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MULTIPLE CHOICE

Dermatology Times® May 2013 Volume

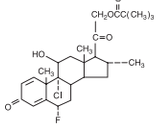
RxOnly

Cloderm® Cream, 0.1%
(clocortolone pivalate)

FOR TOPICAL DERMATOLOGIC USE ONLY–
NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE.
WARNING: KEEP OUT OF REACH OF CHILDREN

DESCRIPTION: Cloderm Cream 0.1% contains the medium potency topical corticosteroid, clocortolone pivalate, in a specially formulated water-washable emollient cream base consisting of purified water, white petrolatum, mineral oil, stearyl alcohol, polyoxyl 40 stearate, carbomer 934P, edetate disodium, sodium hydroxide, with methylparaben and propylparaben as preservatives.

Chemically, clocortolone pivalate is 9-chloro-6α-fluoro-11β, 21-dihydroxy-16α methylpregna-1, 4-diene-3, 20-dione 21-pivalate. Its structure is as follows:



CLINICAL PHARMACOLOGY:
Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics: The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses.
(See **DOSAGE AND ADMINISTRATION**).

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE: Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS: Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

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 which augment systemic absorption include the 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 the 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 upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity.
(See **PRECAUTIONS**-*Pediatric Use*).

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Information for the Patient: Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions especially under occlusive dressing.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

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.

Pregnancy Category C: 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 on pregnant patients, 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 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 mature patients because of a larger skin surface area body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children 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 children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

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, 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**).

DOSAGE AND ADMINISTRATION:
Apply Cloderm (clocortolone pivalate) Cream 0.1% sparingly to the affected areas three times a day and rub in gently.

Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions.

If an infection develops, the use of occlusive dressings should be discontinued and appropriate anti-microbial therapy instituted.

HOW SUPPLIED:
Cloderm (clocortolone pivalate) Cream 0.1% is supplied in 30 gram and 75 gram pump bottles, 45 gram and 90 gram tubes.

30 gram pump bottle	NDC-67857-804-30
75 gram pump bottle	NDC-67857-804-51
45 gram tube	NDC-67857-804-45
90 gram tube	NDC-67857-804-90

STORAGE:
Store Cloderm Cream between 15° and 30° C (59° and 86° F).
Avoid freezing.

Distributed by:

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MULTIPLE CHOICE

HEALTHCARE CLIMATE SPURS PRACTICE MODEL OPTIONS

By Lisette Hilton
Staff Correspondent

DERMATOLOGISTS STILL CAN THRIVE in small private practices — even in this healthcare environment, where bigger is arguably better.

Physicians are jumping the solo practice ship. Like all doctors, dermatologists in private practice are feeling the heat brought on by rising regulatory and practice administration costs and reimbursement woes. The combination is forcing some clinicians to seek refuge in bigger, more powerful environments.

Forty-four percent of dermatologists were in solo practice in 2005, compared to only 38 percent in 2012, according to figures from the American Academy of Dermatology.

VOICES OF THE INDUSTRY

Don't miss this online panel discussion about successful practice models shaped by regulatory complexities.

dermatologytimes.com/successfulpracticemodels

Dermatology group, multispecialty and academic practices grew after 2005.

"We are definitely seeing a trend that younger dermatologists are more likely to join established dermatology group practices or multispecialty groups. Some of this may be generational, but the increasing complexities of regulatory compliance have also made it more difficult to run small or solo practices," says Jack Resneck Jr., M.D., associate professor and vice chairman of dermatology, University of California, San Francisco, School of Medicine.

Unlike many other specialties, though, dermatology stands a chance to survive in private practice amid intense healthcare services integration and consolidation. Why? Dermatologists can supplement or switch to a cash business, which helps them to detach from many of today's practice burdens.

Multiple choice *See page 59*

Melanoma on rise among children

Rockville, Md. — While still rare, the incidence of melanoma in children is trending upward, according to researchers who presented their findings at the annual meeting of the American Association of Cancer Research.

Using data from nine U.S. cancer registries, investigators with the Brown School at Washington University in St. Louis and Harvard University, Cambridge, Mass., found the incidence of childhood and adolescent melanoma has increased an average of 2 percent per year from 1973 to 2009 (95 percent confidence interval, 1.4-2.7), according to the study abstract.

2 PERCENT increase from 1973 to 2009

Girls had higher incidence rates than did boys, as did those ages 15 to 19 compared to younger children. Boys had higher incidence rates on the trunk and face, while girls had higher rates on the lower limbs and hips.

"The only decreased incidence trend we observed was among 15- to 19-year-olds in the high UVB exposure group from 1985 through 2009," authors noted.

Melanoma remains rare in adolescents and children, with 400 to 500 cases diagnosed in the United States each year, according to a news release. But rates have increased in the past several decades, as they have with the adult population.

Researchers concluded that further individual-level studies would be required to determine the reasons for the upward trends in melanoma incidence rates.

The study was published online April 15 in *Pediatrics*. **DT**

FOR MORE **NEWS** *SEE PAGE 12*

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Dermatology Times is the only clinical news resource serving a readership of more than 14,000 dermatologists and other professionals focused on skincare. Through unbiased reporting, we strive to help practitioners put into perspective developments that affect their business. Our goal is to provide practical information that will help them to better understand clinical, regulatory and financial issues, as well as chart business growth.

Let your voice be heard, contact us: sthuerk@advanstar.com

Dermatology Times

publishing & sales

EVP **Georgiann DeCenzo** } gdecenzo@advanstar.com
VP, GROUP PUBLISHER **Ken Sylvia** } (732) 346-3017 ksylvia@advanstar.com
PUBLISHER **Amy Ammon** } (732) 346-3089 cell: (845) 521-6950 | aammon@advanstar.com
NATIONAL ACCOUNT MANAGER **Diane Kebabjian** } (732) 346-3034 cell: (201) 484-9754 | dkebabjian@advanstar.com
ACCOUNT MANAGER, CLASSIFIED/ DISPLAY ADVERTISING **Karen Gerome** } (440) 891-2670 kgerome@advanstar.com
ACCOUNT MANAGER, RECRUITMENT ADVERTISING **Jacqueline Moran** } (440) 891-2762 jmoran@advanstar.com
DIRECTOR, SALES DATA **Gail Kaye** } (732) 346-3042 | gkaye@advanstar.com
SALES SUPPORT **Hannah Curis** } (732) 346-3055 hcuris@advanstar.com
LIST ACCOUNT EXECUTIVE **Renee Schuster** } (440) 891-2613 rschuster@advanstar.com
PERMISSIONS **Maureen Cannon** } (440) 891-2742 mcannon@advanstar.com

REPRINTS Inquiries involving reprints should be directed to 877-652-5295 ext. 121 bkolb@wrightsmedia.com Outside US, UK, direct dial: 281-419-5725. Ext. 121

content

CONTENT CHANNEL DIRECTOR **Heather Onorati** } (440) 826-2868 honorati@advanstar.com
CONTENT CHANNEL MANAGER **Sarah Thuerk** } (440) 891-2770 sthuerk@advanstar.com
DIGITAL & INTERACTIVE CONTENT MANAGER **Brandon Glenn** } (440) 891-2638 bglenn@advanstar.com
CONTENT COORDINATOR **Miranda Hester**
CODING COLUMNIST **Inga Ellzey**
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LEGAL AFFAIRS COLUMNIST **David J. Goldberg, M.D., J.D.**
GROUP ART DIRECTOR **Robert McGarr** } rmcgarr@advanstar.com
ART DIRECTOR **Lecia Landis** } llandis@advanstar.com
SENIOR PRODUCTION MANAGER **Karen Lenzen** } klenzen@media.advanstar.com

audience development

CORPORATE DIRECTOR **Joy Puzzo** } jpuzzo@advanstar.com
DIRECTOR **Christine Shappell** } cshappell@advanstar.com
MANAGER **Joe Martin** } jmartin@advanstar.com
Subscriptions Inquiries, including changes of address, should be directed to (877) 922-2022 or (218) 740-6477

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Full face or balding scalp, we've got AKs covered

ZYCLARA® (imiquimod) Cream, 2.5% and 3.75% are indicated for the topical treatment of clinically typical visible or palpable actinic keratoses (AK) of the full face or balding scalp in immunocompetent adults.

Avoid use in or on the lips and nostrils. Do not use in or near the eyes.

Intense local skin reactions including skin weeping or erosion can occur after a few applications of ZYCLARA Cream and may require an interruption of dosing. Administration of ZYCLARA Cream is not recommended until the skin is healed from any previous drug or surgical treatment.

The safety and efficacy of ZYCLARA Cream has not been established in the treatment of superficial basal cell carcinoma.

See Important Safety Information and brief summary of Full Prescribing Information on the following pages.

Reference: ZYCLARA Cream Package Insert. Scottsdale, AZ: Medicis, the Dermatology Company; February 2012.

MEDICIS®
A DIVISION OF VALEANT PHARMACEUTICALS

FROM HERE

TO HERE

Zyclara®
(imiquimod) Cream
2.5% & 3.75%

BRIEF SUMMARY
(see package insert for
Full Prescribing Information)

ZYCLARA®
(imiquimod) Cream

RX ONLY

FOR TOPICAL USE ONLY
NOT FOR ORAL, OPHTHALMIC, INTRA-ANAL OR INTRAVAGINAL USE

INDICATIONS AND USAGE
Actinic Keratosis
ZYCLARA Cream, 2.5% and 3.75% are indicated for the topical treatment of clinically typical visible or palpable, actinic keratoses (AK), of the full face or balding scalp in immunocompetent adults.

External Genital Warts
ZYCLARA Cream, 3.75% is indicated for the treatment of external genital and perianal warts (EGW)/condyloma acuminata in patients 12 years or older.

Limitations of Use
Imiquimod cream has been evaluated in children ages 2 to 12 years with molluscum contagiosum and these studies failed to demonstrate efficacy.

Treatment with ZYCLARA Cream has not been studied for prevention or transmission of HPV.

Unevaluated Population
The safety and efficacy of ZYCLARA Cream have not been established in the treatment of:
- urethral, intra-vaginal, cervical, rectal or intra-anal human papilloma viral disease.
- actinic keratosis when treated with more than one 2-cycle treatment course in the same area.
- patients with xeroderma pigmentatosum.
- superficial basal cell carcinoma.
- immunosuppressed patients.

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
Local Skin Reactions
Intense local skin reactions including skin weeping or erosion can occur after a few applications of ZYCLARA Cream and may require an interruption of dosing. ZYCLARA Cream has the potential to exacerbate inflammatory conditions of the skin, including chronic graft versus host disease.

Severe local inflammatory reactions of the female external genitalia can lead to severe vulvar swelling. Severe vulvar swelling can lead to urinary retention. Dosing should be interrupted or discontinued for severe vulvar swelling.

Administration of ZYCLARA Cream is not recommended until the skin is healed from any previous drug or surgical treatment.

Systemic Reactions
Flu-like signs and symptoms may accompany, or even precede, local skin reactions and may include fatigue, nausea, fever, myalgias, arthralgias, malaise and chills. An interruption of dosing and an assessment of the patient should be considered.

Lymphadenopathy occurred in 2% of subjects with actinic keratosis treated with ZYCLARA Cream, 3.75% and in 3% of subjects treated with ZYCLARA Cream, 2.5%. This reaction resolved in all subjects by 4 weeks after completion of treatment.

Ultraviolet Light Exposure Risks
Exposure to sunlight (including sunlamps) should be avoided or minimized during use of ZYCLARA Cream. Patients should be warned to use protective clothing (e.g., a hat) when using ZYCLARA Cream. Patients with sunburn should be advised not to use ZYCLARA Cream until fully recovered. Patients who may have considerable sun exposure, e.g. due to their occupation, and those patients with inherent sensitivity to sunlight should exercise caution when using ZYCLARA Cream.

In an animal photo-carcinogenicity study, imiquimod cream shortened the time to skin tumor formation. The enhancement of ultraviolet carcinogenicity is not necessarily dependent on phototoxic mechanisms. Therefore, patients should minimize or avoid natural or artificial sunlight exposure.

Increased Risk of Adverse Reactions with Concomitant Imiquimod Use
Concomitant use of ZYCLARA and any other imiquimod products, in the same treatment area, should be avoided since they contain the same active ingredient (imiquimod) and may increase the risk for and severity of local skin reactions.

The safety of concomitant use of ZYCLARA Cream and any other Imiquimod products has not been established and should be avoided since they contain the same active ingredient (imiquimod) and may increase the risk for and severity of systemic reactions.

Immune Cell Activation in Autoimmune Disease
ZYCLARA Cream should be used with caution in patients with pre-existing autoimmune conditions because imiquimod activates immune cells.

ADVERSE REACTIONS
Clinical Trials Experience: Actinic Keratosis
The data described below reflect exposure to ZYCLARA Cream or vehicle in 479 subjects enrolled in two double-blind, vehicle-controlled trials. Subjects applied up to two packets of ZYCLARA Cream or vehicle daily to the skin of the affected area (either entire face or balding scalp) for two 2-week treatment cycles separated by a 2-week no treatment period.

Local skin reactions were recorded as adverse reactions only if they extended beyond the treatment area, if they required any medical intervention, or they resulted in patient discontinuation from the study. The

Table 1: Selected Adverse Reactions Occurring in ≥ 2% of ZYCLARA-Treated Subjects and at a Greater Frequency than with Vehicle in the Combined Studies (AK)

Adverse Reactions	ZYCLARA Cream, 3.75% (N=160)	ZYCLARA Cream, 2.5% (N=160)	Vehicle (N=159)
Headache	10 (6%)	3 (2%)	5 (3%)
Application site pruritus	7 (4%)	6 (4%)	1 (<1%)
Fatigue	7 (4%)	2 (1%)	0
Nausea	6 (4%)	1 (1%)	2 (1%)
Influenza like illness	1 (<1%)	6 (4%)	0
Application site irritation	5 (3%)	4 (3%)	0
Pyrexia	5 (3%)	0	0
Anorexia	4 (3%)	0	0
Dizziness	4 (3%)	1 (<1%)	0
Herpes simplex	4 (3%)	0	1 (<1%)
Application site pain	5 (3%)	2 (1%)	0
Lymphadenopathy	3 (2%)	4 (3%)	0
Oral herpes	0	4 (3%)	0
Arthralgia	2 (1%)	4 (3%)	0
Cheilitis	0	3 (2%)	0
Diarrhea	3 (2%)	2 (1%)	0

Table 2: Local Skin Reactions in the Treatment Area in ZYCLARA-Treated Subjects as Assessed by the Investigator (AK)

All Grades* (%) Severe	ZYCLARA Cream, 3.75% (N=160)	ZYCLARA Cream, 2.5% (N=160)	Vehicle (N=159)
Erythema Severe erythema	96% 25%	96% 14%	78% 0%
Scabbing/Crusting Severe scabbing/ Crusting	93% 14%	84% 9%	45% 0%
Edema Severe edema	75% 6%	63% 4%	19% 0%
Erosion/Ulceration Severe erosion/ Ulceration	62% 11%	52% 9%	9% 0%
Exudate Severe exudate	51% 6%	39% 1%	4% 0%
Flaking/Scaling/ Dryness Severe flaking/ Scaling/Dryness	91% 8%	88% 4%	77% 1%

* All Grades: mild, moderate or severe

Table 3: Selected Adverse Reactions Occurring in ≥ 2% of ZYCLARA Treated Subjects and at a Greater Frequency than with Vehicle in the Combined Trials (EGW)

Preferred Term	ZYCLARA Cream, 3.75% (N=400)	Vehicle Cream (N=202)
Application site pain	28 (7%)	1 (<1%)
Application site irritation	24 (6%)	2 (1%)
Application site pruritus	11 (3%)	2 (1%)
Vaginitis bacterial*	6 (3%)	2 (2%)
Headache	6 (2%)	1 (<1%)

* percentage based on female population of 6/216 for ZYCLARA Cream 3.75% and 2/106 for vehicle cream

Table 4: Selected Local Skin Reactions in the Treatment Area Assessed by the Investigator (EGW)

All Grades,* (%) Severe, (%)	ZYCLARA Cream, 3.75% (N=400)	Vehicle Cream (N=202)
Erythema* Severe erythema	70% 9%	27% <1%
Edema* Severe edema	41% 2%	8% 0%
Erosion/ ulceration* Severe erosion/ ulceration	36% 11%	4% <1%
Exudate* Severe exudate	34% 2%	2% 0%

* Mild, Moderate, or Severe

incidence and severity of selected local skin reactions are shown in Table 2.

Overall, in the clinical trials, 11% (17/160) of subjects in the ZYCLARA Cream, 3.75% arm, 7% (11/160) of subjects in the ZYCLARA Cream, 2.5% arm, and 0% in the vehicle cream arm required rest periods due to adverse local skin reactions.

Other adverse reactions observed in subjects treated with ZYCLARA Cream include: application site bleeding, application site swelling, chills, dermatitis, herpes zoster, insomnia, lethargy, myalgia, pancytopenia, pruritus, squamous cell carcinoma, and vomiting.

Clinical Trials Experience: External Genital Warts

In two double-blind, placebo-controlled studies 602 subjects applied up to one packet of ZYCLARA Cream or vehicle daily for up to 8 weeks.

The most frequently reported adverse reactions were application site reactions and local skin reactions. Selected adverse reactions are listed in Table 3.

Local skin reactions were recorded as adverse reactions only if they extended beyond the treatment area, if they required any medical intervention, or they resulted in patient discontinuation from the study. The incidence and severity of selected local skin reactions are shown in Table 4.

The frequency and severity of local skin reactions were similar in both genders, with the following exceptions: a) flaking/scaling occurred in 40% of men and in 26% of women and b) scabbing/crusting occurred in 34% of men and in 18% of women.

In the clinical trials, 32% (126/400) of subjects who used ZYCLARA Cream and 2% (4/202) of subjects who used vehicle cream discontinued treatment temporarily (required rest periods) due to adverse local skin reactions, and 1% (3/400) of subjects who used ZYCLARA Cream discontinued treatment permanently due to local skin/application site reactions.

Other adverse reactions reported in subjects treated with ZYCLARA Cream include: rash, back pain, application site rash, application site cellulitis, application site excoriation, application site bleeding, scrotal pain, scrotal erythema, scrotal ulcer, scrotal edema, sinusitis, nausea, pyrexia, and influenza-like symptoms.

Postmarketing Experience

The following adverse reactions have been identified during post-approval use of imiquimod. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Application Site Disorders: tingling at the application site

Body as a Whole: angioedema

Cardiovascular: capillary leak syndrome, cardiac failure, cardiomyopathy, pulmonary edema, arrhythmias (tachycardia, supraventricular tachycardia, atrial fibrillation, palpitations), chest pain, ischemia, myocardial infarction, syncope

Endocrine: thyroiditis

Gastro-Intestinal System Disorders: abdominal pain

Hematological: decreases in red cell, white cell and platelet counts (including idiopathic thrombocytopenic purpura), lymphoma

Hepatic: abnormal liver function

Infections and Infestations: herpes simplex

Musculo-Skeletal System Disorders: arthralgia

Neuropsychiatric: agitation, cerebrovascular accident, convulsions (including febrile convulsions), depression, insomnia, multiple sclerosis aggravation, paresis, suicide

Respiratory: dyspnea

Urinary System Disorders: proteinuria, urinary retention, dysuria

Skin and Appendages: exfoliative dermatitis, erythema multiforme, hyperpigmentation, hypertrophic scar, hypopigmentation

Vascular: Henoch-Schonlein purpura syndrome

OVERDOSAGE

Topical overdosing of ZYCLARA Cream could result in an increased incidence of severe local skin reactions and may increase the risk for systemic reactions.

Hypotension was reported in a clinical trial following multiple oral Imiquimod doses of >200 mg (equivalent to ingestion of the imiquimod content of more than 21 packets or pump actuations of ZYCLARA Cream, 3.75% or more than 32 packets or pump actuations of ZYCLARA Cream, 2.5%). The hypotension resolved following oral or intravenous fluid administration.

Manufactured for:
Medicis, The Dermatology Company
Scottsdale, AZ 85256

April 2012 19110248

Important Safety Information for ZYCLARA (imiquimod) Cream, 2.5% and 3.75%

Intense local skin reactions including skin weeping or erosion can occur after a few applications of ZYCLARA Cream and may require an interruption of dosing. Administration of ZYCLARA Cream is not recommended until the skin is healed from any previous drug or surgical treatment.

Flu-like signs and symptoms may accompany, or even precede, local skin reactions and may include fatigue, nausea, fever, myalgias, arthralgias, malaise and chills.

ZYCLARA Cream should be used with caution in patients with pre-existing autoimmune conditions because imiquimod activates immune cells.

Exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) should be avoided or minimized during use of ZYCLARA Cream. Patients should be advised to wear protective clothing (e.g., hat) when using ZYCLARA Cream.

Avoid concomitant use of ZYCLARA Cream and any other imiquimod cream because of increased risk for adverse events.

In clinical studies, the most common adverse events involved skin reactions in the application area including erythema, scabbing/crusting, flaking/scaling/dryness, edema, erosion/ulceration, and exudate. Most skin reactions were rated as mild to moderate.

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INDUSTRY News

One physician calls on colleagues to fight back against industry forces in the spirit of restoring a vibrant, private patient-physician relationship.
dermatologytimes.com/patientrelations

Two electronic health record systems have had their certifications revoked by the ONC HIT program.
dermatologytimes.com/revoked-certifications

Physicians who fail to report Physician Quality Reporting System data by Oct. 13 will experience a 1.5 percent penalty in 2015.
dermatologytimes.com/PQRSpenalty

A Senate report cites concerns over "code creep" and duplicated records with EHRs that may be leading to higher health costs.
dermatologytimes.com/ehrs-increase-costs

resources in dermatology

Get the latest info on neurotoxins, fillers and what techniques are best for implementing these products. modernmedicine.com/resource-center/botulinum-toxin-injections

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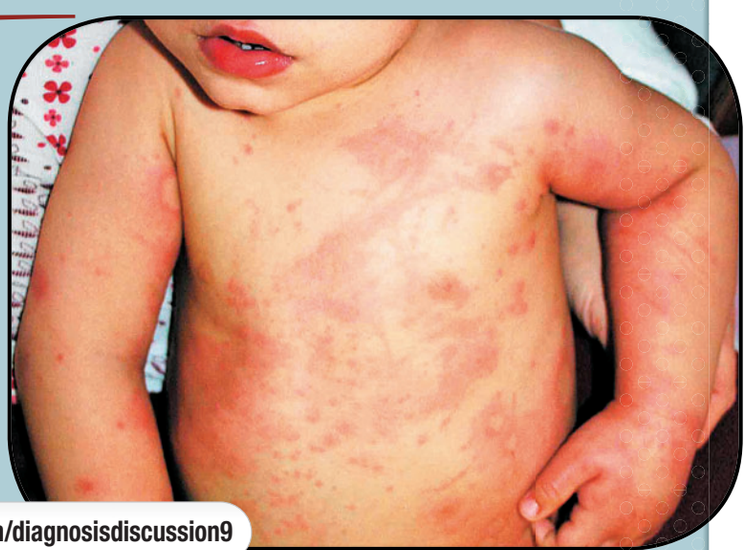
A toddler presents with a diffuse, itchy skin rash that erupted one week ago, a day after he received his mumps/measles/rubella vaccination. He is characteristically normal, running around, laughing and playing. His skin reportedly improves for a few hours after taking Benadryl. What's your diagnosis?



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The Business of Dermatology

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Will fee-for-service end in 5 years?

The stand-alone fee-for-service payment could disappear by the end of the decade if a plan newly released by the National Commission on Physician Payment Reform is followed.

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CLARIFICATION

In the article titled "Derms may be first to spot cardiovascular risks in psoriasis patients" (April 2013 Psoriasis supplement), it should be clarified that Dr. Gelfand says psoriasis patients may be seeing only a dermatologist, with skin disease being their primary concern. Clinicians should inform psoriasis patients about risks of co-morbid diseases and either initiate screening, such as checking blood pressure, weight, glucose and cholesterol, or direct them to a primary care physician for these evaluations. He notes that a patient with more severe psoriasis is 30 times more likely to experience a major cardiovascular event attributable to their skin disease than they are to develop a melanoma.

Dermatology Times regrets the error.

Please see the article at: www.dermatologytimes.com/cardiovascular

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insight & opinion from our advisory board leaders

Helen Torok, M.D., practices at Trillium Creek Dermatology in Medina, Ohio.

Medical missions

In the long term, do patients benefit?

I recently attended a fundraiser organized by medical students for a Peruvian Medical Mission. As physicians, we enter medicine to help, heal and console patients.

For some time, I have contemplated joining an international medical mission to help, heal and console the less fortunate.

Passion to Heal is an organization started and funded by Medicis, to provide just such an opportunity.

This editorial is geared to starting an interactive discussion among dermatologists about the pros and cons of participating in a medical mission. For this discussion the target for a medical mission would be a part of the world completely removed from the modern technological experience of the United States.

Ongoing care

The assumption is being made that the medical needs of the mission area will otherwise be served by traditional, non-medically trained (from a Western standpoint) practitioners.

The question is, how do the patients benefit from the mission? Having never participated in a medical mission myself, I would assume that patients are given, first and foremost, an accurate diagnosis. Then they would be given appropriate surgical interventions when possible and given appropriate medications. Often these medications have to be supplied by the medical mission participants. These treatments should offer relief and comfort.

> To heal and to **console a fellow human** being who has no access to medical care is **what we all strive for.**

Might it be that patients can be disserved by a medical mission? The expectation of being diagnosed correctly and then being given a treatment that resolves the symptoms will be raised.

But the experience and the exposure for the patient consists of only one day or a few days in their ongoing experience of life. There is little realistic expectation that the treatment needed can be continued, monitored and adjusted as needed without the resources being continually available.

A large proportion of dermatological complaints are chronic conditions where one intercession in the patient's life will not significantly alter the course, and disappointment and frustration may follow. The missionary will not be there to evaluate or know the secondary consequences or long-term effects on health.

What are the benefits to the missionary? You will mostly have to make diagnoses based on your knowledge and experience without the aid of laboratory testing. Being required to do this and being able to do it will ensure the confidence that you have chosen wisely in your life's path and used those skills to help another.

Bringing hope, healing

To heal and to console a fellow human being who has no access to medical care is what we all strive for. We leave this world a little better one small step at a time knowing that we helped.

I am optimistic that well-conceived medical missions for dermatologists can bring hope and health to underserved people. I invite those with personal experience to respond to **Dermatology Times** and inform those of us considering participating. DT

Helen Torok, M.D.

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David Goldberg, M.D., J.D., is director of Skin Laser & Surgery Specialists of New York and New Jersey; director of laser research, Mount Sinai School of Medicine; and adjunct professor of law, Fordham Law School.

Security breach

My computer system was hacked. Now what?

Dr. Derm logged into his office computer system, only to find a ransom note from a hacker asking for money in exchange for the safe return of his patients' records. While this might seem far-fetched, this situation happened to a small medical practice outside Chicago, Surgeons of Lake County.

In that office, hackers broke into the practice's server, encrypted the patient data, and demanded a ransom. This is not the first instance of such hacking and certainly will not be the last, as the use of electronic health records (EHR) and electronic medical records (EMR) becomes increasingly widespread.

EMRs are records within the office of a single provider, whereas **EHRs are linked** across multiple offices.

There is a distinction between EHRs and EMRs — EMRs are records within the office of a single provider, whereas EHRs are linked across multiple offices, though many use the terms interchangeably. As with paper medical records, EMRs have both advantages and disadvantages.

Easy access

A big advantage over paper medical records is the ease in which huge amounts of data can be accessed and stored — but a big disadvantage is that the transportability of data makes it that much easier to lose or misplace. While losing a paper chart is a problem, losing, for example, a USB drive with huge amounts of patient data multiplies that problem exponentially. Equally, storing patient data on servers leads to physicians and patients (via patient portals) being able to remotely access their data — but it also opens the door to a determined hacker who could be located anywhere in the world.

The Surgeons of Lake County chose to shut their server down and report the hack to the authorities rather than pay the blackmail. Should Dr. Derm choose to pay blackmail and recover his records or take the chance that he may have to pay fines for breaches in confidentiality, fees for notification, and damage to the practice due to negative exposure?

While the United States has seen a significant increase in EMR usage, it is actually behind the EMR adoption curve compared to many others. Transitions to EMR have had a great degree of success in other countries, such as the United Kingdom, New Zealand, and the Netherlands (where 98 percent of physicians use EMRs). In the United States the number of physicians utilizing EMR in 2011 was substantially lower.

Despite the challenges and costs, few physicians who have adopted EMR would argue that the inconveniences outweigh the benefits, and few would return to a paper-based format. However, with EMR comes the risk of a HIPAA confidentiality breach.

Big data breaches

The Secretary of the Department of Health and Human Services (HHS) maintains records of HIPAA breaches, and reports that nearly 21 million people have had their EMR/EHR records stolen or lost in the past three years alone. The largest individual breach was the loss of records for 4.9 million individuals by TRICARE, the healthcare program for Armed Forces members, retirees, and their families, due to a subcontractor losing a cache of backup tapes in 2009.

Eastern European hackers stole the records of 780,000 Utah residents at the Utah Department of Health in 2012, showing that it is not only physicians and hospitals that have to be vigilant. Medical insurance companies are on the hook, too. Blue Cross Blue Shield and Health Net have had breaches of the data of millions of individuals.

Dr. Derm is liable for his own actions and the actions of his employees. A covered entity must have a privacy plan that includes appropriate sanctions for an employee violating the Privacy Rule or the entity's privacy policies and procedures. The Office for Civil Rights (OCR) within the HHS is the body that investigates, conducts compliance reviews, and educates if it is suspected that the covered entity is in violation of HIPAA. If the OCR investigates and discovers that Dr. Derm was not in compliance, it will attempt to resolve the problem by obtaining voluntary compliance, taking corrective action and/or a resolution agreement. Ultimately, the OCR is able to impose civil money penalties.

Duty to protect data

In light of the possibility of breaches, Dr. Derm has an obligation to adhere to HIPAA and keep his patients' data safe. There are a host of methods by which this can be achieved, ranging from common sense solutions to more advanced technology based solutions. These solutions need to be balanced with usability, however, so safety practices are actually followed. For example, requiring frequent password changes and making users choose complex passwords has limited success in preventing unauthorized access. Users are less likely to remember passwords and will write them down or forget them. Password protection won't prevent unauthorized access if a provider logs in and then walks away from a workstation, leaving the data open and accessible to anyone passing by. Protection of data must also include procedures that staff actually follow.

Annual risk assessments are required by the security management process of the HIPAA regulations, and the results of the assessments can help organize and formulate a plan for compliance, training and encryption. **DT**

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[1]IMS Health, NDTI, December 2011

RESEARCH NEWS

Gene therapy may benefit scleroderma patients

Chicago — Clinicians may one day be able to treat scleroderma more effectively, as researchers have uncovered how gene expression signatures can identify patients who respond well to particular therapies.

Investigators with Northwestern University's Feinberg School of Medicine, Chicago, conducted a small pilot study to assess patients' response to therapy with mycophenolate mofetil. Patients whose conditions did respond to the treatment were classified in the inflammatory gene expression subset, according to a news release. Patients who did not improve were classified in the normal-like or fibroproliferative gene expression subsets.

Researchers identified a mycophenolate mofetil gene expression signature that was composed of genes with expressions that changed "significantly" during treatment in the patients who showed improvement, but the signature was absent in the patients who did not respond to therapy.

A larger trial is under way, which may allow researchers to develop more effective treatment strategies for patients with systemic sclerosis.

The trial results were published in the *Journal of Investigative Dermatology*. DT

Surgery discretionary for elderly NMSC patients

San Francisco — Elderly patients with nonfatal skin cancers may not benefit from surgery, according to recent findings.

The study, led by researchers at the University of California, San Francisco, addressed the current standard of care in the United States for nonmelanoma skin cancers (NMSC). The researchers included nearly 1,400 patients who were diagnosed with NMSC. About 25 percent were considered to have limited life expectancy because they were at least 85 years old at time of diagnosis or presented with multiple comorbidities. The patients were followed for a median of nine years following no treatment, destruction or either elliptical excision or Mohs surgery, according to the study abstract.

Most of the NMSCs (69 percent) were treated surgically, regardless of the patient's life expectancy or tumor characteristics. Although serious complications were rare, about 20 percent of patients with limited life expectancy reported a complication from their skin cancer treatment.

Nearly half (43 percent) of the patients with limited life expectancy died within five years; however, none of them died from NMSC, according to the abstract.

"Our study provides useful evidence for clinicians facing a treatment choice dilemma with their patients — it focuses on a cancer whose natural history is generally benign, where treatment itself may be discretionary," senior author Mary-Margaret Chren, M.D., dermatology professor, UCSF School of Medicine, said in a news release.

The study was published online April 29 in *JAMA Internal Medicine*. DT

QUICKTAKES

T CELLS SHOW PROMISE IN MELANOMA TREATMENT

San Francisco — Genetically modified human immune cells (T cells) may lead to novel melanoma therapies, according to researchers at the University of California, Los Angeles, and California Institute of Technology (CalTech).

Using newly developed nanotechnology chips, the researchers examined the function of genetically modified T cells from blood samples taken at different time points from each patient treated.

Early clinical trials showed the engineered T cells appeared to have a high initial tumor-killing effect, but that effect faded within three weeks.

The researchers noted an antigen spreading effect, in which new T cells that were not modified emerged with the ability to attack the tumor for a short time.

"This study points to the value of these single cell functional analyses for probing the successes and failures of a sophisticated immunotherapy," said the study's first author, Chao Ma, a Ph.D. candidate at CalTech. DT

FDA GRANTS BREAKTHROUGH DESIGNATION FOR MELANOMA DRUG

Washington — The Food and Drug Administration has designated Merck's drug lambrolizumab as a breakthrough therapy for the treatment of advanced melanoma, according to a news release.

The drug, an investigational antibody therapy that targets programmed death receptor (PD-1), is also being evaluated for the treatment of other tumor types, such as non-small cell lung cancer, in addition to melanoma.

The designation as a breakthrough therapy allows the company to expedite the development of a drug candidate that is being planned for use in treating serious or life-threatening diseases.

Early results from a single-arm, open-label, phase 1b study of lambrolizumab given to 85 patients with advanced melanoma were presented at the 9th International Congress of the Society for Melanoma Research in November 2012. A total of 51 percent of patients had an objective anti-tumor response, and of those, 9 percent showed complete response at or after the 12-week assessment, according to the news release. DT

SEIZURE DRUG MAY TURN SKIN BLUE

Washington — A medication used to treat seizures, ezogabine (Potiga, Valeant), can cause blue skin discoloration, the Food and Drug Administration warns, and it is unknown whether the pigmentation changes are reversible.

The drug, approved as an adjunctive for partial-onset seizures in patients ages 18 and older, has reportedly caused cases of blue pigmentation of the skin on and around the lips or in the beds of fingernails and toenails, the FDA states. More widespread involvement of the face and legs has also been reported. Skin discoloration typically occurred after patients took Potiga for four years, but it was reported sooner in some patients.

The FDA urged healthcare professionals to report adverse events and side effects related to ezogabine to the administration's MedWatch Safety Information and Adverse Reporting Program. DT

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References: 1. Data on file. Galderma Laboratories. **2.** Bigotti C, Guala F, Merlo E, Gazzaniga G, Villa G. Zinc and its derivatives: their applications in cosmetic. *J Appl Cosmetol.* 2005;23:139-147. **3.** Rigano L, Merlo E, Guala F, Villa G. Stabilized solutions of zinc coceth sulfate for skin cleansing and skin care. *Cosmetics Toiletries.* 2005;120:103-108. **4.** Schwartz JR, Marsh RG, Draelos ZD. Zinc and skin health: overview of physiology and pharmacology. *Dermatol Surg.* 2005;31:837-847. **5.** Castiel-Higounenc I, Chopart M, Ferraris C. Stratum corneum lipids: specificity, role, deficiencies and modulation. *OCL.* 2004;11(6):401-406.

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RESEARCH NEWS

AACR honors UCLA professor for research

Washington — A researcher who has provided contributions to the understanding of how melanoma escapes from BRAF inhibition was awarded Outstanding Achievement in Cancer Research at the American Association for Cancer Research (AACR) annual meeting recently.

Roger S. Lo, M.D., Ph.D., assistant professor, division of dermatology, David Geffen School of Medicine at the University of California, Los Angeles, earned the distinction for his work into better understanding how BRAF-mutant melanomas adapt to BRAF inhibition. His research shed light on how melanomas reactivate the MAPK signaling pathway, and how this activation can lead to the development of nonmelanoma skin cancer in patients who are being treated with BRAF inhibitors, according to a news release.

Dr. Lo also identified a second pathway that can be responsible for the cancer eluding monotherapy with BRAF inhibitors, which might suggest that combining a BRAF inhibitor with a P13K inhibitor or AKT inhibitor may be clinically effective. **DT**

Melanoma Research Alliance awards $9.6M in grants

Washington — The Melanoma Research Foundation has awarded $9.6 million to 49 scientists at academic institutions across the globe for the investigation of new therapies for the disease.

The grants include funding for 20 separate project awards, eight team science awards, seven young investigator awards and five academic-industry partnership awards.

This year's funding distribution set new records for projects supported by the Melanoma Research Foundation. In addition to the $9.6 million it offered, there was an additional $2.12 million in support from corporate organizations, industry and individuals.

"This year's grants are at the cutting-edge of the most promising areas of inquiry in the field of melanoma research, including better understanding of genetic factors underlying risk and new treatment approaches to cure or control melanoma once it has spread," Wendy K. Selig, president and CEO of the Melanoma Research Foundation, said in a news release. **DT**

Molecular path studies earn innovator award

Houston — An MD Anderson researcher has been awarded $100,000 for his proposal to map the molecular pathway to skin cancer.

Kenneth Tsai, M.D., Ph.D., assistant professor, The University of Texas, MD Anderson Cancer Center, Houston, received the Sixth Annual Landon Foundation AACR INNOVATOR Award for Cancer Prevention Research. He was honored at the American Association for Cancer Research Annual Meeting in Washington in early April.

Dr. Tsai and colleagues are collecting samples of normal tissue, actinic keratosis and cancer samples from patients.

Benefits could help clinicians identify those at greatest risk and those who don't need intensive treatment or surveillance, according to a news release.

"By identifying important genetic differences, we hope to find biomarkers of risk for the precancerous lesions, called actinic keratosis, and for skin cancer progression," Dr. Tsai stated in a news release. "We ultimately aim to identify targets for chemoprevention at all stages and develop therapies for them." **DT**

Diagnostic errors account for most malpractice claims

Baltimore — Diagnostic errors account for the greatest proportion of total payments on malpractice claims in the past 25 years, a recent study indicates.

Analyzing 350,706 paid malpractice claims from the National Practitioner Bank from 1986 to 2010, investigators with Johns Hopkins University School of Medicine, Baltimore, described the error type, outcome severity and payments, according to the abstract. Diagnostic errors accounted for 28.6 percent of all paid claims, and had the highest proportion of total payments, at 35.2 percent.

Death, significant permanent injury and minor and major permanent injury were the most frequent outcomes of claims. There were more diagnostic error claims for outpatient than inpatient cases (68.8 versus 31.2 percent). Inpatient diagnostic errors, however, were more likely to be lethal, at 48.4 versus 36.9 percent.

Adjusting for inflation, the 25-year sum of diagnosis-related payments was $38.8 billion. The median per-claim payout was $213,250; the mean payout was $386,849.

"We found roughly equal numbers of lethal and nonlethal errors in our analysis, suggesting that the public health burden of diagnostic errors could be twice that previously estimated," the study authors concluded.

The study was published online April 22 in *BMJ Quality & Safety*. **DT**

INDUSTRY NEWS

Promius launches isotretinoin product, program

Bridgewater, N.J. — Promius Pharma has launched Zenatane (isotretinoin) capsules for the treatment of acne vulgaris.

A spokeswoman for Promius noted the Food and Drug Administration has indicated that Zenatane is rated as an A/B equivalent to Accutane, the isotretinoin product formerly manufactured by Roche.

Zenatane will also be supported by the Promius Promise, a pharmacy service designed to support both physicians and patients, according to a news release. Promius Promise provides information to patients about treatment requirements and reminders, has staff available to answer questions about the drug, and can deliver Zenatane to patients within 24 hours.

Additionally, the Promius Promise provides payment assistance for patients both with and without insurance. To support the Promius Promise, Promius partnered with an accredited pharmacy that is iPLEDGE-certified.

"The majority of dermatologists believe isotretinoin can make an enormous contribution to the quality of life of a patient with severe recalcitrant nodular acne," Promius head of sales and marketing, Rob D'Urso, stated in a news release. "Yet, based on an FDA review of year five of the iPLEDGE program, over 400,000 attempts to fill isotretinoin prescriptions were denied due to failures to meet iPLEDGE requirements. We hope the Promius Promise can help." **DT**

N.J. bans minors from tanning beds

Trenton, N.J. — New Jersey Governor Chris Christie signed into law a bill that prohibits minors under age 17 from using indoor tanning facilities, and bars minors under age 14 from using spray tanning procedures.

Assembly Bill 2142 requires minors age 17 and older to bring a parent or guardian to tanning facilities for a consultation if the minor wants to tan. In a statement, Gov. Christie said the legislation was the result of an incident in which a parent brought a child into a tanning facility. The tanning salon that allowed the child inside was fined.

"Confidence in the current laws, rather than a rush to add new and perhaps unnecessary provisions, would have seemed the appropriate legislative response," Gov. Christie stated. "Nonetheless, I sign this bill because of the documented and well-understood risks associated with misuse of indoor tanning systems."

The American Academy of Dermatology praised the bill's passage.

"Through national media coverage and reality television, attention has been drawn to the use of indoor tanning devices in New Jersey," Dirk Elston, M.D., AAD president, said in a news release. "This legislation highlights an important step in changing unhealthy behaviors and sends a strong message from the state that tanning is a dangerous behavior and should be avoided."

The law goes into effect Oct. 1. **DT**

BUSINESS NEWS

La Roche-Posay to offer grant aimed at improving quality of life for patients

New York — La Roche-Posay has launched its "Dermatologist from the Heart" program, in which it will provide a $10,000 grant to a dermatologist who demonstrates initiatives that improve the quality of life for patients.

Candidates for the grant must submit a proposal that outlines their project. The project should fall within one of five categories: Information and Prevention; Health Professional Training; Advice and Support; Improving Social Integration; and Improving Access to Healthcare. A panel will review submissions and select a winner based on the proposal's creativity, originality, impact on patients' quality of life, feasibility and method. **DT**

ASSOCIATION NEWS

Galderma teams with AAD for innovative research fellowship

Schaumburg, Ill. — Galderma has teamed with the American Academy of Dermatology to create the American Academy of Dermatology Translational Biotechnology Fellowship, according to a news release.

The fellowship offers dermatologists the chance to work in drug development and translational medical research at Galderma's research and development facility in Sophia Antipolis, France. Fellowship recipients will work to advance science while also exploring career options in a pharmaceutical industry setting.

Two one-year fellowships will be available, with one starting in fall 2013 and a second in fall 2014. The selected fellow will receive from the AAD a stipend to cover costs during the fellowship, and Galderma will host and provide necessary resources to support the fellow.

Candidates who are in their final year of residency at an accredited American College of Graduate Medical Education dermatology residency program will be given preference, according to the news release. Candidates must be physician members of the academy who will have completed a residency no more than three years before the planned start date. Candidates also must be interested in pursuing research and a career in the industry setting.

The AAD plans to review applications and recommend one candidate each year the fellowship is available. More information can be found at www.aad.org/biotechfellowship. **DT**

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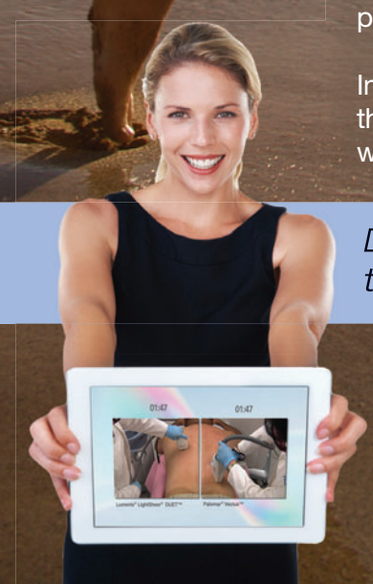

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ABSTRACTS FROM THAT PILE OF PEER-REVIEWED JOURNALS ON YOUR DESK

CLINICAL DERMATOLOGY

Antibiotics reduce acne-related office visits, treatment costs

American Journal of Clinical Dermatology APRIL 2013

ORAL ANTIBIOTIC USE for the treatment of acne is associated with a decreased number of acne-related outpatient visits and lowered acne-related healthcare costs; however, patients are less adherent to this treatment, according to a study published in the April 13 issue of the *American Journal of Clinical Dermatology.*

According to the researchers at Wake Forest University, Winston-Salem, N.C., and colleagues, patients were more adherent to oral retinoids than any other acne drug classes (medication possession ratio [MPR]=0.78, 57 percent adherent); and were less adherent to oral antibiotics (MPR=0.21) and topical retinoids (MPR=0.31).

The researchers used a national healthcare claims database to identify 24,438 acne patients ages 0 to 64 years. Nearly 90 percent were under age 18. Patients were followed for 90 days after their first acne drug prescription to examine acne medication adherence, acne-related outpatient visits, and total acne-related healthcare costs.

The researchers noted that the use of oral antibiotics decreased the number of acne-related outpatient visits by 50.9 percent (P<0.001) and lowered acne-related total costs by 51.7 percent (P<0.001).

Investigators concluded that combining a topical retinoid and an antibiotic agent may be a good treatment approach given their associated healthcare outcomes and costs, but adherence strategies need to be improved.

http://link.springer.com/article/10.1007%2Fs40257-013-0016-x

Darker skin fairs better with fractional microplasma RF

Dermatologic Surgery APRIL 2013

BOTH FRACTIONAL microplasma radiofrequency (RF) technology and the carbon dioxide fractional laser system (CO_2 FS) appear to effectively treat atrophic acne scars, according to findings published in the April issue of *Dermatologic Surgery.*

Researchers from the School of Medicine at Shanghai JiaoTong University, Shanghai, China, performed a randomized split-face treatment of fractional microplasma RF or CO_2 FS on 33 Asian patients. Each patient underwent three treatment sessions.

The authors noted that there was no statistically significant difference between therapies. However, more than a third of the patients experienced postinflammatory hyperpigmentation (PIH) on the side of the face treated with CO_2 FS, while no PIH was observed on the fractional microplasma RF sides, the authors reported. They concluded that fractional microplasma RF might be a better choice for darker skinned patients.

http://onlinelibrary.wiley.com/doi/10.1111/dsu.12103/abstract

Combination treatment improves hypertrophic scars

Lasers in Surgery and Medicine MARCH 2013

A COMBINATION TREATMENT of same-session fractional ablative laser treatment and topical triamcinolone acetonide suspension improves hypertrophic scars, according to a study published in the March issue of *Lasers in Surgery and Medicine.*

Researchers at Miami Dermatology and Laser Institute and colleagues conducted a prospective case series. Fifteen consecutive patients with hypertrophic scars received three to five treatment sessions including fractional ablative laser treatment with immediate postoperative topical application of 10 or 20 mg/mL triamcinolone acetonide suspension. Sessions were conducted at two- to three-month intervals.

Three blinded observers evaluated photos from baseline and at six months. Scores were assigned using a modified Manchester quartile score.

On a 0 to 3 scale, the combination treatment resulted in an average overall improvement score for hypertrophy of 2.73. Dyschromia showed the least amount of average improvement (2.36), and texture the most (3.00).

Although the authors noted the sample size was small and the study lacked a control arm, they concluded that this combination approach may offer an efficient, safe and effective therapy for challenging hypertrophic and restrictive cutaneous scars.

http://onlinelibrary.wiley.com/doi/10.1002/lsm.22120/abstract

Adalimumab has low rate of long-term adverse events

Annals of the Rheumatic Diseases MARCH 2013

THE RATE OF ADVERSE EVENTS in patients using adalimumab remains low over time, with infections indicated as the most common adverse event, according to a study published in the April issue of *Annals of the Rheumatic Diseases.*

Investigators with Charité University Hospital, Berlin, analyzed the long-term safety of the anti-tumor necrosis factor (TNF) agent adalimumab in 23,458 patients from 71 global clinical trials for rheumatoid arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, psoriatic arthritis, psoriasis and Crohn's disease. Researchers calculated events per 100 patient-years using events reported after the first dose through 70 days after the last dose, according to the study abstract.

The most frequently reported adverse events across all indications were infections, and were most common among patients with rheumatoid arthritis and Crohn's disease. Nonmelanoma skin cancer incidence was raised in patients with rheumatoid arthritis, psoriasis and Crohn's disease. The death rates were lower than or equivalent to those expected in the general population, the authors noted.

http://ard.bmj.com/content/72/4/517.abstract

Bean leaves may inspire remedy for bedbugs

Journal of the Royal Society Interface APRIL 2013

MICROSCOPIC HAIRS on kidney bean leaves may serve as a model for a future remedy for bedbugs, according to findings published in the April issue of the *Journal of the Royal Society Interface.*

In eastern Europe, a centuries-old folk remedy for bedbugs had involved using the leaves of bean plants to trap and then destroy the pests, according to researchers with the University of California, Irvine, and the University of Kentucky, Lexington.

"This purely physical entrapment was related to microscopic hooked hairs (trichomes) on the leaf surfaces," the study authors noted. Investigators used videography and scanning electron microscopy to document this trapping mechanism, which resulted in the bedbugs' feet becoming impaled by the trichomes.

"Struggling, trapped bedbugs are impaled by trichomes on several legs and are unable to free themselves. Only specific, mechanically vulnerable locations on the bug tarsi (feet) are pierced by the trichomes, which are located at effective heights and orientations for bedbug entrapment despite a lack of evolutionary association," the authors stated.

Using this information, the

RESEARCH STAT see page 21

From hard-to-reach spots to large body areas...

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KENALOG®
SPRAY *with Spray Tube*
Triamcinolone Acetonide
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- Delivers 0.2% triamcinolone*

RELIEF NEVER FELT SO GOOD

Indication:

Kenalog® Spray (triamcinolone acetonide topical aerosol, USP) is indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

Important Safety Information:

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 which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (see **PRECAUTIONS, Pediatric Use**).

You are encouraged to report negative side effects of prescription drugs to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

For topical use only. Please see adjacent page for full prescribing information.

For more information, visit www.kenalogspray.com

Reference:

1. Data on file. Ranbaxy Laboratories, Inc. Princeton, NJ.

***** After spraying, the nonvolatile vehicle remaining on the skin contains approximately 0.2% triamcinolone acetonide. Each gram of spray provides 0.147 mg triamcinolone acetonide in a vehicle of isopropyl palmitate, dehydrated alcohol (10.3%), and isobutane propellant.

KS 1212

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KENALOG® SPRAY

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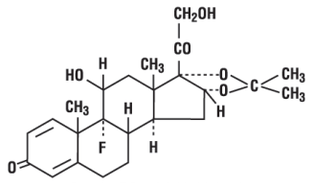
Triamcinolone Acetonide Topical Aerosol, USP (0.147 mg/g)

For dermatologic use only
Not for ophthalmic use

DESCRIPTION

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. The steroids in this class include triamcinolone acetonide. Triamcinolone acetonide is designated chemically as 9-fluoro-11β, 16α, 17, 21-tetrahydroxypregna-1, 4-diene-3, 20-dione cyclic 16, 17- acetal with acetone. The structural formula is:



$C_{24}H_{31}FO_6$, MW 434.50

A two-second application, which covers an area approximately the size of the hand, delivers an amount of triamcinolone acetonide not exceeding 0.2 mg. After spraying, the nonvolatile vehicle remaining on the skin contains approximately 0.2% triamcinolone acetonide. Each gram of spray provides 0.147 mg triamcinolone acetonide in a vehicle of isopropyl palmitate, dehydrated alcohol (10.3%), and isobutane propellant.

CLINICAL PHARMACOLOGY

Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption.

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE

Kenalog Spray (Triamcinolone Acetonide Topical Aerosol, USP) is indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations.

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 which augment systemic absorption include the 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 any 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 the urinary free cortisol and ACTH stimulation tests, and for impairment of thermal homeostasis. If HPA axis suppression or elevation of the body temperature occurs, an attempt should be made to withdraw the drug, to reduce the frequency of application, substitute a less potent steroid, or use a sequential approach.

Recovery of HPA axis function and thermal homeostasis are generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (see **PRECAUTIONS, Pediatric Use**).

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Information for the Patient

Patients using Kenalog Spray should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only; avoid contact with the eyes and inhalation of the spray.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.
6. Do not use Kenalog Spray on the underarms or groin areas unless directed by your physician.
7. If no improvement is seen within 2 weeks, contact your physician.
8. Do not use other corticosteroid-containing products while using Kenalog Spray without first consulting your physician.
9. Kenalog Spray is flammable. Avoid heat, flames or smoking when applying Kenalog Spray.

Laboratory Tests

A urinary free cortisol test and ACTH stimulation test may be helpful in evaluating HPA axis suppression.

Carcinogenesis, Mutagenesis, 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 showed negative results.

Pregnancy: Teratogenic Effects

Category C. 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 on pregnant patients, 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 mature patients because of a larger skin surface area to body weight ratio.

HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children 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 children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

ADVERSE REACTIONS

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

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

Directions for use of the spray can are provided on the label. The preparation may be applied to any area of the body, but when it is sprayed about the face, care should be taken to see that the eyes are covered, and that inhalation of the spray is avoided.

Spray is flammable; avoid heat, flame or smoking when using this product.

Three or four applications daily of Kenalog Spray (Triamcinolone Acetonide Topical Aerosol) are generally adequate.

HOW SUPPLIED

Kenalog Spray (Triamcinolone Acetonide Topical Aerosol, USP)

63 g (NDC 10631-093-62) aerosol can.

100 g (NDC 10631-093-07) aerosol can.

Storage and Handling

Store at room temperature; avoid excessive heat. Contents under pressure; do not puncture or incinerate. Keep out of reach of children.

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

RANBAXY
Jacksonville, FL 32257 USA

Revised August 2011

Printed in the USA DERM-3567-1212

ABSTRACTS FROM THAT PILE OF PEER-REVIEWED JOURNALS ON YOUR DESK

Research stat

RESEARCH STAT from page 18

researchers created microfabricated surfaces that were "indistinguishable in geometry" from the plant's real leaves. They used polymers containing material properties that are similar to plant cell walls.

"These synthetic surfaces snag the bedbugs temporarily, but do not hinder their locomotion as effectively as real leaves," authors wrote.

Eventually, synthetic materials could be a nontoxic alternative to pesticides to eliminate bedbugs.

http://rsif.royalsocietypublishing.org/content/10/83/20130174.abstract?sid=6d51028d-01b5-4c4a-b39d-9cd09f6c51b1

Combined laser approach improves acne

Clinical and Experimental Dermatology APRIL 2013

A COMBINED THERAPY including combination intense pulsed light (IPL) and fractional CO_2 laser appears safe and effective for treating patients with inflammatory acne and atrophic scars, according to a study published online April 3 in *Clinical and Experimental Dermatology*.

Researchers in the department of dermatology, No. 1 Hospital of China Medical University, Shenyang, China, and colleagues at Sheftel Associates Dermatology, Tucson, Ariz., treated 37 Chinese patients with inflammatory acne and scar lesions with four to six successive treatments of IPL followed by two sessions using a fractional CO_2 laser.

Results were evaluated by the dermatologist, the patient and with devices to measure skin color, sebum secretion and skin hydration. The researchers noted that about 90 percent of patients experienced significant or moderate overall improvement with about 80 percent rating their results as excellent or good. After IPL treatments, inflammatory lesion and atrophic scar scores significantly reduced from baseline, which were further reduced with subsequent fractional CO_2 laser treatments, according to the abstract. The scores remained low at six month follow-ups.

In addition, the melanin index (MI), erythema index (EI) and skin sebum level all significantly decreased after IPL treatments. At three-month follow-up assessments, the EI and sebum level were still low; however, MI had increased, the authors noted.

http://onlinelibrary.wiley.com/doi/10.1111/ced.12010/abstract

PEDIATRIC DERMATOLOGY

Parents lack understanding of infantile eczema

Pediatric Dermatology MARCH/APRIL 2013

DOCTORS CAN HELP their small patients suffering from eczema by helping parents better understand what causes flares, suggests a study published in the March/April issue of *Pediatric Dermatology*.

Researchers at the University of Zhejiang, Hangzhou, China, recruited 250 parents of infants ages 1 to 10 months who had been diagnosed with eczema. Parents were asked to complete a questionnaire about the child's condition and treatment.

Data showed 242 (96.8 percent) children had dry skin, 80 percent were bathed with soap or shower gel, 82 percent often perspired, 84.8 percent wore tight-fitting clothes, 80.8 percent dressed in five layers of thick clothing, 85.6 percent were in contact with wool or feathers, and 59.2 percent were exposed to daily sunlight longer than 20 minutes.

Most of the mothers reported avoiding food allergens without impact on 93.6 percent of the children; while 10 percent of 30 infants who consumed Neocate as a substitute for cow's milk showed an improvement in symptoms. About 13 percent of 30 children given food allergens demonstrated exacerbated symptoms.

One hundred twenty-eight (51.2 percent) of the infants were treated with corticosteroid ointment; 62.5 percent had the ointment applied for only two to three days, and 6.2 percent had the corticosteroid ointment applied.

The authors concluded that results demonstrated a need to better educate parents about the condition.

http://onlinelibrary.wiley.com/doi/10.1111/j.1525-1470.2012.01854.x/abstract

Wart prevention should focus on family transmission

Pediatrics APRIL 2013

CUTANEOUS WARTS IN SCHOOLCHILDREN are spread most commonly at home and at school, and preventive measures should be focused on limiting human papillomavirus transmission in families, according to a study published in the April issue of *Pediatrics*.

Although warts are common in school-age children, the way human papillomavirus (HPV) is transmitted is not well known. Researchers with Leiden University Medical Center, Leiden, Netherlands, inspected the hands and feet of more than 1,000 children ages 4 to 12 from three schools. Investigators noted the presence of warts at baseline and after 11 and 18 months of follow-up, according to the study abstract.

Researchers also distributed questionnaires that sought information about pre-existing warts, warts in the family, prevalence of warts at baseline and use of public places such as swimming pools, in an effort to collect data about the degree of HPV exposure.

Overall, the incidence for developing warts was 29 per 100 person-years at risk (95 percent confidence interval [CI] 26-32). Children with white skin had an increased risk of contracting warts (hazard ratio [HR] 2.3, 95 percent CI 1.3-3.9).

Independent environmental risk factors were having family members with warts (HR 2.08, 95 percent CI 1.52-2.86) and wart prevalence in the class (HR 1.20 per 10 percent increase, 95 percent CI 1.03-1.41).

The authors recommend focusing preventive measures on limiting HPV transmission in families and school classes, rather than in public places.

http://pediatrics.aappublications.org/content/early/2013/04/16/peds.2012-2946

Prebiotic supplements may prevent infant eczema

The Cochrane Review MARCH 2013

ADDING A PREBIOTIC SUPPLEMENT to infant formula may prevent eczema in infants up to two years of age, according to a recent study published online March 28 in *The Cochrane Review*.

According to the investigators with the University of Sydney, Australia, food allergy reactions are common and may be increasing. The authors, therefore, sought to clarify evidence that suggest prebiotics may prevent sensitization to foods, preventing the development of eczema and asthma.

The researchers reviewed data for 1,428 infants and found that infants who were fed a formula supplemented with a prebiotic showed a significant reduction in eczema (1,218 infants, typical risk ratio 0.68, 95 percent confidence interval [CI] 0.48 to 0.97; typical risk difference -0.04, 95 percent CI -0.07 to -0.00; number needed to treat to benefit (NNTB) 25, 95 percent CI 14 to >100; P=0.03).

The study authors suggested that further research be performed to confirm these findings before routine use or prebiotics is recommended in allergy prevention.

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006474.pub3/abstract

ONCOLOGY

Lower education level associated with higher melanoma mortality

RESEARCH STAT see page 22

Research stat

ABSTRACTS FROM THAT PILE OF PEER-REVIEWED JOURNALS ON YOUR DESK

RESEARCH STAT from page 21

European Journal of Cancer **APRIL 2013**

MELANOMA PATIENTS IN SWEDEN with a lower level of education are more likely to die from malignant melanoma, according to a study published online April 15 ahead of print in the *European Journal of Cancer*.

Through the Swedish Melanoma Register, researchers from Karolinska Institutet and Linköping University in Sweden and colleagues identified 27,235 patients with a primary invasive cutaneous malignant melanoma diagnosed between 1990 and 2007. The researchers linked the data to nationwide, population-based, health and census registers with a follow-up to 2010, according to the abstract.

The authors found that patients in lower education groups had more advanced disease at the time of diagnosis (odds ratio [OR] stage 2 versus 1 = 1.6; 95 percent confidence interval [CI]=1.5-1.7; OR stage 34 versus 1 = 2.3; 95 percent CI=1.8-2.9). In addition, patients with lower levels of education were at a significantly increased risk of dying from cutaneous malignant melanoma (hazard ratio [HR] low versus high = 2.02; 95 percent CI=1.80-2.26; P<0.0001) compared with patients at an intermediate (HR intermediate versus high = 1.35; 95 percent CI=1.20-1.51; P<0.0001) level of education.

Investigators urged improving early detection strategies.

http://www.ejcancer.com/article/S0959-8049(13)00216-5/abstract

Nonmelanoma skin cancer rates rising, higher in men

Dermatologic Surgery **APRIL 2013**

VISIT RATES FOR NONMELANOMA skin cancer (NMSC) increased from 1995 to 2007 and were significantly higher in men aged 65 and older, according to research published in the April issue of *Dermatologic Surgery*.

Stanford University researchers, along with colleagues the University of California at San Francisco, and Berman Gladstone Skin Institute, Palo Alto, Calif., found that NMSC visits to dermatologists were more likely to be associated with a procedure, and those patients were more likely to be males with private-pay insurance.

The authors evaluated data from the National Ambulatory Medical Care Survey between 1995 and 2007. The study population included adults diagnosed with NMSC according to the International Classification of Diseases, Ninth Revision. The researchers used logistic regression to examine NMSC visit rates and odds ratios of receiving an NMSC-related procedure.

The authors caution that there may be discrepancies in treatment patterns based on insurance type and gender.

http://onlinelibrary.wiley.com/doi/10.1111/dsu.12092/abstract

COSMETIC DERMATOLOGY

Alternative skin lightening agent shows promise

Journal of Cosmetic Dermatology **MARCH 2013**

A SKIN-LIGHTENING COMPLEX consisting of four actives that target melanin formation may be an effective alternative to other skin-lightening actives, according to a recent study published in the March issue of the *Journal of Cosmetic Dermatology*.

Researchers from Duke University School of Medicine, Durham, N.C., and colleagues examined the effects of a topical skin-lightening complex on hyperpigmentation — an oil-in-water emulsion cream comprised of disodium glycerophosphate, L-leucine, phenylethyl resorcinol, and undecylenoyl phenylalanine.

Eighty women with skin types 1-3 and at least moderate mottled hyperpigmentation underwent a one-month wash-out period with sunscreen, after which applied the skin lightening complex cream to their entire face following sunscreen application twice daily for 12 weeks.

Of the 80 women, 57 percent showed a moderate response, 17 percent did not improve, and 3 percent worsened. Mottled hyperpigmentation appeared to decrease by 32 percent after the 12-week treatment period. In addition, the severity and number of lentigines improved, as well as skin tone and skin brightness.

Researchers reported the SLC cream was well tolerated and suggest the skin lightening complex represents an alternative treatment for skin lightening.

http://onlinelibrary.wiley.com/doi/10.1111/jocd.12025/abstract

Less invasive filler may extend hand rejuvenation results

Journal of Cosmetic Dermatology **MARCH 2013**

A POLYCAPROLACTONE-BASED dermal filler appears to be a safe and effective method for hand rejuvenation, according to research published in the March issue of the *Journal of Cosmetic Dermatology*.

Researchers at Clinica Milenio, Lisbon, Portugal, conducted a pilot study to evaluate the safety and efficacy of a 1.0 mL injection of a polycaprolactone based dermal filler on the dorsum of the hands of five subjects. Each patient was treated at one, four, 16 and 24 weeks.

Investigators reported that patients were 88 percent likely to return for repeat treatments. Patient satisfaction at 24 weeks was rated at 82 percent using a Visual Analog Scale. All patients reported an improvement compared with pretreatment on the Global Aesthetic Improvement (GAIS) scale assessment. The physician GAIS results were reported at 90 percent very much improved and 10 percent much improved.

The researchers concluded that the polycaprolactone-based dermal filler may offer a complementary treatment modality, but this should be confirmed in a larger study.

http://onlinelibrary.wiley.com/doi/10.1111/jocd.12020/abstract

Dermoscopic photoaging scale proves reliable

Skin Research and Technology **MAY 2013**

THE DERMOSCOPIC PHOTOAGING SCALE (DPAS) appears to be a reliable and valid diagnostic tool for evaluating photoaged skin, according to a study published in the May issue of *Skin Research and Technology*.

Researchers at Ordu University Research and Education Hospital, Ordu, Turkey, and colleagues who assessed the use of dermoscopy for measuring skin aging, separated 441 participants ages 20 to 88 (mean 48.4±17.7) into six groups by age.

Using dermoscopy, the authors examined sun-exposed areas on each patient's face and determined scores using DPAS for signs of photoaging, including telangiectasia, vascular changes, pigmentation changes, seborrheic keratosis, actinic keratosis, periorbital comedones and cysts, and superficial- deep- criss-cross wrinkles. The authors assessed validity by subsequently using DPAS to evaluate non-sun-exposed, photoaged areas, including the axillar and the gluteal regions.

A Cronbach's alpha coefficient showed the results were highly reliable (0.756). The researchers clinically compared the skin aging of patients from each decade using the Glogou photoaging scale and Monheit-Fulton photoaging index. A significant correlation was calculated as 0.773 and 0.774, respectively.

The researchers noted an increase in photoaging scores from young patients to the older participants according to their ages and found the same linear difference between their mean values.

http://onlinelibrary.wiley.com/doi/10.1111/srt.12033/abstract

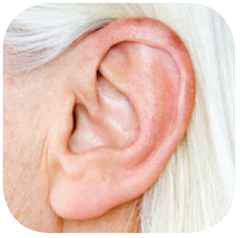
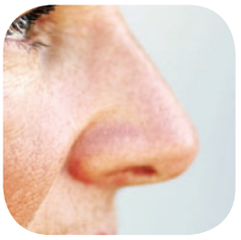
High Clearance[1*]

Low Down Time[†]

Monitored Completion[**]

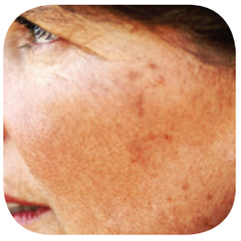
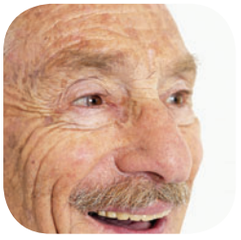
Few AKs

Localized area | Sensitive area | Larger area


Multiple AKs

Localized area | Larger area

The Levulan® Kerastick® for Topical Solution plus blue light illumination using the BLU-U® Blue Light Photodynamic Therapy Illuminator is indicated for the treatment of minimally to moderately thick actinic keratoses of the face or scalp.

*At 8 weeks, 77% of patients treated with Levulan PDT experienced 75% clearance of AK lesions vs 23% of the control group. 83% of the patients treated with Levulan PDT had 75% clearance of face lesions and 60% of the patients had 75% clearance of scalp lesions. 66% of patients treated with Levulan PDT experienced 100% clearance of AK lesions vs 13% of the control group. 70% of the patients treated with Levulan PDT had 100% clearance of face lesions and 55% of the patients had 100% clearance of scalp lesions.

*Results from two identical, randomized, multi-center, two-arm Phase 3 studies with a total of 243 patients. Patients who were not complete responders at week 8 had a retreatment of the persistent target lesions. All patients returned at week 12 after initial treatment.

†Patients treated with Levulan PDT should avoid exposure of the photosensitized lesions to sunlight or prolonged or intense light for at least 40 hours.

**Levulan PDT is a 2-part treatment procedure that can be completed within a 24 hour period.

Important Risk Information

Application of Levulan Kerastick should involve either scalp or face lesions, but not both simultaneously. Levulan Kerastick should not be applied to the periorbital area or allowed to contact ocular or mucosal surfaces. Excessive irritation may be experienced if this product is applied under occlusion.

Contraindicated in patients with cutaneous photosensitivity at wavelengths of 400-450 nm, porphyria, or known allergies to porphyrins, and in patients with known sensitivity to any of the components of the Levulan Kerastick for Topical Solution. Levulan Kerastick has not been tested on patients with inherited or acquired coagulation defects.

Transient local symptoms of stinging and/or burning, itching, erythema, and edema were observed in all clinical studies. Severe stinging and/or burning at one or more lesions being treated was reported by at least 50% of patients at some time during treatment. However, less than 3% of patients discontinued light treatment due to stinging and/or burning. The most common adverse events include scaling/crusting, hypo/hyperpigmentation, itching, stinging and/or burning, erythema and edema. In 99% of active treatment patients, some or all lesions were erythematous shortly after treatment, while in 79% of vehicle-treated patients, some or all lesions were erythematous. In 35% of active treatment patients, some or all lesions were edematous, while no vehicle-treated patients had edematous lesions.

Please see safety information on adjacent page.

1. Levulan® Kerastick® Prescribing Information. DUSA Pharmaceuticals, Inc.®

Levulan® Kerastick®
(aminolevulinic acid HCl)
for Topical Solution, 20%

Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%
Initial U.S. approval: 1999

INDICATIONS AND USAGE

The LEVULAN KERASTICK for Topical Solution, a porphyrin precursor, plus blue light illumination using the BLU-U® Blue Light Photodynamic Therapy Illuminator is indicated for the treatment of minimally to moderately thick actinic keratoses of the face or scalp.

CONTRAINDICATIONS

The LEVULAN KERASTICK for Topical Solution plus blue light illumination using the BLU-U Blue Light Photodynamic Therapy Illuminator is contraindicated in patients with cutaneous photosensitivity at wavelengths of 400-450 nm, porphyria or known allergies to porphyrins, and in patients with known sensitivity to any of the components of the LEVULAN KERASTICK for Topical Solution.

WARNINGS AND PRECAUTIONS

Photosensitivity

During the time period between the application of LEVULAN KERASTICK Topical Solution and exposure to activating light from the BLU-U Blue Light Photodynamic Therapy Illuminator, the treatment site will become photosensitive. After LEVULAN KERASTICK Topical Solution application, patients should avoid exposure of the photosensitive treatment sites to sunlight or bright indoor light (e.g., examination lamps, operating room lamps, tanning beds, or lights at close proximity) during the period prior to blue light treatment. Exposure may result in a stinging and/or burning sensation and may cause erythema and/or edema of the lesions. Before exposure to sunlight, patients should, therefore, protect treated lesions from the sun by wearing a wide-brimmed hat or similar head covering of light-opaque material. Sunscreens will not protect against photosensitivity reactions caused by visible light. It has not been determined if perspiration can spread the LEVULAN KERASTICK Topical Solution outside the treatment site to eye or surrounding skin.

Application of LEVULAN KERASTICK Topical Solution to perilesional areas of photodamaged skin of the face or scalp may result in photosensitization. Upon exposure to activating light from the BLU-U Blue Light Photodynamic Therapy Illuminator, such photosensitized skin may produce a stinging and/or burning sensation and may become erythematous and/or edematous in a manner similar to that of actinic keratoses treated with LEVULAN KERASTICK Photodynamic Therapy. Because of the potential for skin to become photosensitized, the LEVULAN KERASTICK should be used by a qualified health professional to apply drug only to actinic keratoses and not perilesional skin. If for any reason the patient cannot return for blue light treatment during the prescribed period after application of LEVULAN KERASTICK Topical Solution (14 to 18 hours), the patient should call the doctor. The patient should also continue to avoid exposure of the photosensitized lesions to sunlight or prolonged or intense light for at least 40 hours. If stinging and/or burning is noted, exposure to light should be reduced.

Irritation

The LEVULAN KERASTICK Topical Solution contains alcohol and is intended for topical use only. Do not apply to the eyes or to mucous membranes. Excessive irritation may be experienced if this product is applied under occlusion.

Coagulation Defects

The LEVULAN KERASTICK for Topical Solution has not been tested on patients with inherited or acquired coagulation defects.

ADVERSE REACTIONS

In Phase 3 studies, no non-cutaneous adverse events were found to be consistently associated with LEVULAN KERASTICK Topical Solution application followed by blue light exposure.

Photodynamic Therapy Response: The constellation of transient local symptoms of stinging and/or burning, itching, erythema and edema as a result of LEVULAN KERASTICK Topical Solution plus BLU-U treatment was observed in all clinical studies of LEVULAN KERASTICK for Topical Solution Photodynamic Therapy for actinic keratoses treatment. Stinging and/or burning subsided between 1 minute and 24 hours after the BLU-U Blue Light Photodynamic Therapy Illuminator was turned off, and appeared qualitatively similar to that perceived by patients with erythropoietic protoporphyria upon exposure to sunlight. There was no clear drug dose or light dose dependent change in the incidence or severity of stinging and/or burning.

In two Phase 3 trials, the sensation of stinging and/or burning appeared to reach a plateau at 6 minutes into the treatment. Severe stinging and/or burning at one or more lesions being treated was reported by at least 50% of the patients at some time during treatment. The majority of patients reported that all lesions treated exhibited at least slight stinging and/or burning. Less than 3% of patients discontinued light treatment due to stinging and/or burning.

In the Phase 3 trials, the most common changes in lesion appearance after LEVULAN KERASTICK for Topical Solution Photodynamic Therapy were erythema and edema. In 99% of active treatment patients, some or all lesions were erythematous shortly after treatment, while in 79% of vehicle treatment patients, some or all lesions were erythematous. In 35% of active treatment patients, some or all lesions were edematous, while no vehicle-treated patients had edematous lesions. Both erythema and edema resolved to baseline or improved by 4 weeks after therapy. LEVULAN KERASTICK Topical Solution application to photodamaged perilesional skin resulted in photosensitization of photodamaged skin and in a photodynamic response (see Warnings and Precautions).

Other Localized Cutaneous Adverse Experiences: Table 1 depicts the incidence and severity of cutaneous adverse events in Phase 3 studies, stratified by anatomic site treated.

TABLE 1 Post-PDT Cutaneous Adverse Events - ALA-018/ALA-019

	FACE				SCALP			
	LEVULAN (n=139)		Vehicle (n=41)		LEVULAN (n=42)		Vehicle (n=21)	
Degree of Severity	Mild/ Moderate	Severe	Mild/ Moderate	Severe	Mild/ Moderate	Severe	Mild/ Moderate	Severe
Scaling/Crusting	71%	1%	12%	0%	64%	2%	10%	0%
Pain	1%	0%	0%	0%	0%	0%	0%	0%
Tenderness	1%	0%	0%	0%	2%	0%	0%	0%
Itching	35%	1%	7%	0%	14%	7%	10%	0%
Edema	1%	0%	0%	0%	0%	0%	0%	0%
Ulceration	4%	0%	0%	0%	2%	0%	0%	0%
Bleeding/Hemorrhage	4%	0%	0%	0%	2%	0%	0%	0%
Hypo/hyper-pigmentation	22%		20%		36%		33%	
Vesiculation	4%	0%	0%	0%	5%	0%	0%	0%
Pustules	4%	0%	0%	0%	0%	0%	0%	0%
Oozing	1%	0%	0%	0%	0%	0%	0%	0%
Dysesthesia	2%	0%	0%	0%	0%	0%	0%	0%
Scabbing	2%	1%	0%	0%	0%	0%	0%	0%
Erosion	14%	1%	0%	0%	2%	0%	0%	0%
Excoriation	1%	0%	0%	0%	0%	0%	0%	0%
Wheal/Flare	2%	1%	0%	0%	2%	0%	0%	0%
Skin disorder NOS	5%	0%	0%	0%	12%	0%	5%	0%

Adverse Experiences Reported by Body System: In the Phase 3 studies, 7 patients experienced a serious adverse event. All were deemed remotely or not related to treatment. No clinically significant patterns of clinical laboratory changes were observed for standard serum chemical or hematologic parameters in any of the controlled clinical trials.

OVERDOSAGE

LEVULAN KERASTICK Topical Solution Overdose

LEVULAN KERASTICK Topical Solution overdose has not been reported. In the unlikely event that the drug is ingested, monitoring and supportive care are recommended. The patient should be advised to avoid incidental exposure to intense light sources for at least 40 hours after ingestion. The consequences of exceeding the recommended topical dosage are unknown.

BLU-U Light Overdose

There is no information on overdose of blue light from the BLU-U Blue Light Photodynamic Therapy Illuminator following LEVULAN KERASTICK Topical Solution application.

Information for Patients:
LEVULAN KERASTICK Photodynamic Therapy for Actinic Keratoses.

- The first step in LEVULAN KERASTICK Photodynamic Therapy (PDT) for actinic keratoses is application of the LEVULAN KERASTICK Topical Solution to actinic keratoses located on the patient's face or scalp.
- After LEVULAN KERASTICK Topical Solution is applied to the actinic keratoses in the doctor's office, the patient will be told to return the next day. During this time the actinic keratoses will become sensitive to light (photosensitive). Care should be taken to keep the treated actinic keratoses dry and out of bright light. After LEVULAN KERASTICK Topical Solution is applied, it is important for the patient to wear light-protective clothing, such as a wide-brimmed hat, when exposed to sunlight or sources of light.
- Fourteen to eighteen hours after application of LEVULAN KERASTICK Topical Solution the patient will return to the doctor's office to receive blue light treatment, which is the second and final step in the treatment. Prior to blue light treatment, the actinic keratoses will be rinsed with tap water. The patient will be given goggles to wear as eye protection during the blue light treatment.
- The blue light is of low intensity and will not heat the skin. However, during the light treatment, which lasts for approximately 17 minutes, the patient will experience sensations of tingling, stinging, prickling or burning of the treated lesions. These feelings of discomfort should improve at the end of the light treatment.
- Following treatment, the actinic keratoses and, to some degree, the surrounding skin, will redden, and swelling and scaling may also occur. However, these lesion changes are temporary and should completely resolve by 4 weeks after treatment.

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RED HERRING

Facial dermatitis may mask other conditions

By John Jesitus
Senior Staff Correspondent

Miami Beach, Fla. — The archetypal red face of dermatitis may conceal more diagnoses than originally meet the eye, according to an expert who spoke at the annual meeting of the American Academy of Dermatology.

Dr. Watsky

When a patient presents with a red face, "What we see may not necessarily be a single diagnosis. We must consider multiple diagnoses," says Kalman L. Watsky, M.D., clinical professor of dermatology, Yale University School of Medicine, New Haven, Conn. Conditions that commonly present with facial erythema can include actinic erythema, rosacea, allergic contact dermatitis and seborrheic dermatitis, he says.

QUICK READ

Diagnoses that can present with facial erythema include not just dermatitis, but also rosacea, actinic erythema, allergic contact dermatitis and seborrheic dermatitis.

Regarding rosacea, he says, dermatologists have little trouble identifying the characteristic papulopustular, inflammatory type.

"But patients with rosacea also may present with just telangiectasia (erythematotelangiectatic rosacea/ETR), which can be difficult to distinguish from telangectasias related to chronic sun exposure (telangiectatic photoaging)," Dr. Watsky says.

In this regard, Yolanda Helfrich, M.D., assistant professor of dermatology, University of Michigan, Ann Arbor, has presented research suggesting that mast cells and neuropeptide expression are increased in ETR in comparison to telangiectatic photoaging (Helfrich YR, Varani J, Fisher G, et al. *J Invest Dermatol.* 2012;132:S1-S18. Abstract 093).

Clinically, Dr. Watsky says, Dr. Helfrich's research demonstrates that in ETR, the erythema occurs more on the central face, versus a more lateral presentation in telangiectatic photoaging.

"Patients who complain of sensitive skin and/or symptomatic flushing are more likely to have rosacea," Dr. Watsky says.

Presently, he says that for some cases of ETR, "The only effective treatments are vascular lasers."

RED HERRING see page 26

Modified protein could lead to effective vitiligo therapy

DT Extra A genetically modified protein demonstrated a reversal of vitiligo in lab mice and could lead to therapies for the condition in human patients. Researchers with Loyola University Chicago Stritch School of Medicine genetically modified one of the amino acids in HSP70i, a protein that plays a crucial role in the autoimmune response that causes vitiligo. The modification led to a mutant HSP70i, which displaced the normal protein and thus reversed vitiligo's immune response. When investigators gave mice with vitiligo the mutant HSP70i, the "salt-and-pepper" color fur turned black. Some of the effects seen in the mice were also demonstrated in human skin specimens, demonstrating the potential for therapeutic opportunities in human patients. The study was reported in *Science Translational Medicine*.

Source: Loyola University Chicago Stritch School of Medicine

Quotable

"Many of us feel frustrated by the confines of our current healthcare system and the endpoints we are able to achieve with patients."

Reena Rupani, M.D.
Brooklyn, N.Y.

On utilizing integrative dermatology

See story, page 28

voice of the dermatologist

"Integrative dermatology is a rapidly growing field of study that combines the best of conventional dermatology with some of the more holistic options and an alternative treatment approach."

Reena Rupani, M.D., Brooklyn, N.Y. page 28

RED HERRING:

Facial dermatitis can mask underlying conditions from page 25

Additionally, among treatments under development, a study in ETR has shown that once-daily treatment with topical brimonidine tartrate gel 0.5 percent for four weeks achieved statistically superior results versus vehicle within 12 hours on treatment days one, 15 and 29 (all P<0.001; Fowler J, Jarratt M, Moore A, et al. *Br J Dermatol*. 2012;166(3):633-641).

Additional conditions

Patients with rosacea also may have coexisting seborrheic dermatitis, Dr. Watsky says.

"Patients with **ocular rosacea** will typically complain of a **foreign-body sensation** in the eye. They generally **respond well to oral antibiotics**."

Kalman Watsky, M.D.
New Haven, Conn.

"So on a given day, they may present with features that are more consistent with seborrheic dermatitis than rosacea," he says. If a doctor overlooks the rosacea and treats the seborrheic dermatitis with topical steroids, he warns, these will exacerbate the rosacea.

Additionally, "Be on the lookout for ocular rosacea. Patients with ocular rosacea will typically complain of a foreign-body sensation in the eye. They generally respond well to oral antibiotics."

"A characteristic appearance and histology can help," in diagnosing facial dermatitis via biopsy, Dr. Watsky says. "However, a biopsy won't help you make a definitive diagnosis."

To that end, "Look at the whole patient and see if there's evidence for dermatitis in other locations. Also, remember that dermatitis may be multifactorial — for example, a patient with facial dermatitis may have underlying seborrheic dermatitis, and also may have developed an allergy to some topical or airborne contactant. In such cases, patch testing provides an objective tool" to distinguish between these entities.

Generally, he says, "Patch testing with the Food and Drug Administration-approved series of allergens is a reasonable screening tool. But it often misses important allergens," particularly in facial locations.

If this happens, "We then test with an expanded series of allergens, also considering the patient's exposures." If the patient uses certain hair dyes, hair treatments or other personal care products, for example, Dr. Watsky patch tests against these types of allergens.

"If the allergy seems work-related, it's very important to consider airborne exposures in particular." Such tests can tell the patient what materials to avoid, if possible.

Maximizing efficacy

"Even after you've done your evaluation, you may not find a specific etiology. It's something that the patient likely will have to cope with lifelong. For example, we don't cure atopic dermatitis — it requires long-term management, with an eye toward maximizing safety and efficacy."

In such cases, he says, treatments for facial dermatitis largely mirror those of dermatitis in general.

"But some special areas need to be addressed. In particular, people with atopic dermatitis or seborrheic dermatitis commonly have eyelid dermatitis. For people with chronic conditions who need ongoing therapy, if topical steroids don't work well enough that you can use them sparingly, look for steroid alternatives such as tacrolimus and pimecrolimus," Dr. Watsky says.

Conversely, he says that, as with rosacea, dermatologists should not treat the redness and scaling of periorificial dermatitis with anti-inflammatory agents such as steroids. Clinically, he adds, "Periorificial dermatitis looks much like perioral dermatitis. But it occurs around the eyes or nose. You also may see tiny bumps with erythema and a bit of scale."

Dr. Watsky typically treats periorificial dermatitis with low-dose doxycycline, or topical metronidazole or azelaic acid (though the latter can cause irritation).

"If there's a significant inflammatory component, I also will use anti-inflammatories such as tacrolimus and pimecrolimus off-label," he says. DT

Disclosures: Dr. Watsky reports no relevant financial interests.

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Holistic CARE

Integrative dermatology is underused in Western medicine

By Ilya Petrou, M.D.
Senior Staff Correspondent

Miami Beach, Fla. — Integrative dermatology is an underused therapeutic modality in Western medicine. It is a holistic approach to the management of various dermatologic disease and conditions. When implemented appropriately, therapeutic outcomes can be improved, according to a clinician who spoke at the 71st annual meeting of the American Academy of Dermatology.

"Integrative dermatology is a rapidly growing field of study that combines the best of conventional dermatology with some of the more holistic options of an alternative treatment approach. It emphasizes an evidence-based approach to complementary healing modalities, which are hand-in-hand with what we consider to be our current standards of care in our patients," says Reena Rupani, M.D., assistant professor of dermatology, SUNY Downstate Medical Center, Brooklyn, N.Y.

> "Integrative dermatology treatments could be ideal for those diseases and conditions that are recalcitrant to traditional and more conventional therapies."
>
> 
>
> **Reena Rupani, M.D.**
> Brooklyn, N.Y.

QUICK READ

When integrative dermatology is implemented appropriately, therapeutic outcomes of certain dermatologic conditions can be improved.

Whole body approach

Contrary to traditional therapeutic approaches such as pharmacological-based treatments that often target the symptoms of the disease itself, Dr. Rupani says treatment approaches used in integrative dermatology are aimed instead, in part, at addressing factors that precede, trigger or exacerbate a condition.

Integrative therapies could include alterations in diet, nutritional supplements, the use of botanicals and herbal medicine, as well as mind-body interventions such as hypnosis.

Where possible and/or feasible, Dr. Rupani says the appropriate use and integration of such therapeutic modalities together with the current gold standard treatment approaches can result in improved treatment outcomes, as well as the healing of the patient on a whole.

"Changes in nutrition, environment and lifestyle can have a very positive impact on the dermatological disease of a patient. Integrative dermatology treatments could be ideal for those diseases and conditions that are recalcitrant to traditional and more conventional therapies and/or for those patients who prefer to limit their exposure to pharmaceuticals," Dr. Rupani says.

Targeting disease triggers

One of the prototypical dermatologic conditions in which integrative dermatology can have a significant impact is atopic dermatitis.

In adjunct to traditional and proven dermatologic therapies, Dr. Rupani says physicians can counsel patients on good bathing practices, skincare practices, the benefits of a more humidified environment, the importance of reducing stress, the incorporation of meditation in the daily routine, acupuncture, as well as discussing foods and allergenic triggers associated with a given disease.

"Standardization of therapies, however, can be difficult in the sense that each patient's historical and clinical context is unique, underscoring the crucial importance of a detailed history," Dr. Rupani said.

Other common dermatologic conditions that could be improved using integrative dermatology approaches include neurodermatitis, alopecia areata, pruritis, and acne, she says. Acne is of particular interest given the amount of current knowledge regarding the condition's relationship with diet and glycemic loads.

"Like anything else in medicine, an integrative approach would work best in those patients who are open to it. Oftentimes, those patients who are more open for treatments such as changes in diet, lifestyle, acupunc-

HOLISTIC CARE see page 32

WHAT CAN WE SAY?

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Has Returned

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Important Safety Information

Indication: TRI-LUMA® (fluocinolone acetonide 0.01%, hydroquinone 4%, tretinoin 0.05%) Cream is indicated for the short-term (up to 8 weeks) treatment of moderate to severe melasma of the face in the presence of measures for sun avoidance, including the use of sunscreens. **Adverse Events:** In the controlled clinical trials, the most frequently reported events were redness, peeling, burning, dryness, and itching at the site of application. **Warnings/Precautions:** TRI-LUMA contains sulfites which may cause severe, life-threatening allergic reactions in people allergic to sulfites. TRI-LUMA contains hydroquinone, which may cause a gradual blue-black darkening of the skin. If you are pregnant, nursing or trying to become pregnant you should not use TRI-LUMA. Safety and efficacy have not been established in individuals with darker skin. Reversible HPA axis (adrenal function) suppression may result from exposure to the topical corticosteroid, fluocinolone acetonide, so discontinue use if signs and symptoms of this condition occur. Avoid products that may dry or irritate the skin, such as abrasive cleansers, scrubs, or skin-peeling agents. Exposure to sunlight, sunlamps, or UV light and extreme heat, wind, or cold should be avoided. If exposure cannot be avoided, sunscreen products [SPF 30 or more] and protective apparel should be used.

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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *www.fda.gov/medwatch* or call 1-800-FDA-1088.

Please see brief summary of complete Prescribing Information on the following page.

Reference: 1. Balkrishnan R, Kelly AP, McMichael A, Torok H. Improved quality of life with effective treatment of facial melasma: the Pigment Trial. *J Drugs Dermatol.* 2004;3(4):377-381.

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IMPORTANT INFORMATION ABOUT
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BRIEF SUMMARY

This summary contains important information about TRI-LUMA (try-LOOM-ah) Cream. It is not meant to take the place of your doctor's instructions. Read this information carefully before you start using TRI-LUMA Cream. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about TRI-LUMA Cream. For full Prescribing Information and Patient Information see the package insert.

WHAT IS TRI-LUMA CREAM?

TRI-LUMA Cream is a medicine with three active components. You put TRI-LUMA Cream on your face to treat a skin condition called melasma. Melasma consists of dark (hyperpigmented) spots on facial skin, especially on the cheeks and forehead. This condition usually happens with hormone changes. TRI-LUMA Cream is for **SHORT-TERM (up to 8 weeks)** treatment of **moderate to severe** melasma of the face. **TRI-LUMA Cream may improve your melasma, but is NOT a cure.**

WHO IS TRI-LUMA CREAM FOR?

TRI-LUMA Cream is for use in adults. The safety and effectiveness of TRI-LUMA Cream in pediatric patients has not been established. Do **not** use TRI-LUMA Cream if you are allergic to the medicine or any of its ingredients.

WHAT SHOULD I TELL MY DOCTOR BEFORE USING TRI-LUMA CREAM?

If you are pregnant, think you are pregnant, plan to be pregnant or are nursing an infant, tell your doctor. Your doctor will decide with you whether the benefits in using TRI-LUMA Cream will be greater than the risks. If possible, delay treatment with TRI-LUMA Cream until after the baby is born. Tell your doctor about all the medicines and skin products you use, including prescription and nonprescription medicines, cosmetics, and supplements. They may make your skin more sensitive to sunlight.

WHAT SHOULD I AVOID WHILE USING TRI-LUMA CREAM?

- **Sunlight or ultraviolet light.** TRI-LUMA Cream can make your skin more likely to sunburn or develop other unwanted effects from the sun. Staying out of the sun is especially important for women who take birth control pills or hormone replacement therapy and for people who have had dark patches in the past.
- Use an effective sunscreen with an SPF of 30 or more **anytime you** are outside, even on hazy days.
- Weather extremes, such as **heat, wind and cold**, may irritate the skin of patients using TRI-LUMA Cream.
    - Avoid products that may dry or irritate skin including soaps and cleaners that are rough or cause drying, certain astringents, such as alcohol-containing products, soaps and toiletries containing alcohol, spices or lime, certain medicated soaps, shampoos, and hair permanent products.

      Do not use any other medicines with TRI-LUMA Cream unless you have consulted with your doctor.

WHAT ARE THE MOST COMMON SIDE EFFECTS OF TRI-LUMA CREAM?

The most common side effects associated with use of TRI-LUMA Cream are redness, peeling, burning, dryness, or itching.

A very few patients may get severe allergic reactions from TRI-LUMA. This includes people allergic to sulfites. **They may have trouble breathing or severe asthma attacks, which can be life-threatening.**

Some patients using TRI-LUMA develop dark spots on their skin (hyperpigmentation), tingling, increased skin sensitivity, rash, acne, skin redness caused by a condition called rosacea, skin bumps, blisters, or tiny red lines or blood vessels showing through the skin (telangiectasia).

Stop using TRI-LUMA Cream and contact your doctor if you have:

- severe or continued irritation, blistering, oozing scaling, or crusting.
- severe burning or swelling of your skin.
- irritation of your eyes, nose, and mouth.

HOW SHOULD I USE TRI-LUMA CREAM?

- TRI-LUMA Cream should be used as instructed by your doctor.
- Gently wash your face with a mild cleanser, using just your fingers. Rinse and pat dry.
- Unless you have been instructed otherwise, put a small amount (pea sized or less) on your fingertip. Next, apply a thin coat onto the discolored spot(s), at least 30 minutes before bedtime. Include about ½ inch of normal skin surrounding the affected area.
- Rub the medicine lightly and uniformly into your skin. The medicine should become invisible almost at once. If you can still see it, you are using too much.
- Keep the medicine away from the corners of your nose, mouth, eyes and open wounds.
- **Do not** use more TRI-LUMA Cream or apply it more often than recommended by your doctor. Too much TRI-LUMA Cream may irritate your skin, waste medicine, and won't give you faster or better results.
- Do not cover the treated area with anything after applying TRI-LUMA Cream.
- You may use a moisturizer and cosmetics during the day.
- Use a sunscreen of at least SPF 30 and a wide-brimmed hat over the treated areas. It requires only a small amount of sunlight to worsen melasma.

You are encouraged to report negative side effects of prescription drugs to the FDA at *www.fda.gov/medwatch* or call 1-800-FDA-1088. You may also contact GALDERMA LABORATORIES, L.P. AT 1-866-735-4137.

WHERE SHOULD I GO FOR MORE INFORMATION ABOUT TRI-LUMA CREAM?

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Dodging DRUG REACTIONS

Up-to-date information often doesn't reach point of care

By John Jesitus
Senior Staff Correspondent

Miami Beach, Fla. — The key to minimizing drug-related medical mishaps is getting current, accurate information to the point of care precisely when it's needed, according to an expert who spoke at the annual meeting of the American Academy of Dermatology.

"The problem is, the information is expanding so rapidly that it's extremely difficult to keep up-to-date. We need to find more efficient ways of getting information to both the healthcare provider and patient," says Howard I. Maibach, M.D., professor of dermatology, University of California, San Francisco, School of Medicine.

Drugs that have become available since World War II have clearly revolutionized healthcare, he says, "But not without a cost — considerable morbidity and mortality."

The Institute of Medicine has estimated 44,000 to 98,000 Americans annually die from adverse drug reactions (ADRs). A Swedish population-based study showed that approximately 3 percent of randomly selected deaths involved suspected fatal ADRs, most commonly involving anti-thrombotic drugs (Wester K, Jönsson AK, Spigset O, et al. *Br J Clin Pharmacol.* 2008;65(4):573-579).

Since World War II, cooperation between the pharmaceutical industry and regulatory agencies worldwide has produced increasing numbers of effective drugs. Unlike before World War II, most of these drugs have convincing evidence that they're effective, he says.

Additionally, "We must also consider all the other medications that are used but not approved." Examples include drugs that were introduced before 1962, and unapproved copies of approved drugs. Natural and herbal products further complicate the situation, he says.

The result is "a quadratic equation in terms of the relationship of one medication to another," he says.

QUICK READ

Avoiding adverse drug reactions requires improved information sharing and, where possible, conservative prescribing.

Long wait for research

Medication guides given to patients list what is generally known about the interactions of each prescription drug with others. However, Dr. Maibach says, such guides include only well-established research.

"And it often takes quite a while for us to figure out what to put on that computerized interaction sheet. There is an enormously complex literature slowly building up of the things we know less about, that don't appear in the package insert," he says.

The complexity of the legal, scientific and regulatory interaction between drug sponsors and regulators worldwide means that, "There's often a lag of many years between when we've figured out what we should be doing, and when we get that information into the insert."

This lag is particularly perilous, he says, in light of the fact that between 1982 and 2000, 60 percent of drugs worldwide required post-approval dosing changes, according to the World Health Organization (Saggar S, Maibach HI. *Cutan Ocular Toxicol.* 2007;26(3):171-180). Dermatologic drugs that underwent labeling changes between 1985 and 2000 include acyclovir, dapsone, erythromycin, itraconazole and isotretinoin, to name a few, Dr. Maibach adds.

Furthermore, only half of reported ADRs occur in the first seven years of marketing (Lasser KE, Allen PD, Woolhandler SJ, et al. *JAMA.* 2002;287(17):2215-2220).

Oldest, youngest patients left out

"Certain populations are clearly not yet addressed as adequately as we would like in the standard package insert."

For example, he says elderly patients process drugs relatively slowly, and they're usually on several drugs simultaneously. Ideally, Dr. Maibach says, published reports say that whenever a drug is being prescribed or dispensed, providers at the point of care need to know not only the drug's indication, duration and treatment plan, but also the following information:

- adverse effects;
- drug-drug interactions;
- risks for allergy or hypersensitivity;
- usage guidelines;
- age-related dosing requirements;
- what the drug looks like (a picture).

Prescribers, payers, manufacturers and pharmacies also must continue increasing their level of pharmacovigilance, he adds, and improving the efficiency of healthcare informatics.

> "We need to find more **efficient ways** of getting information to both the **healthcare provider and patient.**"
>
> **Howard I. Maibach, M.D.**
> San Francisco

DRUG REACTIONS see page 33

HOLISTIC CARE:

Integrative dermatology incorporates holistic approach from page 28

ture, meditation and other non-pharmacological approaches will show themselves by asking their doctor about such treatment possibilities," Dr. Rupani says.

Diverse demographics

The recent upsurge in interest regarding integrative medicine and integrative dermatology may be due to the change in the diverse demographics in the United States.

According to Dr. Rupani, many patients are increasingly asking about alternative and more holistic treatment approaches and options based in folk healing and non-Western modalities, leading to a huge demand for integrative providers.

Dermatologic conditions that **could be improved** using integrative dermatology include **neurodermatitis** and **alopecia areata.**

"Many of us feel frustrated by the confines of our current healthcare system and sometimes frustrated by the endpoints we are able to achieve with patients," she says. "As such, I think many physicians are looking for other ways that they can offer in healing."

According to Dr. Rupani, it is important for clinicians to remember — and differentiate — that integrative dermatology is not the same as alternative medicine. Thus, the practice should not be hindered by taboos. For instance, integrative dermatology practices do not advocate treating melanoma with hypnosis, Dr. Rupani says. Utilizing hypnosis to treat perioperative anxiety, however, can be very useful in select patients, she says.

"I think that formally using integrative dermatology and promoting physician education on the subject is important, in light of increasing patient interest and demand, as well as medicine's general push towards wellness and preventative care," Dr. Rupani says. DT

Disclosures: Dr. Rupani reports no relevant financial interests.

Simulated image based on locally advanced BCC patient at Week 24.

DRUG REACTIONS:

Avoiding AEs requires improved information sharing

from page 31

For prescribers, Dr. Maibach suggests conservative prescribing (Schiff GD, Galanter WL, Duhig J, et al. *Arch Intern Med.* 2011;171(16):1433-1440).

"When practical," he says, "start one drug per visit. Minimize frequent switches." Generally, Dr. Maibach recommends using relatively few drugs for a given indication — but knowing how to use them expertly. Educating patients about dosing requirements and drug interactions is also a must, he says. DT

Disclosures: Dr. Maibach has authored or co-authored several textbooks regarding evidence-based prescribing and ADRs.

Erivedge® (vismodegib) capsule

ERIVEDGE (vismodegib) capsule
Initial U.S. Approval: 2012

This is a brief summary of information about ERIVEDGE. Before prescribing, please see full prescribing information.

WARNING: EMBRYO-FETAL DEATH AND SEVERE BIRTH DEFECTS

ERIVEDGE (vismodegib) capsule can result in embryo-fetal death or severe birth defects. ERIVEDGE is embryotoxic and teratogenic in animals. Teratogenic effects included severe midline defects, missing digits, and other irreversible malformations.

Verify pregnancy status prior to the initiation of ERIVEDGE. Advise male and female patients of these risks. Advise female patients of the need for contraception and advise male patients of the potential risk of ERIVEDGE exposure through semen [see *Warnings and Precautions (5.1), Use in Specific Populations (8.1, 8.6)*].

1 INDICATIONS AND USAGE

ERIVEDGE capsule is indicated for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.

2 DOSAGE AND ADMINISTRATION

The recommended dose of ERIVEDGE is 150 mg taken orally once daily until disease progression or until unacceptable toxicity [see *Clinical Studies (14)*].

ERIVEDGE may be taken with or without food. Swallow capsules whole. **Do not open or crush capsules.**

If a dose of ERIVEDGE is missed, do not make up that dose; resume dosing with the next scheduled dose.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Embryo-Fetal Death and Severe Birth Defects

ERIVEDGE capsules can cause fetal harm when administered to a pregnant woman based on its mechanism of action. Vismodegib is teratogenic, embryotoxic, and fetotoxic in rats at maternal exposures lower than the human exposures at the recommended dose of 150 mg/day. In rats, malformations included craniofacial anomalies, open perineum, and absent or fused digits. Fetal retardations and variations were also observed.

Verify pregnancy status prior to the initiation of ERIVEDGE. Advise male and female patients of the risks of embryo-fetal death and severe birth defects and the need for contraception during and after treatment. Advise patients to contact their healthcare provider immediately if they suspect they (or, for males, their female partner) may be pregnant. Female and male patients of reproductive potential should be counseled regarding pregnancy prevention and planning. If ERIVEDGE is used during pregnancy or if a patient becomes pregnant while taking (or for a male patient, if his female partner is exposed to) ERIVEDGE, the patient should be apprised of the potential hazard to the fetus. Report immediately exposure to ERIVEDGE during pregnancy to the Genentech Adverse Event Line at 1-888-835-2555. Encourage women who may have been exposed to ERIVEDGE during pregnancy, either directly or through seminal fluid, to participate in the ERIVEDGE pregnancy pharmacovigilance program by contacting the Genentech Adverse Event Line at 1-888-835-2555 [see *Boxed Warning, Use in Specific Populations (8.1, 8.6)*].

5.2 Blood Donation

Advise patients not to donate blood or blood products while receiving ERIVEDGE and for at least 7 months after the last dose of ERIVEDGE.

6 ADVERSE REACTIONS

6.1 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.

ERIVEDGE capsule was administered as monotherapy at doses ≥ 150 mg orally daily in four open-label, uncontrolled, dose-ranging or fixed single dose clinical trials enrolling a total of 138 patients with advanced basal cell carcinoma (BCC). The median age of these patients was 61 years (range 21 to 101), 100% were White (including Hispanics), and 64% were male. The median duration of treatment was approximately 10 months (305 days; range 0.7 to 36 months); 111 patients received ERIVEDGE for 6 months or longer.

The most common adverse reactions (≥ 10%) were muscle spasms, alopecia, dysgeusia, weight loss, fatigue, nausea, diarrhea, decreased appetite, constipation, arthralgias, vomiting, and ageusia (Table 1).

Table 1: Adverse Reactions Occurring in ≥ 10% of Advanced BCC Patients

MedDRA Preferred Term[2]	All aBCC[1] Patients (N = 138)		
	All Grades[3] (%)	Grade 3 (%)	Grade 4 (%)
Gastrointestinal disorders			
Nausea	42 (30.4%)	1 (0.7%)	-
Diarrhea	40 (29.0%)	1 (0.7%)	-
Constipation	29 (21.0%)	-	-
Vomiting	19 (13.8%)	-	-
General disorders and administration site conditions			
Fatigue	55 (39.9%)	7 (5.1%)	1 (0.7%)
Investigations			
Weight loss	62 (44.9%)	10 (7.2%)	-

Table 1: Adverse Reactions Occurring in ≥ 10% of Advanced BCC Patients (cont)

MedDRA Preferred Term[2]	All aBCC[1] Patients (N = 138)		
	All Grades[3] (%)	Grade 3 (%)	Grade 4 (%)
Metabolism and nutrition disorders			
Decreased appetite	35 (25.4%)	3 (2.2%)	-
Musculoskeletal and connective tissue disorders			
Muscle spasms	99 (71.7%)	5 (3.6%)	-
Arthralgias	22 (15.9%)	1 (0.7%)	
Nervous system disorders			
Dysgeusia	76 (55.1%)	-	-
Ageusia	15 (10.9%)	-	-
Skin and subcutaneous tissue disorders			
Alopecia	88 (63.8%)	-	-

[1]aBCC = Advanced Basal Cell Carcinoma.

[2]MedDRA = Medical Dictionary for Regulatory Activities.

[3]Grading according to NCI-CTCAE v3.0.

Amenorrhea:

In clinical trials, a total of 3 of 10 pre-menopausal women developed amenorrhea while receiving ERIVEDGE [see *Non-Clinical Toxicology (13.1)*].

Laboratory Abnormalities:

Treatment-emergent Grade 3 laboratory abnormalities observed in clinical trials were hyponatremia in 6 patients (4%), hypokalemia in 2 patients (1%), and azotemia in 3 patients (2%).

7 DRUG INTERACTIONS

7.1 Effects of Other Drugs on Vismodegib

Drugs that Inhibit or Induce Drug Metabolizing Enzymes

Vismodegib elimination involves multiple pathways. Vismodegib is predominantly excreted as an unchanged drug. Several minor metabolites are produced by multiple CYP enzymes. Although vismodegib is a substrate of CYP2C9 and CYP3A4 *in vitro*, CYP inhibition is not predicted to alter vismodegib systemic exposure since similar steady-state plasma vismodegib concentrations were observed in patients in clinical trials concomitantly treated with CYP3A4 inducers (i.e., carbamazepine, modafinil, phenobarbital) and those concomitantly treated with CYP3A4 inhibitors (i.e., erythromycin, fluconazole).

Drugs that Inhibit Drug Transport Systems

In vitro studies indicate that vismodegib is a substrate of the efflux transporter P-glycoprotein (P-gp). When ERIVEDGE is coadministered with drugs that inhibit P-gp (e.g. clarithromycin, erythromycin, azithromycin), systemic exposure of vismodegib and incidence of adverse events of ERIVEDGE may be increased.

Drugs that Affect Gastric pH

Drugs that alter the pH of the upper GI tract (e.g. proton pump inhibitors, H_2-receptor antagonists, and antacids) may alter the solubility of vismodegib and reduce its bioavailability. However, no formal clinical study has been conducted to evaluate the effect of gastric pH altering agents on the systemic exposure of vismodegib. Increasing the dose of ERIVEDGE when coadministered with such agents is not likely to compensate for the loss of exposure. When ERIVEDGE is coadministered with a proton pump inhibitor, H_2-receptor antagonist or antacid, systemic exposure of vismodegib may be decreased and the effect on efficacy of ERIVEDGE is unknown.

7.2 Effects of Vismodegib on Other Drugs

Results of a drug-drug interaction study conducted in cancer patients demonstrated that the systemic exposure of rosiglitazone (a CYP2C8 substrate) or oral contraceptives (ethinyl estradiol and norethindrone) is not altered when either drug is co-administered with vismodegib.

In vitro studies indicate that vismodegib is an inhibitor of CYP2C8, CYP2C9, CYP2C19 and the transporter BCRP. Vismodegib does not induce CYP1A2, CYP2B6, or CYP3A4/5 in human hepatocytes.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category D

ERIVEDGE capsule can cause fetal harm when administered to a pregnant female based on its mechanism of action. Vismodegib is teratogenic in rats at doses corresponding to an exposure of 20% of the exposure at the recommended human dose (estimated $AUC_{0\text{-}24hr}$ steady-state exposure). In rats, malformations included craniofacial anomalies, open perineum, and absent or fused digits. Fetal retardations and variations were also observed. Vismodegib is embryolethal in rats at exposures within the range achieved at the recommended human dose. If ERIVEDGE is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the embryo or fetus. Report immediately exposure to ERIVEDGE during pregnancy to the Genentech Adverse Event Line at 1-888-835-2555. Encourage women who may have been exposed to ERIVEDGE during pregnancy, either directly or through seminal fluid, to participate in the ERIVEDGE pregnancy pharmacovigilance program by contacting the Genentech Adverse Event Line at 1-888-835-2555 [see *Boxed Warning, Warnings* and *Precautions (5.1)*].

In an embryo-fetal developmental toxicity study, pregnant rats were administered oral vismodegib at doses of 10, 60, or 300 mg/kg/day during the period of organogenesis. Pre- and post-implantation loss were increased at doses of ≥ 60 mg/kg/day (approximately ≥ 2 times the systemic exposure (AUC) in patients at the recommended human dose), which included early resorption of 100% of the fetuses. A dose of 10 mg/kg/day (approximately 0.2 times the AUC in patients at the recommended dose) resulted in malformations (including missing and/or fused digits, open perineum and craniofacial anomalies) and retardations or variations (including dilated renal pelvis, dilated ureter, and incompletely or unossified sternal elements, centra of vertebrae, or proximal phalanges and claws).

8.3 Nursing Mothers

It is not known whether vismodegib is excreted in human breast milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from ERIVEDGE, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

8.4 Pediatric Use

The safety and effectiveness of ERIVEDGE capsule have not been established in pediatric patients.

In repeat-dose toxicology studies in rats, administration of oral vismodegib resulted in toxicities in bone and teeth. Effects on bone consisted of closure of the epiphyseal growth plate when oral vismodegib was administered for 26 weeks at ≥ 50 mg/kg/day (approximately ≥ 0.4 times the systemic exposure (AUC) in patients at the recommended human dose). Abnormalities in growing incisor teeth (including degeneration/necrosis of odontoblasts, formation of fluid-filled cysts in the dental pulp, ossification of the root canal, and hemorrhage resulting in breakage or loss of teeth) were observed after administration of oral vismodegib at ≥ 15 mg/kg/day (approximately ≥ 0.2 times the AUC in patients at the recommended human dose).

8.5 Geriatric Use

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

8.6 Females of Reproductive Potential and Males

ERIVEDGE capsule can cause harm to the embryo or fetus when administered during pregnancy. Counsel female and male patients regarding pregnancy prevention and planning. Advise patients to contact their healthcare provider immediately if they suspect they (or, for males, their female partner) may be pregnant [see *Boxed Warning, Warnings and Precautions (5.1), Use in Specific Populations (8.1)*]

Female patients

Determine pregnancy status within 7 days prior to initiation of treatment in females of reproductive potential. For females with a negative pregnancy test, initiate a highly effective form of contraception (failure rate of less than 1%) prior to the first dose. Continue highly effective contraception during therapy and for 7 months after the last dose of ERIVEDGE. If a patient becomes pregnant while taking ERIVEDGE, or during the 7 months after the last dose of treatment, report the pregnancy to the Genentech Adverse Event Line at 1-888-835-2555. Encourage pregnant females to participate in the ERIVEDGE pregnancy pharmacovigilance program by calling the Genentech Adverse Event Line at 1-888-835-2555. Counsel pregnant females about the teratogenic risk to the fetus.

Amenorrhea has been observed in clinical trials in females of reproductive potential. Reversibility of amenorrhea is unknown [see *Adverse Reactions (6), Nonclinical Toxicology (13.1)*].

Male patients

Male patients should use condoms with spermicide, even after a vasectomy, during sexual intercourse with female partners while being treated with ERIVEDGE capsule and for 2 months after the last dose to avoid exposing an embryo or fetus to vismodegib.

8.7 Hepatic Impairment

The safety and effectiveness of ERIVEDGE capsule have not been established in patients with hepatic impairment [see *Clinical Pharmacology (12.3)*].

8.8 Renal Impairment

The safety and effectiveness of ERIVEDGE capsule have not been established in patients with renal impairment [see *Clinical Pharmacology (12.3)*].

10 OVERDOSAGE

There is no information on overdosage in humans. In clinical trials, ERIVEDGE capsule was administered at 540 mg orally once daily; exposure did not increase between 150 mg and 540 mg daily.

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide).

- Advise patients that ERIVEDGE exposure during pregnancy can cause embryo-fetal death or severe birth defects.
- Instruct female patients of reproductive potential to use a highly effective form of contraception (failure rate of less than 1%) while taking ERIVEDGE and for at least 7 months after the last dose of ERIVEDGE.
- Instruct all male patients, even those with prior vasectomy, to use condoms with spermicide, during sexual intercourse with female partners while taking ERIVEDGE and for at least 2 months after the last dose of ERIVEDGE.
- Instruct patients to immediately contact their healthcare provider if they (or, for males, their female partner) become pregnant or if pregnancy is suspected following exposure to ERIVEDGE.
- Instruct patients to immediately report any pregnancy exposure to ERIVEDGE and encourage participation in the ERIVEDGE pregnancy pharmacovigilance program by calling the Genentech Adverse Event Line at 1-888-835-2555.
- Inform female patients of the potential for serious adverse reactions in nursing infants from ERIVEDGE, taking into account the importance of the drug to the mother.
- Advise patients not to donate blood or blood products while taking ERIVEDGE and for at least 7 months after the last dose of ERIVEDGE.
- Advise patients to swallow ERIVEDGE capsules whole and not to crush or open the capsules.

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36 AESTHETIC TRENDS
Shifting cosmetic goals, treatment advances allow for fewer complications, better outcomes

38 TECHNOLOGY STRIDES
New laser device finds niche in superior tattoo removal treatment

Zoe Diana Draelos, M.D., is a **Dermatology Times** editorial adviser and consulting professor of dermatology, Duke University School of Medicine, Durham, N.C. Questions may be submitted via email to zdraelos@northstate.net.

Quick clean

Which hand sanitizers are most practical and effective?

Q: What are the different types of hand sanitizers? Which is best for dermatologists to use in the office?

a: There are three categories of hand sanitizers in the current marketplace: alcohols, quaternary ammonium compounds and triclosan. The alcohol-based products contain ethanol, which str excellent against gram positive, gram negative, and fungal organisms. It should be recognized that ethanol does not kill bacterial spores and some enveloped viruses. Ethanol functions to denature proteins in infectious organisms, and no resistance to this type of hand sanitizer has been identified.

The second type of hand sanitizer is based on quaternary ammonium compounds, such as benzalkonium chloride or benzethonium chloride. While the ethanol-based hand sanitizers are flammable, the quaternary ammonium compounds are not and can be used around hyfercator or electrocautery devices where a spark may be generated. Quaternary ammonium compounds fungistatic, bacteriostatic against gram-positive bacteria, and bacteriostatic against some gram negative bacteria. Like ethanol, the quaternary ammonium compounds are not active against nonenveloped viruses.

Some species of *Staphylococcus aureus* carry a gene that allows resistance to quaternary ammonium compounds. These organisms are also more likely to be antibiotic resistant, as well. Quarternary ammonium compound hand sanitizers may not be the best choice where methicillin resistant *Staphylococcus aureus* (MRSA) is a concern. Quaternary ammonium compounds adsorb to the cytoplasmic membrane of microbes causing leakage of cytoplasmic contents.

The third type of hand sanitizers contains triclosan. Triclosan is a commonly used antibacterial in a wide variety of products including deodorant soaps, toothpastes and mouth washes. Triclosan kills organisms by damaging the cell membrane, but has weak activity against gram-negative bacteria, such as *Pseudomonas*.

I would say that, in general, the ethanol-based hand sanitizers are the most practical for dermatologists to use daily. The chance of organism resistance to ethanol-based hand sanitizers is the lowest and they are very cost effective. The main problem is their tremendous drying effect, resulting in hand dermatitis. This is a secondary problem that the dermatologist must treat both personally and in patients!

Q: What are the limitations of hand sanitizers?

a: The Centers for Disease Control has credited hand sanitizers with minimizing the severity of the flu outbreak last year, but there are some important organisms that cannot be killed by any type of hand sanitizer. They are not effective against anthrax or *Clostridium difficile*, which has become resistant to antibiotics.

Since there is no mechanical rinsing with hand sanitizers, they do not clean visible dirt from the hands. This means that hand sanitizers are not good if food or other environmental debris are present. Essentially they are good at intermittently cleaning hands that are basically clean, but might contain some microorganisms. For example, they are good for sanitizing after shaking hands, touching a contaminated bathroom door handle, or if soap and water are not available. DT

Laser lipolysis boosts collagen production

DT Extra Laser lipolysis is effective for stimulating collagen production and skin tightening, according to findings presented at the Society of Interventional Radiology's annual meeting. Investigators reviewed outcomes of 2,183 patients ages 17 to 73 who underwent laser-assisted lipolysis and liposuction between 2009 and 2012. Treatments were performed on patients' necks, arms, abdomens, breasts, thighs and calves. Researchers measured patients' weight, diameter of area treated and skin tightness prior to treatment and at all follow-up appointments. All treatment areas demonstrated improvement in skin tightening and reduction of fat bulk.
Source: Society of Interventional Radiology

Quotable

"The PicoSure is very effective in clearing green and blue pigment and quick in lightening other tattoo colors."

Roy G. Geronemus, M.D.
New York

On Cynosure's laser for tattoo clearance

See story, page 38

Aesthetic TRENDS

Shifting cosmetic goals, treatment advances allow for fewer complications

By Ilya Petrou, M.D.
Senior Staff Correspondent

Miami Beach, Fla. — Botulinum toxin injections are more popular than ever in aesthetic medicine and have become a staple in the everyday armamentarium of the cosmetic physician.

Beyond a requisite in-depth knowledge of the local anatomy, one expert says understanding the patient's cosmetic goals as well as a matured aesthetic vision consistent with the times is crucial in achieving superior aesthetic outcomes.

Dr. Landau

Since the inception of cosmetic botulinum toxin treatments, says Marina Landau, M.D., it has become widely known and accepted that the cosmetic treatment is considered safe, and that the complications associated with the treatment are more of an aesthetic issue and less of a functional one.

"What we have learned from our years' experience is that life-threatening complications from the treatment are extremely rare and do not exist as such. However, cosmetic complications do exist in that our cosmetic vision of how our patients should look has changed," says Dr. Landau, dermatology and cosmetic dermatology immediate past-president, Israel Society for Dermatologic Surgery, Herzliya Pituach.

According to Dr. Landau, the pioneering physicians of cosmetic botulinum toxin treatment decades ago did not have the benefit of literature regarding complications because they were the first generation of physicians who started using the treatment cosmetically in patients. What has changed, Dr. Landau says, is the aesthetic view and how physicians usethe botulinum toxin injections to create a more youthful and vibrant-looking patient.

QUICK READ

An appropriate aesthetic vision coupled with candid communication with the patient regarding treatment goals are instrumental in achieving desired botulinum toxin treatment outcomes.

"Our aesthetic vision has been changed so much that currently, I am showing my best cases of the previous era as cosmetic complications. Through our years of experience, our aesthetic and artistic sense has matured and we have learned how a cosmetic patient should look in terms of natural and youthful aesthetic outcomes," Dr. Landau says. "So, the 'complication' so to say, is a question or change in the aesthetic."

Shifting goals

In the past, cosmetic botulinum toxin injections were used to simply paralyze the targeted facial muscles without any particular aesthetic finesse or creative vision, which would often lead to a mask-like appearance of the patient.

One of the typical stigmata of early botulinum toxin treatments, Dr. Landau says, was the "Mephisto-look" following a browlift with the toxin. Here, the central part of the eyebrow at the corrugator supercilii would be paralyzed, causing a compensation of the lateral part of the frontalis muscles, creating a hyperelevation of the eyebrow, particularly at the center.

"While we were paralyzing these muscles, other facial muscles would over-compensate the paralysis, resulting in a new balance of muscular activity of the face," she says. "Today, the primary goal of treatment is not to paralyze the patient's targeted facial muscles, per se, but instead to relax them and create a natural balance of the musculature, resulting in a more relaxed, softer and natural looking appearance in our patients."

Natural appearance

This new balance of facial muscles, Dr. Landau says, is all about creating a natural looking balance between the depressors and elevators of the facial muscle groups in a particular region of the face.

In creating this "new balance," Dr. Landau says it is paramount that the clinician injects the appropriate amount of toxin in a given muscle, measured according to the cosmetic correction to be made.

Using the appropriate amount of toxin at the correct injection site, as well as fewer injection points, can also be instrumental in helping to avoid potential functional complications that could result from botulinum toxin treatment, Dr. Landau says.

Eyelid ptosis used to be one of the most common functional complications in the early days of botulinum toxin treatments, she says. Now that physicians have learned where to place the correct injection site, however, this complication has become uncommon.

"It must not be forgotten that every patient's face is different, and there is no single injection treatment protocol that will fit every patient. Therefore, we need to analyze each face individually in order to establish what our target is, communicate and convey the right aesthetic ideas to the patient, and individualize treatments accordingly. This can help lead to the best results with botulinum toxin," Dr. Landau says. **DT**

Disclosures: Dr. Landau reports no relevant financial interests.

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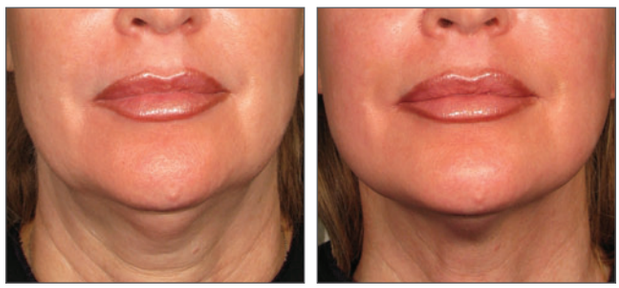

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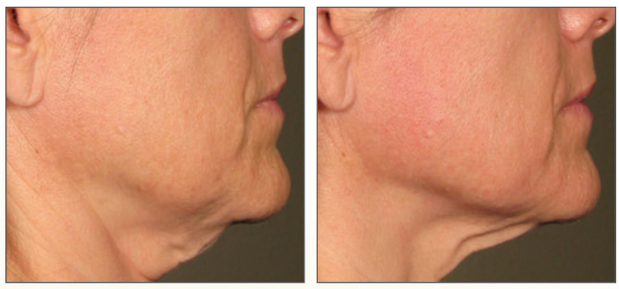
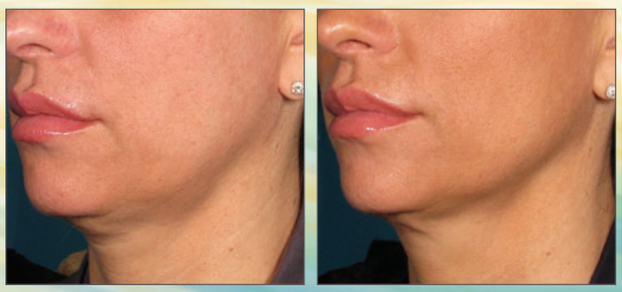


PRE-TREATMENT | DAY 180, *Single Treatment*



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Technology strides

New device finds niche in superior tattoo treatment

By Ilya Petrou, M.D.
Senior Staff Correspondent

Boston — The PicoSure laser (Cynosure) is proving to be a major breakthrough in tattoo removal by helping to clear notoriously stubborn colors quicker and more effectively then other laser technologies, according to an expert.

"The gold standard in tattoo removal is changing very quickly, particularly since the advent of the PicoSure laser," says Roy G. Geronemus, M.D., clinical professor of the department of dermatology at NYU Langone Medical Center and director of the Laser & Skin Surgery Center of New York. He spoke recently at the annual meeting of the American Society for Laser Medicine and Surgery.


Dr. Geronemus

"Picosecond technology can significantly impact the treatment of tattoos, particularly when targeting darker colored blue and green inks, which used to be some of the hardest colors to treat. Black colors can also be cleared much faster with this laser, further saving valuable time for both physician and patient," he says.

Technological advancement

Powered by revolutionary picosecond technology, the novel picosecond 755 nm alexandrite laser delivers ultra-short pulse bursts of energy to the skin in trillionths of a second, he says. The picosecond pulse duration is 100 times shorter than nanosecond technology, allowing the clinician to perform more effective treatments and achieve a superior clearance of tattoos, in fewer treatments and using less fluence.

Using patented pressure wave technology, PicoSure's ultra-short pulse duration goes beyond the photothermal action of nanosecond technology by creating an intense photomechanical impact, fragmenting the targeted tattoo color into tiny ink particles, which are then more easily eliminated via phagocytosis.

Though Q-switched nanosecond lasers are widely viewed as effective, safe and reliable aesthetic tools in removing tattoos of varying colors, Dr. Geronemus says PicoSure treatments are easier, faster and more effective for tattoo removal.

Clinical evidence

Dr. Geronemus and colleagues recently conducted a 22-patient clinical trial with the PicoSure laser, treating a total of 24 tattoos over a two-week period, including 11 previously untreated, multicolored tattoos and 13 that were recalcitrant to previous laser treatments. The mean age of the tattoos treated exceeded 10 years.

Results demonstrated a greater than 80 percent overall tattoo clearance, and on average, a 94 percent clearance was achieved for blue and green ink after only one or two treatments. None of the treated areas showed any pigmentary changes or scarring, he says.

> Results demonstrated a **greater than 80 percent** overall **tattoo clearance.**

"Previously, the removal of green and blue tattoo ink was extremely difficult, if not impossible with other laser devices and technologies," Dr. Geronemus says. "The PicoSure laser allows us to remove these colors more rapidly in approximately half of the time compared to other laser systems."

In the study, the clearance of targeted ink was assessed from baseline using standardized photographs and a grading scale where 0 = less than 25 percent, 1 = 26 to 50 percent, 2 = 51 to 75 percent, and 3 = greater than 75 percent clearance.

All tattoos contained black ink, while green, blue, red and yellow

TECHNOLOGY STRIDES see page 40

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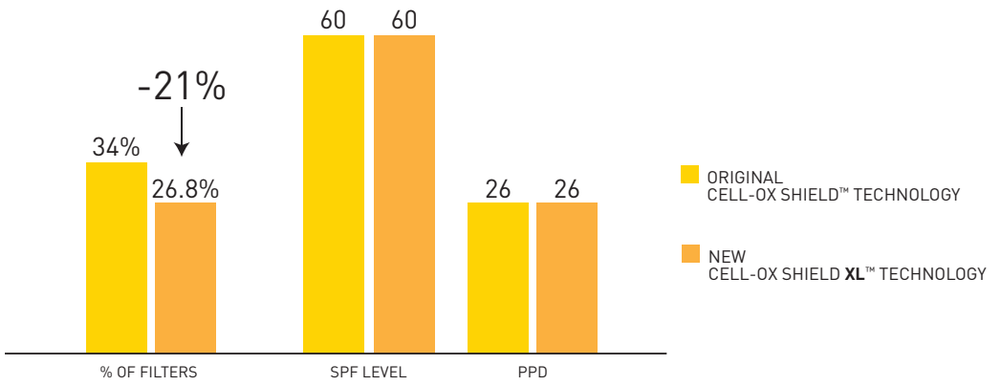
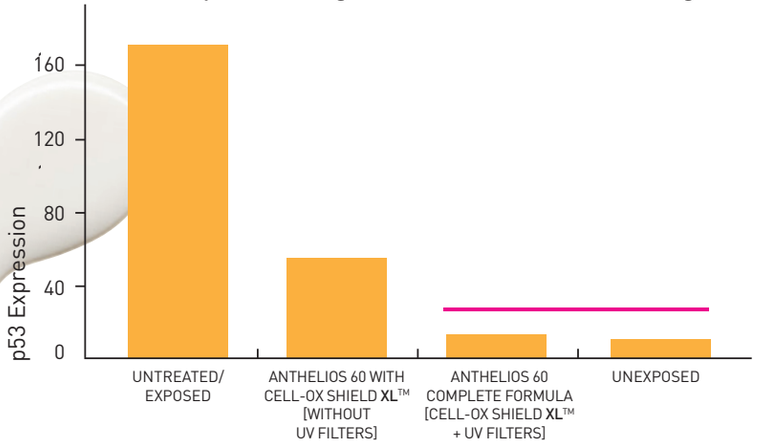


> Independently published in-vivo studies on cell damage show evidence of preventing UV-induced DNA damage.



(1) Christian Oresajo et al. Evaluation of the complimentary effects of antioxidants and sunscreens in reducing UV induced skin damage as demonstrated by skin biomarker expression. 10 subjects, healthy volunteers between 18 and 60 yrs with Fitzpatrick skin type I-III were recruited for this study. Five (5) sites (5cm x 7.5cm) were marked on the back of each volunteer as follows: Formula with UV filters and with anti-oxidants (Anthelios 60), Formula without UV filters, with anti-oxidants (Anthelios–UV), Formula without UV filters and without anti-oxidants (Placebo), Untreated/Exposed, Untreated/Unexposed (Naive). Each formula was applied at a rate of 2µL/cm2 to their corresponding marked areas on the back; no product was applied to either the Untreated/Exposed or the Untreated/Unexposed (Naive) sites. Product applications were done daily for four (4) consecutive days. On Day 3, the individual minimal erythemal dose (MEDi) was determined in each individual on a separate area on the back using a range of UVR intensities (20-70 nJ/cm2 at 10 mJ intervals). On Day 4, the subjects received a single UVR dose of 5X the previously determined MEDi to each of the four sites. On Day 5, colorimetry readings and 4mm punch biopsies were obtained from each site.

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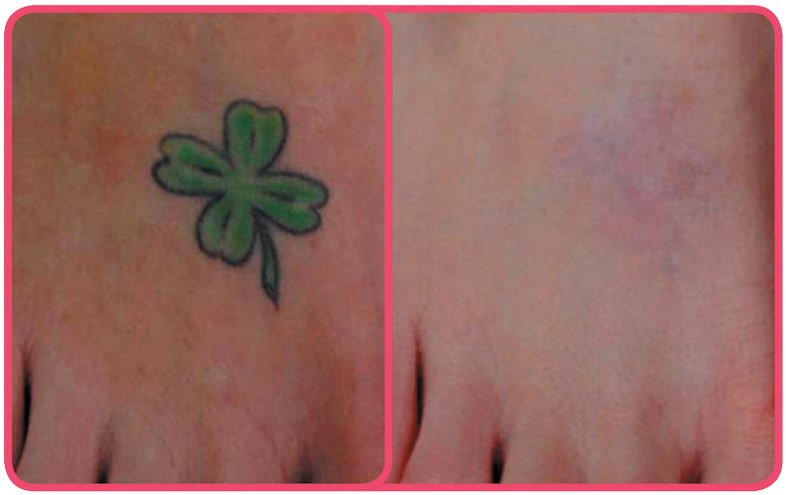
voice of the dermatologist

"Our aesthetic vision has been changed so much that currently, I am showing my best cases of the previous era as cosmetic complications."

Marina Landau, M.D., Herzliya Pituach, Israel page 36

TECHNOLOGY STRIDES:

PicoSure effective for clearing blue and green tattoos from page 38



A patient before (left) three treatments with the PicoSure laser and one month (right) following the last treatment session. (Photos: Roy G. Geronemus, M.D.)

ink was present in 16, 12, 11 and nine tattoos, respectively. Other tattoo colors included pink, purple, orange and white. According to Dr. Geronemus, the PicoSure could remove some colors more effectively than others, with mean clearance scores showing a 3 for green, 2.75 for blue, 1.89 for black, and 0.67 for red ink.

"Picosecond technology can **significantly impact** the treatment of tattoos, particularly when targeting darker colored **blue and green inks**."

Roy G. Geronemus, M.D.
New York

Comparatively speaking

Most green and blue tattoos can be completely removed in as few as one to three treatments, Dr. Geronemus says, whereas the same tattoo would typically require many more treatments using other lasers and technologies. Except for red ink, the PicoSure also can reduce the number of treatments required to clear other colors; however, the reduction in the number of treatments depends on the type of inks used in a given tattoo.

"The PicoSure is very effective in clearing green and blue pigment and quick in lightening other tattoo colors; however, it is less optimal for the removal of red ink," he says. "Here, Q-switched lasers such as the 532 nm Nd:YAG laser still remain the better choice, underscoring their importance in tattoo removal."

Recovery time following tattoo removal treatment, in part, depends on the color of the ink and the skin color of the patient treated. Compared to any of the other Q-switched lasers currently used for tattoo removal; however, Dr. Geronemus says the recovery time following treatment with the PicoSure is faster, typically about seven days, due to less collateral injury of surrounding tissues.

Postinflammatory hyperpigmentation is **less of an issue** with the picosecond laser, including those patients with **darker skin types**.

Though clinicians must always proceed with caution, Dr. Geronemus says postinflammatory hyperpigmentation is less of an issue with the picosecond laser, including those patients with darker skin types.

"Picosecond technology is a new and exciting development in aesthetic lasers. The PicoSure laser may surpass the popularity of Q-switched lasers and, in my opinion, it is the standard of care for the removal of particularly difficult-to-treat colors, such as blue and green," Dr. Geronemus says. **DT**

Disclosures: Dr. Geronemus reports no relevant financial interests.

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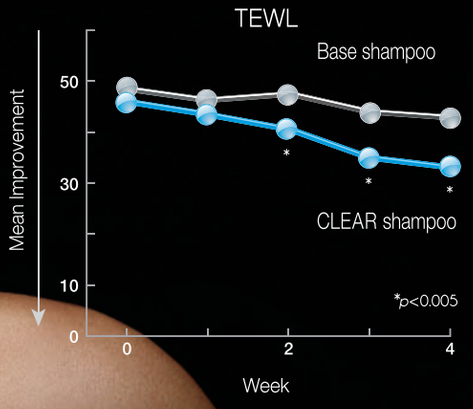

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44 RADIOTHERAPY RESURGENCE
Targeted photon therapy reemerges as out-patient treatment option for NMSC

AK ERADICATION

Newer treatments, reformulations address issues associated with field therapy

QUICK READ

Newer agents and reformulations of standing therapies for actinic keratosis can address issues associated with field therapy while helping to maximize treatment outcomes.

By Ilya Petrou
Senior Staff Correspondent

Maui, Hawaii — New topical agents such as ingenol mebutate (Picato, Leo Pharma), reformulations of standing local treatments as well as combination therapies are not only proving to be very useful in the clearance of actinic keratosis (AK), but they also help address the common issues regarding field therapy.

Although field therapy has become widely recognized as a wise treatment approach in patients with multiple AKs, George Martin, M.D., says the technique still remains an underutilized therapy for patients with significant actinic damage.

Dr. Martin

"Actinic keratosis is a chronic disease and field therapy is imperative because we do not know which of these lesions will evolve into invasive squamous cell carcinoma (SCC)," says Dr. Martin, Dermatology and Laser Center of Maui, Kihei, Hawaii. Dr. Martin spoke at MauiDerm.

Prolonged downtime — which can range from weeks to months — patient compliance issues, drug costs, and patient discomfort during extended therapy all factor into the underutilization of field therapies. In varying degrees, these issues are associated with all of the currently used topical treatment approaches including imiquimod, 5-fluorouracil (5-FU), diclofenac and photodynamic therapy (PDT).

Fast and effective

According to Dr. Martin, newer therapies with shorter downtime — such as ingenol mebutate and short duration 5-FU 0.5 percent cream — as well as combination therapies with combined efficacy and minimal downtime have been developed to address these limiting factors of treatment.

Available in 0.015 percent and 0.05 percent gel strengths, ingenol mebutate is a game-changer, Dr. Martin says, because it only has to be applied on the field area once daily for two to three consecutive days, resulting in a good compliance by patients.

"Ingenol mebutate 0.015 percent applied nightly for three consecutive days to the face or scalp has been a remarkably effective therapy with great patient compliance for not only limited areas (25 cm2), as demonstrated in phase 3 clinical trials, but even when applied over the entire face," he says. "Clinically there appears to be selectivity for AKs with normal areas between the AK lesions. In my hands, it has been a very effective full-face field therapy with limited downtime."

The mechanism of action of ingenol mebutate appears to involve a direct cytotoxic effect, Dr. Martin says, which takes place in the first 24 hours, accompanied by an upregulation of interleukin-8 (IL-8), resulting

AK ERADICATION see page 47

Quotable

"With the advent of modernized and improved radiation technology ... (targeted photon therapy) is being revalued and reconsidered once again as a viable treatment option."

David E. Kent, M.D.
Macon, Ga.

On the radiotherapy options for NMSC

See story, page 44

Many melanoma survivors risk further disease

DT Extra

Nearly half (44.8 percent) of melanoma survivors do not take precautions to avoid further disease risk, according to a poster presented at the American Association of Cancer Research meeting. Analysis of data from 171 melanoma survivors who participated in the 2010 National Health Interview Survey demonstrated that 27.3 percent never put on sunscreen when outdoors for more than an hour, 15.4 percent rarely or never sought shade, and 2.1 percent used an indoor tanning bed in the previous year.

Source: Yale Daily News

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RADIOTHERAPY RESURGENCE

Targeted photon therapy reemerges as outpatient NMSC treatment option

By Ilya Petrou
Senior Staff Correspondent

Miami Beach, Fla. — Recent advances in radiation therapy for the treatment of nonmelanoma skin cancer (NMSC) have resulted in a resurgence of targeted photon therapy, a treatment modality particularly useful in an outpatient setting. In carefully selected patients and cases, radiation therapy can often be the treatment of choice for NMSCs, says a clinician who spoke at the annual meeting of the American Academy of Dermatology.

"The dosimetry or the scheduling of the doses is now made so much easier with total fraction tables. Missed doses can now be quickly recalculated."

David E. Kent, M.D.
Macon, Ga.

"Radiation therapy and the updated targeted photon therapy technology and protocols allow us to treat nonmelanoma skin cancers in those patients who are considered suboptimal candidates for surgical procedures," says David E. Kent, M.D., division of dermatology, department of internal medicine, Mercer University School of Medicine, Macon, Ga. "The improved therapeutic modality gives us a lot of flexibility and versatility in the treatment and management of nonmelanoma skin cancers."

Before the advent of Mohs surgery and larger surgical excision techniques using sophisticated flaps and grafts, radiation therapy was a very commonly used therapeutic tool for the treatment of NMSCs. Over the years, however, dermatologic surgeons gravitated toward using these newer surgical techniques, Dr. Kent says, as they were also effective in treating lesions.

Radiation therapy was always considered to be an effective treatment modality for NMSCs, but Dr. Kent says its use by dermatologists in an outpatient setting was limited by outdated technology and treatment protocols, which was further overshadowed by newer and exciting treatments and techniques such as Mohs micrographic surgery.

Targeted photon therapy

"Until recently, all the old radiation therapy technology was 30 to 40 years old, without the production of newer machines or any new research and development performed. The quality of the older machines became somewhat dated and devices became temperamental, requiring effort to perform radiation treatments," Dr. Kent says.

The status quo has changed with the development of newer more efficient radiation machines that are safer than the technology of old, equipped with standardized double and triple safety features.

"What's really wonderful about targeted photon therapy is that the dosimetry or the scheduling of the doses is now made so much easier with total fraction tables. Missed doses can now be quickly recalculated to ensure that the patient receives the appropriate updated dose for their tumor," Dr. Kent says.

There is a fundamental difference between the electron-based ionizing radiation of linear accelerators used in hospital-based radiation centers, Dr. Kent says, and the photon devices used in a dermatologist's practice. Devices now used in an outpatient setting in private practice deliver targeted photon radiation therapy, which is better suited for treating superficial NMSCs, he says.

Device improvements

The new photon devices are easier to use, emit less radiation than dental X-rays, and undergo yearly rigorous state inspections by the departments of health, according to Dr. Kent.

"With the advent of modernized and improved radiation technology in the machines that are now available, this treatment approach is being revalued and reconsidered once again as a viable treatment option in select patients and cases," Dr. Kent says.

Patient selection is crucial, he says. Ideal candidates for radiation therapy are those individuals who

RADIOTHERAPY see page 46

QUICK READ

Improved technology and treatment protocols have fueled a resurgence in the use of radiation therapy in the dermatologic practice, offering patients and physicians a viable option for treating nonmelanoma skin cancer.

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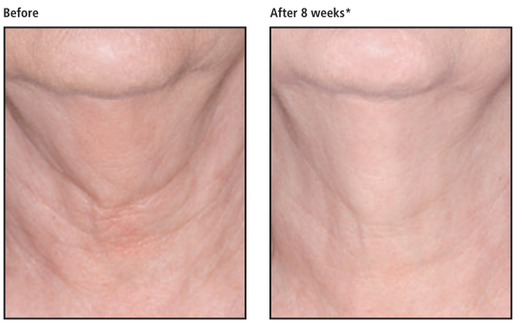

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RADIOTHERAPY:

Targeted photon therapy reemerges as viable option for NMSC from page 44

are of advanced age, have multiple skin lesions and/or lesions in critical areas, are more aesthetically inclined and prefer a non-scarring treatment option, are afraid of surgery, or are contraindicated for surgical interventions due to standing comorbidities.

"One of the benefits of radiation therapy is that we can concurrently treat multiple lesions in one sitting. This can be a great advantage in much older patients who not only do not have to endure multiple surgeries to address their lesions, but they also can have all of their lesions treated in one sitting, quickly and painlessly. Depending on the case, therapy may take a series of treatments, and the number of treatments can be coordinated and individualized to the specific patient and case," Dr. Kent said.

> "One of the **benefits of radiation** therapy is that we can concurrently **treat multiple lesions** in one sitting."
>
> **David E. Kent, M.D.**
> Macon, Ga.

The most common locations where radiation therapy is used for NMSCs are the face, head and neck. While radiation therapy should be reserved for primary NMSCs, Dr. Kent says the therapeutic modality should not be used in those tumors that have aggressive histologic growth features such as often seen in morpheaform basal cell carcinoma. For more invasive and aggressive tumors, he says Mohs surgery may often be the better treatment option.

"For select patients and tumors, targeted photon therapy is an excellent option to consider. In my experience, the new and improved radiation therapy technology offers us a viable, cost-effective and cosmetically attractive treatment option for nonmelanoma skin cancers and is a wonderful addition in our armamentarium," Dr. Kent says. DT

Disclosures: Dr. Kent reports no relevant financial interests.

voice of the dermatologist

"The FDA's decision ... is an important milestone for Merck as we advance ongoing programs in multiple cancer indications."

Gary Gilliland, M.D., Ph.D., senior vice president, Merck Research Laboratories, page 12

AK ERADICATION:

New treatments and formulations improve field treatment from page 42

in neutrophil migration. Patients should expect some burning and irritation in the treated area typically starting around four hours after the application of the gel, and a downtime of approximately 10 days.

Patient compliance

The recommended protocol for imiquimod 5 percent cream (Aldara, Medicis) is twice a week for 16 weeks, which, according to Dr. Martin, can raise issues of compliance in patients. This led to the development of imiquimod 2.5 percent and 3.75 percent cream (Zyclara, Medicis) formulations, which now allow for much shorter treatment times when administered in the recommended two weeks on, two weeks off, two weeks on regimen.

"These protocols make imiquimod easier to comply with as they are shorter but there is still some significant downtime, particularly when compared to ingenol mebutate," Dr. Martin says.

Though the one-week downtime associated with PDT treatment is the shortest of the topical therapies, Dr. Martin says PDT remains one of the more painful treatments in AK therapy and requires premedication, sometimes making patients prefer other, more "gentle" therapeutic options such as 5-FU, imiquimod and now, ingenol mebutate.

One of the cornerstone field therapies for facial AK lesions is topical 5-FU. To shorten treatment times and downtimes while maintaining efficacy, Dr. Martin asks his patients to apply 0.5 percent 5-FU (Carac, Valeant) QD for one week, wait one month, and then continue with two weeks of therapy. According to Dr. Martin, this regimen has gained widespread acceptance by patients and physicians as a more tolerable, yet effective, field therapy.

"In my experience, ingenol mebutate, short-course 5-FU and PDT are some of the more ideal AK treatment approaches in respect to efficacy, efficiency, cost and downtime," he says. "The choice of treatment however should be made according to the individual patient's needs." DT

Disclosures: Dr. Martin is a consultant for Leo Pharma and Valeant. He is a speaker for and serves on the scientific ad boards for Leo Pharma, Valeant and Medicis.

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TAKE CHARGE

Establishing a positive practice starts with leadership

By John Jesitus
Senior Staff Correspondent

Miami Beach, Fla. — Making each patient visit unforgettably positive requires looking honestly at oneself and one's practice, says an expert who spoke at the annual meeting of the American Academy of Dermatology.

Steve Shama, M.D., M.P.H., says that for each dermatologist, what makes a day of practicing medicine unforgettably positive resides "in the eye of the beholder." When he asks fellow physicians to define this quality, however, "The responses we get are, 'the patients are on time; staff is on time; I'm on time — not overbooked or overwhelmed. I'm making the right diagnosis and giving the right treatment.'"

Moreover, doctor, patient and staff are smiling.

QUICK READ

Changing unsatisfying elements of one's practice requires candor and commitment, according to one clinician.

"If I see someone smile when they're telling me this, I know it's a very important quality" they aspire to in their daily practice.

What prevents dermatologists from achieving these ideals?

"We are the biggest obstructionists in our lives and offices. We make these problems — or make them bigger," says Dr. Shama, Brookline, Mass., who spoke at the annual meeting of the American Academy of Dermatology.

Scheduling issues

If scheduling creates problems, Dr. Shama asks, "Who's in charge of the scheduling, and how long we talk to someone? It's the dermatologist. You are ultimately responsible, and can simply make the decision to have a perfect day," or as close to it as possible.

"The 'aha' moment comes when a physician realizes, 'I'm responsible for almost everything in my office that I think is making my day miserable.'"

On a more tangible level, he adds, dermatologists frequently identify factors such as people, systems, managed care and insurance as chief causes of their misery. In workshops he conducts, Dr. Shama says, some dermatologists reject the idea that they're in charge of their practices because they work for an HMO. It might suddenly dictate that instead of seeing four patients per hour, participating physicians must see six.

"And I say, ultimately you do have control. You can push the system back. You can tell the HMO, 'I can't do this anymore.' Or you may start to self-destruct — your patients become very unhappy because you're so flustered. Or, you say to yourself, 'I'm so miserable, I'm leaving.' Sometimes I suggest that to people — leave the HMO and do something else," or, in extreme cases, leave dermatology altogether.

For some frustrated physicians, he says, the label "Dr." becomes a trap because they can't envision themselves enriching the world in any other way.

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Quotable

"If you're being rejected by Medicare repeatedly, eventually you're going to get audited."

Alexander Miller, M.D.
Yorba Linda, Calif.

On attention to detail in coding and billing

See story, page 50

3 steps for controlling staff costs

DT Extra

After provider compensation, costs for support staff are the biggest expense of running a medical practice. To determine the appropriate staffing balance for your practice, first establish a budget. Management consultants commonly find that the most productive doctors have higher-than-average staff counts. Next, adjust benchmarks you find for staff count and costs to account for particular circumstances related to your practice, such as staff productivity and capitation payments. Finally, obtain input from staff on how to stay within budget, and review the data monthly.

Source: *Medical Economics*

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References. 1. Berardesca E, Barbareschi M, Veraldi S, Pimpinelli N. Evaluation of efficacy of a skin lipid mixture in patients with irritant contact dermatitis, allergic contact dermatitis or atopic dermatitis: a multicenter study. *Contact Dermatitis.* 2001;45(5):280-285. **2.** Kao JS, Fluhr JW, Man M-Q, et al. Short-term glucocorticoid treatment compromises both permeability barrier homeostasis and stratum corneum integrity: inhibition of epidermal lipid synthesis accounts for functional abnormalities. *J Invest Dermatol.* 2003;120(3):456-464.

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Attention TO DETAIL

Prompt payment from insurers requires time, legwork by physicians

By John Jesitus
Senior Staff Correspondent

Miami Beach, Fla. — Getting payments from Medicare and other insurers promptly and accurately — and, for many Medicare physicians, continuing to receive payments — requires a strong detail orientation, says an expert who spoke at the annual meeting of the American Academy of Dermatology.

> "If you are **audited for the tests** you ordered, Medicare wants to see that you received the tests, **reviewed them, and took action** based upon the results."
>
> **Alexander Miller, M.D.**
> Yorba Linda, Calif.

For starters, Alexander Miller, M.D., says that out of concerns for fraudulent billing, "Medicare is concentrating on charting requirements for laboratory orders. So if you're ordering any labs, you must sign a requisition for the lab tests. The outside lab is required to have a signed requisition on file," even from dermatologists who use the lab only to process slides that the dermatologists themselves will read. Dr. Miller is a dermatologist and dermatologic surgeon in private practice in Yorba Linda, Calif. He is also an American Medical Association Current Procedural Terminology (CPT) adviser.

QUICK READ

An expert's coding tips range from signing all lab requisitions to tracking your payers' performance.

He adds, "A copy of the signed request may be kept in the chart in hard or electronic form. Or you may sign a note requesting that the lab tests be done.

"Additionally, the signature should be legible. And if not, you must provide a record of the names, signatures or initials you used to identify that you actually signed the document. It doesn't have to be an actual signature — you can use a symbol such as a star, as long as you identify in the master list that the star represents your name" as the requesting physician.

Another Medicare requirement that many physicians are unaware of involves documentation of test results, which requires a signature or initials and a date within the patient record, Dr. Miller says.

In this area, "If you are audited for the tests you ordered, Medicare wants to see that you received the tests, reviewed them, and took action based upon the results — even if that action is just telling the patient that the results are normal."

Revalidation requirements

Regarding Medicare revalidation, which is required of all providers who enrolled before March 25, 2011, Dr. Miller says, "This doesn't happen automatically. You should wait for your Medicare Administrative Contractor (MAC) to send you a revalidation notice, and make your staff aware that if they get any mail from your MAC, put it on your desk. Then you can read and delegate it, but it must be done. You have 60 days after the postmark date — not the date you received the letter."

If you miss this deadline, "Your MAC will call to remind you. From that point, you have 10 days to revalidate. If you still don't follow the rules, you'll be suspended from receiving payment for 30 days. However, you can still bill Medicare. And if you revalidate during this time, you're fine."

But if a physician fails to revalidate during the 30-day payment suspension, Dr. Miller says, "Then your billing privileges are revoked for 120 days, after which you are suspended from the Medicare program."

Dr. Miller also suggests monitoring your practice's insurer billings and payments to ensure accuracy on both sides.

"If you're being rejected by Medicare repeatedly, eventually you're going to get audited," he says.

Furthermore, he asks, "Are you tracking what insurers are paying you — and the hassle factor? Because insurers are tracking you. If they don't like you, they can fire you. But if they're bad for your business, fire them." In this regard, Dr. Miller reports that after quitting three large PPOs, "I got busier, and I got paid better."

Coding questions

For general coding assistance, he suggests consulting American Academy of Dermatology resources including *Dermatology World's*

ATTENTION TO DETAIL see page 54

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GROUP DYNAMICS

Creating a practice 'dream team' could be closer than you think

By John Jesitus
Senior Staff Correspondent

Miami Beach, Fla. — Managing group dynamics requires recognizing and addressing a group's developmental stage and the roles its members are playing — without judgment, an expert says.

"Each group has its own dynamics," says Tammie Ferringer, M.D., head of dermatopathology at Geisinger Medical Laboratories and associate in the department of dermatology at Geisinger Medical Center, Danville, Pa.

Knowing where your group stands developmentally helps highlight strategies for nudging the group toward its desired outcome, says Dr. Ferringer, who spoke at the annual meeting of the American Academy of Dermatology.

"Participation is the key. To get buy-in for whatever the group decides, you need to get everybody's ideas out."

Tammie Ferringer, M.D.
Danville, Pa.

Several years ago, Dr. Ferringer says, someone in Geisinger's dermatology department accidentally switched labels on two biopsy specimens. "The work flow at the time was that the nurses would take the specimen from the room to the nurses' station, where the requisition printed out, and they would label the bottle."

Fortunately, she says, the dermatopathologist who read the biopsies quickly caught the mix-up, and no harm was done.

"Immediately, the dermatology department came together as a group to find out what went wrong, and how it could be fixed," she says. "After all the brainstorming, the decision was that we would print out a label with the patient's name whenever a patient checks in, and send it to the exam room with the patient. And if there's a biopsy done in that room, that label goes directly on that bottle. The department communicated effectively and did a wonderful job as a group."

Conversely, Dr. Ferringer says, a group that communicates poorly might succumb to the sentiment that when such a problem arises, "Someone else will handle it. Everybody's sure that somebody will do it. Anybody can do it. But nobody actually does it."

A group of people on an elevator doesn't constitute a team, she says. "A team forms when that elevator gets stuck. Suddenly that group of people must work together to figure out how to get out of the elevator — they share a single goal, and everyone is accountable to the whole group, not just themselves."

Along with sharing a goal, Dr. Ferringer adds, "The process of getting there is just as important — and often not thought about." This requires understanding the stages of group development.

From forming to performing

Dr. Ferringer describes "forming" as the polite phase in which people get acquainted. Next comes "storming," in which people air concerns and criticism as they seek to understand their roles. "Norming," or building trust and cooperation, follows. Finally, "performing" involves communicating freely and respectfully toward a goal.

"There's still conflict, but it's handled well." It's also common for groups to bounce between various stages, she adds, and/or get stuck in one stage.

Understanding individuals' roles within the group can help group leaders identify strategies to restore or maintain focus. Individual roles can include the devil's advocate, the blocker (who torpedoes everyone's suggestions) and the aggressor (who attacks personally rather than considering the merits of others' ideas). Although some roles may sound inherently negative or positive, she says, this is largely a matter of context. For example, being a brainstormer (generating "outside the box" ideas) is generally helpful — unless the group needs to conclude deliberations and reach a decision.

Dr. Ferringer says that a group leader is not the only one responsible for managing group dynamics. Individual roles often shift, and anyone can step up as needed. For example, a "summarizer/clarifier" may ask questions or restate suggestions to ensure everyone is on the same page — regarding anything from the substance of an idea, to what the group should be doing at that moment.

To get back on track, Dr. Ferringer says, sometimes it's necessary to ask a "blocker" to provide a positive suggestion. In other cases, an overly dominant leader might need feedback, sometimes with a touch of flattery. Often, "Leaders don't get any feedback, because of fear."

A group's "followers" often need prompting to speak up or perhaps write their ideas down. Ultimately, "Participation is the key. To get buy-in for whatever the group decides, you need to get everybody's ideas out." This way, whether or not someone's suggestion is adopted, all members feel they've been heard. **DT**

QUICK READ

Successfully managing group dynamics requires some basic education — and some tact, an expert says.

Disclosures: Dr. Ferringer is a member of the American Academy of Dermatology leadership development steering committee.

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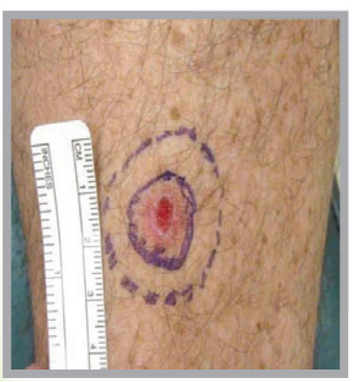

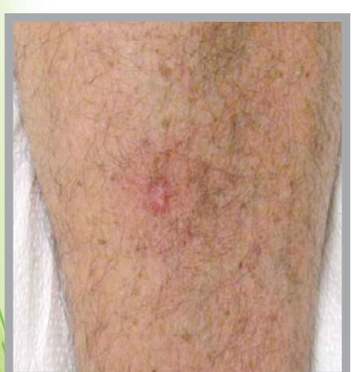

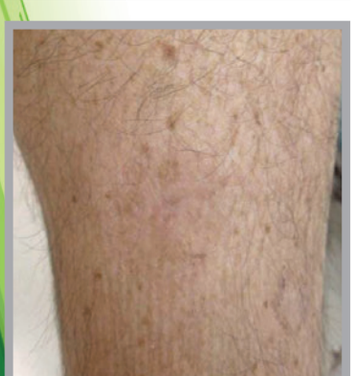

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TAKE CHARGE:

Dermatologists can make the office atmosphere positive from page 48

"Ask your family and friends what your greatest value is. They'll say it's being a good friend, a good spouse, or a good parent. But many people — especially doctors — value 'doing' over simply 'being.'"

However, Dr. Shama says, "It's the 'soft' values that really drive us."

> "Recognize that you're the **captain of the ship**, and tackle the **key issues** that are bothering you."
>
> **Steve Shama, M.D.**
> Perkinsville, Vt.

Accordingly, he says, getting more fulfillment from one's practice begins by deciding "what are you really there for — to make money, or to be happy and make the world a better place?"

Next, "Recognize that you're the captain of the ship, and tackle the key issues that are bothering you. You can actually decide to see fewer patients — and spend more time with each one."

Similarly, he suggests scheduling the occasional patients who take the most time not randomly, but strategically — at the end of the morning session, for example, so that running overtime impacts only your lunch hour, not the rest of your day.

"We've become very skilled at taking care of the average patient. But there's no such thing as the average patient. If we schedule 20 patients for a morning, because we're so skilled at taking care of the average patient, by noon we will be finished — whether we've taken care of them well or not."

Don't try ploys

Ultimately, Dr. Shama says, happier physicians find it easier to put themselves in their patients' shoes — to be truly patient-centered. In this regard, he says, "Any wait longer than 30 minutes must have an explanation, otherwise, you're really not valuing their time."

When wait times stretch into this territory, "One trick people use is to move patients from place to place — they'll have an extra waiting area, a room to put them in. And the patient assumes they're going to be seen soon. But now they're worse off — they're in a gown, naked, waiting in an unfamiliar place. Patients ultimately understand this ploy and often are not happy about it."

Over time — or after the good vibes of a weekend seminar fade — sustaining a positive approach requires commitment, Dr. Shama says. This could include a "buddy system" of peer support, he adds, as well as setting manageable goals — such as addressing scheduling issues for one month.

On a broader scale, "Try a mental diet for 30 days. Commit to thinking of only positive things in your life and in your practice in particular. See the world of gratefulness rather than the broken parts. And every time you have a negative thought, start over." Cultivating positive thoughts for 30 consecutive days will create "a habit that's very tough to break," Dr. Shama says. **DT**

Disclosures: Dr. Shama presents the workshop "How to Have an Unforgettably Positive Office Visit" with patient advocate Tena Brown to medical audiences around the country.

ATTENTION TO DETAIL:

Getting prompt payments from insurers requires legwork from page 50

"Cracking the Code" column, which is searchable online, plus the quarterly "Derm Coding Consult" and the "2013 Coding and Documentation for Dermatology" manual.

Additionally, Dr. Miller suggests becoming familiar with the latest National Correct Coding Initiative (NCCI) edits. "This list specifies whether CPT codes may be bundled — billed and paid together. It also tells which procedural code needs to be billed first for a particular modifier, and which procedural codes get modifiers. It's not always intuitive."

For instance, he says, the NCCI specifies that complex repair codes are subservient to destruction codes (and should carry modifiers, if applicable), though the former procedures often have higher technical requirements and monetary value.

For benchmarking, Dr. Miller recommends consulting resources such as the Medicare Part B National Summary Data File (formerly called BESS). "It allows you to compare your code utilization patterns to regional and national patterns. Medicare is auditing people who are three standard deviations away from the norm. Anthem BlueCross BlueShield is doing the same thing." **DT**

Disclosures: Dr. Miller is an AMA CPT adviser.

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Alice Gosfield is principal of Alice G. Gosfield & Associates, PC, in Philadelphia, and a *Medical Economics* editorial consultant.

STARK REALITIES YOUR GROUP NEEDS TO KNOW

What you can and cannot do when formulating a compensation plan in your practice

Many physicians don't understand that the laws covering self-referral — known collectively as the Stark statute—reach inside their practices by prescribing acceptable compensation models that entail referrals within a group for Stark "designated health services" (DHS).

To be Stark-compliant, a practice has to meet the statutory definition of a group practice, so as to meet the exceptions that allow referrals to physicians in the group or for in-office ancillary services. It is in the definition of a group that the statute addresses compensation. The basic premise, according to the U.S. Code, is that a physician "in a group practice may be paid a share of overall profits of the group or a productivity bonus based on services personally performed or services 'incident to' such personally performed services, so long as the shared work bonus is not determined in any manner which is directly related to the volume or value of referrals."

This article looks at overhead issues, productivity, profit sharing, incident-to services, and shared-visit revenue allocation. It explains why compliance matters, even after passage of the Affordable Care Act (ACA).

Overhead and cost centers

Among the indicia of a group, the statute addresses overhead and expenses, requiring that joint use of shared office space, facilities, equipment, and personnel exist. The overhead expenses from the practice must be allocated according to previously determined methods.

The statutory definition of a group has been addressed in fairly detailed regulations, but many misconceptions exist. The regulations address overhead but take no position regarding cost allocations as long as they are applied prospectively and not retrospectively considering the volume of referrals for DHS. Practices can use cost centers by location, by specialty, or by any other reasonable measure that does not directly reward the volume or value of DHS referrals.

Productivity

The regulations take the position that permissible payment for productivity means compensating the physician for the fruits of his or her own labors. The doctor must be the one to perform the service that generates the revenue, with three exceptions:

- cases in which the productivity bonus is based on the physician's total patient encounters or relative value units;
- instances in which the bonus is based on non-DHS revenues, or;
- cases in which revenues derived from DHS are less than 5 percent of the group's total revenues and the allocated portion is less than 5 percent of the physician's total compensation from the group.

Productivity can be calculated before or after expenses are deducted.

Among the myths about productivity is that a practice cannot pay independent contractors a percentage of what they generate. In reality, productivity compensation for independent contractors is specifically recognized in the prefatory discussion to the regulations. Another myth is that physicians can only receive a base salary and cannot be paid on productivity. No such condition exists.

Some physicians believe they must treat all revenues — DHS, non-DHS, non-Medicare — the same way. The Stark statute, however, only pertains to Medicare; a referral, as defined in the regulations, is only for Medicare DHS.

Another common belief is that practices cannot allocate DHS revenues to a physician as productivity. In fact, practices may do so, but only if the physician performs the service himself or herself.

Incident-to revenues

To meet Medicare's incident-to standards, the services of non-physicians must be rendered under the direct supervision of a doctor in the group who is on the premises and in the office suite. Ancillary personnel need not be employees or leased employees, although Medicare will not pay for the services of physician assistants (PAs), other than to their direct W-2 employer.

As is the case in incident-to services, generally, a physician professional

service must be rendered to which ancillary services are incidental. Supervision itself is not a physician service. Diagnostic services never can be considered "incident to," so the revenues from the technical components of DHS diagnostic services must float up to an overall profit distribution pool unless the physician personally performed them. The services must be of a kind commonly furnished in a doctor's office and commonly rendered without charge or included in the physician's bill.

PAs, nurse midwives, nurse practitioners, and clinical nurse specialists are permitted under general Medicare reimbursement rules to bill their own relevant evaluation and management (E/M) codes incident to a physician. For any other personnel, the only E/M code that may be billed is a 99211.

A concept related to, but not strictly "incident to," is that of shared visits. Where the doctor and a non-physician practitioner are in the same group and in a hospital setting, either clinician may see the patient first. The non-physician could perform almost the entire visit. If the doctor performs any portion of the visit in a face-to-face encounter with the patient, then their entire combined services are billable at 100 percent of the physician fee schedule under the doctor's number.

This scenario is similar to incident-to services where the ancillary personnel are invisible on the claim. In shared visits, however, the two clinicians do not have to be in the hospital at the same time. These shared visits count as personally performed services for Stark purposes.

Some people believe that practices cannot allocate DHS revenues that are incident to the ordering physician. In fact, regulators have repeatedly recognized that incident-to services and supplies, such as chemotherapy and physical therapy rendered incident to a doctor, may be allocated directly to the ordering physician. Some people believe it is not permissible to credit the treating doctor for non-incident-to evaluation and management services rendered by non-physicians and billed on their own numbers at 85 percent of the fee schedule. Of course you can. Stark has nothing to say about these services, which have nothing to do with DHS.

Others people believe you can give doctors credit for the professional component of a diagnostic study they order if it meets the requirements for in-office ancillary services. This practice is not permissible. The professional component of a diagnostic service is not covered by the in-office ancillary services exception. It is covered by the exception that allows referral to another physician. Because someone other than the doctor performs this service, he or she cannot get credit for those revenues.

Profit-sharing

Unlike productivity, profit-sharing is where physicians are allocated a portion of the revenues that are the fruits of others' labors. These monies can be revenues from the entire group or any subgroup of at least five physicians (a "pod"). The regulators offer three safe harbors:

- a per-capita equal division of the profits;
- a distribution of DHS revenues based on the distribution of the group practice's revenues attributable to the services that are not DHS, and;
- any distribution of the group practice

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STARK REALITIES

Know what you can do before formulating a compensation plan from page 57

DHS revenues with no physician's allocated portion of those revenues more than 5 percent of the doctor's or the group's total compensation.

The regulators have made it clear that other methods are fine. They mention allocation of these revenues per ownership interest, based on seniority, or any other method that is adequately documented for which supporting information can be made available on request. All profits on the technical component of diagnostic testing DHS services have to be allocated according to a profit-sharing formula. The professional components of diagnostic testing can be allocated to the physician who performed that service or according to a profit-sharing formula.

Much more flexibility is available under these rules than you may realize. Not all doctors in the practice have to participate in all pods. For example, in a larger practice, some physicians might be in the imaging services pod, whereas others are in the infusion services pod and still others are in the physical therapy pod. As long as each pod includes at least five physicians, these allocations are legitimate.

No requirement says that all revenues generated by productivity must be allocated as productivity. Some practices allocate some of their profits from interpretations of studies performed by interventionists to others in the practice.

Now is the moment

Why does any of this matter when no one can point to a single enforcement action by the government with regard to whether a group has met the compensation rules? With passage of the ACA, Congress eliminated any question as to whether Stark violations can be pursued by whistle-blowers.

Failure to repay within 60 days monies received pursuant to noncompliant Stark transactions will convert the claims submitted to Medicare into false claims. This opens the door to whistle-blowers challenging the compensation within groups. Because the penalties for a Stark violation are not only false claims but also overpayments made to the entity submitting the claims, where a group practice does not meet the definition of a group, including in its compensation formulas, all of the claims that it submits to Medicare become tainted.

Don't be anxious about whether your compensation formulas meet the relevant standard. Given the change in the law with the ACA, your group should examine its compensation practices now rather than wait for disgruntled former employees or the government to tidy up the matter. **DT**

MULTIPLE CHOICE:

The changing landscape comes down to simple economics from page 1

"For dermatologists, the ability to stay independent as solo practitioners will depend, in part, on how much they rely on health insurance and how much of their practice is cash payments. To the extent that health insurance is not a driving force in the practice, it is easier to maintain independence," says Alice G. Gosfield, Esq., of Alice G. Gosfield and Associates, Philadelphia.

"Insurance companies ... have, to some degree, made it nearly impossible to practice without being casually affiliated with a hospital system."

Joel Schlessinger, M.D.
Omaha, Neb.

CHANGING LANDSCAPE

Jackson Healthcare's 2012 Medical Practice and Attitude Report found while 56 percent of the physicians surveyed were in private practice (including solo, single and multispecialty practices), 6 percent claimed to be leaving private practice in 2012, most commonly citing high overhead costs and reimbursement cuts.

Norman Levine, M.D., who has a private dermatology practice with a part-time associate in Tucson, Ariz., says he was the last dermatologist in the city to have started a solo practice, and that was six and a half years ago.

It's simple economics, he says.

"Bigger practices can ... more efficiently deliver care than private practices can. They can afford to purchase big equipment — expensive equipment — such as lasers, light boxes and what not. Bigger practices can afford to employ people like practice managers, and practice managers can run the business much more effectively," Dr. Levine says. "Lastly, the rulers of medicine now are the insurance carriers, in the sense that a patient will go to a doctor who is contracted with his insurance company, in many cases. There are many insurance carriers who would prefer to deal with larger practices."

Dr. Levine plans to practice privately for the rest of his career, because, he says, he can deliver high-quality care in a personal way, and that makes patients happy. But when asked if he thinks solo or small practices will survive, he says no.

"If you're in solo practice you might as well remain and enjoy your life. I don't see a reason to necessarily change that unless the financial realities, regulatory realities and all the other things start to impinge on your practice," Dr. Levine says. "For people going into practice, I wouldn't recommend that they start in solo private practice."

Rather, Dr. Levine says, larger groups have the financial clout, size and business know-how needed to power through today's healthcare environment. Unfortunately, that's at the cost of freedom and autonomy, he says.

IT IS WHAT IT IS

Staying in private practice might require an adjustment, as Deborah S. Sarnoff, M.D., discovered. Dr. Sarnoff, a clinical professor of dermatology at NYU Langone Medical Center, is changing the emphasis of her New York practice from Mohs surgery to cosmetic.

The shift is bittersweet, she says.

"The landscape is most definitely changing ... and to survive, I believe it has been necessary for me to change with the times," Dr. Sarnoff says. "Once upon a time, my practice was literally the first and only office on Long Island dedicated exclusively to Mohs surgery. Our referrals came primarily from other dermatologists from a 120-mile stretch, from Queens to Montauk Point. Slowly but surely, many Long Island dermatology groups hired their own itinerant Mohs surgeons. Needless to say, the number of Mohs referrals decreased."

She opened a Park Avenue practice, specializing in Mohs surgery and cosmetic dermatology. While she would have liked to keep the medical and cosmetic sides of practice thriving, cosmetic dermatology won out.

"Over the past year, hospitals and multidisciplinary groups on Long Island have been 'purchasing' or 'partnering' with dermatologists," Dr. Sarnoff says. "With declining reimbursements from managed care companies, general dermatologists are tempted to align themselves with a hospital or large multispecialty group in order to receive better-negotiated contracts and better reimbursement for their procedures. [But] once affiliated with a larger group, general dermatologists are limited as to where they may refer their patients. For example, to prevent 'leakage,' they may no longer be permitted to refer a basal cell on the nose to a Mohs surgeon outside their group."

GROUP PRACTICE PROS, CONS

There are good reasons to be in a larger, integrated group practice, says Todd A. Rodriguez, Esq., partner and co-chairman of the health law group Fox Rothschild, Exton, Pa.

"Certainly there are ... opportunities to improve the delivery and quality of care because you have a larger patient population, and you can share information among doctors in the group practice. You can analyze patient statistics and see what kinds of treatment modalities work better than others. And you can do all that in an integrated basis ... that's one of the big pushes for health care reform ... to integrate the delivery system," Mr. Rodriguez says.

From cost and administrative standpoints, being in a larger practice allows dermatologists to share financial risks and practice burdens.

"So, if you have to buy a half million-

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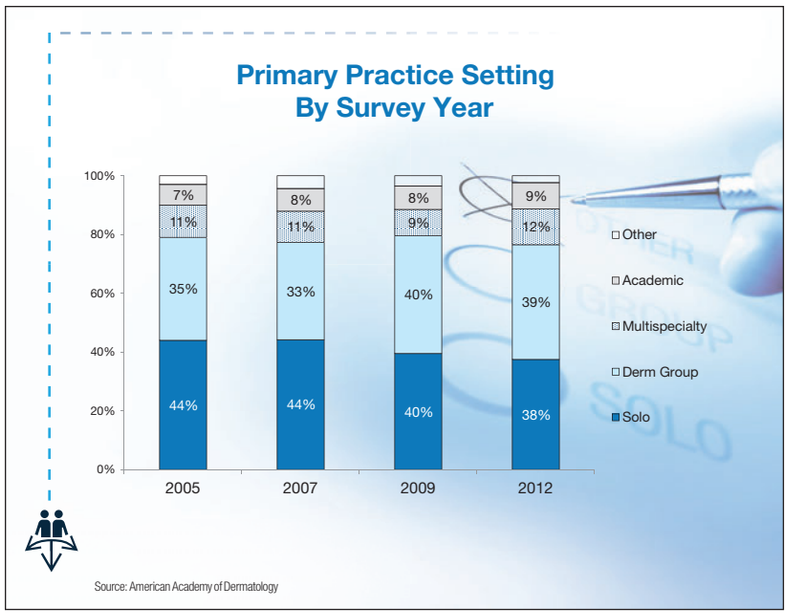
MULTIPLE CHOICE:

The changing landscape comes down to simple economics from page 59



dollar electronic medical record system and you spread that over 20 doctors, it's certainly a lot more tolerable than bearing that cost yourself or sharing it with two or three doctors," Mr. Rodriguez says. "You can generally hire more expensive advisers ... You may be able to hire people who specifically focus on compliance within the practice. Smaller practices can't afford a compliance officer, for example."

Whether it's better to go with a single specialty or multispecialty group is a matter of preference.

"The common thinking with multispecialty is that you have a built-in referral base," Mr. Rodriguez says. "On the other hand, all the other primary care doctors in the community may not want to refer to you because they are afraid of losing their patients to your partners who are in primary care."

According to Mr. Rodriguez, multispecialty practices often struggle with income division issues because some specialties are more labor intensive and don't generate as much revenue as other specialties.

"I have seen situations where there can be some contention over how different specialties in a group practice should share in practice profits," Mr. Rodriguez says.

Joel Schlessinger, M.D., a dermatologist and dermatologic cosmetic surgeon in Omaha, Neb., who has been in solo practice for 20 years, says multispecialty groups suffer from a prevailing jealousy of dermatology.

"Many specialties and physicians don't understand the pressures and challenges that dermatologists face on a daily basis and/or the rewards that they earn through running an efficient practice," Dr. Schlessinger says.

EMPLOYMENT OPTION

When physicians sell their solo practices, it's typically to hospitals, according to Mr. Rodriguez. Sellers will likely get a cookie-cutter employment arrangement, with a limited term (maybe two or five years), until they have to renegotiate the contract terms.

Working for a hospital can stabilize a dermatologist's income at a reasonable level for a period of time, while the employer assumes much of the work and cost associated with running the practice.

But whether an employment relationship with a hospital is truly secure is up for debate. Ms. Gosfield says many healthcare experts warn that hospitals are promising physicians more money than they'll be able to pay them.

Why? Among the reasons, she says: hospitals are looking at across-the-board cuts, no payment for preventable 30 day readmission, no payment for hospital-acquired conditions and value-based payment modifiers (so the lower-performing hospitals are going to get less than the higher-performing hospitals). In addition, in a quality-driven environment where community-based care better manages chronic diseases, hospitals might lose some of those admissions, according to Ms. Gosfield.

Hospitals, she says, "are standing on a burning platform."

Another issue is whether dermatologists can find suitable hospital buyers. Dermatology isn't a first pick for hospitals; it's among the last.

Jackson Healthcare documented in its Trend Watch: Physician Practice Acquisition 2012-2013 that nearly half of the 118 hospital executives it surveyed are on the prowl for physician practice acquisitions. While primary care and internal medicine are primary targets, dermatology is barely on hospitals' radar screens for possible acquisition. In 2012, Jackson Healthcare didn't list the specialty, and in 2013, dermatology came after a long list of specialties — lumped in as 2 percent of hospital acquisitions, along with such specialties as critical care medicine, hematology, maternal and fetal medicine, nephrology and occupational medicine.

SOLO (OR SMALL GROUP) AND LOVING IT

Dermatologists who want to start or remain in small private practices should explore a high-end practice model — one not largely dependent or wholly dependent on insurance reimbursement, Mr. Rodriguez says.

"(Try to) situate your practice in a well-to-do area of the country or in a community where people are going to pay out-of-pocket for high-end kinds of care — what's commonly referred to as concierge," Mr. Rodriguez says. "This includes cosmetic and greater access to the physician by telephone and email. But you have to be in an area of the country where people are willing to pay for those kinds of things."

Carolyn Jacob, M.D., director of

MULTIPLE CHOICE see page 62

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MULTIPLE CHOICE:

The changing landscape comes down to simple economics from page 60

the Chicago Cosmetic Surgery and Dermatology in Chicago, and co-chair of the Women's Dermatology Society's Business Interest Group, has a hybrid small group practice.

"We have one full- time and two part-time derms, a consulting plastic surgeon and consulting oculoplastic surgeon, as well as a PA and an esthetician. We are adding another full-time dermatologist in July," she says. "I actually started this as a solo practice and have slowly added other providers. I always wanted to work with colleagues who had the same work and patient care philosophy."

Dr. Jacob, who owns the practice and has been able to maintain both medical and cosmetic dermatology services, says she plans to use this model indefinitely. Having the consulting surgeons aboard is a win-win.

"We actually have a lot of patients who ask us for plastic surgery treatments that we don't do, so we are a good referral source for them. However, we benefit financially by having them here instead of referring to other plastics who are not part of our office," Dr. Jacob says.

Dr. Schlessinger is convinced solo practice is here to stay. According to the dermatologist, who practices with two physician assistants, the lure to be in private practice is too strong.

"I think that there is a general desire by dermatologists to do their own thing," Dr. Schlessinger says. "And given the unique circumstances, which allow dermatologists to be independent of hospitals and other physicians, there exists the ability to continue to be solo."

Dermatology is naturally suited to be independent, he says.

"There are a few specialties where the practitioners are not as dependent upon other physicians or a hospital affiliation, and dermatology is one of these," Dr. Schlessinger says. "The insurance companies … have, to some degree, made it nearly impossible to practice without being casually affiliated with a hospital system. But, to my mind, this is the only absolute necessity that drives dermatologists to be aligned with others."

Generally speaking, he says, hospitals bid on insurance companies' groups of customers and then allow their affiliated doctors to be in the network. Therefore, dermatologists who do not have hospital affiliations might have a tough time getting on the coveted panels. Dr. Schlessinger has been able to skirt that issue because, he says, local hospitals in his area are interested in having dermatologists on their panels and understand the solo nature of the dermatology practice.

"For that reason, they are generally OK with the thought of (my) being courtesy or adjunct staff, rather than an active participant in the goings on in the hospital," Dr. Schlessinger says.

He also admits that acquiring the EMR can be daunting for solo practitioners (but he has one).

While the environment has become slanted against the solo practitioner, the practitioner's motivation and savvy prevail, according to Dr. Schlessinger, who has no plans to make changes.

"The benefits of solo practice and the ability to do those things that I wish to do far outweigh any minor inconveniences, at least for now," he says.

EMPOWER YOURSELF

To thrive in any kind of practice, become business savvy and tap professional resources when needed, experts say.

Mr. Rodriguez says that while the push for integration may seem all-consuming now, it might not take hold. Rather than try to predict the future, physicians should aim to thrive in whatever climate there might be.

"For any medical practice to survive, no matter what specialty, they have to become more sophisticated," Mr. Rodriguez says. "They have to learn how to run a business and focus on running a business and running a business profitably, and being able to evolve as the marketplace changes." **DT**

AAD offers resources for solo practices

Schaumburg, Ill. — Dermatologists in solo practice can turn to the American Academy of Dermatology (AAD) as a resource for navigating these challenging times. Among the support tools for solo practices: a full range of practice management essential manuals on the AAD's website, under the AAD store tab, at www.aad.org/store/search/default.aspx?catid=3.

The Academy website houses information about AAD webinars and webcasts, which provide office managers in solo settings with the information necessary to code correctly and follow changing regulations.

For up-to-date coding information, how to adopt and implement an electronic health record (EHR), compliance strategies and regulatory requirements, go to "practice management resources," under the academy's "member tools and benefits" section (www.aad.org/member-tools-and-benefits/practice-management-resources).

On the advocacy side, the academy calls for fewer regulatory requirements for solo practices, such as those imposed to demonstrate the meaningful use of EHRs, according to an AAD spokeswoman. **DT**

ALMA LASERS

Q-switched technology decreases wrinkles

The ClearLift nonablative laser treatment from Alma uses 1,064 nm Q-switched technology to penetrate deep beneath the skin, to 3 mm, helping to decrease fine lines and wrinkles by stimulating collagen growth. ClearLift causes a controlled dermal wound but avoids harming the epidermis. It is appropriate for use around the mouth, the eyes and on the chest and neck.

Treatments can be performed in as little as 20 minutes. It can be used on all skin types, and results in no downtime. The module is also indicated for tattoo removal, pigmented and vascular lesions, and nail fungus.

For more information:
www.almalasers.com

SKINMEDICA

Brightener is hydroquinone-free

The Lytera Skin Brightening Complex includes a blend of ingredients designed to even and brighten skin tone by reducing the appearance of discoloration. Antioxidants help to create a smooth, luminous complexion, according to the company.

A recent clinical study demonstrated that the complex provided a greater overall improvement in skin condition after 12 weeks in 85 percent of patients, compared to 68 percent for patients treated with 4 percent hydroquinone, according to the company. Seventy-nine percent of patients using the complex also reported a greater improvement in evenness of skin tone.

For more information:
www.skinmedica.com

OBAGI MEDICAL PRODUCTS

Sunscreen leaves sheer, matte finish

Sun Shield Matte SPF 50 by Obagi Medical Products provides broad-spectrum protection while leaving behind a sheer, matte finish.

The formulation helps to prevent the damaging effects of UVA and UVB rays using 10.5 percent zinc oxide and 7.5 percent octinoxate. The sunscreen doesn't leave behind a shine or residue, and is appropriate for use on all skin types, according to the company.

For more information:
www.obagi.com

LIFELINE

Eye cream aids collagen production

New Eye Firming Complex uses human nonembryonic stem cells to help the skin surrounding the eyes to produce more collagen. The formulation is designed to improve skin thickness and protect the skin from premature aging, according to the company.

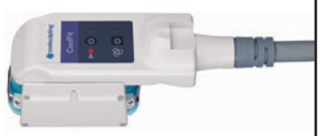
Natural proteins, peptides and growth factors stimulate collagen, leading to firmer skin and reduced puffiness. Other active ingredients replenish moisture and supply nutrients to the eye area, the company states.

For more information:
www.lifelineskincare.com

ZELTIQ

Applicator covers larger treatment areas

The CoolFit applicator is the latest addition to the platform for the CoolSculpting system. Its configuration provides a larger treatment area, which can allow clinicians to treat a broader range of patients, according to the company.



The applicator's design features a flat applicator cup and cooling plates that are 38 percent larger than the CoolCore applicator. This design allows for treatment on more areas of the body, and greater flexibility for customizable treatment plans, especially in areas with hard-to-reach fat bulges.

CoolSculpting is cleared for noninvasive fat reduction of the abdomen and trunk.

For more information:
www.zeltiq.com

MUSTELA

Sun protection keeps babies covered

Mustela's new Broad Spectrum SPF 50+ Mineral Sunscreen Lotion and Broad Spectrum SPF 50+ Mineral Sunscreen Stick are designed to be easy to apply and ideal for travel. Tested under the Food and Drug Administration's most recent requirements for sunscreens, the products are 100 percent mineral-based, using titanium dioxide and zinc oxide to protect delicate skin without using harsh chemicals.

The stick product is convenient for use on-the-go, for touch-ups on areas of skin where children sweat or get more sun exposure, or for unexpected time spent outdoors.

For more information:
www.mustelausa.com

To have information about your company's product or service considered for this section, send news releases and photos to:
New Products and Services
Dermatology Times
24950 Country Club Blvd.
Suite 200
North Olmsted, OH 44070
or fax to (800) 788-7188

Publication is subject to space availability and appropriateness, at the editors' discretion.

upcoming events

Dermatology Times lists meeting announcements for the following three months in our print issue.

American Society for Mohs Surgery 18th Annual Clinical Symposium: Focus on Skin Cancer
www.mohssurgery.org
May 23-26, 2013
Omni Amelia Island Plantation Resort
Amelia Island, Fla.

Anti-Aging Medicine World Congress — Eastern Europe 2013
www.euromedicom.com
June 14-15, 2013
Moscow

Cosmetic Bootcamp — Didactic and Live Technique Symposium
www.cosmeticbootcamp.com
June 20-23, 2013
St. Regis Aspen Resort
Aspen, Colo.

EAACI-WAO World Allergy & Asthma Congress 2013
www.eaaci-wao2013.com
June 22-26, 2013
Milano Convention Centre
Milan

Canadian Dermatology Association Annual Conference
www.dermatology.ca
June 27-30, 2013
Quebec City Convention Centre
Quebec City

Society of Dermatology Physician Assistants Annual Summer Conference
www.dermpa.org
June 27-30, 2013
Hyatt Regency at the Arch
St. Louis

Society for Pediatric Dermatology 39th Annual Meeting
www.pedsderm.net
July 11-14, 2013
Pfister Hotel
Milwaukee

American Academy of Dermatology 2013 Summer Meeting
www.aad.org
July 31-Aug. 3, 2013
New York

Pacific Dermatologic Association 65th Annual Meeting
www.pacificderm.org
Aug. 14-18, 2013
The Palace Hotel
San Francisco

American Dermoscopy Meeting
www.americandermoscopy.com
Aug. 15-17, 2013
The Lodge at Whitefish Lake
Whitefish, Mont.

International Society for Dermatologic Surgery 34th Annual Meeting
www.isdsworld.com
Aug. 29-31, 2013
Valamar Hotel Lacroma Dubrovnik
Dubrovnik, Croatia

American Academy of Dermatology Association 2013 Legislative Conference
www.aad.org
Sept. 8-10, 2013
Willard Intercontinental Hotel
Washington

Alabama Dermatology Society Seminar at Sea
www.alabamaderm.org
Sept. 11-19, 2013
Crystal Cruise Line - Crystal Serenity
Barcelona, Spain

For a full listing of events, go to *www.dermatologytimes.com*

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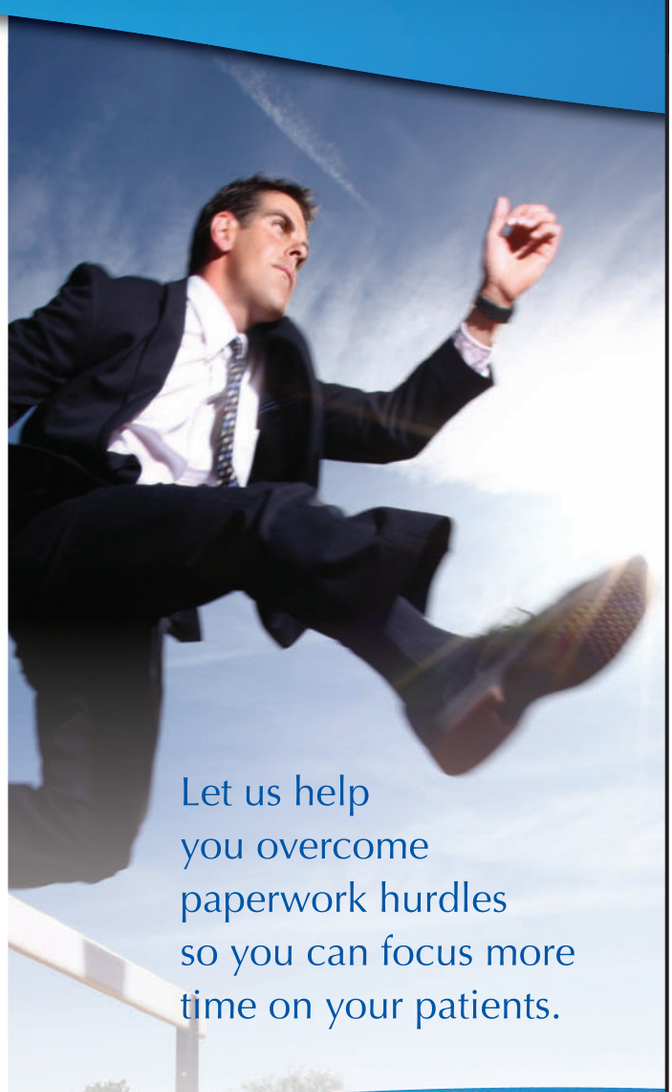

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Interviews arranged thru
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Lyle Melick is IT manager for SS&G Healthcare Services in Akron, Ohio.

IT CONSIDERATIONS

Using a single vendor has its benefits & drawbacks

QUICK READ

Complying with new federal laws and regulations will require a greater use of information technology. Here are the pros and cons of using a single vendor versus multiple vendors for IT needs.

New federal laws and regulations in recent years — ranging from penalties for not using electronic health records to new requirements for safeguarding patient information under updates to the Health Insurance Portability and Accountability Act — have many medical practices are taking a closer look at their technology requirements. Physicians and their practice managers are starting to see that complying with these laws and mandates will require a greater use of information technology (IT) and are exploring the pros and cons of using a single vendor versus multiple vendors for their IT needs.

Hiring a **single vendor** ... can seem expensive, but doing so **may be more economical.**

PROS

What are the benefits of using a single, core vendor?

› **ONE POINT OF CONTACT.** To start with, you have only one point of contact for all your IT needs. You don't have to partially troubleshoot a problem to decide which vendor to call or mediate between vendors if the practice management software vendor says the Internet service provider is causing the problem.

› **MORE RESOURCES.** Core IT vendors usually have a larger staff to pull into large projects as well as access to all the equipment and software required to fully troubleshoot and solve any problems you may experience.

CONS

What are the cons?

› **EXPENSE.** Larger vendors will have more overhead than smaller, niche vendors and can be more expensive. So although the vendor may only assign one technician and the help desk to your account full-time, the costs of all its other technicians, sales staff and office staff will factor into the pricing of its services.

› **POTENTIAL DELAYS.** Core vendors may try to solve all your problems in-house, delaying escalation to equipment and software vendors until they've exhausted everything they can think of. Although they are less likely to encounter a problem requiring vendor intervention than is a smaller, niche vendor, delays in seeking additional support could affect your practice.

WHAT TO LOOK FOR

Base your decision on a provider on three factors:

› **EXPERIENCE.** An experienced IT vendor will have standard policies for dealing with equipment failures and Internet outages. It should be able to monitor your equipment and software around the clock for signs of impending problems and undertake proactive maintenance to help prevent failures. It should have the capability to monitor and routinely test your data backups to ensure that your data are protected, possibly including some form of off-site archival.

› **CONNECTIONS.** Check client references for your potential new IT vendor. Ask them about the problem that has taken the longest to resolve and about any surprises they may have encountered after signing with the vendor. Ask how long they have been a client and what vendor staff turnover has been like. Good IT service companies pride themselves on attracting and keeping good talent.

› **LEADERSHIP.** Ask your potential IT vendor about the company's approach to customer service. Look for a company that acts more like a partner and finds creative ways to meet your technology needs.

Hiring a single IT vendor to address your hardware, software and networking needs can seem expensive, but doing so may be more economical for your practice in the long run. Having one number to call to solve a technology problem can get you back in action quicker because you can avoid vendor squabbles. Look for a vendor that can meet your needs, matches your service philosophy, and wants to support your business so that you can spend more time caring for your patients. **DT**

IMPORTANT INFORMATION ABOUT

EPIDUO® GEL

(adapalene and benzoyl peroxide) Gel, 0.1% / 2.5%

BRIEF SUMMARY

This summary contains important information about EPIDUO (EP-E-Do-Oh) gel. It is not meant to take the place of your doctor's instructions. Read this information carefully before you start using EPIDUO gel. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about EPIDUO gel. For full Prescribing Information and Patient Information please see the package insert.

WHAT IS EPIDUO GEL?

EPIDUO gel is a prescription medicine for skin use only (topical) used to treat acne vulgaris in people 9 years of age or older. Acne vulgaris is a condition in which the skin has blackheads, whiteheads, and pimples.

WHO IS EPIDUO GEL FOR?

EPIDUO gel is for use in people 9 years of age and older. It is not known if EPIDUO gel is safe and effective for children younger than 9 years old.

Do not use EPIDUO gel for a condition for which it was not prescribed. Do not give EPIDUO gel to other people, even if they have the same symptoms you have. It may harm them.

WHAT SHOULD I TELL MY DOCTOR BEFORE USING EPIDUO GEL?

Before you use EPIDUO gel, tell your doctor if you:

- have other skin problems, including cuts or sunburn.
- have any other medical conditions.
- are pregnant or planning to become pregnant. It is not known if EPIDUO gel can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if EPIDUO gel passes into your breast milk and if it can harm your baby. Talk to your doctor about the best way to feed your baby if you use EPIDUO gel.

Tell your doctor about all of the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

- Especially tell your doctor if you use any other medicine for acne. Using EPIDUO gel with topical medicines that contain sulfur, resorcinol or salicylic acid may cause skin irritation.
- Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

WHAT SHOULD I AVOID WHILE USING EPIDUO GEL?

- You should avoid spending time in sunlight or artificial sunlight, such as tanning beds or sunlamps. EPIDUO gel can make your skin sensitive to sun and the light from tanning beds and sunlamps. You should wear sunscreen and wear a hat and clothes that cover the areas treated with EPIDUO gel if you have to be in the sunlight.
- You should avoid weather extremes such as wind and cold as this may cause irritation to your skin.
- You should avoid applying EPIDUO gel to cuts, abrasions and sunburned skin.
- You should avoid skin products that may dry or irritate your skin such as harsh soaps, astringents, cosmetics that have strong skin drying effects and products containing high levels of alcohol.
- You should avoid the use of "waxing" as a hair removal method on skin treated with EPIDUO gel.
- EPIDUO gel may bleach your clothes or hair. Allow EPIDUO gel to dry completely before dressing to prevent bleaching of your clothes.

WHAT ARE THE MOST COMMON SIDE EFFECTS OF EPIDUO GEL?

The most commonly reported side effects when using EPIDUO gel include erythema, scaling, dryness, application site irritation, stinging and burning.

Depending upon the severity of these side effects, patients should be instructed to use a moisturizer, reduce the frequency of the application of EPIDUO gel, or discontinue use.

Tell your doctor right away if these side effects continue for longer than 4 weeks or get worse, you may have to stop using EPIDUO gel. Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of EPIDUO gel. For more information, ask your doctor or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA at *www.fda.gov/medwatch* or call 1-800-FDA-1088. You may also contact GALDERMA LABORATORIES, L.P. at 1-866-735-4137.

HOW SHOULD I USE EPIDUO GEL?

- Use EPIDUO gel exactly as your doctor tells you to use it. EPIDUO gel is for skin use only. Do not use EPIDUO gel in or on your mouth, eyes, or vagina.
- Apply EPIDUO gel 1 time a day.
- Do not use more EPIDUO gel than you need to cover the treatment area. Using too much EPIDUO gel or using it more than 1 time a day may increase your chance of skin irritation.

APPLYING EPIDUO GEL:

- Wash the area where the gel will be applied with a mild cleanser and pat dry.
- EPIDUO gel comes in a tube and a pump. If you have been prescribed the:
  - Tube: Squeeze a small amount (about the size of a pea) of EPIDUO gel onto your fingertips and spread a thin layer over the affected area.
  - Pump: Depress the pump to dispense a small amount (about the size of a pea) of EPIDUO gel and spread a thin layer over the affected area.

WHERE SHOULD I GO FOR MORE INFORMATION ABOUT EPIDUO GEL?

- Talk to your doctor or pharmacist
- Go to **www.epiduo.com** or call **1-866-735-4137**

GALDERMA LABORATORIES, L.P., Fort Worth, Texas 76177 USA
Revised: February 2013

Reference: 1. IMS Health - Monthly Midas Database, all countries selected - Topical Anti Acne Market - November 2012 MAT, retail RX market - at sales manufacturer local currency dollar value - Copyright IMS Health or its affiliates. All rights reserved.

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Important Safety Information

Indication: EPIDUO® Gel is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.
Adverse Events: In controlled clinical studies, the most commonly reported adverse events (≥1%) in patients treated with EPIDUO® Gel were dry skin, contact dermatitis, application site burning, application site irritation and skin irritation.
Warnings/Precautions: Patients taking EPIDUO® Gel should avoid exposure to sunlight and sunlamps and wear sunscreen when sun exposure cannot be avoided. Erythema, scaling, dryness, stinging/burning, irritant and allergic contact dermatitis may occur with use of EPIDUO® Gel and may necessitate discontinuation.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *www.fda.gov/medwatch* or call 1-800-FDA-1088.

Please see brief summary of full Prescribing Information on next page.

www.epiduo.com/hcp