By Anna Hsu, MS, PA-C, Klaudia Konopka, MS, PA-C, David Lobo, MS, PA-C, Mary Matthews, MS, PA-C, Cierra Omlor, MS, PA-C, Rachel Samardak, MS, PA-C, Travis Hayden, MPAS, PA-C, Patricia Kriegisch Kondapi, MBA, MA, CCC-SLP

ABSTRACT

CONTEXT The debilitating presentation of psoriasis on the skin has caused many patients to seek care from a dermatology provider; however, it has become evident the inflammatory nature of the disease has repercussions that extend beyond the integumentary system. Because of the comorbidities associated with psoriasis, it has become important to know if dermatology physician assistants (PAs) are screening for these comorbidities appropriately.

OBJECTIVE To determine the extent of dermatology PAs' knowledge on the comorbidities of psoriasis, and how they screen for them. Also, to determine what types of educational resources dermatology PAs are using to stay up to date on current medical protocols.

DESIGN This study was a cross-sectional research design that utilized an anonymous online survey formatted using SurveyMonkey®. The survey was administered via secure email containing a hyperlink for participants to access the survey. The results from the survey were downloaded from the SurveyMonkey® website, then stored and analyzed using SPSS.

SETTING The survey was administered to 400 members of the SDPA who were attending the annual Fall 2018 Society of Dermatology Physician Assistants (SDPA). The survey was available during the entirety of the conference from October 31, 2018 to November 4, 2018.

PARTICIPANTS Dermatology physician assistants who attended the SPDA Fall 2018 Conference voluntarily completed the survey. A total of 105 participants completed the survey, while 92 participants met the inclusion criteria.

MAIN OUTCOME MEASURES In this study, the explanatory variables were the PAs' location, available educational resources, clinical setting, and years of experience, which were assessed using demographic questions. The response variable explored was whether PAs are being educated on screening methods for the comorbidities of psoriasis, and if they are putting this knowledge into practice. This was assessed using questions that asked the PAs about their level of knowledge of psoriatic comorbidities, and how comfortable they feel treating and screening comorbidities of psoriasis.

RESULTS It was found that the majority (75%) of dermatology PAs reported adequate to extensive knowledge of the comorbidities of psoriasis. Contrary to what was hypothesized, there was no statistical significance when comparing participants' years of experience to their perceived knowledge of comorbidities (P=.23). The level of participants' perceived knowledge of comorbidities, however, was found to have a significant impact on both the level of comfort (P<.001) and regular screening for psoriatic comorbidities (P<.001)

CONCLUSIONS As research continues to prove that psoriasis is a systemic inflammatory condition, adequate knowledge of psoriatic comorbidities is important for the holistic care of patients with psoriasis. This study demonstrated that regardless of years of experience, dermatology PAs are confident in their knowledge of psoriatic comorbidities, which was shown to have a greater impact on both comfort level and screening for comorbidities. Given this, it is important that dermatology PAs are properly educated on the screening methods and guidelines in regard to psoriatic comorbidities in order to enhance the overall care of this patient population.

» CME

This program has been reviewed and is approved for a maximum of .5 hours of AAPA Category I CME credit by the Physician Assistant Review Panel.

Approval is valid for 1 year from the issue date of October 2019. Participants may submit the self-assessment exam at any time during that period.

This program was planned in accordance with AAPA's CME Standards for Enduring Material Programs and for Commercial Support of Enduring Material Programs.

SDPA members may access the posttest at www.jdpa.org

Learning Objectives:

1. *Review the comorbidities known to be associated with psoriasis.*
2. *Discuss whether dermatology PAs are being educated on screening methods for the comorbidities of psoriasis and if they are putting this knowledge into practice.*
3. *Consider improving dermatology PAs perceived knowledge of the comorbidities of psoriasis in order to improve on their comfort level and regular screening of psoriatic comorbidities.*

INTRODUCTION

Psoriasis is a systemic inflammatory disease most notably characterized by the chronic skin appearance of erythematous plaques with a dry, silvery scale. The debilitating presentation of psoriasis on the skin causes many patients to seek care from a dermatology specialist; however, it is evident that the inflammatory nature of the disease has repercussions extending beyond the integumentary system.[1] Recognizing the comorbid diseases of psoriasis is essential for ensuring comprehensive care of patients with psoriasis. Because of these comorbidities associated with psoriasis, and the fact that many of these patients are initially seeking care from a dermatology specialist, it has become important to know if physician assistants (PAs) working in dermatology are screening for these comorbidities appropriately.

This investigation sought to determine the extent of dermatology PAs' knowledge on the comorbidities of psoriasis, and how they are screening for them. Additionally, this study explored various modes of learning dermatology PAs are using to stay up-to-date on current medical protocols. A survey was used to query dermatology PAs affiliated with the Society of Dermatology Physician Assistants (SDPA) about their demographic characteristics, years of experience, knowledge of psoriasis comorbidities, screening tests used for psoriasis comorbidities, and use of educational resources.

A full review of the clinical implications of the comorbid diseases that are associated with psoriasis and recommendations for their clinical management are beyond the scope of this article. The purpose of this study was to identify the knowledge and screening habits of dermatology PAs regarding psoriatic comorbidities as well as to determine the educational preferences and needs of dermatology PAs for future discussions and literature.

PSORIATIC COMORBIDITIES

A multitude of studies have linked psoriasis with significant comorbidities that increase with duration and severity of the condition, including: cardiovascular diseases, obesity, hypertension, diabetes, dyslipidemia metabolic syndrome, psychiatric illnesses such as anxiety and/or depression, malignancy such as non-Hodgkin lymphoma and cutaneous T cell lymphoma, pulmonary diseases such as sleep apnea and chronic obstructive pulmonary disease (COPD), and gastrointestinal disease such as nonalcoholic steatohepatitis (NASH), and psoriatic arthritis.[2,3,4] These comorbidities tend to have a significant impact on quality of life and increase the risk of mortality in patients.[1,5,6,7] Recognition of psoriasis as an inflammatory process has also led to the identification of environmental stressors, such as diet, that impact psoriasis severity.[8] Knowledge of psoriatic comorbidities, and stressors, that influence patient well-being has allowed for holistic treatment plans to target areas beyond the skin; however, adequate treatment relies on the acknowledgement and screening of psoriatic comorbidities by the patient's healthcare provider.[7] With increased recognition of comorbidities by their provider, patients with psoriasis will be able to receive preventative education, early disease recognition and improve long-term health outcomes.[9,10]

A systematic review compiled information from numerous studies to evaluate the burden of psoriasis by measuring the odds ratio of several cardiovascular (CV) risk factors.11 Odds ratios ranged from 1.18 (95% CI 1.14–1.23) to 5.49 (95% CI 3.09–9.74) for obesity, 1.30 (95% CI 1.1–1.4) to 5.92 (95% CI 2.78–12.8) for metabolic syndrome, 1.20 (95% CI 1.14–1.25) to 2.80 (95% CI 2.68–2.99) for diabetes, 1.00 (95% CI 1.0–1.3) to 2.09 (95% CI 1.23–3.54) for dyslipidemia, and 1.09 (95% CI 1.05–1.14) to 3.27 (95% CI 2.41–4.43) for hypertension.[11] The significant association between these conditions and psoriasis patients suggests these parameters should be evaluated on a routine basis. Another article concerning the diagnosis and management of psoriasis stated that 30% of patients had additional psoriatic arthritis, and 60% had some form of depression and/or anxiety. Based on these statistics, it is imperative that healthcare providers, especially dermatology providers, adequately screen patients due to the likelihood of having at least one other significant concern aside from their psoriasis.[4]

It is important that psoriatic comorbidities are properly followed by dermatology providers, as many psoriatic patients seek their care for skin treatment. Collaborations between dermatology providers and other specialists can then be used to optimize disease management.[12,13] Involvement of multiple providers is often crucial for control and monitoring of patients on systemic therapies to access both safety and long-term efficacy.[14] A panel consisting of 10 dermatologists with expertise in managing moderate-severe psoriasis, a cardiologist, and psychiatrist recommend referrals for adjunct specialty care only when abnormal parameters are noted by dermatology providers.[11] This recommendation requires that providers are educated on the risks, screenings and preventive measures for comorbidities, including appropriate lifestyle modifications.

To provide holistic treatment, it is essential for healthcare providers to be well-educated and up-to-date regarding current treatment and monitoring of psoriasis patients.[7] Guidelines have been posted by the American Academy of Dermatology (AAD) in an effort to screen for comorbidities and improve patient care.[7] Knowledge of screening guidelines has been shown to improve provider adherence, resulting in higher-quality care.[7] The guidelines have established a need for holistic management, such as lifestyle modifications, in addition to direct treatment methods.[1,11] Recent studies suggest that weight loss interventions, both dietary and surgical, can be preventive measures and adjunctive therapies for psoriasis and psoriatic arthritis.[15] The role of diet in the exacerbation of inflammatory processes is increasingly discussed in literature, and a study by Afifi et al sought to investigate the prevalence of diet modification in the management of psoriasis.[8] It found that the role of diet in disease management is believed to be very, or somewhat, important in 88.8% of psoriasis patients; however, only 30.7% report having discussed dietary changes with their dermatologist.[8] These findings suggest a lack of consideration in the clinical setting for factors that may impact the severity of disease in psoriasis patients.[8]

Research has also proven an increased risk in cardiovascular conditions, such as cardiovascular disease (CVD), peripheral vascular disease, atherosclerosis, hypertension, and dyslipidemia in individuals with psoriasis, and the National Psoriasis Foundation recommends screening beginning as early as age 20 for proper care.[16,17] A longitudinal study conducted between January 2013 and January 2016, by the National Institute of Health, demonstrated a correlation between the duration of psoriasis, and an increased risk for CVD. The study concluded that for each year a patient suffered from psoriasis, their risk of having a cardiovascular event increased by 1%.[16] The outcome of the study raises concern over whether comorbidities, such as CVD, are adequately evaluated by the patient's healthcare provider. This concern was investigated in a study, published by the Journal of the American Academy of Dermatology, which assessed the knowledge of CV risk factors in psoriasis patients by both cardiologists and primary care providers (PCPs), based on screening recommendations.[17] It was found that a majority (58%) of PCPs were not aware of the increased CV risk associated with psoriasis. In comparison, cardiologists were 2.5 times more likely to be aware of adverse CV outcomes among the psoriasis population, and 3.5 times more likely to screen for dyslipidemia.[17] The study also suggests that the likelihood for primary care physicians and cardiologists to screen for CV risks is highly associated with the amount of experience with psoriasis patients.[17] These results allow us to question whether CV risks, in addition to other comorbidities, are evaluated in a dermatology setting.

METHODS

A survey was used to determine the extent of dermatology PAs' knowledge on the comorbidities of psoriasis, how dermatology PAs screen for them, and what types of educational resources dermatology PAs are using to stay up to date on current medical protocols. The participants of this study were SDPA Fellow members (dermatology PAs practicing full-time or part-time in dermatology while collaborating with a board-certified dermatologist) who attended the SDPA 16th Annual Fall Dermatology Conference in Orlando, FL and completed the voluntary survey.[20] The study design was a cross-sectional research design that began October 31, 2018 and ended November 4, 2018. The study used an online survey formatted by SurveyMonkey® and was administered via secure email containing a hyperlink to 400 members of the SDPA that were attending the SPDA 16th Annual Fall Dermatology Conference. The survey included questions regarding participants' clinical setting, years of experience, level of knowledge of the comorbidities of psoriasis, screening and management of comorbidities, and educational preferences. A total of 105 participants completed the survey, while 92 participants met the inclusion criteria.

For the statistical analysis at the conclusion of our survey, we assessed the proportion of dermatology PAs that consider comorbidities when caring for patients with psoriasis and determined what those comorbidities are, in addition to assessing the preferred methods of learning for PAs, and topics of interest for continued learning. We also assessed PA comfort in identifying comorbidities and performed an odds ratio to determine any association with PA methods used to screen comorbidities. Odds ratios was calculated to determine if there are additional associations between PA's location, clinical setting, age range, years of experience, experience in clinical fields other than dermatology, percentage of time spent managing patients with psoriasis and how PAs apply the knowledge of comorbidities into practice based on screenings, adjustment of pharmacological treatments, and referrals. Logistic regression analysis was then performed to form associations between preferred methods of continuing education for dermatology PAs and how they screen and treat for comorbidities in psoriasis patients.

RESULTS

After data analysis of the survey results, it was found that 75% of the dermatology PAs who participated in the survey reported having adequate to extensive knowledge of the comorbidities of psoriasis. Of the various psoriatic comorbidities, psoriatic arthritis was found to be the most well understood, followed by anxiety and depression, obesity and cardiovascular disease. Contrary to what was hypothesized (that dermatology PAs with greater years of experience would be more knowledgeable on the comorbidities of psoriasis and regularly screen their patients for these comorbidities), no statistical significance was identified when comparing participants' years of experience to their perceived knowledge of comorbidities (P=.23) or whether the dermatology PA regularly screened for comorbidities (P=.50). The level of participants' perceived knowledge of comorbidities, however, was found to have significant impact on the level of comfort (P<.001) and regular screening for psoriatic comorbidities (P<.001) *(summary of this data can be found in Table 1, Table 2, and Figure 1).*

Screening of Comorbidities - Over 50% of dermatology PAs who were surveyed reported regularly screening their patients with psoriasis for comorbidities. When asked what screening methods are used to assess psoriasis patients for comorbidities, 50 dermatology PAs responded that they use no screening methods (54.3%). Twenty-one dermatology PAs reported using a fasting lipid panel (22.8%), 18 have used screening questionnaires for psoriasis (19.6%), 13 have used BMI (14.1%), and 11 have used fasting serum glucose levels *(see Figure 2).*

Management of Comorbidities - Of the dermatology PAs who were surveyed, 64 reported they have adjusted pharmacological treatment based on comorbidities of psoriasis (69.6%). Eighty-eight dermatology PAs reported they have referred their patients with psoriasis to respective specialists for follow-up regarding comorbidities (95.7%).

Preferred Modes of Learning - To assess the educational needs and preferences of dermatology PAs, participants were asked to report up to 3 topics preferred for continuing education. Long-term management of patients with psoriasis was the most preferred topic by 61 individuals of the sample population (66.3%). Screening guidelines for psoriatic comorbidities and psoriasis treatment algorithms were also highly preferred by 57 (62.0%) and 50 (54.3%) respondents, respectively. Forty-two participants preferred learning about special scenarios in psoriasis (45.7%) *(see Figure 3).* To determine what method of continuing education is favored by dermatology PAs, participants were asked to indicate their preferred mode of learning using a Likert scale. Medical conferences were the most preferred among the participants with 55 PAs (59.8%) indicating this mode of learning. *(see Figure 4).*

Does knowledge of psoriatic comorbidities impact the care of psoriatic comorbidities? - It was found that the higher the perceived knowledge of psoriatic comorbidities, the more comfortable the dermatology PA felt in identifying a patient with psoriatic comorbidities (P<.001). Regarding comorbidity screening, 45 of the 50 dermatology PAs that responded "yes" to regularly screening their patients with psoriasis for comorbidities had also rated their knowledge of these comorbidities as "adequate" or "extensive;" the higher the perceived knowledge the dermatology PA had, the more likely they were to screen for comorbidities (P<.001). A dermatology PA was also more likely to adjust pharmacological treatment due to comorbidities if they had a higher perceived knowledge of psoriasis comorbidities (P=.034). No significance was found between perceived knowledge of comorbidities and the likelihood for dermatology PAs to refer patients with psoriatic comorbidities to a specialist (P=.054).

Do years of dermatology experience impact the care of psoriatic comorbidities? - It was found that years of experience did not significantly impact the dermatology PA's perceived knowledge of comorbidities (P=.23), whether the dermatology PA regularly screened for comorbidities (P=.50), whether the dermatology PA adjusted pharmacological treatment due to comorbidities (P=.41), or whether the dermatology PA referred the patient with psoriatic comorbidities to a specialist (P=.30).

Does time spent managing patients with psoriasis impact the care of psoriatic comorbidities? - It was found that time spent managing patients with psoriasis did not significantly impact the dermatology PA's amount of perceived knowledge of psoriatic comorbidities (P=.89), screening for comorbidities (P=.48), adjustment of pharmacological treatment (P=.97), or tendency to refer patients to a specialist (P=.50).

Does the number of dermatology patients seen per day impact the care of psoriatic comorbidities? - It was found that the number of dermatology patients seen per day did not significantly impact the dermatology PA's amount of perceived knowledge of psoriatic comorbidities (P=.59), screening for comorbidities (P=.90), adjustment of pharmacological treatment (P=.34), or tendency to

refer patients to a specialist (P=.30).

Does dermatology practice location and setting impact the screening for psoriatic comorbidities? - It was determined that dermatology practice location did not significantly impact a dermatology PA's tendency (P=.18) nor methods used (P=.25) to screen patients for psoriatic comorbidities. It was also determined that the clinical setting did not significantly impact a dermatology PA's tendency (P=.16) nor methods used (P=.11) to screen patients for psoriatic comorbidities.

DISCUSSION

Due to the relationship between psoriasis and systemic comorbidities, this investigation sought to determine the knowledge dermatology PAs have of the comorbidities of psoriasis, as well as how they screen for these comorbidities. It was hypothesized that dermatology PAs with greater years of experience would possibly be more knowledgeable on the comorbidities of psoriasis and regularly screen their patients for these comorbidities. In addition, based on the lack of research and screening guidelines (at the time of this

Table 1. Years practicing as a dermatology PA and its impact on knowledge of psoriatic comorbidities and regularly screening for psoriatic comorbidities.

		Years practicing as dermatology PA					*P* Value
	Variable	<5	5 -10	11-15	>16	Total	
Perceived knowledge of comorbidities							
	Minimal	2	0	0		2	
	General	13	3	1		17	
	Adequate	39	7	2		48	
	Extensive	14	9	0		23	
	Total	68	19	3		90	0.29
Regularly screen for comorbidities							
	Yes	13	11	15	11	50	
	No	15	11	11	5	42	
	Total	28	22	26	16	92	0.51

Table 2. Dermatology PA's perceived knowledge of psoriatic comorbidities and the impact on comfort level in identifying and regularly screening for psoriatic comorbidities.

		Perceived knowledge of comorbidities					*P* Value
	Variable	Minimal	General	Adequate	Extensive	Total	
Comfort level identifying comorbidities							
	Not	2	0	0	0	2	
	Somewhat	0	3	6	0	9	
	Neutral	0	7	6	0	13	
	Moderately	0	10	34	5	49	
	Very	0	1	7	11	19	
	Total	2	21	53	16	92	<0.001
Regularly screen for comorbidities							
	Yes	0	5	30	15	50	
	No	2	16	23	1	42	
	Total	2	21	53	16	92	<0.001

Figure 1.
Dermatology PAs' perceived knowledge of various psoriatic comorbidities.

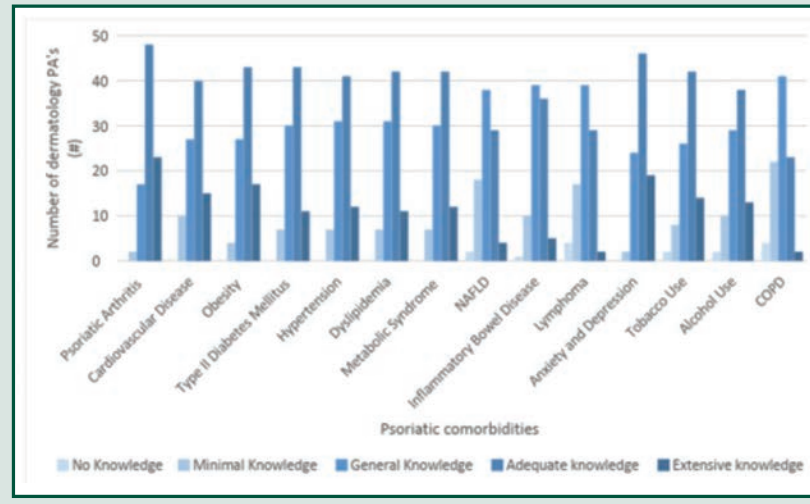


Figure 2.
Dermatology PAs' use of screening methods for psoriatic comorbidities.

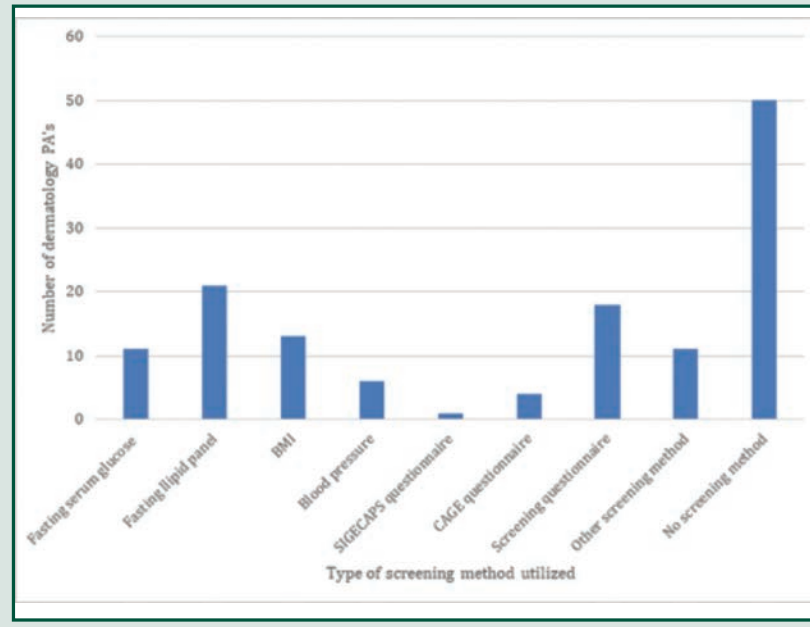


Figure 3.
Dermatology PAs' preferred topics for continuing medical education.

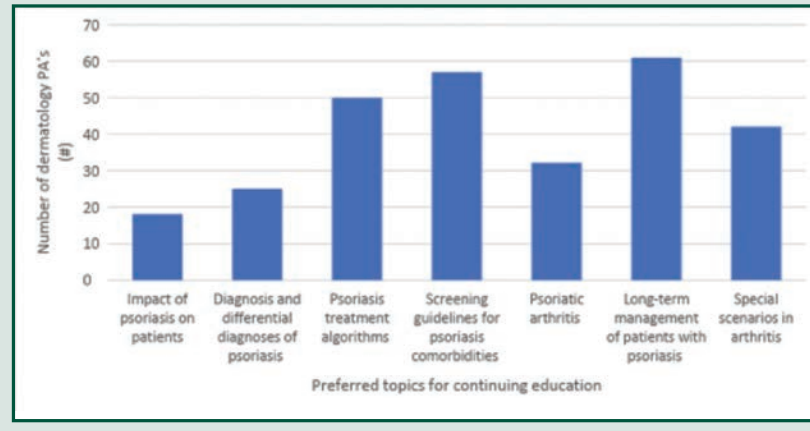
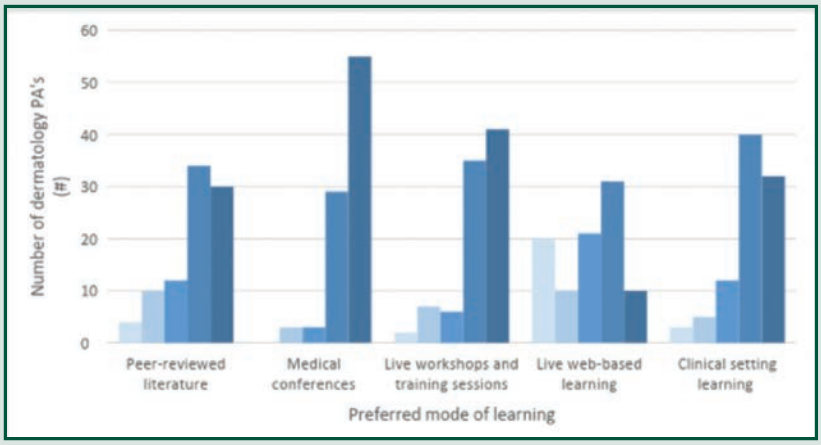


Figure 4. Dermatology PAs' reported preferences for various modes of continued learning.



study) for comorbidities in patients with psoriasis, it was hypothesized that more than 51% of dermatology PAs are not regularly screening for comorbidities when treating patients with psoriasis.

Analysis of the data derived from participant responses yielded several significant findings. It was found that the majority (75%) of dermatology PAs reported adequate to extensive knowledge of the comorbidities of psoriasis, and 74% of dermatology PAs also rated their comfort level of identifying comorbidities of psoriasis as moderately to very comfortable. Contrary to what was hypothesized, there was no statistical significance when comparing participants' years of experience to their perceived knowledge of comorbidities (P=.23). It was also found that years of experience did not significantly impact screening for comorbidities (P=.50), pharmacological adjustments (P=.41), or referral of patients with psoriatic comorbidities to respective specialists (P=.30). These findings suggest that regardless of years of experience, dermatology PAs are confident in their knowledge and ability to identify patients with psoriatic comorbidities.

Interestingly, 54.3% of dermatology PAs reported regularly screening for psoriatic comorbidities; however, when asked to specify screening methods used, the same percentage of participants indicated "no screening methods used" in their practice. This raises the question as to whether dermatology PAs are adequately and appropriately screening their patients for comorbidities. Among the highest reported screening tools used by dermatology PAs were lipid panels (22.8%), screening questionnaires for psoriasis (19.6%), BMI (14.1%), and fasting glucose (12.0%). The limited utilization of screening tools in dermatology practice may be a result of factors aside from level of knowledge including lack of definitive screening guidelines and overlapping of patient care with other healthcare providers.

It was found to be statistically significant that the more knowledge a dermatology PA has of psoriatic comorbidities, the more comfortable the PA feels in identifying and managing such comorbidities in their patients (P<.001). It was also found that the higher the perceived knowledge of psoriatic comorbidities a PA had, the more likely they were to screen for comorbidities (P<.001) and adjust pharmacological treatment (P=.034). This supports the importance and need for continued educational resources for dermatology PAs to strengthen their knowledge, recognition, and screening of psoriatic comorbidities, as well as enhance the overall care of patients with psoriasis.

In an attempt to understand the educational needs of dermatology PAs, this study also aimed to determine the type of educational resources and topics pertaining to psoriasis that are preferred by participants. Medical conferences were found to be the most preferred with 90% of respondents having strong or moderate preference, followed by live workshops and training sessions (82%). Live-web based learning was found to have the highest percentage of "not preferred." This finding was not expected as the use of online resources, which has grown exponentially over the recent years, allows for more efficient, timely, and conveniently accessible access to information for dermatology PAs.[19] The results suggest topics reviewed in the setting of conferences and training sessions are effective in impacting PAs practice and education. Among the most preferred continuing

education topics on psoriasis reported by dermatology PAs are long-term management of patients with psoriasis (66%), screening guidelines for comorbidities (62%), and psoriasis treatment algorithms (54%). This information aids in identifying the interests and educational needs of dermatology PAs for future conferences and medical discussions.

LIMITATIONS

The greatest limitations to this investigation are sample size, exclusion criteria, and that only conference attendees were surveyed. While nearly a quarter of SDPA members attending the SDPA 16th Annual Fall Dermatology Conference responded to the survey, the final sample consisting of 92 dermatology PAs limited the validity of the findings. Extending the window of availability and sending reminders to complete the survey in a separate email are factors that might have increased the number of respondents. Participants who were not currently practicing as dermatology PAs were also omitted from the data analysis. This potentially limited responses from those PAs attending the SDPA 16th Annual Fall Dermatology Conference who have previously worked in dermatology, who are unemployed, or who may work in primary care as the sole provider. In addition, only members of the SDPA that were in attendance at the conference were surveyed. This likely resulted in the finding that 90% of respondents chose medical conferences as their preferred mode of learning. Opening the survey to members of the SDPA that were not in attendance at the conference may have resulted in a different outcome.

RECOMMENDATIONS

The purpose of this study was to identify the knowledge and screening habits of dermatology PAs regarding psoriatic comorbidities as well as to determine the educational preferences and needs of dermatology PAs for future discussions and literature. The findings of the study suggest that maintaining dermatology PAs knowledge of the comorbidities of psoriasis is essential for the screening and management of patients with psoriasis, and adequate educational opportunities should be offered in the form of medical conferences or training sessions.

The findings regarding the screening methods utilized by dermatology PAs is reflective of the lack of screening guidelines for psoriatic comorbidities and is a potential hindrance to holistic management and care for patients with psoriasis. The use of various laboratory tests and measures to assess cardiovascular, metabolic, psychologic and other risk factors in the dermatology setting is a cause for debate due to the overlap with other specialties and primary care. The Journal of European Academy of Dermatology and Venereology published an article providing consensus regarding the management of comorbidities in patients with moderate-severe psoriasis from a panel of dermatologists with expertise in psoriasis.[11] The panel advised referrals be made to appropriate specialties when abnormal findings are noted first by dermatologists. Reaching a consensus for similar screening practices in the United States may be beneficial in regulating care for psoriasis patients, in addition to developing a standardized screening questionnaire.

While this study provides a glimpse of the knowledge and screening tendencies for psoriatic comorbidities by dermatology PAs, it lacks depth into how comorbidities are managed in a dermatology setting. Previous reports have suggested a particular need for discussion regarding diet and lifestyle changes of patients with psoriasis, and future research into how and if dermatology PAs utilize discussions such as these in practice is necessary to understand preventative and treatment measures for psoriatic comorbidities being carried out in dermatology settings.[8,11] After the conclusion of our investigation, in April 2019 the American Academy of Dermatology (AAD) joined by the National Psoriasis Foundation (NPF) published joint guidelines for the management and treatment of psoriasis and its comorbidities; the published report was titled *Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with awareness and attention to comorbidities.*[21] The new guidelines provide detailed and useful recommendations for the overall management of each psoriatic comorbidity. Future use of these guidelines in dermatology offices will most likely look to improve on the holistic care that patients with psoriasis receive, and in the end help to improve long-term outcomes for these patients.

CONCLUSION

The role of a PA in dermatology practice has drastically increased in the past decade in response to demands in dermatologic care.[18] With this changing dynamic in medicine, this study sought to determine the knowledge of dermatology PAs on the comorbidities of psoriasis and whether they screen for such comorbidities. The data from this study did not show any statistical significance between years of experience of dermatology PAs with their knowledge of comorbidities or frequency of screening for comorbidities. However, it did find that higher levels of knowledge of psoriatic comorbidities significantly impacted the participants' level of comfort

and screening for comorbidities. This finding suggests a need for continuing education topics in regard to the comorbidities of psoriasis.

With continued research proving that psoriasis is not only a disease of the skin, but a systemic inflammatory disease affecting many other organ systems, adequate knowledge of the comorbidities of psoriasis is important for the holistic care of patients with psoriasis.[1,11,21] Research has shown that when dermatology providers are properly educated on the risks, screening guidelines, and preventative measures for comorbidities of psoriasis, higher-quality care is the result.[7] In order to provide the best care for their patients, dermatology PAs must utilize the educational resources available and put this knowledge into practice. In April 2019, the American Academy of Dermatology (AAD) and the National Psoriasis Foundation (NPF) released joint guidelines on the management of psoriasis which includes discussions and recommendations for various comorbidities.[21] In addition to the development of the new guidelines, the AAD, NPF, and similar organizations would benefit both patients and providers by reviewing the guidelines and highlighting psoriatic comorbidities at medical conferences, as this was discovered to be the preferred mode of learning for dermatology PAs in this study. Availability of proper screening guidelines for dermatology PAs, may increase the utilization of screening tools in dermatology practices, as well as, patient referrals to appropriate specialists for the management of psoriatic comorbidities. Further investigation into this topic will benefit both dermatology PAs and patients with psoriasis, as increased screening and recognition of comorbidities by dermatology PAs may result in improved long-term patient outcomes.

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This study was approved by the IRB at Le Moyne College, Syracuse, NY.

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IN MODERATE-TO-SEVERE PLAQUE PSORIASIS

DEFY THE LAWS OF PSORIASIS

RESULTS WITH JUST A FEW DOSES[1,2]

- With **just 2 doses** at Week 12, 64% and 61% achieved PASI 75 (reSURFACE 1 and reSURFACE 2, respectively)
  - vs placebo: 6% and 6% (reSURFACE 1 and reSURFACE 2, respectively)
- With **just 3 doses** at Week 28, 74% and 70% achieved PASI 75 (reSURFACE 1 and reSURFACE 2, respectively)*

RESULTS THROUGH WEEK 64[1]

Based on PASI 75 responders at Week 28 (reSURFACE 1)

- 84% maintained PASI 75*
  - vs 22% placebo

LIGHTEN THE BURDEN OF FREQUENT DOSING[1,3]

- ILUMYA™ is dosed at Weeks 0, 4, and **every 12 weeks** thereafter

DURABLE SAFETY PROFILE[1]

64 WEEKS

- **Through Week 64**, the frequency of adverse reactions was similar to that during the placebo-controlled period of the trial, and no new adverse reactions were identified
- ILUMYA™ may increase the risk of infection
- The most common (≥1%) adverse reactions that were more frequent than in the placebo group are upper respiratory infections, injection-site reactions, and diarrhea

reSURFACE 1 and 2 were Phase 3, double-blind, placebo-controlled trials of ILUMYA™ given at Weeks 0, 4, and every 12 weeks thereafter. Patients in reSURFACE 1 (N=463) and reSURFACE 2 (N=463) with moderate-to-severe plaque psoriasis who were candidates for phototherapy or systemic therapy were randomized to ILUMYA™ 100 mg or placebo. At Week 28, patients in reSURFACE 1 initially randomized to ILUMYA™ who achieved at least PASI 75 were re-randomized to either continue initial treatment or to receive placebo up to 64 weeks. The co-primary endpoints of both trials were: 1) the proportion of subjects who achieved at least PASI 75 and 2) the proportion of subjects with a PGA 0 or 1 and at least a 2 point improvement, both at Week 12. Other evaluated outcomes included PASI 90/100 at Week 12 and PASI 75 at Week 28. reSURFACE 1 also measured maintenance of efficacy in responders up to Week 64.[1,2]

*These endpoints were considered "other" secondary endpoints in reSURFACE 1 and 2.

All results based on the recommended 100 mg dose of ILUMYA™.

PASI=Psoriasis Area and Severity Index; PGA=Physician Global Assessment.

INDICATION

ILUMYA™ (tildrakizumab-asmn) is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ILUMYA™ is contraindicated in patients with a previous serious hypersensitivity reaction to tildrakizumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity

Cases of angioedema and urticaria occurred in ILUMYA™-treated subjects in clinical trials.
If a serious allergic reaction occurs, discontinue ILUMYA™ immediately and initiate appropriate therapy.

ILUMYA™
tildrakizumab-asmn
Injection 100 mg/mL

VISIT ILUMYAPRO.COM

IMPORTANT SAFETY INFORMATION *(cont'd)*

Infections
ILUMYA™ may increase the risk of infection. Treatment with ILUMYA™ should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated.

Consider the risks and benefits of treatment prior to prescribing ILUMYA™ in patients with a chronic infection or a history of recurrent infection. Instruct patients receiving ILUMYA™ to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection, or is not responding to standard therapy, closely monitor and consider discontinuation of ILUMYA™ until the infection resolves.

Pretreatment Evaluation for Tuberculosis
Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with ILUMYA™. Do not administer ILUMYA™ to patients with active TB infection. Initiate treatment of latent TB prior to administering ILUMYA™. Consider anti-TB therapy prior to initiation of ILUMYA™ in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Patients receiving ILUMYA™ should be monitored closely for signs and symptoms of active TB during and after treatment.

Immunizations
Prior to initiating therapy with ILUMYA™, consider completion of all age-appropriate immunizations according to current immunization guidelines. Patients treated with ILUMYA™ should not receive live vaccines.

Adverse Reactions
The most common (≥1%) adverse reactions associated with ILUMYA™ treatment that were more frequent than in the placebo group are upper respiratory infections, injection-site reactions, and diarrhea.

Please see brief summary of Full Prescribing Information on next page or visit ILUMYApro.com

References: 1. ILUMYA™ [package insert]. Princeton, NJ: Sun Pharmaceuticals, Inc. **2.** Data on File. Sun Pharmaceutical Industries, Inc. **3.** Rigopoulos D, Ioannides D, Chaidemenos G, et al. Patient preference study for different characteristics of systemic psoriasis treatments (Protimisis). *Dermatol Ther*. 2018;31(3):e12592.

SUN DERMATOLOGY

Brief Summary of Prescribing Information for ILUMYA™ (tildrakizumab-asmn)
ILUMYA™ (tildrakizumab-asmn) injection, for subcutaneous use
See package insert for full Prescribing Information

INDICATIONS AND USAGE ILUMYA™ is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

CONTRAINDICATIONS
ILUMYA is contraindicated in patients with a previous serious hypersensitivity reaction to tildrakizumab or to any of the excipients *[see Warnings and Precautions]*.

WARNINGS AND PRECAUTIONS
Hypersensitivity: Cases of angioedema and urticaria occurred in ILUMYA treated subjects in clinical trials. If a serious hypersensitivity reaction occurs, discontinue ILUMYA immediately and initiate appropriate therapy *[see Adverse Reactions]*.

Infections: ILUMYA may increase the risk of infection. Although infections were slightly more common in the ILUMYA group (23%), the difference in frequency of infections between the ILUMYA group and the placebo group was less than 1% during the placebo-controlled period. However, subjects with active infections or a history of recurrent infections were not included in clinical trials. Upper respiratory infections occurred more frequently in the ILUMYA group than in the placebo group *[see Adverse Reactions]*.

The rates of serious infections for the ILUMYA group and the placebo group were ≤0.3%. Treatment with ILUMYA should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated.

In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing ILUMYA. Instruct patients to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection or is not responding to standard therapy, monitor the patient closely and consider discontinuation of ILUMYA until the infection resolves *[see Adverse Reactions]*.

Pretreatment Evaluation for Tuberculosis: Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with ILUMYA. Initiate treatment of latent TB prior to administering ILUMYA. In clinical trials, of 55 subjects with latent TB who were concurrently treated with ILUMYA and appropriate TB prophylaxis, no subjects developed active TB (during the mean follow-up of 56.5 weeks). One other subject developed TB while receiving ILUMYA. Monitor patients for signs and symptoms of active TB during and after ILUMYA treatment. Consider anti-TB therapy prior to initiation of ILUMYA in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Do not administer ILUMYA to patients with active TB infection.

Immunizations: Prior to initiating therapy with ILUMYA, consider completion of all age appropriate immunizations according to current immunization guidelines. Avoid the use of live vaccines in patients treated with ILUMYA. No data are available on the response to live or inactive vaccines.

ADVERSE REACTIONS
The following serious adverse reactions are discussed elsewhere in the labeling:
Hypersensitivity Reactions *[see Warnings and Precautions]*
Infections *[see Warnings and Precautions]*

Clinical Trial Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In clinical trials, a total of 1994 subjects with plaque psoriasis were treated with ILUMYA, of which 1083 subjects were treated with ILUMYA 100 mg. Of these, 672 subjects were exposed for at least 12 months, 587 for 18 months, and 469 for 24 months.

Data from three placebo-controlled trials (Trials 1, 2, and 3) in 705 subjects (mean age 46 years, 71% males, 81% white) were pooled to evaluate the safety of ILUMYA (100 mg administered subcutaneously at Weeks 0 and 4, followed by every 12 weeks [Q12W]) *[see Clinical Studies]*.

Placebo-Controlled Period (Weeks 0-16 of Trial 1 and Weeks 0-12 of Trials 2 and 3)
In the placebo-controlled period of Trials 1, 2, and 3 in the 100 mg group, adverse events occurred in 48.2% of subjects in the ILUMYA group compared to 53.8% of subjects in the placebo group. The rates of serious adverse events were 1.4% in the ILUMYA group and 1.7% in the placebo group.

Table 1 summarizes the adverse reactions that occurred at a rate of at least 1% and at a higher rate in the ILUMYA group than in the placebo group.

Table 1: Adverse Reactions Occurring in ≥1% of Subjects in the ILUMYA Group and More Frequently than in the Placebo Group in the Plaque Psoriasis Trials 1, 2, and 3

Adverse Reaction	ILUMYA 100 mg (N=705) N (%)	Placebo (N=355) N (%)
Upper respiratory infections*	98 (14)	41 (12)
Injection site reactions†	24 (3)	7 (2)
Diarrhea	13 (2)	5 (1)

* Upper respiratory infections include nasopharyngitis, upper respiratory tract infection, viral upper respiratory tract infection, and pharyngitis.

† Injection site reactions include injection site urticaria, pruritus, pain, reaction, erythema, inflammation, edema, swelling, bruising, hematoma, and hemorrhage.

During the placebo-controlled period of Trials 1, 2, and 3, adverse reactions that occurred at rates less than 1% but greater than 0.1% in the ILUMYA group and at a higher rate than in the placebo group included dizziness and pain in extremity.

Specific Adverse Reactions
Hypersensitivity Reactions
Cases of angioedema and urticaria occurred in ILUMYA-treated subjects in clinical trials *[see Warnings and Precautions]*.

Infections
Infections were slightly more common in the ILUMYA group. The difference in frequency of infections between the ILUMYA group (23%) and the placebo group was less than 1% during the placebo-controlled period. The most common (≥1%) infections were upper respiratory infections. The rates of severe infections for the ILUMYA group and the placebo group were ≤0.3%.

Safety Through Week 52/64
Through Week 52 (Trials 1 and 3) and Week 64 (Trial 2), no new adverse reactions were identified with ILUMYA use and the frequency of the adverse reactions was similar to that observed during the placebo-controlled period.

Immunogenicity
As with all therapeutic proteins there is the potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of incidence of antibodies to tildrakizumab in the studies described below with the incidences of antibodies in other studies or to other products may be misleading.

Up to Week 64, approximately 6.5% of subjects treated with ILUMYA 100 mg developed antibodies to tildrakizumab. Of the subjects who developed antibodies to tildrakizumab, approximately 40% (2.5% of all subjects receiving ILUMYA) had antibodies that were classified as neutralizing. Development of neutralizing antibodies to tildrakizumab was associated with lower serum tildrakizumab concentrations and reduced efficacy.

DRUG INTERACTIONS
Live Vaccinations
Avoid use of live vaccines in patients treated with ILUMYA *[see Warnings and Precautions]*.

USE IN SPECIFIC POPULATIONS
Pregnancy: Risk Summary
Limited available data with ILUMYA use in pregnant women are insufficient to inform a drug associated risk of adverse developmental outcomes. Human IgG is known to cross the placental barrier; therefore, ILUMYA may be transferred from the mother to the fetus. An embryofetal developmental study conducted with tildrakizumab in pregnant monkeys revealed no treatment-related effects to the developing fetus when tildrakizumab was administered subcutaneously during organogenesis to near parturition at doses up to 159 times the maximum recommended human dose (MRHD). When dosing was continued until parturition, a small increase in neonatal death was observed at 59 times the MRHD *[see Data]*. The clinical significance of this nonclinical finding is unknown.

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data: *Animal Data*
In an embryofetal developmental study, subcutaneous doses up to 300 mg/kg tildrakizumab were administered to pregnant cynomolgus monkeys once every two weeks during organogenesis to gestation day 118 (22 days from parturition). No maternal or embryofetal toxicities were observed at doses up to 300 mg/kg (159 times the MRHD of 100 mg, based on AUC comparison). Tildrakizumab crossed the placenta in monkeys.

In a pre- and postnatal developmental study, subcutaneous doses up to 100 mg/kg tildrakizumab were administered to pregnant cynomolgus monkeys once every two weeks from gestation day 50 to parturition. Neonatal deaths occurred in the offspring of one control monkey, two monkeys at 10 mg/kg dose (6 times the MRHD based on AUC comparison), and four monkeys at 100 mg/kg dose (59 times the MRHD based on AUC comparison). The clinical significance of these nonclinical findings is unknown. No tildrakizumab-related adverse effects were noted in the remaining infants from birth through 6 months of age.

Lactation: Risk Summary
There are no data on the presence of tildrakizumab in human milk, the effects on the breastfed infant, or the effects on milk production. Human IgG is known to be present in human milk. Tildrakizumab was detected in the milk of monkeys *[see Data]*.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ILUMYA and any potential adverse effects on the breastfed child from ILUMYA or from the underlying maternal condition.

Pediatric Use: Safety and effectiveness of ILUMYA in pediatric patients (<18 years of age) have not been established.

Geriatric Use: A total of 1083 subjects were exposed to ILUMYA 100 mg during Phase 2 and 3 trials. A total of 92 subjects were 65 years or older, and 17 subjects were 75 years or older. Although no differences in safety or efficacy were observed between older and younger subjects, the number of subjects aged 65 and over is not sufficient to determine whether they respond differently from younger subjects.

OVERDOSAGE: In the event of overdosage, monitor the patient for any signs or symptoms of adverse reactions and administer appropriate symptomatic treatment immediately.

PATIENT COUNSELING INFORMATION: Advise the patient and/or caregiver to read the FDA-approved patient labeling (Medication Guide).

Instruct patients and/or caregivers to read the Medication Guide before starting ILUMYA therapy and to reread the Medication Guide each time the prescription is renewed. Advise patients of the potential benefits and risks of ILUMYA.

Hypersensitivity
Advise patients to seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions *[see Warnings and Precautions]*.

Infections
Instruct patients of the importance of communicating any history of infections to the doctor and contacting their doctor if they develop any symptoms of infection *[see Warnings and Precautions]*.

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SUN PHARMA

From The Patient's Perspective

The Skin I'm In

By Kendra-Anne W.

When I was about five or six years old, I remember thinking it was a rash appearing on both my legs. "Mom," I said. "What's this?" The "rash" started to get worse and more cracks were appearing. I remember trying to scrub it off while in the bathtub, but whatever this "thing" was, it would not go away. I remember getting frustrated and crying when I realized whatever this was on my legs was not leaving any time soon. Since I was so young, I don't remember my mother talking to me about how to take care of the problem. As I got older and started to complain, she mentioned something like "Kendra, it runs in the family, whatever it is."

The doctors didn't even know what "it" was, but they knew to treat it as if it were eczema. Once into adulthood, I discovered what "it" was when I ran across a picture on the internet of a leg that looked exactly like mine! I said to myself, "Hold it! What is this?" When I showed it to my father, he was just as stunned as I was. "It" was a genetic skin disorder called "ichthyosis." I learned that there are different types of this disorder. It appears that I have the ichthyosis vulgaris type.

I began thinking back to when I was teased constantly in school, especially by the boys. I was a shy person and not the most popular, so I took the teasing really hard. "What's wrong with your legs? What are you, related to an alligator?" I'd pretend like it wouldn't bother me so I would seem tough, but it did. I'd go straight to my room after school and stare at my skin with anger, frustration, and with tears in my eyes. I didn't want to be different. I wanted to be like everybody else.

Unfortunately, this embarrassment would lead all the way up to high school where I'd constantly try to cover my legs, even when it was hot outside. I'd dress in male shorts so they would be long enough for people to not notice what was there. Thankfully, the guys that liked me growing up never really paid attention to it, or did but just didn't care. I've had some serious relationships, and I'd explain to them what it is. Fortunately for me they'd listen, understand, and continue to date me because they liked me. You'd think that would be enough for me to let the embarrassment go, but it wasn't.

I remember my ex-fiancé asking me a few years ago, "Hey what's that on your back?" And I thought to myself, "No! It's beginning to spread." I'm thinking not only do I have this on my legs, but it has become very noticeable on my lower back and the back of my arms. Into my adult years, I learned to accept the situation, but would still find myself longing for it to disappear. Now at twenty-five years old, I still find myself embarrassed. I'm not embarrassed around the people that know about me, but around new people who don't know about my skin until summer comes around. Once in a while I would hear, "What's that?" Or, I would catch someone glancing every now and then. Sometimes I find myself trying to hide my legs by curling them behind me when company visits, or if

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For Ichthyosis Awareness Month 2019, FIRST asked their members to answer two simple questions: Pick a point in your life and write about your challenges or successes, and How has FIRST impacted your life? Some responses are difficult or painful to read due to some circumstances in member's lives, but in the end these member stories are all so truthful and inspirational. One thing is for sure, FIRST members are resilient and they are living each day to the fullest. Ichthyosis and related skin types is a part of who they are, but it does not define them

Please visit the following website to read stories from FIRST members:

http://www.firstskinfoundation.org/awareness-month-member-stories-2019

I'm in a place where there are people that I don't know.

Thankfully for me, with the help of family members like my older sister, cousins, and my best friend, I'm learning how to accept the skin that I'm in. I have a degree in theatre and I have been trained to be ready for whatever comes my way. I am very aware that certain things will be very challenging for me when it comes to my profession because I'm different. I can't tell you how many times I've been asked, "Why don't you show those beautiful calves of yours?" or, "Why don't you model Kendra?" And I'd answer, "Because I don't like showing my skin." When the reality is, I know a lot of people in the industry can have a hard time accepting "bad skin," so I find myself already accepting rejection before I'm even rejected. That kind of thinking can do more harm than good when you're trying to strengthen your esteem level when it comes to being comfortable with what you have, flaws and all.

Now, instead of being so uncomfortable about my difference from others, I am learning to accept it, and to not be scared; to support people with the same problem that I have. It doesn't even mean having a skin disorder, it can be anything that makes you feel different, whether it's your skin, the loss of your hair to cancer, not having the ability to walk or talk anymore, or even the loss of hearing or sight.

You see, we are all created differently. If we were the same, the world would be a dull place. So if someone were to stop me today and ask me that usual question, "What's going on with your legs, back, or arms?," I will just have to take a deep breath, explain to them what it is, and educate them on the disorder. When you think about it, I guess there really isn't anything to be ashamed of. Instead of hiding from this disorder every time someone asks, we should take that same energy and use it as an opportunity to educate others who are unaware of the disorder so that they can get a better understanding and know that "I'm just like you. I just came with a little decoration." Actually, I'll keep that in mind as I go on my first full photo shoot a week from now. Who told me that I couldn't model because I'm "different" anyway? I forget.

Instead of hiding from this disorder every time someone asks, we should take that same energy and use it as an opportunity to educate others who are unaware of the disorder so that they can get a better understanding and know that "I'm just like you. I just came with a little decoration."

Be comfortable in the skin you're in!

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Journal Club: *Practice Changing Articles for Dermatology PAs*

Pharmacologic and Nonpharmacologic Interventions for Perioperative Anxiety in Patients Undergoing Mohs Micrographic Surgery: A Systematic Review.

Dermatol Surg. 2019 Aug 22. doi:10.1097/DSS.0000000000002062

Wan AY[1], Biro M, Scott JF[2]

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2. All authors are affiliated with the Department of Dermatology, University Hospitals Case Medical Center, Cleveland, Ohio.

Background

Perioperative anxiety is associated with negative patient outcomes in Mohs micrographic surgery (MMS). Both pharmacologic and nonpharmacologic therapies have been used to alleviate perioperative anxiety in MMS.

Objective

To systematically evaluate the efficacy of therapies aimed at reducing perioperative anxiety in MMS.

Methods and Materials

Eligible articles were identified using PubMed MEDLINE, Cochrane Central Register of Controlled Trials, metaRegister of Controlled Trials, ClinicalTrials.gov, and World Health Organization International Clinical Trials Registry Platform. All available studies investigating interventions to reduce perioperative anxiety during MMS were considered.

Results

Of the 183 abstracts identified and screened, 5 studies met inclusion criteria. Three studies reported a postintervention reduction in patient anxiety (midazolam, educational video, and personalized music). Two studies reporting on similar interventions did not find an effect.

Conclusions

There is currently limited evidence to support either pharmacologic or nonpharmacologic therapy for alleviation of perioperative patient anxiety in MMS. Midazolam may provide patients a short-term benefit, though any estimate of the effect is very uncertain. Personalized music may be a promising nonpharmacologic intervention for future research.

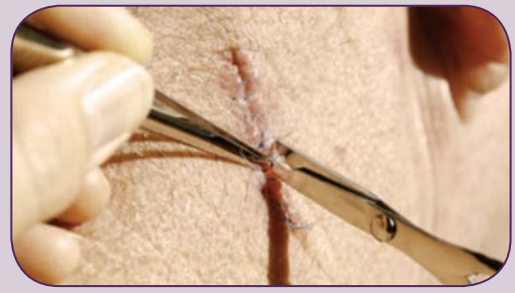
From MEDLINE®/PubMed®, a database of the U.S. National Library of Medicine. PreMedline Identifier: 31453905.

Journal clubs are a great way to review and critically evaluate the most current literature impacting the practice of dermatology. For PAs who are new to the practice of dermatology, journal clubs can assist them to become more familiar with advanced medical literature and improve their understanding of current issues within the field. The articles selected for the JDPA Journal Club are meant to be shared and discussed with your colleagues, peers, and collaborating physicians. If you have any articles to recommend for the JDPA Journal Club, please email them to editor@jdpa.org

Dermcast.tv Blog - *Know Your Pain Meds: Which One Is Best Following Derm Procedures?*

By Martha L. Sikes, MS, RPh, PA-C

There are a wide variety of pain relief medications that can be prescribed after a procedure, with different mechanisms of action and varied side effects and concerns for patients. In the past, for example, there have been fears that NSAIDs come with an increased risk of postoperative bleeding, so typically providers avoid prescribing those to patients. Clinicians also need to consider patients' history with medications, whether they expect pain levels to be mild or severe, or whether the patient will need to be alert post procedure.



A recent study looked at what we know about common analgesics and presented recommendations for each one depending on pain level and patient characteristics. For patients with mild pain that would be expected from an incision, for example, the author recommends acetaminophen for a first line treatment and NSAID for a second line option. For moderate to severe pain, the authors recommend first line analgesics such as acetaminophen, NSAIDs and codeine, and for second line a weak opioid such as codeine or tramadol. The authors note that codeine may not be an optimal choice because it has to be converted to morphine in the body, and not all patients can metabolize codeine. Therefore, unpredictable metabolism must be considered especially in patients at risk of opioid toxicity.

For patients with moderate to severe pain that cannot tolerate opioids, tramadol may be a useful alternative. Although one of its mechanisms of action is via the opioid receptors, it causes minimal respiratory depression and reduced cardiovascular and gastrointestinal side effects. Looking at NSAIDs and bleeding risk, the authors state that based on several large studies there is no increased bleeding following the use of NSAIDs in the adult population. However, caution should be used if the patient is on an anticoagulant.

The authors state that clinicians should use an individual approach to managing post-procedure analgesia, and develop a thorough understanding of the pharmacology of analgesics. The two in combination should help determine which treatment would be best for each patient.

Dermcast.tv Blog Post: April 8, 2019
Source: Wiley Online
Adapted from the original article
Photo credit: Carolina K. Smith MD /Shutterstock.com

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INDICATION AND USAGE

CORDRAN® Tape (Flurandrenolide Tape, USP) is a corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses, particularly dry, scaling localized lesions.

IMPORTANT SAFETY INFORMATION

Topical corticosteroids are contraindicated in patients with a history of hypersensitivity to any of the components of these preparations. Use of CORDRAN® Tape is not recommended for lesions exuding serum or in intertriginous areas.

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. Use over large surface areas, prolonged use, and the addition of occlusive dressings augment systemic absorption. Pediatric patients may absorb proportionately larger amounts of topical corticosteroids and thus may be more susceptible to systemic toxicity.

HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in pediatric patients receiving topical corticosteroids. Patients receiving a large dose applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression, and therapy should be modified or discontinued as appropriate.

Topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively for pregnant patients or in large amounts or for prolonged periods of time. Caution should be exercised when topical corticosteroids are administered to a nursing woman.

Local adverse reactions may occur more frequently with the use of occlusive dressings. These reactions are listed in approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis. Reactions that may occur more frequently with occlusive dressings include: maceration of the skin, secondary infection, skin atrophy, striae, and miliaria.

Please see Brief Summary of CORDRAN® Tape full Prescribing Information on the following page.

IT STICKS. IT STAYS. IT WORKS.*

*CORDRAN Tape should be applied on clean and dry skin. It should always be cut, never torn. Topical corticosteroids are contraindicated in patients with a history of hypersensitivity to any of the components of these preparations. CORDRAN Tape is not recommended for lesions exuding serum or in intertriginous areas. Replacement of the tape every 12 hours produces the lowest incidence of adverse reactions, but it may be left in place for 24 hours if it is well tolerated and adheres satisfactorily. If irritation or infection develops, the use of CORDRAN Tape should be discontinued and appropriate antimicrobial therapy instituted, as necessary.[3]

USCOT0383b 08-2019

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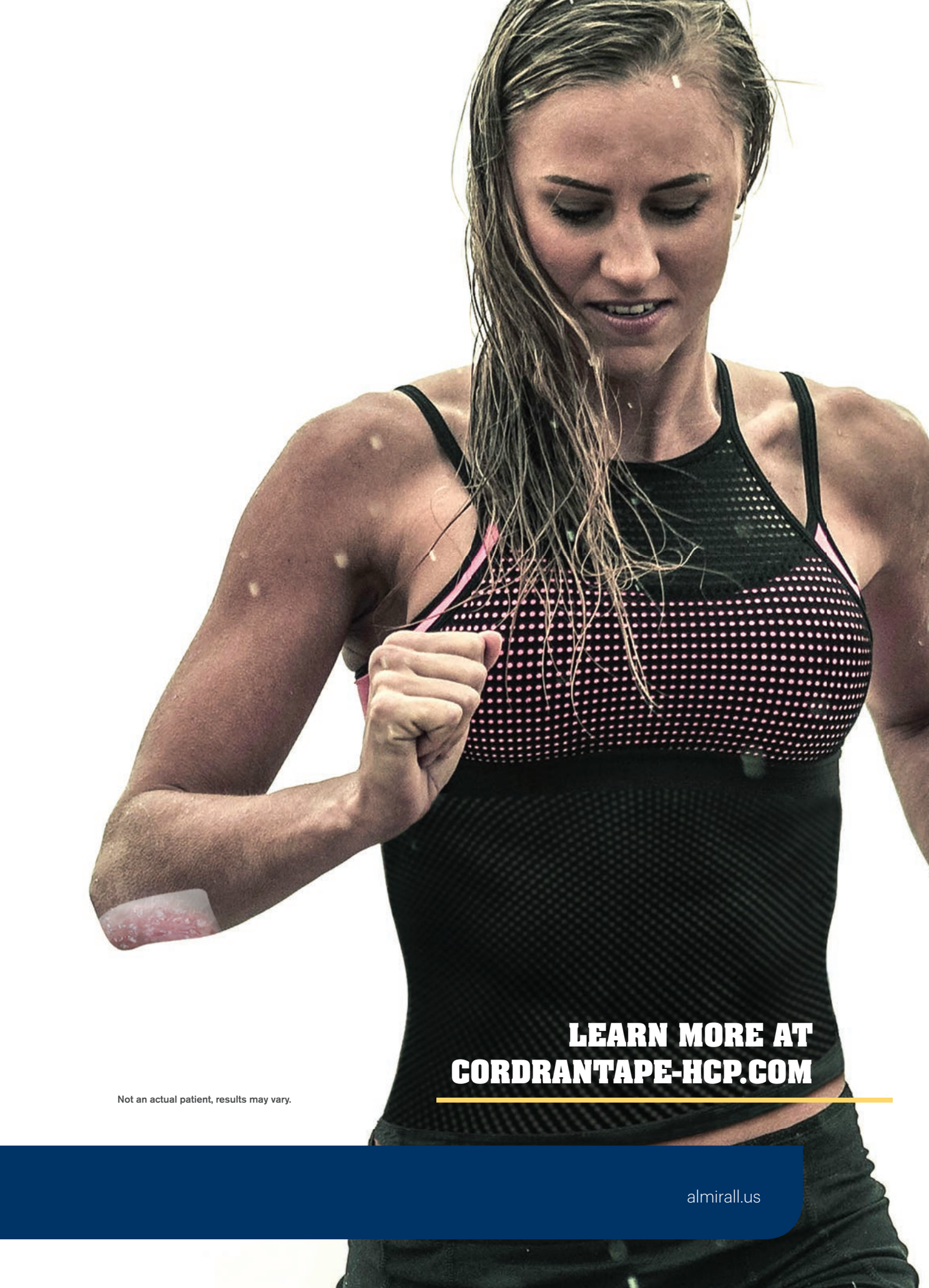

Not an actual patient, results may vary.

CORDRAN TAPE BRIEF SUMMARY OF PRESCRIBING INFORMATION

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION FOR CORDRAN® TAPE (Flurandrenolide Tape, USP)

This brief summary does not include all the information needed to use Cordran Tape safely and effectively. See full Prescribing Information for Cordran Tape.

INDICATIONS AND USAGE

For relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, particularly dry, scaling localized lesions.

CONTRAINDICATIONS

Topical corticosteroids are contraindicated in patients with a history of hypersensitivity to any of the components of these preparations. Use of Cordran Tape is not recommended for lesions exuding serum or in intertriginous areas.

PRECAUTIONS

General: Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions that augment systemic absorption include application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using urinary-free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Recovery of HPA axis function is generally prompt and complete on discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, so that supplemental systemic corticosteroids are required. Pediatric patients may absorb proportionately larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (see Pediatric Use under PRECAUTIONS). If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. In the presence of dermatologic infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, Cordran Tape should be discontinued until the infection has been adequately controlled.

Laboratory Tests: The following tests may be helpful in evaluating the HPA axis suppression: Urinary-free cortisol test, ACTH stimulation test.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids. Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Usage in Pregnancy: Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively for pregnant patients or in large amounts or for prolonged periods of time.

Nursing Mothers: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use: Pediatric patients may demonstrate greater susceptibility to topical-corticosteroid-induced HPA axis suppression and Cushing's syndrome than do mature patients because of a larger skin surface area to body weight ratio. Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in pediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in pediatric patients include linear growth retardation, delayed weight gain, low plasma-cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. Administration of topical corticosteroids to pediatric patients should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of pediatric patients.

ADVERSE REACTIONS

The following local adverse reactions are reported infrequently with topical corticosteroids but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis.

The following may occur more frequently with occlusive dressings: maceration of the skin, secondary infection, skin atrophy, striae, miliaria.

OVERDOSAGE

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see PRECAUTIONS).

Manufactured for:
Almirall LLC
Exton, PA 19341.

Revised: 10/2018

USCOT0291 03-2019

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Dermatologists Share Skin Care Tips for People With Vitiligo

Millions of people worldwide have vitiligo, a condition that causes the skin to lose its natural color, resulting in patches of light skin. Although the white or light patches do not typically cause other symptoms, the condition can cause low self-esteem and depression in patients - of whom nearly half develop vitiligo before the age of 21. Although there is no cure for vitiligo, dermatologists from the American Academy of Dermatology say there is a lot patients can do at home to make vitiligo less visible and help prevent the condition from spreading.

"Many people with vitiligo do not have any other signs or symptoms and feel completely healthy," says board-certified dermatologist Anisha Patel, MD, FAAD. "However, the change in appearance caused by vitiligo can affect people emotionally, especially those who are younger and more concerned about their appearance. The good news is that there are things patients can do at home to make the condition more manageable."

To help vitiligo patients care for their skin, Dr. Patel recommends the following tips:

1. Protect your skin from the sun. Exposure to the sun's harmful ultraviolet (UV) rays increases your risk of skin cancer, including melanoma, the deadliest form. Since vitiligo skin can burn more easily, it's important to protect your skin whenever you're outdoors. To do this, seek shade, wear protective clothing -including a lightweight, long-sleeved shirt, pants, a wide-brimmed hat and sunglasses, and apply sunscreen to all areas of the body not covered by clothing. Use a broad-spectrum, water-resistant sunscreen with an SPF of 30 or higher, and remember to reapply every two hours when you're outside or after swimming or sweating.
2. Avoid tanning. Just like the sun, tanning beds also emit damaging UV rays that cause sunburn and skin cancer, including melanoma. Further, if you have a light skin tone, tanning may make your vitiligo more pronounced by increasing the contrast between your natural skin color and the light patches.
3. If desired, safely add color to your skin. If you wish to conceal patches of light skin, consider using a concealing cream or makeup. For the best results, look for one that is waterproof. If you want the color to last for longer periods of time, try a self-tanner or skin dye that contains dihydroxyacetone. Ask your dermatologist for recommendations on which products to try.
4. Be careful with your skin. Trauma to the skin, such as scrapes, cuts or burns, can cause new vitiligo patches to develop. Although accidents can happen, do your best to avoid injuring your skin.
5. Do not get a tattoo. A tattoo ultimately wounds the skin; the tattoo gun punctures the skin with a needle that has ink in it. Because of this trauma, getting a tattoo can cause a new patch of vitiligo to appear on your skin about 10 to 14 days later.
6. Maintain a healthy lifestyle. To support the immune system, reduce stress and eat a balanced, nutritional diet. Since stress may cause vitiligo patches to appear, use techniques such as deep breathing, meditation or exercise to minimize stress. Your mental health is important too. If you feel depressed, ashamed or self-conscious about changes to your appearance, it can help to connect with others who have vitiligo. Make sure to communicate these feelings to your dermatologist who can refer you to a vitiligo support resource.

"There are many treatment options available for people with vitiligo, including creams, light therapy and surgical treatments," says Dr. Patel. "If treatment is desired, see a board-certified dermatologist as soon as possible, as the more active your vitiligo, the better it responds to treatment. A dermatologist will work with you to create a treatment plan that's customized for you and may also test for thyroid disease, as people who have vitiligo often have thyroid disease, and treatment can successfully control your vitiligo."

Anisha Patel, MD is a board-certified dermatologist and dermatopathologist who currently practices in Houston, TX. She is an Associate Professor of Dermatology at UT MD Anderson Cancer Center and UT McGovern Medical School and specializes in the diagnosis and management of pigmentary disorders and cutaneous toxicities to chemotherapy.

COSMETIC pearls

Dermcast.tv Blog

What Does Nail Décor Do to Nail Health?

By Martha L. Sikes, MS, RPh, PA-C

There are many creative ways to decorate nails and many preparations to do so: nail polish, gel polish hybrid, gel nails, or acrylic nail powders, for example. A recent study looked at the effects of applying these substances to the nail plate and the changes in pH of the nail as a result.

Healthy nails are typically pink, smooth, and shiny. When the nail plate is damaged the nails become fragile, cracked, brittle, and discolored, and the pH changes to be more basic. An acidic pH helps the nail and skin be protected from damaging external factors. The authors looked at both nail changes and pH levels from application of substances to both prepare nails for decoration and the decorations themselves to determine their effects of pH and nail quality. The authors recruited about 120 volunteers who answered questions about their use of nail polishes and gels. The second step involved about 70 participants whose nails were evaluated to characterize the effect of nail polish, gel polish hybrid, gel nail, and acrylic nail powder and the removal of these formulas on the nail.

The results showed that both methods used to get nails ready for decoration and all the methods of removing the preparations damaged healthy nail plates. The extent of the damage depends on the method used, and is most commonly brittleness and nail splitting. The use of gel polish hybrid, gel nail, and acrylic nail powders lead to the biggest rise in pH change. These preparations caused the pH value of nail plates to rise above 6.0, which may be associated with susceptibility to infection and a greater tendency to have nail injury. Traditional nail polish and gel polish hybrids are the most popular for nail decoration. The application of traditional nail polish seemed potentially less damaging, resulting in a normal pH level of 5.8.

Overall, these preparations (and the mechanisms to remove them) all had negative influence on the nail plates. Participants were eager to take a break from nail decorations after seeing what the effects were to their nails.

Dermcast.tv Blog Post: April 1, 2019
Source: Wiley Online
Adapted from the original article

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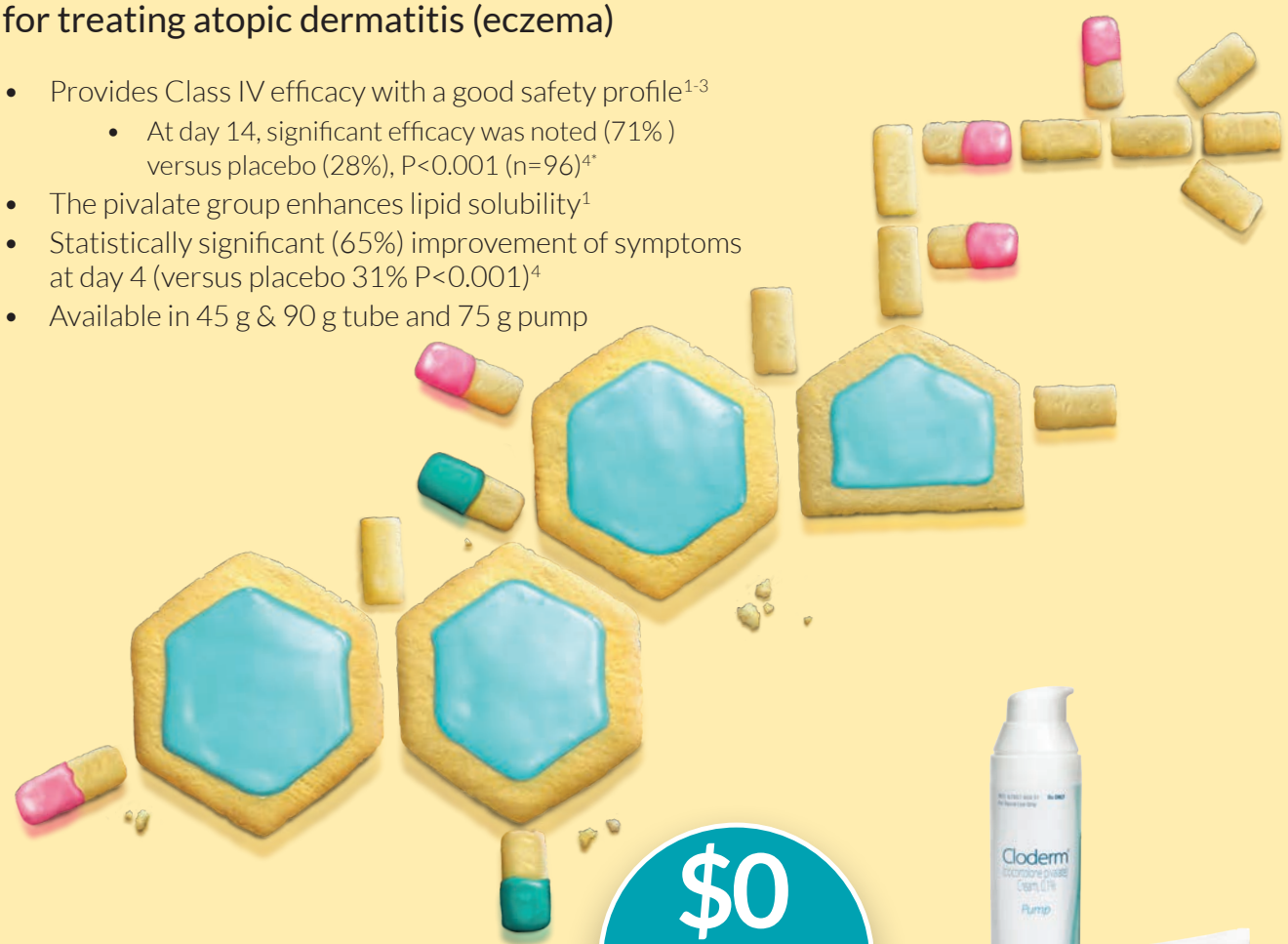

Brief Summary of Package Insert

Cloderm® Cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. The most common adverse events with Cloderm® Cream include burning, itching, irritation, dryness, and folliculitis. Cloderm® Cream is contraindicated in patients who are hypersensitive to any of the ingredients of this product. As with all topical corticosteroids, systemic absorption can produce reversible HPA-axis suppression. Full prescribing information is at www.clodermcream.com

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NOTES from your Office Manager

Electronic Health Records – What is Being Recorded?

By Mia VanAuken, Esq.
Fager Amsler Keller & Schoppmann, LLP – Counsel to Medical Liability Mutual Insurance Company

In the age of electronic health records (EHRs), all users should be aware of the electronic "footprint" that is left behind when they log out. All electronic documents, such as word processing documents and spreadsheets, contain metadata, which is the "data about the data." This information does not appear on the face of a document, but it is a part of the document, nonetheless.

Metadata includes a file's name, location, format, and size, but it can also include the dates and times of its creation and modification, as well as the dates and times of users' access. Similarly, the software and hardware of EHR systems also automatically generate this type of information, which is not readily seen by the user, but is still maintained by the system.

In fact, both the state and federal regulations dictate what type of metadata must be maintained when an EHR system is used.[1] These regulations require medical centers to have certain technical capabilities within their technology to ensure security and confidentiality. The regulations require the assignment of a unique identifier, usually the username, and the user must certify in writing that the account is confidential and accessible only to the authorized person.[2] These provisions ensure that any activity is performed by the assigned individual and allows for the tracking of a particular individual's activity.[3] This authentication is also meant to prevent unauthorized alteration or destruction of protected health information.[4] The act of sharing usernames is not only a violation of a medical center's policies, but it impedes the purpose of these regulations.

For example, within New York's regulation for the authentication of medical records, the state requires each electronic entry, order, or authentication to be recorded in the medical record as to: (1) date, (2) time, (3) category of practitioner, (4) mode of transmission, and (5) point of origin.[6] Likewise, the federal regulation imposes the use of hardware or software that records activity in the information system.[6] The federal audit log must contain: (1) the "exact date and time of the access event and the exit event," (2) "[u]nique identification of the patient," (3) "[u]nique identification of the user of the health information system," (4) specific "inquiry, any changes made, and a delete specification," and (5) "[s]pecific category of data content, such as demographics, pharmacy data, test results, and transcribed notes type."[7]

This mandatory metadata is recorded in an audit log, which is required to be accessible by the medical center. As attorneys, administrators, and regulators become increasingly aware of the existence of an audit log, this information is playing a larger role in legal proceedings.

When a user logs into the medical record system, nearly every action is recorded, as well as the location of the access, e.g., residence, hospital, or office. This means that any alteration of an EHR is recorded in detail and no information can be deleted permanently. Some of the logged data that is less conspicuous includes the length of time of a user's activity or the areas of the record that were accessed.

In legal proceedings, audit logs can be used to authenticate a medical record.[8] For example, this information could be used to verify or disprove a user's testimony regarding the time he or she was present at the hospital or the time the lab results were viewed. In one medical malpractice action, the audit log was used to quantify the level of involvement of the emergency department physician in a plaintiff's care.[9] Users should be aware that their memories of events can be verified or nullified with more than just the EHR; the audit log behind the record can also be used.

It is safe to assume that every action taken on an EHR – from access to exit – is recorded and, thus, capable of being produced. Accordingly, users of EHRs should approach their access to these systems with the acknowledgment that their actions can be examined. Any abuse or inappropriate access can be recalled by the medical records system. To avoid actions being wrongly attributed to him or her, a user should never leave a work station without logging out and should never share password information.

REFERENCES:

[1]*See 45 C.F.R. §§ 164.312; 170.210 (The objective of the Health Information Technology for Economic and Clinical Health Act is to protect electronic health information) and 10 N.Y.C.R.R. § 405.10(c)(3-4).*
[2]*See 10 N.Y.C.R.R. § 405.10(c)(4)(i-ii); see also 45 C.F.R. 164.312(d).*
[3]*See id.*
[4] *See 45 C.F.R. 164.312(c)(1-3).*
[5]*See 10 N.Y.C.R.R. § 405.10(c)(3).*
[6]*See 45 C.F.R. 164.312(b).*
[7]*See 45 C.F.R. § 170.210(e)(1)(i).*
[8]*See Vargas v. Lee, 2015 N.Y. Slip Op. 31048(U) (June 10, 2015); Gilbert v. Highland Hosp., 52 Misc. 3d 555 (Sup. Ct. Monroe Cty. Mar. 24, 2016))*
[9]*See Gilbert, 52 Misc. 3d 555.*

Mia VanAuken, Esq. *is with Fager Amsler Keller & Schoppmann, LLP and serves as Counsel to Medical Liability Mutual Insurance Company*

Outside & Inside the 9 to 5...

The SDPA's New Community Site - Connect

Are you curious about how to become involved with legislation affecting our profession? Do you want to know what wisdom veteran dermatology PAs have to share about your first few years of practice? Would you love to be able to know what details you should pay attention to when structuring your work contract? Have you ever thought it would be nice to meet fellow PAs and discuss the latest trends in surgical, cosmetic, and medical dermatology? The possibilities are endless. The beauty is in the delivery and accessibility.

You can have all of these questions and any others that are pressing in your minds answered while you are in clinic, from the comfort of your own home, while you are traveling, or anywhere you choose. You can engage and connect with fellow dermatology PAs at your own convenience- any time and any place.

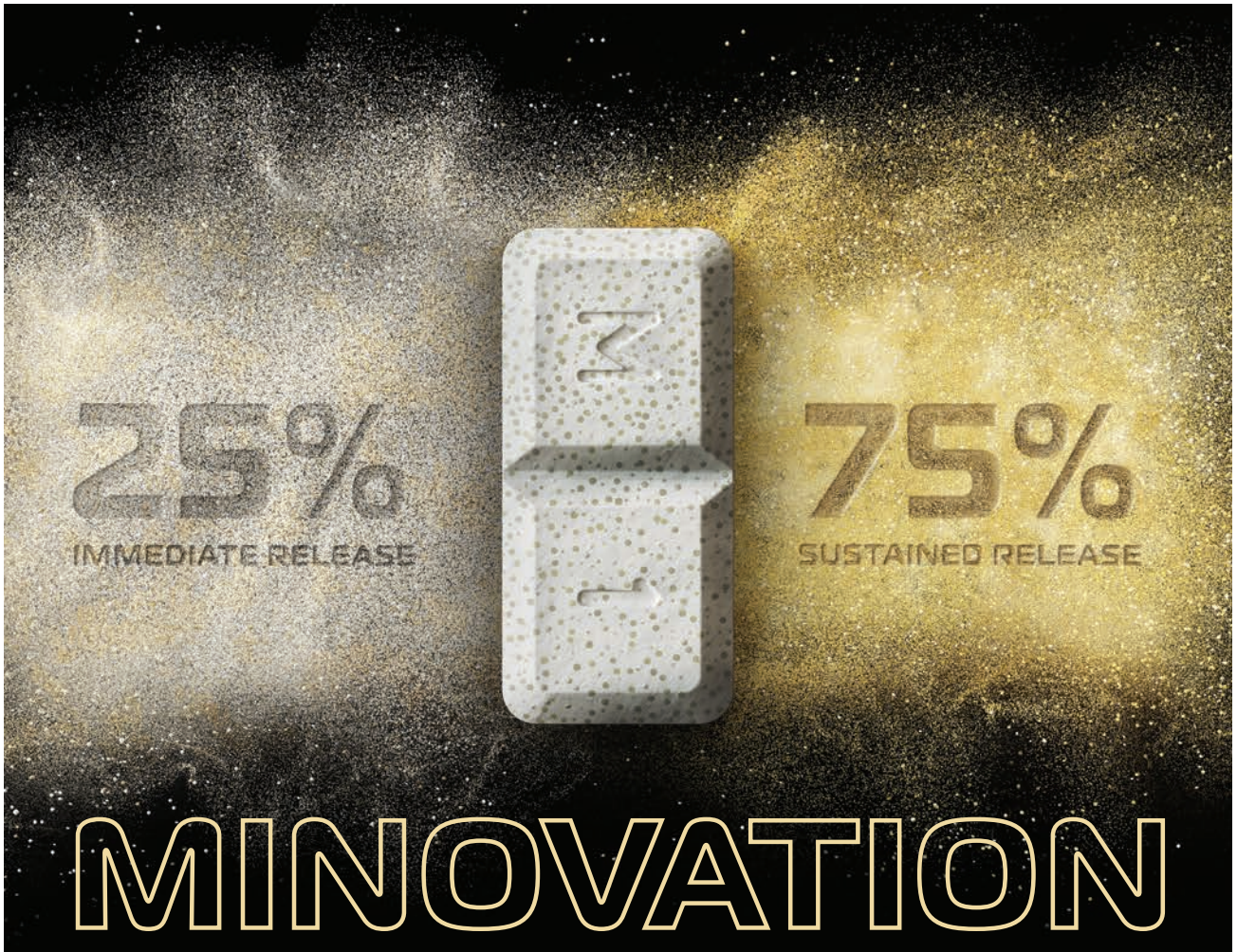
The SDPA's new community site, Connect has launched! Thank you to all who have taken a moment to check out the SDPA's Connect, where you can chat with your professional peers from around the country to learn, share, and have fun in the process.

We encourage you to visit SDPA Connect again or for the first time, complete your profile, upload a picture, and join the conversation! Add your own post in our General Discussion community or respond to a question or idea from a fellow SDPA member.

Some examples of the topics of discussion include:

- The Pros and Cons of working in corporate dermatology
- A student member looking for advice on securing a position in dermatology
- What the profession will look like in 25 years
- Great experiences with professional mentors
- And more!

Your fellow members want to hear from you, so log in through the SDPA website and share your thoughts! This is another great resource being offered to SDPA members. You no longer need to wait for conferences to connect with your fellow dermatology PAs. With SDPA Connect, networking is at your disposal anytime and anywhere.



MINOVATION

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INDICATION AND USAGE

MINOLIRA is indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

MINOLIRA did not demonstrate any effect on non-inflammatory acne lesions. Safety of MINOLIRA has not been established beyond 12 weeks of use. This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, MINOLIRA should be used only as indicated.

IMPORTANT SAFETY INFORMATION

- This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.
- Minocycline, like other tetracycline-class drugs, can cause fetal harm when administered to a pregnant woman.
- The use of MINOLIRA during the second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years may cause permanent discoloration of the teeth (yellow-gray-brown) and reversible inhibition of bone growth.
- If pseudomembranous colitis occurs, discontinue MINOLIRA.
- If renal impairment exists, MINOLIRA doses may need to be adjusted to avoid accumulations of the drug and possible liver toxicity.
- Minocycline may cause central nervous system side effects, including light-headedness, dizziness, or vertigo.
- Minocycline may cause intracranial hypertension and autoimmune disorders in adults and adolescents. Discontinue MINOLIRA if symptoms occur.
- Minocycline has been associated with anaphylaxis,serious skin reactions, erythema multiforme, and DRESS syndrome. Discontinue MINOLIRA immediately if symptoms occur.
- The most commonly observed adverse reactions are headache, fatigue, dizziness, and pruritus.

To report SUSPECTED ADVERSE REACTIONS, contact EPI Health, LLC at 1-800-499-4468 or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

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REFERENCE: 1. MinoLira Tablets [Package Insert]. Charleston, SC: EPI Health, LLC; 2018.

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MIN-JAD9X12

Collaborating Physician Corner

American Academy of Dermatology-Choosing Wisely

Part 1 of 2

The ABIM Foundation's Choosing Wisely® campaign is focused on encouraging physicians and patients to talk about medical tests and procedures that may be unnecessary, and, in some instances, can cause harm. To join, a medical society must provide expert guidance on five medical tests or treatments commonly used in its field.

The Academy has identified 10 evidence-based recommendations that can support conversations between patients and dermatologists about treatments, tests, and procedures that may not be needed.

We will highlight recommendations 1-5 in this issue of the JDPA and will feature recommendations 6-10 in the next issue of the JDPA.

Statement #1: ***Don't prescribe oral antifungal therapy for suspected nail fungus without confirmation of fungal infection***

Explanation: Approximately half of nails with suspected fungus do not have a fungal infection. As other nail conditions, such as nail dystrophies, may look similar in appearance, it is important to ensure accurate diagnosis of nail disease before beginning treatment. By confirming a fungal infection, patients are not inappropriately at risk for the side effects of antifungal therapy, and nail disease is correctly treated.

Source:

1. Kreijkamp-Kaspers S, Hawke K, Guo L, Kerin G, Bell-Syer SE, Magin P, Bell-Syer SV, van Driel ML. Oral antifungal medication for toenail onychomycosis. The Cochrane Library. 2017.

2. Ameen M, Lear JT, Madan V, Mohd Mustapa MF, Richardson M. British Association of Dermatologists' guidelines for the management of onychomycosis 2014. Br J Dermatol. 2014 Nov;171:937-58.

Statement #2: ***Don't perform sentinel lymph node biopsy, or other diagnostic tests for the evaluation of early, thin melanoma because they do not improve survival***

Explanation: Patients with early, thin melanoma, such as melanoma in situ, T1a melanoma, or T1b melanoma ≤ 0.5mm, have a very low risk of the cancer spreading to the lymph nodes or other parts in the body. Further, patients with early, thin melanoma have a 97 percent five-year survival rate which also indicates a low risk of the cancer spreading to other parts of the body. As such, the performance of sentinel lymph node biopsy is unnecessary.

Additionally, baseline blood tests and radiographic studies (e.g. chest radiographs, CT scans, and PET scans) are not the most accurate tests for the detection of cancer that is spreading as they have high false-positive rates. These tests have only shown benefit when performed as indicated for suspicious signs and symptoms based on the patient's history and physical exam.

Source:

1. Rosko AJ, Vankoevering KK, McLean SA, Johnson TM, Moyer JS. Contemporary management of early-stage melanoma: A systematic review. JAMA Facial Plast Surg. 2017;19:232-8.

2. Swetter, SM, Tsao H, Bichajkian CK, Curiel-Lewandrowski C, Elder DE, Gershenwald JE, Guild V, Grant-Kels JM, Halpern AC, Johnson JM, Sober AJ, Thompson JA, Wisco OJ, Wyat S, Hu S, Lamina T. Guidelines of care for

the management of primary cutaneous melanoma. J Am Acad Dermatol. 2019;80(1):208-50
3. American Joint Committee on Cancer, AJCC Cancer Staging Manual, Eighth Edition: 2017.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Melanoma (Version 3.2015).

Statement #3: *Do not treat uncomplicated, non-melanoma skin cancer less than one centimeter in size on the trunk and extremities with Mohs Micrographic Surgery*

Explanation: In healthy individuals, the use of Mohs Micrographic Surgery for low-risk small (< 1cm), superficial, or non-aggressive (based on appearance under a microscope) Squamous Cell Carcinomas and Basal Cell Carcinomas is inappropriate for skin cancers on the trunk and extremities. In these areas of the body, the clinical benefits of this specialized surgical procedure do not exceed the potential risks. It is important to note that Mohs Micrographic Surgery may be considered for skin cancers appearing on the hands, feet, ankles, shins, nipples, or genitals, as they have been shown to have a higher risk for recurrence or require additional surgical considerations.

Source:

1. Bichakjian C, Armstrong A, Baum C, Bordeaux JS, Brown M, Busam KJ, Eisen DB, Iyengar V, Lober C, Margolis DJ, Messina J. Guidelines of care for the management of basal cell carcinoma. J Am Acad of Dermatol. 2018;78(3):540-59.
2. Alam M, Armstrong A, Baum C, Bordeaux JS, Brown M, Busam KJ, Eisen DB, Iyengar V, Lober C, Margolis DJ, Messina J. Guidelines of care for the management of cutaneous squamous cell carcinoma. J Am Acad Dermatol. 2018;78(3):560-78.
3. Connolly SM, Baker DR, Coldiron BM, Fazio MJ, Storrs PA, Vidimos AT et al. AAD/ACMS/ASDSA/ASMS 2012 appropriate use criteria for Mohs micrographic surgery: a report of the American Academy of Dermatology, American College of Mohs Surgery, American Society for Dermatologic Surgery Association, and the American Society for Mohs Surgery. J Am Acad Dermatol. 2012 67:531-50.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Basal cell and Squamous Cell Skin Cancers. (Version 1.2015)

Statement #4: *Do not use oral antibiotics for treatment of atopic dermatitis unless there is clinical evidence of infection*

Explanation: The presence of high numbers of the Staphylococcus aureus (Staph) bacteria on the skin of children and adults with atopic dermatitis (AD) is quite common. While it is widely believed that Staph bacteria may play a role in causing skin inflammation, the routine use of oral antibiotic therapy to decrease the amount of bacteria on the skin has not been definitively shown to reduce the signs, symptoms (e.g. redness, itch), or severity of atopic dermatitis. In addition, if oral antibiotics are used when there is not an infection, it may lead to the development of antibiotic resistance. The use of oral antibiotics also can cause side effects, including hypersensitivity reactions (exaggerated immune responses, such as allergic reactions). Although it can be difficult to determine the presence of a skin infection in atopic dermatitis patients, oral antibiotics should only be used to treat patients with evidence of bacterial infection in conjunction with other standard and appropriate treatments for atopic dermatitis.

Source:

1. Francis NA, Ridd MJ Thomas-Jones E, Butler CC, Hood K, Shepherd V, Marwick CA, Huang C, Longo M, Wootton M, Sullivan F. Oral and topical antibiotics for clinically infected eczema in children: a pragmatic randomized controlled trial in ambulatory care. Ann Fam Med. 2017;15:124-30.
2. Sidbury R, Davis DM, Cohen DE, Cordoro KM, Berger TG, Bergman JN, et al. Guidelines of care for the management of atopic dermatitis: section 3. Management and treatment with phototherapy and systemic agents. J Am Acad Dermatol. 2014 Aug;71(2):327-49.

Statement #5: *Don't routinely use topical antibiotics on a surgical wound*

Explanation: Any possible reduction in the rate of infection from the use of topical antibiotics on clean surgical wounds compared to the use of non-antibiotic ointment or no ointment is quite small. Risk reduction may be overshadowed by the risks of wound irritation or contact dermatitis. When topical antibiotics are used in this setting, there is a significant risk of developing contact dermatitis, a condition in which the skin becomes red, sore, or inflamed after direct contact with a substance, along with the potential for developing antibiotic resistance. Only wounds that show symptoms of infection should receive appropriate antibiotic treatment.

Source:

1. Heal CF, Banks JL, Lepper PD, Kontopantelis E, van Driel ML. Topical antibiotics for preventing surgical site infection in wounds healing by primary intention. Cochrane Database of Systemic Reviews. 2016.

2. Norman G, Dumville JC, Mohapatra DP, Owens GL, Crosbie EJ. Antibiotics and antiseptics for surgical wounds healing by secondary intention. Cochrane Database of Systematic Reviews. 2016.
3. Dixon AJ, Dixon MP, Dixon JB. Randomized clinical trial of the effect of applying ointment to surgical wounds before occlusive dressing. Br J Surg. 2006 Aug;93:937-43.
4. Smack DP, Harrington AC, Dunn C, Howard RS, Szkutnik AJ, Krivda SJ, Caldwell JB, James WD. Infection and allergy incidence in ambulatory surgery patients using white petrolatum vs bacitracin ointment. A randomized controlled trial. JAMA. 1996;276:972-7.
5. Campbell RM, Perlis CS, Fisher E, Gloster HM Jr. Gentamicin ointment versus petrolatum for management of auricular wounds. Dermatol Surg. 2005;31:664-9.
6. Sheth VM, Weitzul S. Postoperative topical antimicrobial use. Dermatitis. 2008;19:181-9.
7. Gehrig KA, Warshaw EM. Allergic contact dermatitis to topical antibiotics: Epidemiology, responsible allergens, and management. J Am Acad Dermatol. 2008;58(1):1-21.
8. Saco M, Howe N, Nathoo R, Cherpelis B. Topical antibiotic prophylaxis for prevention of surgical wound infections from dermatologic procedures: a systematic review and meta-analysis. J Dermatolog Treat. 2014 Apr 8: 1-8.

To date, 75 national organizations representing medical specialists have joined the conversations about appropriate care. With the release of these recommendations, the campaign will have covered nearly 500 tests and procedures that the specialty society partners say are overused or inappropriate, and that physicians and patients should discuss. For more information on the campaign, visit www.ChoosingWisely.org.

The Academy's Choosing Wisely® list was selected by the AAD's Choosing Wisely® workgroup, who identified areas with the greatest potential for overuse/misuse, a need for quality improvement, and the availability of strong evidence-based research to support the recommendation. The final list was reviewed and approved by the Academy's Council on Science and Research and the Academy's Board of Directors.

Listening To Patients
Tyranny By the Numbers

By Alan Rockoff, MD

"How come you retired?" I asked.

A few years my junior, Marty had taught in public school for years. "It was the MCAS," he said. That's the Massachusetts Comprehensive Assessment System, a standardized test meant to gauge student performance and teacher competence.

"They demanded that my students test at a fifth-grade lever," Marty said. "But they were all at a second-grade level.

"Plus, I had been teaching for thirty years, and some kid right out of college was telling me how to do my job. So I left."

Of course, this tale will sound familiar to health care providers. Pay for performance. Bean counters calling the shots, along with dismissal of clinical experience as useless and self-serving.

A recent book lays it all out: Jerry Z. Muller's, "*The Tyranny of Metrics*." This book is punchy, witty, and succinct - you can read it in a day. A historian of economics and culture, Muller shows the extent of what I had guessed at from chats with people in different fields. The cult of metrics has taken over many parts of society: teaching, medicine, the police, the military, business, as well as philanthropy. In all of these, if you don't count it, it doesn't count.

Metrics, it is assumed, are "hard and objective." They must "replace judgment based on experience with standardized measurement." Their promise is transparency, efficiency, and accountability.

Muller began to study this when he became Chair of his academic department. He thought his job was to nurture scholars and help students learn, only to find much of his time taken up with feeding often-worthless data to remote administrators. He traces the metrical impulse, at root, to lack of trust. It's not only healthcare providers whom society doesn't trust, but experts of all kinds.

"Principal agents…employed in institutions are not to be trusted…their activity [is] be monitored and measured…those measures need to be transparent *to those without firsthand knowledge of the institutions* (my emphasis)... and…pecuniary rewards and punishments are the best way to motivate 'agents.'"

What this analysis ignores, argues Muller, is that professionals respond not just to "extrinsic motivation[s]" (money) but to intrinsic ones: commitment to profession and clients, to do the right thing, make people happier and better, be recognized and honored by peers, do interesting and stimulating work. When society denigrates and dismisses those considerations, professionals become demoralized. They leave, or they learn to game the system.

Muller gives many examples. Punish hospitals for readmissions within thirty days of discharge? Fine - readmit patients under "observation status" and call them outpatients. Dock hospitals for deaths within thirty days of leaving? Keep the respirator on for an extra day, and let the patient die on Day 31. Tough case? Don't operate. "Juke the stats" - arrest many small-fry drug pushers instead of focusing on the kingpins. Does *"U.S News and World Report"* rank a college higher for classes with under twenty students? Schedule seminars with a maximum of 19. (My example, not Muller's.) Teach to the MCAS (unless, like Marty, you decide that's hopeless and just quit). Buff the numbers.

You know the drill. And if you need to learn it to succeed - or not be judged a failure - you'll learn it.

Studies show that "Pay for Performance" often doesn't work. Metric advocates ignore these and call for more studies. In Muller's words, "Metric fixation, which aspires to resemble science, too often resembles faith."

Muller argues with balance and nuance. He affirms that objective measurement has helped

sweep away old dogmas no one had ever tested and culled markedly substandard teachers. But he shows that over the past thirty years just counting what you know how to count, counting things that cannot be counted, and privileging belief over disconfirming evidence has conferred on metrics "elements of a cult," whose baleful effects health care providers and others toiling in their professional vineyards know too well.

Faith in metrics will wane and its cult will pass away, though likely well after we have done so ourselves. At some point "situated knowledge" - what people know who actually do something - will again be valued.

In the meantime, please rate this column highly (give it a 6 on a scale of 1-5), and confirm that there are no barriers to your implementing its wisdom, which comes unsullied by any financial conflicts of interest.

And check out Muller's book. You have nothing to lose but your chains.

Measurement without meaning is tyranny!

Alan Rockoff, MD *practices dermatology in Boston, MA. He graduated with his medical degree in 1972 from the Albert Einstein College of Medicine in New York and then completed a pediatric internship and residency at Bronx Municipal Hospital Center. Continuing his education, Dr. Rockoff completed a dermatology residency program at the combined program at Boston University and Tufts University. Dr. Rockoff is a Clinical Assistant Professor of Dermatology at Tufts University School of Medicine. He has taught senior medical students and other trainees for over thirty-five years.*

Dr. Rockoff has been named one of Boston's Top Doctors by Boston Magazine for five years. Dr. Rockoff is board certified by the American Board of Pediatrics and the American Board of Dermatology. Dr. Rockoff is a Fellow of the American Academy of Dermatology and a member of the Massachusetts Medical Society and the Massachusetts Academy of Dermatology.

Dr. Rockoff's publications have appeared in a number of journals. He writes a monthly column for his dermatologic colleagues in Dermatology News as well as a blog for the magazine Psychology Today. His first book, "Under My Skin: A Dermatologist Looks at His Profession and His Patients" is available on Amazon and is his second book, "Act Like a Doctor, Think Like a Patient: Teaching Patient-focused Medicine" is available on Amazon and at Barnes and Noble.

From the Desk of...

Renata Block, MMS, PA-C
Vice President, SDPA Board of Directors

LEADERSHIP BINGO

I am thrilled to take you inside the world of leadership! The SDPA Annual Leadership Retreat took place Thursday, July 25th - Sunday, July 28th, and was nothing less than inspirational. The 2019-2020 Board, Committee, and SDPA Staff had a productive three days of a packed agenda that included BINGO, yes BINGO, to get to know leaders more on a personal level. Little did we know that the SDPA leaders are made up of a beekeeper, a prior correctional officer, and even a descendant of an Italian Princess. There is also someone who was hypnotized by the FBI in a murder investigation. This group of "go-getters" is set to lead the SDPA over the coming year, and each of us is excited to work with our members, a fantastic group of individuals that includes YOU!

This year's retreat was held at the beautiful Belmond Charleston Place Hotel in Charleston, SC. The location was chosen by current SDPA President, Ms. Gina Mangin, who helped us all with our Southern Charm. Yes, we had some fun, but a lot of work was accomplished as well. We started with leadership and communication training by Drew Lawson, MD. The course taught us self-awareness of the mind and how powerful it can be, how we can control it, and what to do with it. Did you know that each of us has a "Judge," within us? It is true that each of us is our own harshest critic. Yes, ALL of us. It was an eye-opening experience to learn from such an inspirational person and I plan to take the lessons learned into my daily activities, whether personal or professional. Without a doubt, champions are born from this lesson.

Our second day consisted of reviewing the SDPA's strategic plan timeline and focused on the work of the SDPA Committees. Talk about teamwork! No stone went unturned as smaller breakout groups held discussions about the CME Conference, Distance CME, Industry Relations, House of Delegates (HOD), Legislative Affairs, Membership, State Constituents, and Publications & Communications (which included Public Education). The synergy, brainstorming of ideas, and execution of plans were all well documented. You can look forward to the implementation of exciting things within the next few years at the SDPA. Look out, here we come…stronger, bolder, and better!

There is a lot to look forward to, and we would love for you to be a part of all of it. The SDPA has a variety of individual committees on which members, just like you, can serve and become more involved with the organization. Whether you put in one hour per week or five, the SDPA is always looking for new leaders, perspectives and ideas. This year's retreat in Charleston proved to me that everyone is truly unique, and each of us can contribute to the SDPA from a different perspective.

Leadership - it's an honor to serve. The SDPA is always seeking new leaders and it would be an honor for you to be a part of our BINGO. Are you ready?

Renata Block, MMS, PA-C *lives in Chicago, IL. She is a past President of the Illinois Society of Dermatology Physician Assistants and serves as the current Vice President of the SDPA. She has indicated no relationships to disclose relating to the content of this article.*

JDPA Journal of Dermatology for Physician Assistants

INFORMATION FOR AUTHORS – The JDPA is a peer-reviewed publication that delivers innovative clinical, surgical, cosmetic, and professional content exclusively for dermatology PAs. Submissions to the JDPA are peer-reviewed by a panel of experienced dermatology PAs, educational PAs, and dermatologists before articles are accepted for publication.

Manuscripts submitted for publication will be reviewed with the understanding that they are original and have not been submitted elsewhere nor are being considered by other journals. Electronic submissions are accepted and should be sent to editor@jdpa.org.

The five main sections featured in each issue of the JDPA are listed below along with a brief description of the various topics that authors can contribute to. Regardless of the section, all articles must follow the following criteria:

- ***Formatting*** - Times New Roman font, 12 point, double-spaced, left aligned.
- ***Article Order*** - Title, Author(s), Author bios (including disclosures), Text of Article, References, Tables, and Figures
- ***Reference Citations*** - Utilize the AMA Manual of Style, 10th Edition.

DERMATOLOGY PA NEWS AND NOTES

Feature Articles

Write a review about a new or innovative dermatological procedure, device, and/or approach to patient care (500-1000 words).

From The Desk Of…

Write an opinion essay sharing your insight regarding a current "hot item" issue *(e.g., specialty PA credentialing, dermatology access to care, supervising physician relationships, etc.)* or any other topic regarding the field of dermatology (250-1000 words).

CLINICAL DERMATOLOGY

CME articles

Content should be specific to the field of dermatology following any of the following formats:

Study – Original research (clinical or basic science).
Professional issues or health policy papers.
Review – Scholarly review of a topic.

Content length:

6 pages (requires 4 self-assessment Q&A) = .5hr of Cat. I CME.
12 pages (requires 8 self-assessment Q&A) = 1hr of Cat. I CME.

Article should include written learning objectives (3-4 required).

Dermatology Case Report

Write a report and discuss a case(s) that illustrate an important or interesting observation (500-1500 words).

Journal Club: Dermatology PA Perspectives

Write a review of an already published article from an established dermatology journal *(e.g., JAAD, Cos Dermatol, Dermatol Surg, etc.),* summarizing the practical thoughts and clinical issues (250-1000 words).

From the Patient's Perspective

Patients' stories published in their own words. JDPA staff can even assist patients with writing their stories (250-1000 words).

Clinical Snapshots

Write a brief written description and clinical facts about an interesting cutaneous anomaly (250-500 words).

Drugs in Dermatology

Write about the current information regarding a particular dermatological medication, drug interaction, or medication side effect/adverse reaction (250-1000 words).

Dermatology Evidence-Based Medicine (derm EBM)

Write a brief, evidence-based assessment of the one or two most relevant studies retrieved to answer a focused clinical question that may have arisen from a real-life situation. A derm EBM is not a comprehensive review of a subject or a synthesis of all the available knowledge (500–1500 words).

SURGICAL DERMATOLOGY

Feature Articles

Write a review about a new or innovative surgical procedure, device, and/or approach to patient care (500-1000 words).

Surgical Wisdom

Write a brief article on a fact or pearl for the surgical setting (250-500 words).

Surgical Dermatology Case Report

Write a report and discuss a case(s) that illustrate an important or interesting observation (500-1500 words).

Journal Club: Dermatology PA Perspectives

Write a review of an already published article from an established dermatology journal *(e.g., JAAD, Cos Dermatol, Dermatol Surg, etc.),* summarizing the practical thoughts and clinical issues (250-1000 words).

COSMETIC DERMATOLOGY

Feature Articles

Write a review about a new or innovative cosmetic procedure, device, and/or approach to patient care (500-1000 words).

Cosmetic Pearls

Write a brief article on a fact or pearl for the cosmetic setting (250-500 words).

Cosmetic Dermatology Case Report

Write a report and discuss a case(s) that illustrate an important or interesting observation (500-1500 words).

Journal Club: Dermatology PA Perspectives

Write a review of an already published article from an established dermatology journal *(e.g., JAAD, Cos Dermatol, Dermatol Surg, etc.),* summarizing the practical thoughts and clinical issues (250-1000 words).

PROFESSIONAL DEVELOPMENT

Feature Articles

Write an article that explores the professional issues dermatology PAs face such as reimbursement, education, medical trends, contracts, office management, etc. (500-1500 words).

Outside & Inside the 9 to 5

Allow us to share your story of the good work that you do either outside or inside your practice of dermatology. You can write this article yourself or the JDPA staff can interview you to write the article (250-1000 words). **Notes From Your Office Manager**
Write a brief article on a fact or pearl for the office setting (250-500 words).

Judicial and Ethical Affairs

Write an article that explores the complex or multifaceted ethical or judicial professional issues that affect the practice of dermatology for PAs (250-1000 words).

To read the JDPA publication's Ethics and Malpractice Statement, please visit www.jdpa.org/write.html.

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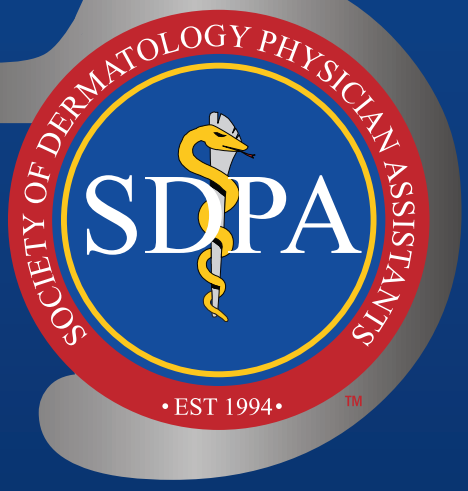

Together

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