Dermatology Times®
Clinical Analysis for Today's Skincare Specialists
March 2014 VOL. 35, NO. 3

CUTANEOUS ONCOLOGY

Guidelines aim to standardize, advance AK treatments

Cheryl Guttman Krader | Staff Correspondent

VENOUS DISEASE

Avoiding pitfalls requires deliberate approach

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Guidelines aim to standardize, advance AK treatments

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DERMATOLOGISTS and other medical specialists around the world who treat patients with actinic keratoses (AKs, or solar keratoses) will soon be able to refer to new evidence-based (S3) guidelines for management.

AK GUIDELINES see page 70

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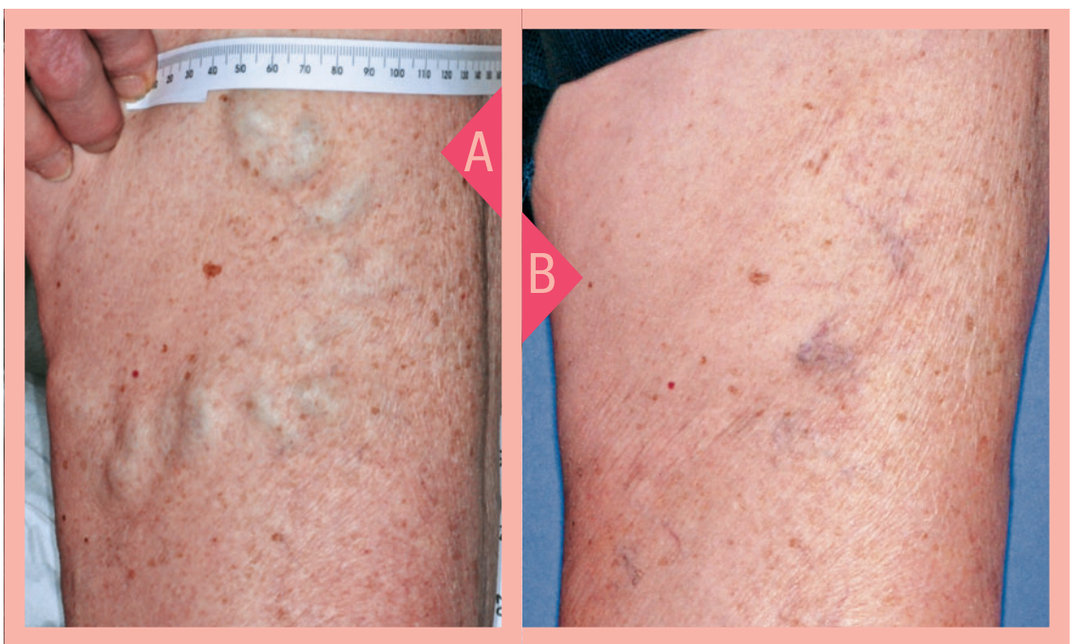

A The patient is a 73-year-old woman with advanced chronic venous insufficiency. She underwent endovenous laser ablation of her bilateral great saphenous veins, bilateral small saphenous veins, and left anterior accessory saphenous vein as well as extensive phlebectomy of tortuous varicosities. B Postoperative photo was taken 12 weeks after treatment of the left and shows absence of varicosities with complete resolution of edema and stasis dermatitis. The patient did not want any sclerotherapy of her reticular and spider veins, which are still present.

Photos: Todd V. Cartee, M.D.

John Jesitus | Senior Staff Correspondent

From diagnosis to treatment of leg veins, avoiding pitfalls requires attention to detail, according to an expert.

For starters, says Todd V. Cartee, M.D., "History and physical are critical when evaluating any of your patients with leg vein disease." He is assistant professor of dermatology at Penn State Hershey Medical Center, Hershey, Pa.

Commonly, he says, patients present seeking cosmetic treatment of spider veins. In such cases, Dr. Cartee says it's critical to establish whether their problem is purely cosmetic or deeper. In this regard, "You can be fooled and wind up treating the symptom of a much more significant disease."

To help determine which patients require referrals for vascular studies, Dr. Cartee offers the BEDPANS mnemonic: look for Bulging varicosities, Edema/stasis dermatitis, DVT (history of), Prior sclerotherapy (unsuccessful), Ankle telangiectasias, Nature (family history) and Symptoms.

"Spider veins localized around the medial ankle are a reliable indicator of great saphenous reflux," he says. Similarly, if everyone in a 35-year-old patient's family has varicose veins after age 60, "She's probably on that trajectory; the spider veins are just the beginning."

Such patients often already have some underlying saphenous vein leakage, he says. "If you don't address that and just go after the spider veins, patients are unlikely to get a durable response."

SPIDER VEINS AND RETICULAR VEINS

For spider veins and reticular veins of the leg, Dr. Cartee says, visual sclerotherapy represents the gold standard,

VENOUS DISEASE see page 55

INDICATION

XEOMIN® (incobotulinumtoxinA) for injection, for intramuscular use is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of XEOMIN and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children and adults, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and at lower doses.

CONTRAINDICATIONS

XEOMIN is contraindicated in patients with a known hypersensitivity to the active substance botulinum toxin type A or to any of the components in the formulation and in the presence of infection at the proposed injection site(s), as injection could lead to severe local or disseminated infection.

WARNINGS AND PRECAUTIONS

- The potency units of XEOMIN are not interchangeable with other preparations of botulinum toxin products. Therefore, units of biological activity of XEOMIN cannot be compared to or converted into units of any other botulinum toxin products.
- Hypersensitivity reactions have been reported with botulinum toxin products (anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea). If serious and/or immediate hypersensitivity reactions occur further injection of XEOMIN should be discontinued and appropriate medical therapy immediately instituted.
- Treatment with XEOMIN and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. When distant effects occur, additional respiratory muscles may be involved. Patients may require immediate medical attention should they develop problems with swallowing, speech, or respiratory disorders. Dysphagia may persist for several months, which may require use of a feeding tube and aspiration may result from severe dysphagia *[See Boxed Warning]*.
- **Glabellar Lines:** Do not exceed the recommended dosage and frequency of administration of XEOMIN. In order to reduce the complication of ptosis the following steps should be taken:
  - » avoid injection near the levator palpebrae superioris, particularly in patients with larger brow depressor complexes;
  - » corrugator injections should be placed at least 1 cm above the bony supraorbital ridge.
- Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junctional disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including severe dysphagia and respiratory compromise from typical doses of XEOMIN.
- XEOMIN contains human serum albumin. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and Creutzfeldt-Jakob disease (CJD). No cases of transmission of viral diseases or CJD have ever been reported for albumin.

ADVERSE REACTIONS

Glabellar Lines: The most commonly observed adverse reaction (incidence ≥ 2% of patients and greater than placebo) for XEOMIN was Headache (5.4%).

DRUG INTERACTIONS

Concomitant treatment of XEOMIN and aminoglycoside antibiotics, spectinomycin, or other agents that interfere with neuromuscular transmission (e.g., tubocurarine-like agents), or muscle relaxants, should be observed closely because the effect of XEOMIN may be potentiated. The effect of administering different botulinum toxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin.

USE IN PREGNANCY

Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. XEOMIN should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

PEDIATRIC USE

The safety and effectiveness of XEOMIN in patients less than 18 years of age have not been established.

Please see Brief Summary of full Prescribing Information on the following pages.

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BRIEF SUMMARY. Visit www.XEOMIN.com for full Prescribing Information.

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of XEOMIN and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children and adults, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and at lower doses *[see Warnings and Precautions]*.

CONTRAINDICATIONS

Hypersensitivity-Use in patients with a known hypersensitivity to the active substance botulinum neurotoxin type A, or to any of the excipients (human albumin, sucrose), could lead to a life-threatening allergic reaction. XEOMIN is contraindicated in patients with known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation *[see Warnings and Precautions]*.

Infection at Injection Site-Use in patients with an infection at the injection site could lead to severe local or disseminated infection. XEOMIN is contraindicated in the presence of infection at the proposed injection site(s).

WARNINGS AND PRECAUTIONS

- **Spread of Toxin Effect-**Postmarketing safety data from XEOMIN and other approved botulinum toxins suggest that botulinum toxin effects may, in some cases, be observed beyond the site of local injection. The symptoms are consistent with the mechanism of action of botulinum toxin and may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties *[see Boxed Warning (above)]*.
- **Lack of Interchangeability between Botulinum Toxin Products-**The potency Units of XEOMIN are specific to the preparation and assay method utilized. They are not interchangeable with the other preparations of botulinum toxin products and, therefore, Units of biological activity of XEOMIN cannot be compared to or converted into Units of any other botulinum toxin products assessed with any other specific assay method.
- **Hypersensitivity Reactions-**Hypersensitivity reactions have been reported with botulinum toxin products (anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea). If serious and/or immediate hypersensitivity reactions occur further injection of XEOMIN should be discontinued and appropriate medical therapy immediately instituted.
- **Dysphagia and Breathing Difficulties in Treatment of Cervical Dystonia-**Treatment with XEOMIN and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or swallowing. When distant effects occur, additional respiratory muscles may be involved. Deaths as a complication of severe dysphagia have been reported after treatment with botulinum toxin. Dysphagia may persist for several months, and require use of a feeding tube to maintain adequate nutrition and hydration. Aspiration may result from severe dysphagia and is a particular risk when treating patients in whom swallowing or respiratory function is already compromised. In general, limiting the dose injected into the sternocleidomastoid muscle may decrease the occurrence of dysphagia. Patients treated with botulinum toxin may require immediate medical attention should they develop problems with swallowing, speech or respiratory disorders. These reactions can occur within hours to weeks after injection with botulinum toxin *[see Warnings and Precautions and Adverse Reactions in Full Prescribing Information for more information]*.
- **Pre-existing Neuromuscular Disorders and other Special Populations-**Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junctional disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including severe dysphagia and respiratory compromise from typical doses of XEOMIN *[see Adverse Reactions]*.
- **Corneal Exposure, Corneal Ulceration, and Ectropion in Patients Treated with XEOMIN for Blepharospasm-**Reduced blinking from injection of botulinum toxin products in the orbicularis muscle can lead to corneal exposure, persistent epithelial defect and corneal ulceration, especially in patients with VII nerve disorders. Careful testing of corneal sensation in eyes previously operated upon, avoidance of injection into the lower lid area to avoid ectropion, and vigorous treatment of any epithelial defect should be employed. This may require protective drops, ointment, therapeutic soft contact lenses, or closure of the eye by patching or other means. Because of its anticholinergic effects, XEOMIN should be used with caution in patients at risk of developing narrow angle glaucoma. To prevent ectropion, botulinum toxin products should not be injected into the medial lower eyelid area. Ecchymosis easily occurs in the soft tissues of the eyelid. Immediate gentle pressure at the injection site can limit that risk.
- **Risk of Ptosis in Patients Treated with XEOMIN for Glabellar Lines-**Do not exceed the recommended dosage and frequency of administration of XEOMIN. In order to reduce the complication of ptosis the following steps should be taken:
  - » Avoid injection near the levator palpebrae superioris, particularly in patients with larger brow depressor complexes.
  - » Corrugator injections should be placed at least 1 cm above the bony supraorbital ridge.
- **Human Albumin and Transmission of Viral Diseases-**This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) is also considered extremely remote. No cases of transmission of viral diseases or CJD have ever been reported for albumin.

ADVERSE REACTIONS

The following adverse reactions to XEOMIN are discussed in greater detail in other sections of the labeling:

- Hypersensitivity *[see Contraindications and Warnings and Precautions]*
- Spread of Effects from Toxin *[see Warnings and Precautions]*

Glabellar Lines In three placebo-controlled trials in 803 subjects with glabellar lines, 535 subjects received a single dose of 20 Units XEOMIN and 268 subjects received placebo. XEOMIN treated subjects were 24 to 74 years old, and were predominantly female (88%). The most frequent adverse reactions in XEOMIN treated subjects were: headache 29 (5.4%), facial paresis 4 (0.7%), injection site hematoma 3 (0.6%) and eyelid edema 2 (0.4%). Four serious adverse events occurred in two placebo-treated subjects. Six XEOMIN treated subjects experienced six serious adverse events. All serious adverse events were assessed as unrelated to study drug. The adverse reactions below reflect exposure to XEOMIN with glabellar lines in placebo-controlled studies. Adverse reactions are adverse events in which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Table 4: Adverse Reactions in Placebo-Controlled Trials

Adverse reactions	XEOMIN (N=535) (%)	Placebo (N=268) (%)
Nervous system disorders	**33 (6.1)**	**6 (2.2)**
Headache[1]	29 (5.4)	6 (2.2)
Facial paresis (brow ptosis)	4 (0.7)	0
General disorders and administration site conditions	**5 (0.9)**	**2 (0.7)**
Injection site hematoma	3 (0.6)	0
Injection site pain	1 (0.2)	0
Facial pain	1 (0.2)	0
Injection site swelling	0	1 (0.4)
Sensation of pressure	0	1 (0.4)
Eye disorders	**5 (0.9)**	**0**
Eyelid edema	2 (0.4)	0
Blepharospasm	1 (0.2)	0
Eye disorder	1 (0.2)	0
Eyelid ptosis	1 (0.2)	0

In open label, multiple dose trials, adverse reactions were reported for 105 of the 800 subjects (13.1%). Headache was the most common adverse reaction, reported for 57 subjects (7.1%), followed by injection site hematoma in 8 subjects (1.0%). Adverse reactions reported in less than 1% of subjects were: facial paresis (brow ptosis), muscle disorder (elevation of eyebrow), injection site pain, and eyelid edema.

Immunogenicity-As with all therapeutic proteins, there is a potential for immunogenicity.

Postmarketing Experience-The following adverse reactions have been reported during post-approval use with XEOMIN. 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: eye swelling, eyelid edema, dysphagia, nausea, flu-like symptoms, injection site pain, injection site reaction, allergic dermatitis, localized allergic reactions like swelling, edema, erythema, pruritus or rash, herpes zoster, muscular weakness, muscle spasm, dysarthria, myalgia and hypersensitivity.

DRUG INTERACTIONS

No formal drug interaction studies have been conducted with XEOMIN. Coadministration of XEOMIN and aminoglycoside antibiotics or other agents interfering with neuromuscular transmission, e.g., tubocurarine-type muscle relaxants, should only be performed with caution as these agents may potentiate the effect of the toxin. Use of anticholinergic drugs after administration of XEOMIN may potentiate systemic anticholinergic effects. The effect of administering different botulinum toxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin. Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of XEOMIN.

USE IN SPECIFIC POPULATIONS

Pregnancy-Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. XEOMIN should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers-It is not known whether botulinum toxin type A is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when XEOMIN is administered to a nursing woman.

Pediatric Use-Safety and effectiveness of XEOMIN in patients less than 18 years of age have not been established *[see Warnings and Precautions]*.

Geriatric Use-Glabellar Lines There are limited clinical data with XEOMIN in subjects over 65 years of age and over in clinical studies with glabellar lines. Of the total number of subjects in the placebo-controlled clinical studies GL1 and GL2, 21 (4%) subjects were 65 and over. Efficacy was observed in 20% (3/15) of XEOMIN subjects 65 years and over. For the entire safety database of geriatric subjects, there was no increase in the incidence of adverse events related to treatment with XEOMIN.

OVERDOSAGE

Excessive doses of XEOMIN may be expected to produce neuromuscular weakness with a variety of symptoms. Respiratory support may be required where excessive doses cause paralysis of the respiratory muscles. In the event of overdose, the patient should be medically monitored for symptoms of excessive muscle weakness or muscle paralysis *[see Warnings and Precautions].* Symptomatic treatment may be necessary. Symptoms of overdose are not likely to be present immediately following injection. Should accidental injection or oral ingestion occur, the person should be medically supervised for several weeks for signs and symptoms of excessive muscle weakness or paralysis. In the event of overdose, antitoxin raised against botulinum toxin is available from the Centers for Disease Control and Prevention (CDC) in Atlanta, GA. However, the antitoxin will not reverse any botulinum toxin-induced effects already apparent by the time of antitoxin administration. In the event of suspected or actual cases of botulinum toxin poisoning, please contact your local or state Health Department to process a request for antitoxin through the CDC. If you do not receive a response within 30 minutes, please contact the CDC directly at 770-488-7100. More information can be obtained at http://www.cdc.gov/ncidod/srp/drugs/formulary.html#1a.

Please visit www.xeomin.com for full Prescribing Information.

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AESTHETIC PROCEDURES ON UPWARD TREND

According to an American Society for Dermatologic Surgery survey, the number of medical and aesthetic procedures increased from 2012 to 2013. Laser and light-based procedures increased 34 percent in 2013. Nonsurgical treatments, such as neurotoxins and soft-tissue fillers, have increased 20 and 8 percent, respectively. "The public is becoming more aware that dermatologic surgeons are the go-to people not only for skin cancer, but for cosmetic procedures," says Mitchel P. Goldman, M.D., ASDS president. "We're seeing an increase in the economy, and that's allowing patients more leeway to do cosmetic procedures."
dermatologytimes.com/aestheticsincrease

resources in dermatology

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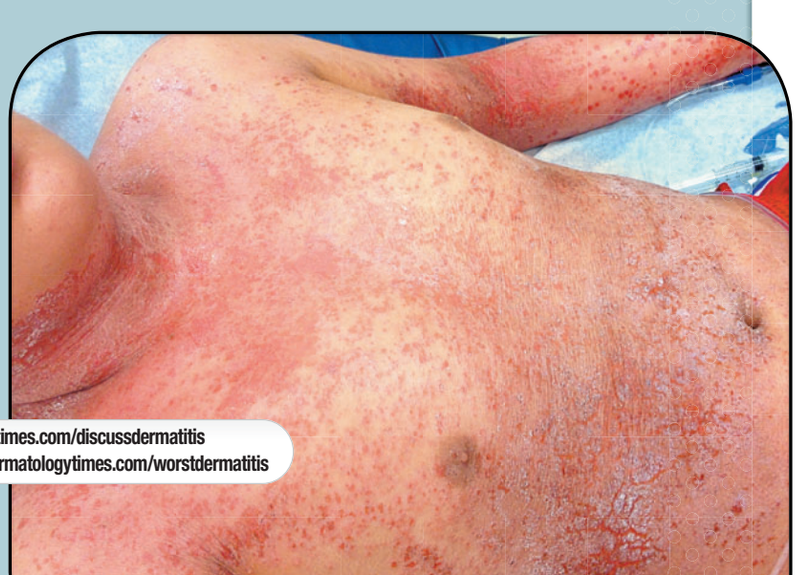

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insight & opinion from our advisory board leaders

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The silver lining around 'eFrustration'

I am spending more and more time in cyberspace. But as I approach 60, my long-term memories of life before the Internet are becoming more vivid. Like many of our ancestors, I often marvel at the advantages of progress, but sometimes long for the good old days.

I remember roaming the bowels of the medical library for articles identified via the Index Medicus, taking time to sneer at the cigarette ads preserved in the bound journals. I also gathered every day at noon, a time to socialize with a group of fellow medical students on my VA rotation, waiting for the long, continuous sheaf of paper to roll off the dot-matrix printer, get torn at the scored lines and distributed to review the morning phlebotomy results.

Back to basics

As a pediatrics resident I had limited computer access, and all medical records were handwritten on paper, kept in giant notebooks, or tattered folders with torn or missing pages. We often had to call the lab for results, which gave us a chance to get to know the pathology residents. One of these discussions helped diagnose a case of Munchausen's by proxy after we worked together to confirm a mother's blood type from a smear on the diaper of her infant, who had been hospitalized several times for "bloody stools."

Record-keeping during my dermatology residency was technologically advanced by comparison, but a little less personal. We dictated onto microcassette tapes. A team of nameless, faceless typists transposed the prose onto 8-by-8 inch folded cards.

Our chairman, John Strauss, was generous in many ways, but one of the most enduring was in building an image library for the entire department. We took pictures with the department camera — 15 or more shots of each view. Hand-labeled Kodachrome slides were distributed, one for every resident and one for the archive file. I still have a shelf full of notebooks with plastic-sleeve pages of carefully organized cardboard slides. Over the years, the best images disappeared into black plastic carousels. I may spend the same number of hours creating every new lecture, but PowerPoint, handheld devices, video animation, and the cloud have completely transformed the art of teaching.

My first home desktop computer arrived in 1986, a generous gift from my brother, who founded a computer company that year. It was a 15-inch with monochrome amber type (swankier than the green). It was a big step up from a typewriter, but couldn't do much more than word processing and calculating.

A few years later, I rented my first car phone, a DC plug-in contraption that came in a small black suitcase. I didn't get a personal desktop computer at work until 1992, along with a university email account. After that, the cyber changes were more frequent and more ubiquitous.

In 1994 we opened a bank account in California because online banking was not available locally. Back then, I spent more time sitting at the desktop computer, but without remote Internet access, I could leave a large fraction of work behind while on vacation. In 1999, I envied the BlackBerrys used by my early-adopter, multitasking colleagues.

Constantly connected

But by 2002, the "crackberry" phenomenon was unsettling. I vividly recall my discomfort that year, sitting around a table at a meeting, surrounded by incessant texters. I joined their ranks by 2007, happily discovering that texting was the most effective way to communicate with my teenage children. I resisted getting an iPhone until 2012. But since then, having 24/7 access to Google, apps, imaging and cloud-based files is no longer an option. I never leave home without it; it is an essential tool in my clinic, during my academic time, while traveling and even when grocery shopping.

The downside of this growing dependence is gradually materializing. Although there are significant risks like loss of privacy or the environmental impact of cyberspace, the daily hassles consume my attention: the need to sort through hundreds of new emails a day, increasingly complex online electronic requirements for manuscript submission, professional certification, IRB approvals and EMR documentation compliance.

Even the once-simple task of creating and remembering a personal login and password has become byzantine. I am now working in a system with two different servers, one for the university and one for the hospital. This generally necessitates manual computer sign-on multiple times a day, to overcome the three-minute, automatic logoff. Each system assigned me a slightly different user name and requires me to change my password at different three- and four-month staggered intervals.

For both systems the passwords can never be repeated and the requirements are unique: six characters for one, eight for the other with a different combination of numbers, symbols, letters and capitals. These identifiers are a small fraction of an ever-growing list of changing, nonsense codes that are beyond memorization, but need maximum protection.

The use of security questions only complicates matters for me. For example, was my birthplace Michigan or Saulte Ste. Marie? Did I enter the more common township name for my high school (Ladue) or the official name (Horton Watkins)? Which was my favorite movie? Did I name my oldest niece by blood or marriage? Did I capitalize the answer or not? Fortunately I have an app to store my logins, passwords and hints on the iPhone that is always by my side, with backups to support my addiction.

Whenever the dark cloud of eFrustration becomes overwhelming, I try to look for the silver lining. In the short term, the need to memorize nonsense passwords is good exercise for an aging brain. Technology will soon make fingerprint or iris recognition more readily available, and someday a computer that recognizes voices and takes notes will allow me to ignore it and interact with my patients — in person or online. **DT**

Elaine C. Siegfried, M.D.

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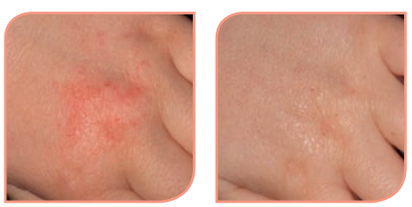

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DAVID J. GOLDBERG, M.D., J.D., *is director of Skin Laser & Surgery Specialists of New York and New Jersey; director of laser research, Mount Sinai School of Medicine; and adjunct professor of law, Fordham Law School.*

Guarding against age discrimination

Doctor Doc has a large practice with many productive happy employees. One of his employees has been with him for more than 20 years and is now 67 years old. Over the past two years, she has become increasingly combative and difficult for both staff and patients.

Since nobody in his office has any contract, Doctor Doc decides one day to terminate this employee on the spot. Immediately his office becomes calmer and more productive. Six months later, he receives notification that he is the defendant in an age discrimination lawsuit by the former employee. How can this be?

The general assumption is that employees do not sue happy, worker-friendly companies like most dermatology offices. Employee lawsuits supposedly happen in companies with bad bosses, poor working conditions and hostile environments. This is just not correct.

Employee lawsuits can and do happen anywhere. According to Department of Labor statistics, in 2011 alone, disgruntled employees filed 23,465 age discrimination complaints, 30,512 in the harassment category and 37,334 complaints of employer retaliation. Our society is becoming increasingly litigious, and the workplace is a prime focus.

If one looks at some of the reasons employees sue the companies where they used to work, physicians begin to feel like they are entering a minefield of spurious claims and scattershot complaints. Dermatologists, among all physicians, need protection. However, if you think you can protect yourself and your office from complaints and lawsuits simply by providing a thorough write-up to go along with each termination, you are starting way too late in the game. Bulletproof human resources (HR) documentation requires a paper trail that starts much, much earlier — before you even hire.

The steps include:

Definine the job description. It can be tough to convince a judge that an employee failed to live up to expectations if those expectations were not carefully defined in the first place. The job description is a central document in any employer/employee relationship, and one that should be shared prior to hiring and revisited at each performance review. If the job description changes, this change must be documented and agreed to by both employer and employee.

Job application. A well-crafted job application will eliminate unnecessary information that may appear on a resume, such as date of college graduation (i.e., age) or religious affiliation. It provides a vehicle for all applicants to compete on a level playing field and offers a baseline for discrimination-free hiring (and firing).

Offer letter. A clear offer letter outlines the terms of employment and does not make promises that could lead to false expectations or disagreements.

Employee handbook. Company HR policies should be spelled out in writing — use a consultant experienced in employment law to help create or review the manual — and managers and employees alike should receive an employee handbook when they start. Have everyone sign their receipt and acceptance of baseline employment policies.

Follow the law. Acts as simple as posting government-required documents can make a difference. Make sure you know what is required, and do it. Create and maintain a good filing system. Employee personnel, medical and confidential records must be stored separately, to ensure the wrong manager or employee does not gain access to privileged information. There is no need to create a medical or confidential file for each employee, but when the occasion arises, that information should not be placed into the main personnel file. Designate a secure place for storing sensitive information.

Document retention policy. What HR documents do you need to keep? What files — paper or digital — can or should be discarded on a regular basis? Old emails and other digital records can help or hurt the company. Deleting them on a schedule might be a good idea. But there must be a written policy — and the company must stick to it.

Performance reviews. If an employee is not living up to expectations, the annual or biannual performance review is your main opportunity to document this failure. Remember, the performance review is where you can — and must — inform an employee of what he or she is doing wrong, and warn of the consequences if performance or behavior does not improve. Be specific — and be sure that you are describing a behavior, and not a personality. Make sure you take notes to document the meeting, and include an account of the employee's responses. A negative performance review should lead to an action plan. Remember, it's not enough to tell an employee what he or she is doing wrong. Work together to formulate a plan for improvement, with a clear time frame. Put it in writing. Have both parties sign it. Then, be sure to revisit it together at the planned dates.

Terminate compassionately. If you have done your work well, then in the unfortunate situation where termination becomes a necessity, it will not be a surprise to the employee. Bear in mind, though, that termination is always unpleasant for the person being terminated, and a calm and compassionate attitude might ease the moment — and steer the employee in the positive direction of finding new employment that is a better fit, rather than seeking retribution through legal action.

This termination could and should have been an easy process for Doctor Doc. Had he taken the above approach, a lawsuit likely would not have happened. **DT**

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Indications and Usage

An external treatment for the inflammation and irritation associated with many common forms of dermatitis, including certain eczematoid conditions. These conditions include complications associated with pyodermas. Indicated also in the treatment of insect bites, burns, and fungal infections.

Important Safety Information

- BENSAL HP is contraindicated for use in those patients who are hypersensitive to topical polyethylene glycols.
- BENSAL HP is for external use only. Not to be used in eyes.
- It is not known if BENSAL HP interacts with other topical medications applied to the treatment area. Use with other topical agents has not been studied.
- A small percentage of patients may experience a temporary burning sensation upon application of the ointment.
- Safety and effectiveness in pediatric patients has not been established.

Please see full Prescribing Information on the following page.

Reference: Bensal HP [prescribing information]. Easley, SC: 7 Oaks Pharmaceutical Corp; 2010.

VALEANT® Dermatology

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Bensal HP®
Topical Ointment

Bensal HP®

TOPICAL OINTMENT

Rx Only

Prescribing Information

DESCRIPTION: Bensal HP® ointment contains 30 mg salicylic acid per gram in a base containing: Benzoic acid, polyethylene glycol 400, polyethylene glycol 3350 and oak bark extract (QRB-7).

CLINICAL PHARMACOLOGY: The mechanism of action of Bensal HP® is not known. While the following animal data are available, their clinical significance is unknown. It has been demonstrated that Bensal HP® significantly reduces methicillin-resistant Staphylococcus aureus (MRSA) protected by biofilms in wounds using porcine models. In addition, Bensal HP® stimulates re-epithelialization of second-degree burns in porcine models.

CLINICAL STUDIES: A randomized, double-blind, placebo-controlled study evaluated the rate of wound re-epithelialization. Four partial-thickness wounds (2x2 cm & 0.2 mm deep) were created under local anesthesia on the thighs of 13 normal, healthy, male volunteers with an electrokeratome. Bensal HP® substantially increased the rate of re-epithelialization by 63% over the vehicle alone ($p<0.01$) and 77% over untreated control ($p<0.005$).

INDICATIONS AND USAGE: An external treatment for the inflammation and irritation associated with many common forms of dermatitis, including certain eczematoid conditions. These conditions include complications associated with pyodermas. Indicated also in the treatment of insect bites, burns and fungal infections.

CONTRAINDICATIONS: Bensal HP® is contraindicated for use in those patients who are hypersensitive to topical polyethylene glycols.

PRECAUTIONS: For external use only. Not to be used in eyes.

DRUG INTERACTIONS: It is not known if Bensal HP® interacts with other topical medications applied to the treatment area. The use of Bensal HP® with other topical drugs has not been studied.

ADVERSE REACTIONS: Bensal HP® is generally well tolerated and non-irritating. A small percentage of patients may experience a temporary burning sensation upon application of the ointment.

DOSAGE AND ADMINISTRATION: Patients should be advised to follow these step-by-step instructions for application of Bensal HP® Ointment:

Hands should be washed thoroughly.

When using tubes, the tip of the tube should not come into contact with the area to be treated; the tube should be recapped tightly after each application.

If applying with a cotton-tipped applicator, which is recommended, use once and discard.

Bensal HP® Ointment should be applied twice a day for best results.

Gently rinse the area to be treated with saline or water and then pat dry. Bensal HP® Ointment can be applied directly to the wound or placed on dry gauze and then placed on the wound. Wet-Packs or Wet-To-Dry Dressings are not recommended since they will dilute the ointment and decrease its effectiveness. Bensal HP® is designed to provide moisture to the wound.

Spread a generous quantity of Bensal HP® Ointment evenly over the desired area to yield a thin continuous layer of approximately 1/8 of an inch of thickness. There may be a mild warming sensation, or slight burning, to the treated area for 3-5 minutes after application. If irritation occurs or symptoms persist after 10 days, discontinue use and consult your physician.

Try to keep the area being treated clean and exposed to air when possible. Apply an appropriate dressing to shield the area from clothes or exposure to water or dirt.

If there is no improvement in the wound within 7 days, consult your physician for further evaluation of the wound. If there is no response to the ointment at all, then the wound should be re-evaluated for other contributing factors to the wound healing process.

PEDIATRIC USE: Safety and effectiveness in pediatric patients has not been established.

HOW SUPPLIED:

15 g tube	NDC 63801 - 0107 - 09
30 g tube	NDC 63801 - 0107 - 01
4 g tube	NDC 63801 - 0107 - 12
2 g sample packet	NDC 63801 - 0107 - 13
10 count 2 g sample packet carton	NDC 63801 - 0107 - 10

Store at 20ºC to 25ºC (68ºF to 77ºF), excursions permitted between 15ºC and 30ºC (between 59ºF and 86ºF). Brief exposure to temperatures up to 40ºC (104ºF) may be tolerated provided the mean kinetic temperature does not exceed 25ºC (77ºF); however, such exposure should be minimized.

Bensal HP® inhibited all tested microbial strains, both Gram negative and Gram positive, in a Minimum Inhibitory Concentration (MIC) test against the following 49 select pathogens.

Minimum Inhibitory Concentration Testing of QRB-7

The minimum inhibitory concentrations (MIC) of QRB-7 are listed below in parts per million (PPM)*.

Microorganism	**QRB-7**	**Microorganism**	**QRB-7**
Microorganism	*Parts Per Million*	*Microorganism*	*Parts Per Million*
Staphylococcus aureus, ATCC 6538	25,000	Pseudomonas stutzeri, ATCC 17588	50,000
Salmonella choleraesuis, ATCC 10708	25,000	Salmonella typhi, ATCC 6539	12,500
*Enterococcus faecalis, ATCC 19433	50,000	Enterobacter aerogenes, ATCC 15038	25,000
Pseudomonas cepacia, ATCC 10856	3,125	Group D enterococcus	50,000
Staphylococcus epidermidis, ATCC 17917	12,500	Trichophyton mentagrophytes CDC y68+	50,000
Alcaligenes faecalis, ATCC 8750	25,000	Rhodotorula rubra HTB Isolate	50,000
Streptococcus uberis ATCC 27958	12,500	Enterobacter cloacae, Hosp/Envi isolate	25,000
Escherichia coli, ATC 25922	25,000	Escherichia coli, Hosp/Envi isolate	25,000
Klebsiella pneumoniae, ATCC 13883	25,000	Pseudomonas cepacia, Hosp/Envi isolate	25,000
Pseudomonas aeruginosa, ATCC 10145	25,000	Klebsiella pneumoniae, Hosp/Envi isolate	25,000
Shigella flexneri type 1A ATTC 9199	12,500	Staphylococcus aureus, Hosp/Envi isolate	50,000
Pseudomonas paucimobilis, ATCC 29837	1,563	Acinetobacter calcoaceticus, ATCC 17961	25,000
Streptococcus sanguis, ATCC 10556	12,500	Alcaligenes faecalis, ATCC 337	25,000
Acinetobacter lewoffii, ATCC 9957	25,000	Enterobacter cloacae, ATCC 23355	25,000
Pseudomonas putida, HTB Isolate	6,250	Achromobacter xylosoxidans, HTB isolate	25,000
Aeromonas sobria, ATCC 9071	25,000	Salmonella typhi, ATCC 19430	25,000
Staphylococcus hominus, ATCC 27844	12,500	Listeria monocytogenes, ATCC 15313	12,500
Staphylococcus haemolyticus, ATCC 29970	25,000	Serratia marcesans, ATCC 14756	25,000
Staphylococcus saprophyticus, ATCC 15305	25,000	Serratia marcesans, ATCC 13880	25,000
Staphylococcus simulans, ATCC 27848	25,000	Candida albicans, ATCC 10231	12,500
Micrococcus lylae, ATCC 27566	50,000	Serratia marcensans, Hosp/Envi isolate	25,000
Streptococcus agalactiae ATCC 13813	12,500	Salmonella enteritidis, ATCC 13076	25,000
Streptococcus equisimilis ATCC 9542	12,500	Escherichia coli, ATCC 11229	25,000
Pseudomonas alcaligenes, ATCC 14909	25,000	Proteus mirabilis, ATCC 9240	25,000
Klebsiella oxytoca, ATCC 15764	12,500		

*Data on file: 7 Oaks Pharmaceutical Corp., Easley, SC

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BCC treatment with laser combination shows promise

Lasers in Surgery and Medicine, January 2014

dermatologytimes.com/noninvasive-BCCtx

NONINVASIVE, NONSCARRING treatment of basal cell carcinoma (BCC) could be on the horizon.

A team of Harvard researchers has examined the possibility of combining pulsed dye laser (PDL) and Nd:YAG laser therapy to treat BCC, as opposed to the traditional surgical excision, Mohs surgery, or electrodessication and cautery.

Their study is based on 13 biopsy-proven BCCs that received four combined PDL and Nd:YAG treatments over the course of two to four weeks. None of the cancers examined met the criteria for Mohs surgery. The tumors and a small area of surrounding skin were treated and later excised and evaluated for residual tumor. The primary endpoint of the study was histologic clearance of tumor, while the secondary endpoint was blinded investigator assessment of clinical endpoint and adverse effects.

The authors wrote that BCC are characterized by a tumor-associated microvasculature interwoven throughout the tumor bed. Vascular-specific lasers can target and destroy these abnormal blood vessels — and thus the BCC cells — with minimal damage to surrounding tissue. Previous studies have shown the efficacy of vascular-specific lasers such as pulsed dye and alexandrite lasers in the treatment of BCC, and the new study appears to confirm the efficacy of combined pulsed dye and Nd:YAG vascular-specific laser therapy.

According to study researcher Mathew M. Avram, M.D., director of the MGH Dermatology Laser & Cosmetic Center at Massachusetts General Hospital, Boston, the therapy is most efficacious with certain-size tumors.

"In this and in prior studies, basal cell size less than 1.5 cm was associated with the best improvement," he tells **Dermatology Times**. "Side effects were minimal. There was temporary bruising, but no long-term side effects such as pigmentary change or scarring." **DT**

Drinking linked to higher risk of melanoma

British Journal of Dermatology
February 2014

dermatologytimes.com/alcohol-melamoma

DRINKING ALCOHOL regularly may increase the risk of developing melanoma by up to 55 percent, according to a new study.

Researchers from Italy, Sweden, the United States, Iran and France conducted a meta-analysis of the results of more than 6,200 cases of melanoma from 16 previous investigations, according to a news release. The researchers found that moderate-to-heavy alcohol use, defined as more than 12.5 grams of ethanol per day, increases the risk of melanoma by 20 percent. Little research has been done on the melanoma risks of heavy of drinking — defined as more than 50 g of ethanol per day — but researchers found that the risk increased proportionately with the amount of alcohol consumed, which led to the estimated 55 percent greater risk of melanoma.

"This is an interesting study, and I think it is important that dermatologists keep well informed on the latest research and potential risk factors relating to skin cancer so that they can pass on this information to their patients," professor Chris Bunker, president of the British Association of Dermatologists, tells **Dermatology Times**. "Prevention is better than cure, and understanding how to minimize risk is very important."

Past studies have shown that alcohol use can increase the severity of sunburn — a major risk factor for all kinds of skin cancer, including melanoma. Alcohol also can affect behavior, which can lead to staying out in the sun too long or failure to apply appropriate sunscreen.

The authors noted that more research needs to be done, especially in correlating heavy drinking with melanoma. **DT**

Cryotherapy outperforms CO_2 lasers in treating AKs

British Journal of Dermatology
February 2014

CRYOTHERAPY may be more effective than CO_2 laser ablation in treatment of actinic keratosis (AKs) on the face and scalp, according to a recent study.

Researchers from the University of Brescia, Italy, and from NorthShore University HealthSystem, Evanston, Ill., conducted a single-center, open-label, randomized and controlled clinical trial comparing the effects of CO_2 laser ablation with cryotherapy when used to treat isolated AKs on the scalp and face.

78 PERCENT
The complete remission rate of AK patients treated with cryotherapy at three months

The study followed 200 patients with a total of 543 isolated AKs. The patients were randomized to receive either CO_2 laser ablation or cryotherapy. The researchers assessed the overall complete remission rates, and correlated and assessed lesion thickness grade.

Three-month results showed a 78 percent complete remission rate of AKs treated with cryotherapy, compared with a 72 percent complete remission rate for patients treated with CO_2 ablation. The 12-month results showed nearly 72 percent of cryotherapy patients in remission, compared with 63 percent of CO_2 ablation patients.

The study also found that cryotherapy is especially effective in treating thicker lesions. The researchers report that cosmetic outcomes were considered good for all patients. **DT**

Mirvaso shows long-term efficacy for facial redness

Journal of Drugs in Dermatology
January 2014

dermatologytimes.com/brimonidine-study

BRIMONIDINE is effective in treating moderate-to-severe facial erythema caused by rosacea, results of a long-term, multicenter study indicate. Researchers studied brimonidine (Mirvaso, Galderma) in 449 patients ages 18 and older, 276 of who used the gel for at least 12 months.

Patients applied the treatment once a day, during which time the severity of erythema and adverse events were noted and evaluated. Patients were permitted to use other treatments for rosacea, both topical and oral. The study noted that treatments were effective starting on the first day of use.

"The most significant finding is that we now have a safe and effective treatment for the persistent redness of rosacea that can be used long-term and does not lose its efficacy," study author Jonathan Weiss, M.D., tells **Dermatology Times**. The study noted no evidence of tachyphylaxis. The authors also noted that there were no new major safety problems or side effects aside from the ones noticed in the first round of testing. Some of the side effects noted in the original testing were flushing, erythema, worsening of rosacea, nasopharyngitis, burning sensation on the skin, increased intraocular pressure, and headache.

Brimonidine received approval by the Food and Drug Administration in August 2013, following two identical studies involving 553 participants, 269 of who were treated with the drug for 29 days, with a subsequent four-week follow-up period. These studies demonstrated the safety and efficacy of brimonidine as a treatment for persistent, nontransient facial erythema of rosacea. **DT**

Focus on aging prompts teen sunscreen use

Journal of the American Academy of Dermatology
February 2014

dermatologytimes.com/teensunscreen

EDUCATIONAL VIDEOS focused on premature aging caused by sun exposure were more likely to improve teens' sunscreen use than videos focused on skin cancer risk, a recent study suggests.

Researchers with the University of California, Davis, and University of Colorado, Denver, conducted a randomized, controlled study of 50 high school students from February to March 2012. Students viewed either a video focused on appearance — showing UV-induced premature aging — or a video that explained the skin cancer risk associated with UV exposure.

The students who viewed the health-based video had a nonstatistically significant increase in sunscreen use (0.9 ± 1.9 d/week, P=0.96), while the group that viewed the appearance-focused video showed a statistically significant increase in sunscreen use (2.8 ± 2.2, P<0.001). **DT**

PSOLAR results show no patterns of cardiovascular events

MauiDerm 2014, Poster Presentation

dermatologytimes.com/PSOLAR

RECENT REPORTS on results from the Psoriasis Longitudinal Assessment and Registry (PSOLAR) study show there are no distinct patterns of major adverse cardiovascular events (MACE), and there are limited rates of malignancy, overall.

Results of the PSOLAR study were revealed in a poster presentation at MauiDerm 2014.

"PSOLAR is a multicenter, longitudinal, observational study evaluating long-term safety and clinical outcomes for patients receiving (or eligible to receive) treatment for psoriasis with biologics and/or conventional systemic agents," according to the reports.

One report that analyzed MACE among the 11,900 patients enrolled in PSOLAR (as of Aug. 23, 2012), found that a total of 57 MACE occurred across biologic treatment groups. Of those, 20 of the MACE were reported among patients who initiated a new biologic.

Of the 20 patients who had MACE after initiating a new biologic treatment, the breakdown of reported MACE per treatment is as follows:

- Adalimumab — 10/1121 (0.89 percent);
- Etanercept — 3/468 (0.64 percent);
- Infliximab — 3/250 (1.20 percent);
- Ustekinumab — 4/1576 (0.25 percent).

Another recent report from PSOLAR also looked at the 11,900 patients enrolled in the study as of Aug. 23, 2012. This report examined the accrual of malignancies excluding nonmelanoma skin cancers in study patients. Of the study's patients, the rates of malignancies excluding nonmelanoma skin cancers for the following treatments are as follows:

- Ustekinumab — 0.53 events per 100 patient years of observation;
- Infliximab/golimumab — 0.70 per 100 patient years of observation;
- Other biologics (almost exclusively etanercept/adalimumab) — 0.68 per 100 patient years of observation;
- Nonbiologic therapy — 0.83 per 100 patient years of observation;
- Overall — 0.68 per 100 patient years of observation.

"Formal comparison will require statistical modeling to adjust for patients characteristics and risks, including consideration of multiple treatments," the report states.

Unadjusted rates in ustekinumab-treated patients tended to be lower than other treatment groups, despite the rules of event attribution, that report stated.

"These are preliminary results — PSOLAR will follow patients for up to eight years, providing additional data over time," the report stated. **DT**

57
Number of MACE occurring among 1,900 patients across biologic treatment groups

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Derms score well in physician lifestyle report

dermatologytimes.com/lifestyle-report

DERMATOLOGISTS report high job satisfaction and are among the most likely of all specialties to take dietary supplements, a recent report suggests.

News source Medscape published its Lifestyle Report 2014, a collection of statistics gleaned from sources such as Gallup, Pew Research and the Centers for Disease Control and Prevention (CDC). The Lifestyle Report compares and ranks physicians by specialty according to their responses to lifestyle questions.

In the latest CDC report on obesity, for example, about 35 percent of Americans are obese (defined as having a body mass index [BMI] of 30 or more). Of the physician categories, the dermatologist percentage was lowest on the list: Just 23 percent reported being overweight to obese.

The report notes that about half of all Americans take some form of dietary supplement. About two-thirds of dermatologists take supplements — the highest rate of any physician category. About 37 percent of dermatologists also take vitamin D.

About one-third of dermatologists take complementary and alternative medicine (CAM) treatments for medical conditions.

Sixteen percent of dermatologists say they take more than four weeks of vacation per year, while 13 percent of plastic surgeons say they do.

At 70 percent, dermatologists (along with ophthalmologists) are the most content at home, while dermatologists are also the happiest at work, with 53 percent claiming to be very or extremely happy there. The least happy in their work are family and emergency medicine physicians, with only internists and radiologists close behind.

In 2012 Gallup poll, 54.7 percent of Americans exercised three or more times a week, while in a Gallup poll of physicians that same year, 58 percent of physicians claimed to exercise the same amount. When looking at exercise frequency by weight group, dermatologist respondents in the current Medscape survey who claimed normal weight did best, with 73 percent of them exercising at least twice a week. The heavier dermatologists came closer to the Gallup poll results, with 54 percent of those who are overweight and only 50 percent of those who are obese saying they exercise at least twice a week.

53 PERCENT
Dermatologists extremely happy at work

At 96 and 95 percent, respectively, almost all dermatologists and ophthalmologists claimed their health is good to excellent. But in general, the great majority of physicians who responded to the survey reported a high level of health.

Dermatologists are light drinkers. Thirty percent of male dermatologists and 27 percent of female derms are teetotalers, while 47 of males and 49 percent of females say they have fewer than one drink a week.

"It was gratifying to see that our specialty ranks among the happiest at work with the lowest BMI, and I believe the reason for this is that we are in specialty a that is gratifying in many aspects," says Helen M. Torok, M.D., medical director of Trillium Creek Dermatology in Medina, Ohio. "It's fascinating, that one out of three dermatologists has utilized CAM treatments for medical conditions, and that about half take supplements, with the No. 1 supplement being vitamin D. I am amazed that so many of us take vitamin D, as I believe its deficiency has still to be proven.

"The vacation of more than four weeks proves that we are committed and responsible physicians who are dedicated to their patients and family," she adds.

Dermatologist Joel Schlessinger, M.D., who practices in Omaha, Neb., says the survey is "very interesting, but not terribly surprising."

"It confirms what we know about dermatologists, which is that they are intelligent and make wise life choices, both in terms of work/life balance, drinking and life partners," he says. "The one thing that was a little surprising to me was the fact that dermatologists were some of the harder working of the professions in terms of weeks of vacation per year. This is likely due to the fact that many dermatologists still run solo or small practices, which ends up leaving less vacation opportunity in comparison to the larger practices of radiology or anesthesiology, which topped the list."

"All in all, this (report) confirms the health and focus on wellness for most dermatologists." **DT**

Light-based therapies show potential for onychomycosis

Lasers in Surgery and Medicine
February 2014

dermatologytimes.com/light-therapy-for-onychomycosis

LASER AND OTHER LIGHT-BASED therapies show potential as a treatment for onychomycosis, according to a recent study.

As part of the study, a research team led by Arisa Ortiz, M.D., of Massachusetts General Hospital in Boston, reviewed literature on the effectiveness of laser and other energy-based treatments for onychomycosis.

Topical therapies have limited success in treating the condition, due to their inability to penetrate the nail plate, while systemic treatments are more successful but carry much greater risks of side effects, OAs a result of the literature review, the researchers found that although laser and other energy-based treatments show much promise, there is a great deal of research that must be done in order to determine specifics of the treatments, such as ideal light source, pulse duration and a schedule for long-term successful treatment.

"Onychomycosis is a therapeutic challenge for dermatologists," Dr. Ortiz tells **Dermatology Times**. "Nd:YAG lasers, such as the 1,320 nm laser, offer a safe and effective alternative for improving the appearance of onychomycosis. Further investigation is warranted to determine the optimal treatment settings."

The authors noted that among the study's limitations was the fact that it was a literature review and that many of the studies they reviewed were small or poorly designed — thus necessitating further investigation. **DT**

Topical hydration reduces damage to skin

Lasers in Surgery and Medicine
February 2014

dermatologytimes.com/plasmaskinregeneration

TOPICAL HYDRATION can reduce thermal damage to skin treated with a plasma skin regeneration (PSR) device, according to a recent study.

The pilot study, published online in *Lasers in Surgery and Medicine*, found that topical hydration applied to skin 30 minutes before use of PSR reduces thermal damage.

A research team led by Alicia Sanderson, M.D., of the University of California, Irvine, examined results from facelifts performed using PSR (1.8 J and 3.5 J). The PSR was done after zero, 30 or 60 minutes of topical anesthetic. The skin was fixed for histologic analysis during the facelift. The study involved four patients, with two control patients and four treatment sites per patients.

The researchers used a scoring system for tissue injury, consisting of epidermal injury, presence of vacuolization, blistering, adnexal structure damage and dermal collagen change depth. These were evaluated in more than 1,400 high-power microscopy fields.

"When resurfacing the skin, hydration of the skin with topical anesthetics affects the degree of thermal injury," Dr. Sanderson tells **Dermatology Times**.

A significant difference was noted in the epidermal injury, average thermal injury score, and depth of thermal damage between controls and 30 minutes of hydration. There was no statistical difference between controls and 60 minutes of hydration and no differences between 30 and 60 minutes of hydration. The study authors also noted epidermal vacuolization at low energy and patchy distribution of thermal injury.

"The data suggest that application of topical anesthetic for a short period of time prior to treatment with the PSR device is cost-effective, safe and may be clinically beneficial," the authors wrote.

The study was sponsored by the Beckman Laser Institute. **DT**

Cloderm better moisturizer than alternative corticosteroids

CLOCORTOLONE PIVALATE 0.1 PERCENT (Cloderm, Promius Pharma) resulted in better hydration when compared with hydrocortisone butyrate 0.1 percent cream (Locoid Lipocream, Onset Dermatologics) and hydrocortisone butyrate 0.1 percent lotion (Locoid Lotion, Onset Dermatologics), according to a recent trial.

The small trial, which was conducted by researchers at Mount Sinai Medical Center, New York; Indiana University School of Medicine, Indianapolis; and DermResearch, Louisville, Ky., compared the occlusivity and moisturization potential of the three products on dry-shaved skin with a disrupted skin barrier.

Researchers enrolled 18 patients ages 23 to 55. Four test sites on the volar forearm were dry-shaved with a disposable razor, which increases transepidermal water loss (TEWL) and decreases skin surface hydration levels compared to normal skin sites, according to the study. The three products were randomly applied to one of three sites, while the fourth site was the control.

Measurements of TEWL and capacitance were taken at one, two, and four hours following a 30-45 minute acclimation period. Results indicated that the application of clocortolone pivalate increased skin surface hydration significantly ($P<0.001$) better than hydrocortisone butyrate cream and hydrocortisone butyrate lotion. Clocortolone pivalate and hydrocortisone butyrate cream produced comparable, significant ($P<0.001$) decreases in TEWL; however hydrocortisone butyrate lotion did not significantly decrease TEWL rates compared to control.

"We now understand that epidermal barrier dysregulation plays an important role in the pathogenesis of atopic dermatitis, along with immunologic factors," said lead investigator Leon Kircik, M.D. "It is important to utilize topical corticosteroids in vehicles that will help, at least to maintain, if not repair, the already disrupted epidermal barrier in atopic dermatitis patients."

The study was supported by Promius Pharma. **DT**

Dermoscopy useful in pinpointing carcinoma types

Journal of the American Academy of Dermatology
February 2014

dermatologytimes.com/dermoscopystudy

DERMOSCOPY can be a useful and reliable tool to differentiate between superficial basal cell carcinoma (sBCC) and other basal cell carcinoma (BCC) subtypes, according to a recent study.

The study, led by Aimillios Lallas, M.D., of Arcispedale Santa Maria Nuova, Reggio Emilia, Italy, attempted to determine the role of dermoscopy in identifying BCC tumor subtypes. Because management of BCC is dependent on histopathologic subtype, this could be an important new step in treating BCC.

Researchers for this study retrospectively examined dermoscopic images of histopathologically confirmed BCCs, looking for predefined criteria. Study authors found that certain characteristics, including maple leaf-like areas, short, fine superficial telangiectasia, multiple small erosions, and shiny white or red structureless areas tended to predict sBCCs. The presence of these characteristics made diagnosis more than five times more likely. The study also found characteristics that could possibly exclude sBCCs from being diagnosed.

Seventy-seven sBCCs, along with 258 non-sBCCs, were examined as part of the study. Limitations include the fact that all patient images were from Caucasians and the retrospective nature of the research. **DT**

Dermatology Times

Intraoperative hemostasis keeps complications to a minimum

Ilya Petrou, M.D. | Senior Staff Correspondent

BORDEAUX, FRANCE — Although still considered rare, hemorrhagic complications remain the most common of the complications that can occur following dermatologic surgery, according to results of a study.


Dr. Guillot

Performing a meticulous hemostasis intraoperatively is key in helping to keep complications at a minimum.

"Various complications including infectious, hemorrhagic and anesthesia-associated complications can all occur in the perioperative period and of these, hemorrhagic-associated complications appear to be the most common," says Patrick Guillot, M.D., department of dermatology, Hospital C.H.U. of Bordeaux, and medical surgical center, Arès-France, and president of the surgical group of the French Society of Dermatology. "Nevertheless, the frequency of all of these complications is very low, underscoring the safety of the dermatologic surgery procedures performed."

QUICK READ

Followed by vasovagal syncope, a recent study showed that hemorrhagic complications remain the most common of the perioperative complications seen in dermatologic surgery.

6 PERCENT
Complications in 3,788 surgical procedures

COMPLICATIONS STUDY

Dr. Guillot and colleagues recently conducted a study to evaluate the frequency of the surgical complications seen during and after dermatologic surgery (Amici JM, Rogues AM, Lasheras A, et al. *Br J Dermatol*. 2005;153(5):967-971). In the prospective multicenter study, data was collected over a three-month period on 3,788 consecutive dermatologic surgery cases performed by 84 dermatologists across France. Ages of study participants ranged from 13 to 99 years (mean 51.5 years).

The cutaneous surgeries included in the evaluation were all of the excisions of malignant and benign tumors located on the face and neck

COMPLICATIONS see page 30

Quotable

"We saw improved acanthosis and decreases in CD11c+ and CD4+ T cells. That's pretty remarkable following a safe and single injection."

Erin Gilbert, M.D.
New York

On neuromodulators for treating psoriasis
See story, page 38

DTExtra

Skincare company PhotoMedex has signed an agreement to acquire LASIK provider LCA-Vision for more than $106 million. PhotoMedex, which offers products addressing skin conditions such as actinic keratosis, acne and psoriasis, has an opportunity to utilize LCA-Vision's existing infrastructure, according to a news release. "LasikPlus centers and staff ... are ideally suited for expanding procedures beyond LASIK to include XTRAC laser treatments for various dermatologic disorders ... as well as utilizing the patient interaction for additional clinical brand dispensing," Dolev Rafaeli, Ph.D., PhotoMedex CEO, said in the statement.

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 AUR DT 03/14

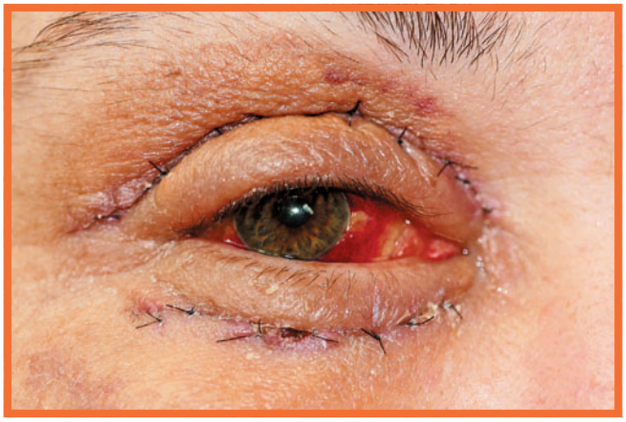
Onset DERMATOLOGICS

COMPLICATIONS:

Hemorrhagic complications remain the most common after dermatologic surgery from page 28

(54 percent), trunk (28 percent) and limbs (18 percent), and excluded surgeries of sebaceous cysts and pyodermas. Procedures ranged from small excisions with simple suture closure to larger excisions with skin flap or skin graft closure techniques.

Patient demographics included 770 smokers (20 percent), 232 taking antiplatelet agents (6 percent), 105 taking anticoagulants (3 percent), 61 with immunosuppressants (2 percent), 108 with diabetes (3 percent), and 29 who received antibiotics before the surgical procedure due to previous infection not related to the procedure (1 percent). Ninety-six percent of surgeries were performed under local anesthesia, and all were performed on an outpatient basis.



A patient with ecchymosis, edema and chemosis after xanthelasma excision. There was spontaneous regression without any treatment.

Photo: Patrick Guillot, M.D.

Of the 3,788 surgical cases reviewed, the researchers found that only 236 complications (6 percent), mostly minor, had occurred in 213 of the dermatologic surgical procedures performed. Of the complications that occurred, bleeding was the most common (3 percent), including 38 percent during surgery, 32 percent immediately after surgery, and 33 percent postsurgical hematoma. Data showed that the hemorrhagic complications were much

References: 1. Bieber T, Prolss J. Atopic Dermatitis. In: Gaspary AA, Tyring SK, Eds. Clinical and Basic Immunodermatology, Springer-Verlag, London, 2008:93-206. **2.** Yosipovitch G, Papoiu ADP. What causes itch in atopic dermatitis? *Curr Allergy Asthma.* 2008;8:306-311.

more frequent in male patients, when anticoagulant, antiplatelet or immunosuppressed agents were used, and in cases of prolonged procedures, skin flaps or full skin grafts.

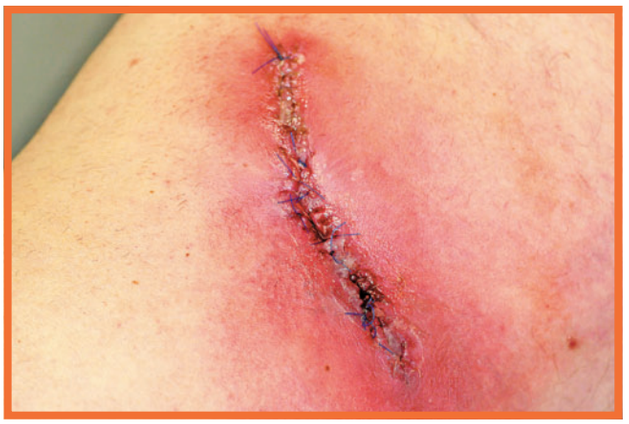
BLOOD TESTS

In the past, it was common practice to simply stop anticoagulant therapy prior to surgical procedures; however, Dr. Guillot says the current conventional wisdom is to closely check international normalized ratio (INR) or prothrombin time (PT) levels in the blood in order to help avoid any potential hemorrhagic complications. According to Dr. Guillot, these blood tests should be performed two to three days before the surgical procedure to closely monitor the patient's clotting status. Anticoagulant treatment can then be reduced appropriately until a satisfactory INR or PT level is reached, allowing for the surgical procedure to proceed, while maintaining the necessary benefits of the anticoagulant for the patient's comorbidities.

> "We do not readily practice antibiotic prophylaxis in our dermatologic surgery patients."
>
> **Patrick Guillot, M.D.**
> Bordeaux, France

"Performing a meticulous intraoperative hemostasis with fine and precise electrocoagulation is essential in helping to prevent potential hemorrhagic complications. In addition, an appropriate management of a patient's anticoagulant therapy — if they are concomitantly taking these medications — is equally important in minimizing hemorrhagic events throughout the perioperative period," Dr. Guillot says.

The second most frequent complication seen was vasovagal syncope in 51 patients (1 percent), the most frequent of the anesthesia-associated complications, and had an onset before surgery in 6 percent, during surgery in 45 percent and after surgery in 37 percent of patients, with 12 percent of unknown onset. According to Dr. Guillot, the anesthetic complications were always benign and without any allergic reaction, and were likely related to the level of anxiety associated with the surgical procedures.



A patient with postoperative infection with superficial suppuration on the lower limb. Antibiotic treatment was prescribed.

Photo: Patrick Guillot, M.D.

3 PERCENT
Complications due to bleeding, the most common complication

Infectious complications occurred in 79 patients (2 percent) and here, the vast majority (92 percent) of infections that occurred were graded as superficial and were confined to the surgical site, while four cases (5 percent) were classified as abscess. Only 1 percent (22 cases) of all of the surgeries performed required antibiotic therapy or revision surgery.

INTERNATIONAL CONSENSUS

In the past, Dr. Guillot says, an international consensus was still lacking regarding recommendations for patients who are at risk for endocarditis or those with prosthetic devices. But now, a consensus recently put forth by the European Society of Cardiology advocates in most cases the absence of necessity of a prevention of the endocarditis by a preliminary antibiotic treatment. Therefore, Dr. Guillot says the decision to administer antibiotic prophylaxis must be carefully weighed from case to case.

"In dermatologic surgery procedures, prophylaxis is not needed because the overall incidence of infection is low. For this reason, we do not readily practice antibiotic prophylaxis in our dermatologic surgery patients. This is in following with the recommendation of the Société Française d'Anesthésie Réanimation (SFAR). Even in those patients who may be at high risk of infection such as in immunosuppressed patients, we do not choose a prophylaxis," he says.

Other study data showed that there was no statistical significant correlation with the characteristics of the dermatologic surgeons in respect to their training and amount of surgical experience, and no link was established between the complications seen and the surgical conditions.

"In respect to our very large study cohort in this trial, we found that the incidence of the complications seen were very low, which first and foremost supports the safety of dermatologic surgical procedures currently performed in France," Dr. Guillot says. "Moreover, we believe that the positive results seen are in part a reflection of the quality and care associated with the dermatologic surgery procedures performed." **DT**

Disclosures: Dr. Guillot reports no relevant financial interests.

Finding cure for onychomycosis remains a complicated objective

Louise Gagnon | Staff Correspondent

PORTLAND, ORE. — Topical therapies currently in use have not effectively treated onychomycosis, a condition that is recurrent.

"The reason that they are not as effective is because the condition is a nail bed problem," says Phoebe Rich, M.D., F.A.A.D., adjunct professor of dermatology, Oregon Health Sciences University, Portland, Ore. "It (the fungus) is primarily under the nail. Topical antifungal drugs applied to the surface of the nail plate don't always penetrate to the site of the infection. At least, the traditional agents do not."

In contrast, systemic therapies reach the nail bed through the circulation and are deposited in the nail plate from the nail matrix, making them much more effective in treating onychomycosis, but they present a greater potential risk of side effects, Dr. Rich says.

New topicals, however, are on the horizon, Dr. Rich notes. Efinaconazole is a triazole antifungal that has been extensively studied and has demonstrated mycologic cure rates that far exceed rates with placebo, p<0.001. Complete cure rates were also much greater, p<0.001 (Elewski BE, Rich P, Pollak R, et al. *J Am Acad Dermatol.* 2013;68(4):600-608).

Devices such as lasers would be a preferred modality for managing onychomycosis, Dr. Rich says, but she notes that the data that has emerged from studies thus far is not as compelling as data on systemic or topical therapies.

ACHIEVING A CURE

Defining cure in onychomycosis is complex. Clinical cure is the appearance of a healthy nail, mycologic cure is demonstrated by the absence of fungus by mycology, and complete cure is achieving both, Dr. Rich explains.

"It may be that a nail is free of fungus and returns back to baseline, but that back to baseline is not a normal (looking) nail," she says.

QUICK READ

Since other conditions can mimic onychomycosis, clinical judgment alone cannot be employed to arrive at the diagnosis.

It is important that clinicians not use solely clinical judgment to diagnose onychomycosis, Dr. Rich says.

"Lots of other nail conditions like psoriasis and traumatic nail dystrophy can look like onychomycosis," she says. "You need to confirm the presence of fungal organisms prior to treating so that you don't treat nonfungal conditions with an antifungal."

A potassium hydroxide (KOH) preparation and a clipping for periodic acid-Schiff (PAS)-stain can be done fairly quickly and inexpensively.

> "You need to confirm the presence of fungal organisms prior to treating so that you don't treat nonfungal conditions with an antifungal."
>
> **Phoebe Rich, M.D.**
> Portland, Ore.

The limitation is that a KOH test and PAS clippings will not tell you if the organism is a dermatophyte, a yeast, or a mold, Dr. Rich says.

"When you need to identify the organism, a culture should be performed," she says, but notes that the sensitivity of culture and KOH is far less than 100 percent.

Polymerase chain reaction (PCR) technology to diagnose onychomycosis is currently not commonly used in the community setting, but it's a definitive test in spotting fungus, Dr. Rich says. "There are fewer false negatives (with PCR)."

SYSTEMIC TREATMENTS

Systemic options available in the United States for treatment of onychomycosis include terbinafine and itraconazole. Fluconazole, although not approved by the Food and Drug Administration for onychomycosis, can be used to treat nail fungus with once weekly dosing, Dr. Rich says. Recent reports of fatal liver toxicity related to ketoconazole has made this drug no longer a systemic option to treat onychomycosis, she says.

Given onychomycosis is a recurrent condition, it is important to take steps to avoid recurrence and reinfection, according to Dr. Rich.

"The real issue is that some patients have a genetic predisposition to this condition, and have the tendency to develop it again," she says.

For those individuals, using a topical antifungal daily on their feet and toenails may prevent reinfection by acting as a barrier if they are exposed to spores in settings like gyms, suggested Dr. Rich.

Recent published data point to other preventative measures that can be taken to ensure nail fungal infections do not recur.

When patient footwear is contaminated with fungal material, ozone gas is an effective tool for sanitizing footwear (Gupta AK, Brintnell WC. *J Cutan Med Surg.* 2013;17(4):243-249).

Laundering is another step to prevent recurrence of onychomycosis. One study concluded that doing laundry when the water temperature was 60 degrees Celsius eliminated both *Trichophyton rubrum and Candida albicans* (Hammer TR, Mucha H, Hoefer D. *Mycopathologia.* 2011;171(1):43-49). **DT**

Disclosures: Dr. Rich is a clinical trials investigator for Valeant Pharmaceuticals.

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Meta-analyses clarify psoriasis comorbidities

John Jesitus | Senior Staff Correspondent

NEW YORK — As research begins to clarify the relationship between severe psoriasis and comorbidities such as heart disease and metabolic syndrome, additional questions arise, according to a clinician.

In psoriasis, says Robert E. Kalb, M.D., "The hot topic is the relationship of psoriasis to comorbidities including diabetes, hypertension and cardiovascular disease." He is a clinical professor of dermatology at the State University of New York, Buffalo, N.Y.

To date, he says, six separate meta-analyses have concluded that psoriasis is an independent risk factor for cardiovascular disease.[1-6] One such analysis included nine studies representing nearly 220,000 patients with mild or severe psoriasis. Investigators ultimately found that mild psoriasis was associated with a significantly increased relative risk (RR) of myocardial infarction (1.29; 95 percent confidence interval/CI: 1.02 to 1.63) and stroke (RR: 1.12; 95 percent CI: 1.08 to 1.16). Severe psoriasis was associated with a significantly increased risk of cardiovascular mortality (RR: 1.39; 95 percent CI: 1.11 to 1.74), myocardial infarction (RR: 1.70; 95 percent CI: 1.32 to 2.18) and stroke (RR: 1.56; 95 percent CI, 1.32 to 1.84).[1]

Similarly, another meta-analysis revealed an odds ratio of 1.28 (95 percent CI: 1.18 to 1.38) for cardiovascular events in psoriatic patients versus non-psoriatic controls.[2]

In light of these data, Dr. Kalb says, "One of the issues we're facing is, does treatment for the psoriasis improve any of these cardiovascular risk factors? If you treat with methotrexate or the TNF (tumor necrosis factor) inhibitors, for example, will you reduce the patient's risk of having a heart attack?"

In this regard, he says, early data suggest this might be the case. For example, a retrospective cohort study involving more than 8,000 health plan members showed that treatment with oral agents or phototherapy yielded an odds ratio for myocardial infarction of 0.57 compared to treatment with topical agents, and an odds ratio of 0.45 for treatment with TNF inhibitors versus topicals (P<0.001 in both analyses).[7] However, he says, it's too soon to draw any definitive conclusions in this area.

QUICK READ

Studies are only beginning to explore the relationship between severe psoriasis and comorbidities such as heart disease and metabolic syndrome.

0.57

Odds ratio for myocardial infarction for patients treated with oral agents or phototherapy

'AGGRESSIVE MANAGEMENT'

It's also important to clarify that the comorbidities mentioned above — especially cardiovascular disease — only affect patients with severe psoriasis, or psoriasis covering 10 percent or more of the body surface area, he says.

Accordingly, "Patients with severe psoriasis need aggressive management of their underlying risk factors." This could involve treatment of hypertension and hyperlipidemia, plus weight management and smoking cessation, to name a few interventions, Dr. Kalb says. "And certainly they need psoriasis treatment. It may turn out that it also helps their cardiovascular risk factors."

Additionally, a prospective, randomized study investigated the effect of controlled weight loss on psoriasis severity. Investigators enrolled 60 overweight or obese patients (body mass index: 27-40). Half of them followed a low-energy diet (800 to 1,000 kcal daily) for eight weeks, followed by eight weeks of normal food intake (1,200 kcal daily).

After 16 weeks, median psoriasis area and severity index (PASI) score in the low-calorie group had declined from 5.4 at baseline to 3.4 (P=0.06).[8]

"Investigators were looking for a PASI decrease of three points for statistical significance. But the study did show statistically significant improvements in Dermatology Life Quality Index (DLQ I) scores, blood sugars and insulin levels," Dr. Kalb says. For example, median DLQ I score dropped two points (P=0.02).

USTEKINUMAB EFFICACY

In early October, the Food and Drug Administration approved ustekinumab for psoriatic arthritis. Previously, he says, "The two main treatments for psoriatic arthritis were methotrexate and the TNF blocking agents." In phase 3 clinical trials, the proportions of patients who received ustekinumab doses of 90 mg and 45 mg who experienced a 20 percent reduction in American College of Rheumatology symptoms (ACR 20) were 50 percent and 42 percent, respectively.[9]

"It's hard to compare studies, but ustekinumab was about 10 percent less effective than the TNF agents. That's still definitely efficacious," Dr. Kalb says. As such, he says that ustekinumab may prove helpful for patients with psoriatic arthritis who do not respond to, or lose response to, TNF inhibitors and methotrexate. **DT**

Disclosures: Dr. Kalb is a speaker, consultant and investigator for Abbott and Janssen, an investigator for Amgen, and a consultant for Leo and Taro. He also serves on dermatology safety monitoring boards for Eli Lilly and Apopharma.

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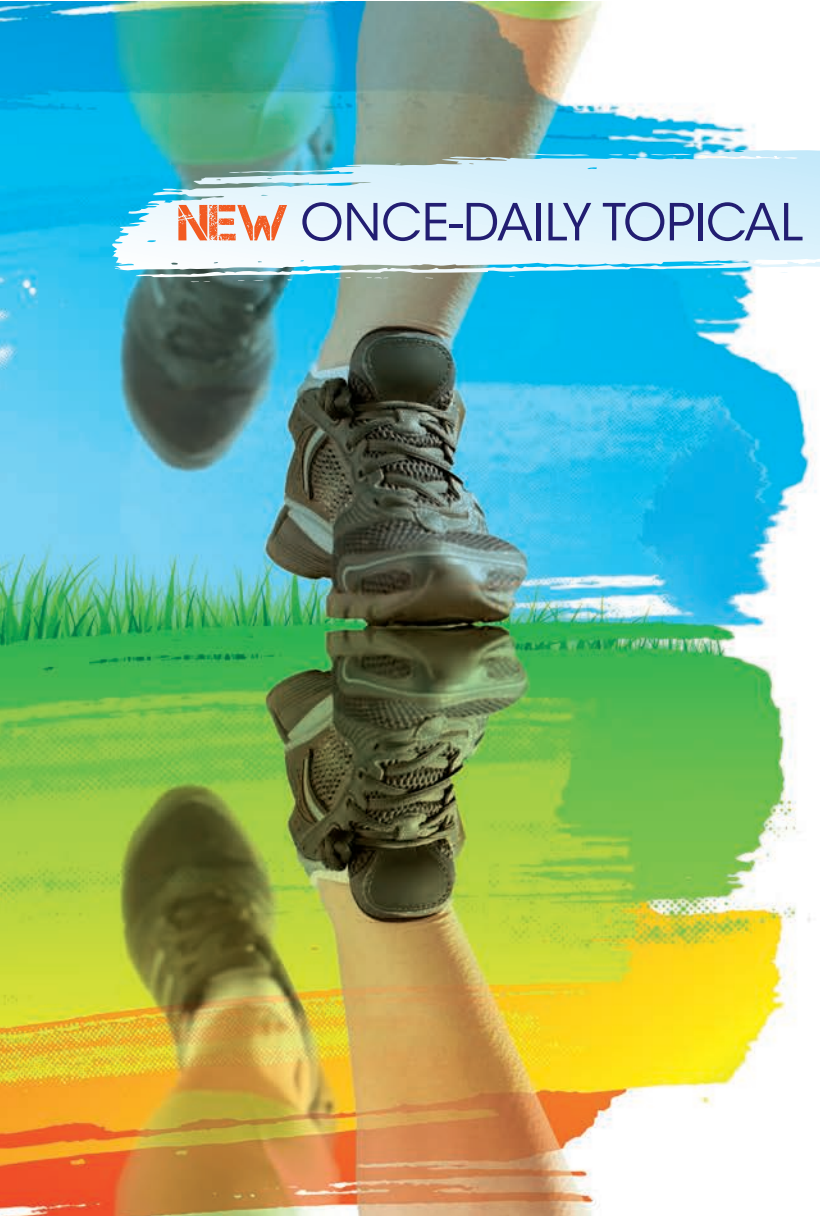

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PROVEN EFFICACY
in step with
SKIN RESTORATION

Only ECOZA™ FOAM combines the proven antifungal efficacy of econazole nitrate with the skin-restoring properties of patented Proderm Technology®

- Kills fungi that cause interdigital tinea pedis[1]
- Unique foam delivery system helps protect and restore skin[2-4]
- Convenient once-daily dosing[1]
- Nongreasy foam penetrates quickly, dries rapidly[5]
- Alcohol-free[1]

INDICATIONS AND USAGE

Ecoza™ (econazole nitrate) topical foam, 1%, is indicated for the treatment of interdigital tinea pedis caused by *Trichophyton rubrum, Trichophyton mentagrophytes,* and *Epidermophyton floccosum* in patients 12 years of age and older.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Flammability: Ecoza™ topical foam is flammable. Avoid heat, flame, and smoking during and immediately following application. Contents under pressure.

ADVERSE REACTIONS

Clinical Trials Experience: During clinical trials with Ecoza™ topical foam, the most common adverse reactions were application site reactions which occurred in less than 1% of subjects in both the Ecoza™ and vehicle arms.

DRUG INTERACTIONS

Warfarin: Concomitant administration of econazole and warfarin has resulted in enhancement of anticoagulant effect. Most cases reported product application with use under occlusion, genital application, or application to a large body surface area which may increase the systemic absorption of econazole nitrate. Monitoring of International Normalized Ratio (INR) and/or prothrombin time may be indicated especially for patients who apply econazole to large body surface areas, in the genital area, or under occlusion.

Please see Brief Summary of full Prescribing Information on adjacent page.

References: 1. Ecoza [prescribing information]. Jamison, PA: Quinnova Pharmaceuticals, LLC; 2013. **2.** Ghadially R, Silvander M. Penetration study results using proderm technology foam. Poster presented at: 7th Annual Caribbean Dermatology Symposium; January 15-19, 2008; St. Thomas, US Virgin Islands. **3.** Fowler JF Jr. Efficacy of a skin-protective foam in the treatment of chronic hand dermatitis. *Am J Contact Dermat.* 2000;11(3):165-169. **4.** Man M-Q, Feingold KR, Thornfeldt CR, Elias PM. Optimization of physiological lipid mixtures for barrier repair. *J Invest Dermatol.* 1996;106(5):1096-1101. **5.** Kircik LH, Bikowski JB. The science of topical foam formulations. *Pract Dermatol.* 2012;9(1):S1-S16.

NEW
ecoza™
(econazole nitrate)
topical foam, 1%

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KILL FUNGUS. RESTORE SKIN.

ecoza™
(econazole nitrate) topical foam, 1%

Rx Only

INDICATIONS AND USAGE:
Ecoza (econazole nitrate) topical foam, 1%, is indicated for the treatment of interdigital tinea pedis caused by *Trichophyton rubrum, Trichophyton mentagrophytes,* and *Epidermophyton floccosum* in patients 12 years of age and older.

DOSAGE AND ADMINISTRATION:
Ecoza topical foam, 1% is for topical use only. Ecoza topical foam, 1% is not for oral, ophthalmic, or intravaginal use.

Ecoza topical foam, 1% should be applied to cover affected areas once daily for 4 weeks.

CONTRAINDICATIONS:
None

WARNINGS AND PRECAUTIONS - *Flammability:*
Ecoza topical foam is flammable. Avoid heat, flame, and smoking during and immediately following application. Contents under pressure. Do not puncture and/or incinerate the containers. Do not expose containers to heat and/or store at temperatures above 120°F (49°C) even when empty. Do not store in direct sunlight.

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

In two double-blind, vehicle-controlled clinical trials, 495 subjects were exposed to Ecoza topical foam or vehicle (246 subjects were exposed to Ecoza topical foam, 1% and 249 were exposed to vehicle). Subjects with interdigital tinea pedis applied foam or vehicle once daily for approximately 28 days. During clinical trials with Ecoza topical foam, the most common adverse reactions were application site reactions which occurred in less than 1% of subjects in both the Ecoza and vehicle arms.

DRUG INTERACTIONS - *Warfarin:*
Concomitant administration of econazole and warfarin has resulted in enhancement of anticoagulant effect. Most cases reported product application with use under occlusion, genital application, or application to a large body surface area which may increase the systemic absorption of econazole nitrate. Monitoring of International Normalized Ratio (INR) and/or prothrombin time may be indicated especially for patients who apply econazole to large body surface areas, in the genital area, or under occlusion.

USE IN SPECIFIC POPULATIONS - *Pregnancy:*

Pregnancy Category C
There are no adequate and well-controlled trials with Ecoza topical foam in pregnant women. Ecoza topical foam should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Econazole nitrate has not been shown to be teratogenic when administered orally to mice, rabbits or rats. Fetotoxic or embryotoxic effects were observed in Segment I oral studies with rats receiving 10 to 40 times the human dermal dose. Similar effects were observed in Segment II or Segment III studies with mice, rabbits and/or rats receiving oral doses 80 or 40 times the human dermal dose.

USE IN SPECIFIC POPULATIONS - *Nursing Mothers:*
It is not known whether econazole nitrate is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when econazole nitrate is administered to a nursing woman. Following oral administration of econazole nitrate to lactating rats, econazole and/or metabolites were excreted in milk and were found in nursing pups.

USE IN SPECIFIC POPULATIONS - *Pediatric Use:*
Of the 173 subjects treated with Ecoza topical foam, 1% in the clinical trials, 2 subjects were 12 to 17 years old. In a pediatric maximal use trial, Ecoza topical foam, 1% was applied once daily to eighteen subjects aged 12 to 17 years with interdigital tinea pedis for 28 days [*see Clinical Pharmacology (12.3)*]. The safety findings for subjects 12 to 17 years were similar to those in adult population.

USE IN SPECIFIC POPULATIONS - *Geriatric Use:*
Of the 173 subjects treated with Ecoza topical foam, 1% in the adult clinical trials, 6 subjects were 65 years or older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects.

Practice gaps leave room for improvement

Ilya Petrou, M.D. | Senior Staff Correspondent

WAIKOLOA, HAWAII — Practice gaps may exist within an office setting, even though the physician is not aware of them, underscoring the need for and advantages of continuing medical education on all fronts of the medical spectrum.

With the ever-changing fast-paced developments occurring in the medical arena, it behooves physicians to stay up-to-date regarding every aspect of their practice. But some physicians — especially those who work in very busy practices — may find it challenging to find the time to stay current with literature in their specialty, and therefore may be unaware of and victim to the potential practice gaps. Continuing medical education (CME) is one avenue that offers physicians an opportunity to stay abreast with the latest developments in their specialty, and may help to close relevant practice gaps.

"A professional practice gap can be defined as the difference between actual and ideal performance and/or patient outcomes, or, the gap between what the professional is doing or accomplishing (current reality) compared to what is achievable on the basis of current professional knowledge," says Erik J. Stratman, M.D., chairman, department of dermatology, Marshfield Clinic, Marshfield, Wis. He spoke at the 38th annual Hawaii Dermatology Seminar in February. "Identifying a practice gap and working towards closing that gap is essential in providing the highest level of patient care."

MINDING THE GAPS

There are three reasons why a physician may experience a practice gap, Dr. Stratman says. A practice gap may be a gap in knowledge, meaning there is new information available regarding the diagnostics and/or treatment of a specific disease or condition, or information that the clinician was not aware of existed that told them they should be doing something different.

There could also be a gap in physician performance, Dr. Stratman says, where physicians know the information, but in providing care, they are unable to implement that knowledge into practice.

QUICK READ

Though many physicians may feel they provide the highest level of care and best treatments for every patient, they may have so-called practice gaps. Recognition of these gaps is the first step towards improving patient care.

The third is a gap in patient outcomes, where the physician knows the information and is doing everything right in practice, but the patient — for whatever reason (patient factors being what they are) — still might not get better.

One of the central objectives of CME traditionally has been to try to close the gaps in knowledge. Dr. Stratman says, however, that a more meaningful step in CME can occur if session objectives are aimed at trying to build a clinician's performance and actually result in performing differently in clinic.

"The competence and the performance of a clinician are very closely linked. Unfortunately, it is difficult to measure performance through a CME session, unless physicians are bringing in with them some practice data," Dr. Stratman says.

COMPETENCY BOOSTERS

One potential competency-boosting approach at CME sessions would be for the speaker to describe certain clinical scenarios in a case-based fashion, and then poll the audience or individual physician for potential responses. Based on the response, Dr. Stratman says those in the CME session sometimes can identify relevant practice gaps, which then could be further explored by the speaker or individual and addressed appropriately.

Practice gaps can occur across the spectrum of the specialty and can include how a physician manages pediatric skin diseases, adult dermatology, surgical dermatology, cosmetic dermatology, and how dermatopathology is read. Identifying and then correcting practice gaps is part and parcel in offering patients the highest standard of care.

"The exploration of practice gaps is really connected to the quality improvement mantra of 21st century medicine. Physicians should always be in search of what they could do to provide better care," Dr. Stratman says.

All physicians are individually responsible for their professional development, he says, which usually involves staying up to date with the latest available information in the medical literature. According to Dr. Stratman, specialty journals are increasingly addressing practice gaps and are including relevant articles in dedicated sections that specifically address these issues.

"Traditionally, a journal publishes an article and the savvy reader would need to interpret practice gaps. But now, journals such as *JAMA Dermatology* and *Dermatologic Surgery* are taking it one step further and actually trying to translate what is being published into a more practice gap-focused interpretation of the literature, serving as a kind of Cliff's Notes for the clinician," Dr. Stratman says.

Identifying practice gaps can serve as the foundation for an in-office quality improvement project, Dr. Stratman says, which may result not only in patients receiving a higher standard of care but, if applied correctly, could qualify the physician to meet some of their Maintenance of Certification needs.

"Every clinician has ways that they could provide potentially better care as new information comes out to guide us in our treatments and in our approach to our dermatology patients. The fact that we have a gap does not make us a bad doctor. The goal is to start looking at the best available evidence differently to see how it can impact us in practice, and make efforts locally to try and improve," Dr. Stratman said. **DT**

Disclosures: Dr. Stratman reports no relevant financial interests.

MOST COMMON PRACTICE GAPS

1. **Failure to ensure patients with psoriasis receive health screening for metabolic syndrome**
2. **Inappropriate use of preoperative and postoperative antibiotics for cutaneous surgeries**
3. **Failure to ensure dermatology patients on prednisone therapy receive bone-protective measures**
4. **Failure to communicate effectively with primary care about patients with new melanoma diagnoses**
5. **Making errors in identifying correct site for cutaneous surgeries**

Source: Erik J. Stratman, M.D.

Neuromodulators have therapeutic potential for psoriasis

John Jesitus | Senior Staff Correspondent

LAS VEGAS — Outside of their aesthetic applications, neuromodulators show promise in treating inflammatory skin conditions including psoriasis, according to an expert at Cosmetic Surgery Forum, held here.


Dr. Gilbert

Regarding inflammatory skin diseases, Erin Gilbert, M.D., Ph.D., proposed that dermatologists look increasingly at type A neuromodulators (onabotulinum, abobotulinum, incobotulinum) in particular as a potential therapeutic option for psoriasis. Type B neuromodulators still have issues with duration of response, says Dr. Gilbert, who is an assistant professor of dermatology at SUNY Downstate Medical Center, New York.

At the neuromuscular junction, type A neuromodulators inhibit acetylcholine release, thereby decreasing skeletal muscular contraction.

"But we also know from some published data that type A neuromodulators reduce pain and itch. This is a curious phenomenon that we've seen in many different contexts," she says. Additionally, she said that many dermatologists don't know that these neuromodulators also inhibit the release of other neuroactive peptides including substance P, calcitonin gene-related peptide (CGRP), glutamate and vasoactive intestinal peptide.

PSORIASIS SOLUTIONS

Regarding psoriasis, Dr. Gilbert has worked with her colleague Nicole L. Ward, Ph.D., assistant professor of dermatology at Case Western Reserve University, Cleveland, on the effects of botulinum type A toxin in a mouse model. Dr. Ward's lab works extensively with the KC-Tie2 mouse model to evaluate potential therapies. The KC-Tie2 mouse is a transgenic mouse with increased numbers of cutaneous nerves.

"Much like in human psoriasis," Dr. Gilbert says, "this mouse also exhibits increased acanthosis and shares some immunologic features with the disease at the cellular level."

QUICK READ

Potential therapeutic uses for type A neuromodulators include psoriasis and infections, an expert says.

Dr. Gilbert says her work and Dr. Ward's work complement each other, as they are both neuroscientists. Dr. Ward noted first that lesional and nonlesional skin of patients with psoriasis contains increased numbers of nerves, according to Dr. Gilbert.

"Neuropeptide expression is higher in psoriatic skin. There's also a lot of data regarding the immunologic component of psoriasis," she says.

EXAMINING NERVE DAMAGE

Factors including psychological stress, immunosuppression and chronic inflammation due to background diseases such as diabetes or hypertension, as well as comorbidities such as alcohol consumption or smoking, can exacerbate psoriasis, according to Dr. Gilbert.

In one clinical report, a human patient with bilateral psoriasis who experienced nerve damage as the result of a brachial plexus injury experienced complete resolution of the psoriasis on the corresponding side of his body (Joseph T, Kurian J, Warwick DJ, Friedmann PS. *Br J Dermatol*. 2005;152(1):185-186). Other patients with bilateral psoriasis, such as those with breast cancer who have undergone unilateral mastectomy, have reported similar focal resolution of psoriasis following nerve damage, Dr. Gilbert says.

Building on this knowledge, Dr. Ward performed cutaneous axotomy on the mice, harvested skin 10 days later, and found decreased nerve numbers on the denervated side versus the control side. This led to a 30 percent improvement in acanthosis, plus a 40 percent decrease in CD11c$^+$ dendritic cells.

"This is important because these dendritic cells are also found in human psoriasis. Dr. Ward also found a 30 percent decrease in the number of CD4$^+$ T cells (Ostrowski SM, Belkadi A, Loyd CM, et al. *J Invest Dermatol*. 2011;131(7):1530-1538. Epub 2011 Apr 7). Therefore, we know that this mouse model mimics human disease," Dr. Gilbert says.

Drs. Gilbert and Ward then attempted chemical denervation of the mice using nine units of abobotulinumtoxinA (Dysport, Merz) per kilogram.

"Two weeks and six weeks postinjection," Dr. Gilbert says, "we harvested skin from the treated and the control side. Exactly like the surgically denervated mice, we saw improved acanthosis and decreases in CD11c$^+$ and CD4$^+$ T cells (Ward NL, Kavlick KD, Diaconu D, et al. *J Invest Dermatol*. 2012;132(7):1927-1930). That's pretty remarkable following a safe and single injection."

FURTHER STUDIES

Based on this success, Dr. Ward has continued to work on the effects of botulinum type A toxin with further mouse studies, under a grant to Case Western Reserve University. Dr. Gilbert simultaneously has pursued off-label, single-treatment protocols, and has been successful in treating refractory plaque psoriasis. For example, she injected one patient with 10 units of Dysport in the left buttock, which was the site of a psoriasis plaque.

"One month after the injection, she had completely cleared this lesion, although lesions elsewhere on her body remained completely intact," Dr. Gilbert says.

"It was a focal effect that lasted for seven months in this woman, due to a single Dysport injection. Essentially this is just the beginning" of research that she and Dr. Ward have planned.

Dr. Gilbert also has been evaluating type A neuromodulators for infections, with fairly impressive preliminary results, she added. She qualified this statement: "These are early days in our studies of human responses to botulinum toxin type A injections for inflammatory skin diseases, and we can't expect that any two subjects will behave in the exact same manner. Randomized, controlled studies are ultimately needed." **DT**

Disclosures: Dr. Gilbert is a consultant to Allergan and Merz Aesthetics.

A CLEAR PATH FOR TREATING AK LESIONS...

Levulan® + BLU-U®

HIGH CLEARANCE* LOW DOWNTIME† PHYSICIAN CONTROLLED**

Levulan® Kerastick® 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.

IMPORTANT RISK INFORMATION

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.

The most common adverse events include scaling/crusting, hypo/hyper-pigmentation, itching, stinging and/or burning, erythema and edema. 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, these effects are temporary and should completely resolve by 4 weeks after treatment.

*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. Most common adverse events are temporary and should completely resolve by 4 weeks after treatment.

**Levulan® PDT is a 2-part treatment procedure that can be completed within a 24 hour period. Levulan must be applied by a qualified healthcare professional.

Please see full prescribing information on adjacent page.

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

BLU-U® 4170
Blue Light Photodynamic Therapy
Illuminator Model 4170

MKT-1749AW Rev A

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%	19%	0%
Pain	1%	0%	0%	0%	0%	0%	0%	0%
Tenderness	1%	0%	0%	0%	2%	0%	0%	0%
Itching	25%	1%	7%	0%	14%	7%	19%	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	7%	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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Pediatric woundcare requires collaboration in hospital, community

Louise Gagnon | Staff Correspondent

TORONTO — Pediatric woundcare differs from adult woundcare, and that principle should guide what clinicians do in the community setting and in hospitals, according to clinicians here speaking at a pediatric woundcare symposium.

"We don't tend to see many things like diabetic ulcers in pediatric woundcare," says Irene Lara-Corrales, M.D., M.Sc., a staff pediatric dermatologist at the Hospital For Sick Children in Toronto, discussing community needs in pediatric woundcare. "If we see ulcers, these usually have other etiologies, like a genetically predisposed condition."

The wound-healing process in children has not been well studied, and there is information lacking about timing of the phases in wound healing in children and how these phases and their timing may differ in adults. In addition, best practice guidelines in pediatric woundcare are lacking, according to Dr. Lara-Corrales, an assistant professor in the department of pediatrics at the University of Toronto.

> "I urge you to have a woundcare committee at your hospital."
>
> **Joel Fish, M.D.**
> Toronto

MANAGEMENT GAPS

There are management gaps in addressing issues such as pain and itch in pediatric woundcare, she adds.

Depending on the age of the child, there are different concerns about the care of wounds.

"If it is a teenager, the child does not want dressings to be noticed," Dr. Lara-Corrales says.

QUICK READ

Pediatric woundcare in the hospital setting should aim to incorporate evidence-based interventions.

Families are not always able to access woundcare for their children at pediatric tertiary centers, so family members need to be educated about the woundcare needs of their child. Other members of the collaboration team can include nurses in schools who may come into contact with children, family physicians, community pediatricians, and daycare workers, Dr. Lara-Corrales explains.

Healthcare providers and family members should be directed to informative websites and provided pamphlets with information about pediatric woundcare. Initiatives such as teledermatology will facilitate follow-up care of pediatric patients with wounds. The cost of pediatric woundcare can be expensive, she says.

Like pediatric woundcare in the community setting, in the hospital setting it is a collaborative effort, according to Joel Fish, M.D., F.R.C.P.C., medical director of the burn unit of the Hospital for Sick Children in Toronto, and a plastic surgeon and associate professor in the department of surgery and research director for the division of plastic surgery at the University of Toronto.

When approaching a pediatric wound, clinicians need to consider local and systemic factors.

"Local factors are sometimes missed in the clinic," Dr. Fish says. "These are factors that are likely reversible. Compared to systemic causes, they are usually irreversible, and there is not that much that you can do."

There are some areas in wound healing that are typically not considered such as nutritional requirements for neonates, according to Dr. Fish.

"There is rapid growth happening in a newborn, and the energy requirements are often underestimated," he says, adding that the classification of wounds in neonates is another challenge.

The tolerance for repeated interventions in pediatric care is much different than in adult care, which is another variable to take into account, he says.

> Initiatives such as teledermatology will facilitate follow-up care of pediatric patients with wounds.

LEADERSHIP ROLE

Clinicians should take a leadership role in pediatric woundcare at their hospitals with a goal to enhancing care, according to Dr. Fish.

"I urge you to have a woundcare committee at your hospital," Dr. Fish says, noting the Hospital for Sick Children's woundcare committee is aiming to standardize pediatric woundcare. Some of the committee's initiatives include screening new woundcare products for their efficacy and safety, and studying the impact of negative pressure therapy in pediatric wounds.

Skin substitutes are being employed in pediatric woundcare, and the experience is that these substitutes are very effective, but these substitutes are not well studied, Dr. Fish says.

There are some areas of controversy in pediatric woundcare, such as the use of anesthetics in children under 1 year of age, Dr. Fish says.

The area of genetics is rapidly advancing, and a better understanding of genetic disorders that lead to wounds will have an impact on woundcare, he says.

Disclosures: Drs. Lara-Corrales and Fish report no relevant financial interests.

Dermatology Times

Newer lasers, older modalities find their niche for resurfacing

John Jesitus | Senior Staff Correspondent

NEW YORK — Although use of older resurfacing modalities is falling in favor of fractional lasers and fillers, experts say, dermabrasion and chemical peels continue to play a role for some operators.


Dr. Geronemus

Roy Geronemus, M.D., says that in his opinion, recognized advantages of ablative fractional resurfacing (AFR) versus older modalities — including fully ablative lasers, chemical peels and dermabrasion — include safety, consistency of results and the ability to vary patients' response based on the technology and parameters chosen. He is director of the Laser & Skin Surgery Center of New York and clinical professor of dermatology at New York University Medical Center.

QUICK READ

Use of ablative fractional resurfacing techniques continues to grow, generally at the expense of older techniques. Whatever one's preference, familiarity with several resurfacing modalities helps to provide optimal patient service.

Conversely, says New York-based plastic surgeon Daniel C. Baker, M.D., "Dermabrasion, which has around for more than 50 years, can produce comparable results — and even better results — than just about anything on the market today. Most plastic surgeons and dermatologists would agree with that."

Both physicians agree regarding the drawbacks of fully ablative CO_2 laser resurfacing. In this regard, Dr. Geronemus says that for postprocedural hypopigmentation, "We reported an incidence of 16 percent with nonfractional CO_2 lasers (Bernstein L, Kauvar A, Grossman M, Geronemus RG. *Dermatol Surg.* 1997;23(7):519-525). And I believe this is an understatement compared to what happens in typical practices."

Dr. Baker adds, "The older CO_2 lasers used to generate a lot of heat" that penetrated beyond the epidermis, accounting for the risk of post-treatment hypopigmentation. But because dermabrasion produces a cold-induced injury that does not extend beyond the skin's surface, "It tends to produce less hypopigmentation than a phenol peel or a fully ablative CO_2 laser."

RESURFACING see page **44**

Quotable

"Anybody who comes out with a longer-lasting neuromodulator will take over the market, because that's what our patients complain about."

Mark G. Rubin, M.D.
Beverly Hills, Calif.

On mixing neuromodulators with epinephrine
See story, page 56

DTExtra


VIDEO CREDIT: XMEDICA/2013 VEGAS COSMETIC SURGERY AND AESTHETIC DERMATOLOGY

Michael Persky, M.D., asked at a recent aesthetic dermatology meeting: Should you talk with your patients about dental work history? He referenced two patients who presented with nodules following hyaluronic acid filler injections. Listen to experts discuss this issue in our exclusive video roundtable.

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JUVÉDERM VOLUMA™ XC injectable gel is indicated for deep (subcutaneous and/or supraperiosteal) injection for cheek augmentation to correct age-related volume deficit in the mid-face in adults over the age of 21.

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- Product use at specific sites in which an active inflammatory process (skin eruptions such as cysts, pimples, rashes, or hives) or infection is present should be deferred until the underlying process has been controlled

PRECAUTIONS

- The safety and effectiveness for the treatment of anatomic regions other than the mid-face have not been established
- As with all transcutaneous procedures, dermal filler implantation carries a risk of infection. Follow standard precautions associated with injectable materials
- The safety for use during pregnancy, in breastfeeding females, and in patients with very thin skin in the mid-face region has not been established
- The safety for use in patients under 35 years or over 65 years has not been established
- The safety in patients with known susceptibility to keloid formation, hypertrophic scarring, and pigmentation disorders has not been studied
- JUVÉDERM VOLUMA™ XC injectable gel should be used with caution in patients on immunosuppressive therapy
- Patients who are using products that can prolong bleeding (such as aspirin, nonsteroidal anti-inflammatory drugs, and warfarin) may experience increased bruising or bleeding at treatment sites
- Patients who experience skin injury near the site of JUVÉDERM VOLUMA™ XC implantation may be at a higher risk for adverse events
- Patients may experience late onset nodules with use of dermal fillers including JUVÉDERM VOLUMA™ XC
- Patients should be limited to 20 mL of JUVÉDERM VOLUMA™ XC per 60 kg (130 lbs) body mass per year. The safety of injecting greater amounts has not been established
- JUVÉDERM VOLUMA™ XC should only be used by physicians who have appropriate experience and who are knowledgeable about facial anatomy and the product for use in deep (subcutaneous and/or supraperiosteal) injection for cheek augmentation

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Side effects in > 5% of subjects were temporary injection-site tenderness, swelling, firmness, lumps/bumps, bruising, pain, redness, discoloration, and itching. They were predominantly moderate in severity, with a duration of 2 to 4 weeks.

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1. JUVÉDERM VOLUMA™ XC Directions for Use, 2013. **2.** Data on file, Allergan, Inc.

THE NEXT DIMENSION

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VOLUMA™ XC

RESURFACING:

Familiarity with variety of modalities ensures optimal patient care from page 42

SIDE EFFECTS AND RESULTS

Dr. Baker says his practice stopped doing fully ablative CO_2 laser treatments because of their side effects and prolonged healing periods. In the latter area, Dr. Geronemus says ablative technologies and deeper peels produce postprocedural peeling that lasts up to 10 days, and erythema that lasts from weeks to months. Conversely, he says, "Healing following AFR is significantly faster than with nonfractional ablative treatments. While wounding does occur with AFR, re-epithelialization often occurs within a few days, and in most cases postoperative redness is reduced from months to weeks."

For nonfacial treatments as well, Dr. Geronemus says, "With the older techniques, the risk of scarring and pigmentary change was so high that in many cases, these devices were contraindicated." Similarly, he says, "The incidence of hypertrophic scarring that we saw with older techniques was considerably higher than what we see today with AFR."

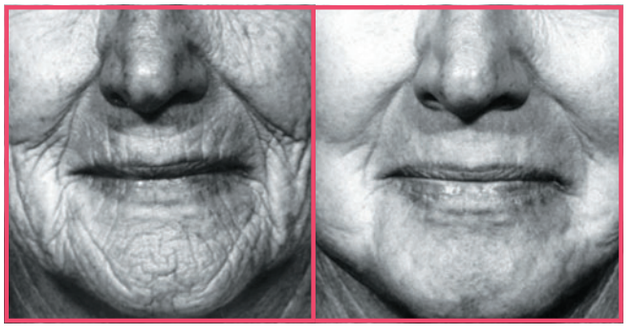
Regarding the ability to modify treatments, Dr. Geronemus says, AFR allows physicians to factor in the patient's condition and skin type. Conversely, he says, "Darker skin types have always been extremely challenging for chemical peels and dermabrasion. We worry about hyper- or hypopigmentation as a result of these aggressive procedures."

In contrast, he calls AFR's ability to alter treatment techniques for darker skin types a major breakthrough. Before the advent of AFR, Dr. Geronemus says, treating scars, lines and pigmentation problems in skin types IV through VI was so difficult that he would not even attempt it.

"Now we do these treatments routinely," Dr. Geronemus says. For superficial problems, "I might treat Caucasian patients with lighter skin types using a density of 50 to 70 percent. I may cut that in half if I'm treating somebody with a darker skin type."

A patient before (left) and one year after a treatment of perioral dermabrasion and no additional filler therapy.

Photos: Daniel C. Baker, M.D.



86.6 PERCENT

Reduction in lesions with nonablative fractional 1,927nm thulium laser

NONABLATIVE ADVANTAGES

Similarly, Dr. Geronemus says that nonablative resurfacing techniques provide significant advantages for all skin types in treating acne scars, photodamage, actinic keratoses (AKs), surgical scars and burn scars. Side effects are mild and include dryness, scaling and erythema that can last up to four to five days, he adds.

Likewise, Dr. Geronemus says that compared to dermabrasion and deep chemical peels, nonablative resurfacing is safe and free of concerns for pigmentary changes and, usually, significant downtime.

"Patients can go about their lives without being encumbered by an open wound or prolonged healing time," he says.

Nevertheless, "One downside of the fractional technology is that the duration of cosmetic benefit may not be quite as long for treatment of photodamage or for skin tightening," Dr. Geronemus says.

For these indications, "Perhaps you're better off with the older, fully ablative technologies. But still you must balance that off with the risk of pigmentary change, the higher risk of scarring and the longer healing time required," he says.

Therefore, Dr. Geronemus says, "There's a trade-off between having to repeat a treatment and having a higher level of safety. On the other hand, results with many of the scars that we treat with fractional technologies tend to be more permanent."

ADDRESSING AKS

For AKs, a study that included six months' follow-up showed that, "The nonablative fractional 1,927 nm thulium laser is as good as anything out there, with no wounding of the skin (Weiss ET, Brauer JA, Anolik R, et al. *J Am Acad Dermatol.* 2013;68(1):98-102)," he says. In that study, an independent physician assessment noted an 86.6 percent reduction in absolute number of lesions.

Dermabrasion, meanwhile, provides the most value in treating very deep lines around the lips and in the perioral region — often with a single treatment, Dr. Baker says. While other modalities usually require multiple treatments for this indication, "For a physician with experience and skill, usually one treatment will provide improvement anywhere from 75 percent to 90 percent."

Any of the other modalities can handle superficial lines, he says. "For general fine lines and sun damage, the Fraxel (Solta) laser is excellent, as are TCA (trichloroacetic acid) peels and phenol peels. But the side effect profile of deep laser treatments, deep peels and deep dermabrasion includes hypopigmentation."

Logistically, dermabrasion requires little equipment invest-

RESURFACING see page 52


WHEN ACNE HAS
YOUR PATIENTS
LOOKING DOWN...
Turn the page to see
how you can help.

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 whensun 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.

*A phase 3, randomized, multicenter, double-blind, active- and vehicle-controlled, parallel-group study evaluating the efficacy and safety of adapalene 0.1%–BPO 2.5% fixed-dose combination gel relative to adapalene 0.1% monotherapy, BPO 2.5% monotherapy, and gel vehicle in a large population for the treatment of acne vulgaris (N=1670).

†A multicenter, randomized, vehicle-controlled, double-blind study evaluating the efficacy and safety of adapalene 0.1%—BPO 2.5% fixed-dose combination gel in subjects 9 to 11 years of age with acne vulgaris (N=285).

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

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IMPORTANT INFORMATION ABOUT

EPIDUO® GEL

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

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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**

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Revised: February 2013

References: 1. Gollnick HPM, Draelos Z, Glenn MJ, et al; Adapalene–BPO Study Group. Adapalene–benzoyl peroxide, a unique fixed-dose combination topical gel for the treatment of acne vulgaris: a transatlantic, randomized, double-blind, controlled study in 1670 patients. *Br J Dermatol*. 2009;161(5):1180-1189. **2.** Czernielewski J, Michel S, Bouclier M, Baker M, Hensby C. Adapalene biochemistry and the evolution of a new topical retinoid for treatment of acne. *J Eur Acad Dermatol Venereol*. 2001;15(suppl 3):5-12. **3.** Tenaud I, Khammari A, Dréno B. In vitro modulation of TLR-2, CD1d and IL-10 by adapalene on normal human skin and acne inflammatory lesions. *Exp Dermatol*. 2007;16:500-506. **4.** Thiboutot D, Gollnick H, Bettoli V, et al; Global Alliance to Improve Outcomes in Acne. New insights into the management of acne: an update from the Global Alliance to Improve Outcomes in Acne group. *J Am Acad Dermatol*. 2009;60(5)(suppl):S1-S50. **5.** Eichenfield LF, Draelos Z, Lucky AW, et al. Preadolescent moderate acne vulgaris: a randomized trial of the efficacy and safety of topical adapalene-benzoyl peroxides. *J Drugs Dermatol*. 2013;12(6):611-618.

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Q&A WHICH HAND SANITIZER IS BEST FOR USE IN THE PHYSICIAN'S OFFICE?

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

COSMETIC CONUNDRUMS

Q. What are the different types of hand sanitizers? Which is the best one for the dermatologist 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 has excellent killing 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 have been identified.

The second type of hand sanitizer is based on quaternary ammonium compounds, such as benzaklonium chloride or benzethonium chloride. While the ethanol-based hand sanitizers are flammable, the quaternary ammonium compounds are not and can be used around hyfrecator 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. Quaternary 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*.

With all of this background, I would say that in general the ethanol-based hand sanitizers are the most practical for the dermatologist to use on a daily basis. 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 on the skin 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: While the CDC (Centers for Disease Control and Prevention) has credited hand sanitizers with minimizing the severity of the flu outbreak last year, there are some important organisms that cannot be killed by any type of hand sanitizer. Dermatologists should know that hand sanitizers do not kill anthrax, which was an organism of great concern several years ago. Further, hand sanitizers are not effective against *Clostridium difficile*, which has become another antibiotic resistant organism.

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 to good sanitize the hands after shaking hands, touching a contaminated bathroom door handle, or if soap and water are not available.

Q. How is the dryness from hand sanitizers best counteracted?

A: All formulations of hand sanitizers are drying to the hands. The ethanol-based products discussed earlier are the most drying because they remove the intercellular lipids from the skin efficiently increasing transepidermal water loss. Ideally, a hand cream should be used after every hand sanitizer use, but most people will not do this as they feel their hands are again dirty due to the moisturizer film. The best time to apply a hand cream is at bedtime when the hands are rest and no hand sanitizer is used. Glycerin-based creams with petrolatum are the best because the glycerin acts as a humectant to attract water while the petrolatum inhibits the water from evaporating to the environment through the damaged skin barrier. Creams are definitely more effective than lotions because of a lower water contact and a higher concentration of moisturizing ingredients. Hand sanitizers may be the provocative agent in many types of eczematous, dyshidrotic, and irritant hand dermatitis. **DT**

Holistic approach can address signs of aging face

Ilya Petrou, M.D. | Senior Staff Correspondent

ISTANBUL — A multitude of topical and oral therapies can be skillfully used to help patients achieve their anti-aging goals, according to a clinician who spoke at the European Academy of Dermatology and Venereology Annual Congress.

"We often will combine systemic and topical treatments in our cosmetic patients in order to achieve not just a youthful looking face, but a healthy-looking one as well," says Demetrios Ioannides, M.D., Ph.D., professor of dermatology, Hospital for Skin and Venereal Diseases, Thessaloniki, Greece. "However, as all patients differ in their needs in this regard. The appropriate treatment regimen for each patient can differ, and the therapeutic approach chosen depends on varying factors including the age of the patient, skin type, general health status, previous cosmetic procedures performed, as well as the individual patient's goals and expectations."

Dermatologists can take a holistic approach when addressing skin rejuvenation in their patients, Dr. Ioannides says. A holistic approach aims to reduce, postpone and even repair the effects of endogenous as well as exogenous aging.

VARIETY OF STRATEGIES

According to Dr. Ioannides, a complete anti-aging treatment can consist of many strategies, such as avoiding exogenous factors of aging, changing one's lifestyle and habits (i.e. smoking, UV radiation, nutrition, physical activity, stress), and using topical cosmeceutical agents and/or oral nutraceuticals. There is also an array of cosmetic procedures such as chemical peels, injectable skin biostimulation and rejuvenation techniques, and a multitude of evolving laser and light therapies, to name a few.

Systemic anti-aging agents such as the nutraceuticals are formulated from a multitude of different ingredients, Dr. Ioannides says, which target all levels of intrinsic and extrinsic aging processes and enhance the beauty and health of the skin. Melatonin is one popular oral nutraceutical that is commonly used. Although it has been shown to have a favorable influence on the aging process, Dr. Ioannides says definitive data is still lacking and there is no substantial evidence in the literature to support the anti-aging action of the supplement.

Among the ingredients used in nutraceuticals, Dr. Ioannides says the antioxidants represent the most crucial of them all, and include vitamins C, E, A, D and E, carotenoids, copper and selenium, as well as flavonoids and polyphenols.

"Systemic antioxidants not only have anti-aging properties but also a probable role in the prevention of various diseases associated with oxidative stress such as cancer, cardiovascular and neurodegenerative diseases," he says.

In his middle-aged cosmetic patients, Dr. Ioannides says he will often recommend resveratrol — a natural antioxidant found in the skin of grapes and other fruits — as well as silymarin, as these systemic antioxidants have a significant anti-aging action and antioxidant effect on the liver and other organs. To this, he may suggest a daily regimen of vitamins E and C.

CARE WITH COSMECEUTICALS

Topical products known as cosmeceuticals contain biologically active ingredients that can improve the appearance of the skin, Dr. Ioannides says, without altering its structure and function.

"These topical agents hold a significant role in the anti-aging skincare regimen, as they not only support and maintain the outcomes of cosmetic surgery and other more invasive cosmetic procedures, but also improve skin texture and dyspigmentations that often cannot be ideally addressed with other treatment modalities," he says.

HOLISTIC see page 52

QUICK READ

Complete facial rejuvenation therapy can consist of a mosaic of treatment approaches including topical and/or systemic cosmeceuticals and/or nutraceuticals used alone, or in combination with cosmetic procedures such as injectables and laser and light devices.

Main categories of cosmeceuticals

1. **Products that prevent collagen and matrix degradation:** Broad-spectrum sunscreens, matrix metalloproteinase inhibitors (retinoids, beta carotene, aloe vera, etc.), antioxidants (resveratrol, silymarin, coenzyme Q10, green tea, vitamins, etc.)
2. **Collagen and matrix producers:** Retinoids (tretinoin, tazarotene, retinaldehyde, etc), peptides (acetyl hexapeptide-3, copper peptide etc.), topical growth factors processed skin-cell proteins, cell rejuvenation serum, etc.), vitamins C and E
3. **Texture improvement:** Retinoids and alpha hydroxy acids
4. **Dyschromia correction:** Melaninogenesis inhibitors (hydroquinone, kojic acid, azelaic acid, resorcinol derivatives, etc), retinoids, vitamins C and E
5. **Hydration:** Humectants (hyaluronic acid, urea, collagen, honey, etc.) and occlusive agents (petrolatum, niacinamide, silicone, olive oils, etc.)

*Source: Demetrios Ioannides, M.D., Ph.D.

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HOLISTIC APPROACH:

Facial rejuvenation can include mosaic of treatment approaches from page 50

Although many topical cosmeceuticals are readily used — including broad-spectrum sunscreens, various moisturizers, exfoliating agents (i.e. salicylic acid, alpha-hydroxy acids) and depigmenting agents (i.e. hydroquinone, retinol, ascorbic acid, kojic acid, lactic acid, and azelaic acid) — Dr. Ioannides says the antioxidants remain as some of the most important of these agents in skin rejuvenation treatments.

"Topical antioxidants not only reduce the free radical damage that is implicated on both the intrinsic and extrinsic aging processes, but also inhibit inflammation which leads to collagen depletion, as well as provide protection against photoaging and skin cancer," he says.

ADDITIONAL TOPICAL OPTIONS

In his patients, Dr. Ioannides will often recommend various topical products containing different antioxidants such as vitamins C, E and B3, the polyphenols and flavonoids (i.e. green tea extract, lycopene, ferulic acid, resveratrol, silymarin, glutathione and caffeine), as well as co-enzyme Q10 and alpha-lipoic acid.

"Aside from recommending topical products containing resveratrol and silymarin, I frequently will also recommend those with co-enzyme Q10 and alpha-lipoic acid," he says. "There are excellent products on the market with these two antioxidants, which are very cosmetically acceptable, and there is also evidence in the literature that supports their ability to protect the skin from oxidative stress."

Systemic anti-aging treatments: Vitamins, antioxidants, minerals

- Vitamins (A, C, D, E, F)
- Carotenoids
- Tocopherol
- Flavonoids
- Fatty acids (lipoic acid)
- Melatonin
- Coenzyme Q10
- Collagen-hyaluronic acid
- Polyphenols
- Estrogens (HRT)

*Source: Demetrios Ioannides, M.D., Ph.D.

For ideal skin rejuvenation outcomes in the long term, Dr. Ioannides says cosmetic patients should take daily anti-aging regimens for months or years — if not indefinitely — as the aging process is ongoing. Sun protection and appropriate lifestyle and habits are conducive to keeping the skin looking young, he says.

"Prophylaxis is absolutely key in helping us look and feel younger and healthy. Many of these topical and oral anti-aging products work very well and ... they can produce a visible effect when used regularly," he says. "In addition, it is very useful to combine these with a healthy diet consisting of abundant fruits and vegetables." **DT**

Disclosures: Dr. Ioannides reports no relevant financial interests.

RESURFACING:

Familiarity with variety of modalities ensures optimal patient care from page 44

ment, upkeep and floor space. Nevertheless, says Dr. Baker, who has performed thousands of dermabrasion procedures over 30 years, "I use less dermabrasion today."

Patients with deep perioral lines increasingly want fillers, he explains. However, "You can only do so much with a filler without creating distortion." Therefore, he finds dermabrasion — which he usually performs in the same session as a facelift — to be most effective for patients who want to address these deep lines with a single treatment.

However, Dr. Baker says that like surgical procedures, dermabrasion carries a learning curve: 50 to 100 cases before one achieves proficiency. "There's a certain technical expertise required in terms of using your hands and being able to accurately analyze the depth of the peel."

UNITED AGAINST HYPE

It's not that dermatologists or plastic surgeons as a whole favor one technology over the other, Dr. Baker says. Rather, "Because lasers are new technology, there's tremendous marketing and hype behind them. But for those of us who've tried many of the lasers, there's a bit of disappointment between what's promoted and the results."

> "For those of us who've tried many of the lasers, there's a bit of disappointment between what's promoted and the results."
>
> **Daniel Baker, M.D.**
> New York

Some patients get excellent results with fractional ablative or nonablative lasers, Dr. Baker notes. Furthermore, he says that generally, "Younger plastic surgeons probably find the lasers a little easier and perhaps more predicable when they haven't had as much experience. There's a greater comfort level with the lasers, where you choose a certain setting based on patient needs to produce a predictable result."

As laser resurfacing technology continues to improve, Dr. Baker says, "There may come a time when that's the only thing we do" for patients who want resurfacing treatments. But for now, "There's really no single absolutely best technique. It varies with the operator, the patient and how he or she responds."

Whatever one's preference, he advises, "Become skilled in several techniques so you have options available in your armamentarium. And you need to be familiar with each modality's capabilities, and what types of skin each modality works best with. That way, you have different treatments to offer your patients." **DT**

Disclosures: Drs. Geronemus and Baker report no relevant financial interests.

VALCHLOR is an alkylating drug indicated for the topical treatment of Stage IA and IB mycosis fungoides–type cutaneous T-cell lymphoma (MF-CTCL) in patients who have received prior skin-directed therapy

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DOSING AND APPLICATION

VALCHLOR is for topical dermatologic use only. Apply a thin film once daily to affected areas of the skin. Caregivers must wear disposable nitrile gloves when applying VALCHLOR. Patients and caregivers must wash hands thoroughly after handling or applying VALCHLOR.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

VALCHLOR is contraindicated in patients with known severe hypersensitivity to mechlorethamine. Hypersensitivity reactions, including anaphylaxis, have occurred with topical formulations of mechlorethamine.

WARNINGS AND PRECAUTIONS

- **Mucosal or eye injury:** Exposure of mucous membranes to mechlorethamine such as the oral mucosa or nasal mucosa causes pain, redness and ulceration, which may be severe. Exposure of the eyes causes pain, burns, inflammation, photophobia, and blurred vision. Blindness and severe irreversible anterior eye injury may occur. Should eye exposure or mucosal contact occur, immediately irrigate for at least 15 minutes with copious amounts of water, followed by immediate medical consultation.
- **Secondary exposure:** VALCHLOR is a cytotoxic drug. Avoid direct skin contact with VALCHLOR in individuals other than the patients due to risk of dermatitis, mucosal injury, and secondary cancers.
- **Dermatitis:** Monitor patients for redness, swelling, inflammation, itchiness, blisters, ulceration, and secondary skin infections. Stop treatment or reduce dose frequency.
- **Non-melanoma skin cancer:** Monitor patients during and after treatment.
- **Embryo-fetal toxicity:** Women should avoid becoming pregnant or nursing while using VALCHLOR due to the potential hazard to the fetus.
- **Flammable gel:** VALCHLOR is an alcohol-based gel. Avoid fire, flame, and smoking until the gel has dried.

ADVERSE REACTIONS

The most common adverse reactions (≥ 5%) are dermatitis, pruritus, bacterial skin infection, skin ulceration or blistering, and hyperpigmentation. These reactions may be mild to severe. Elderly patients may be more susceptible. Depending on severity, dosing changes or discontinuation may be required.

To report SUSPECTED ADVERSE REACTIONS, contact Actelion Pharmaceuticals US, Inc., at 1-855-4-VALCHLOR (1-855-482-5245) or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Please see Brief Summary of Prescribing Information on adjacent page.

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BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

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

- **INDICATIONS AND USAGE**

  VALCHLOR is an alkylating drug indicated for the topical treatment of Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy.

- **CONTRAINDICATIONS**

  The use of VALCHLOR is contraindicated in patients with known severe hypersensitivity to mechlorethamine. Hypersensitivity reactions, including anaphylaxis, have occurred with topical formulations of mechlorethamine.

- **WARNINGS AND PRECAUTIONS**

  >> Mucosal or Eye Injury

  Exposure of the eyes to mechlorethamine causes pain, burns, inflammation, photophobia, and blurred vision. Blindness and severe irreversible anterior eye injury may occur. Advise patients that if eye exposure occurs, (1) immediately irrigate for at least 15 minutes with copious amounts of water, normal saline, or a balanced salt ophthalmic irrigating solution and (2) obtain immediate medical care (including ophthalmologic consultation).

  Exposure of mucous membranes such as the oral mucosa or nasal mucosa causes pain, redness, and ulceration, which may be severe. Should mucosal contact occur, immediately irrigate for at least 15 minutes with copious amounts of water, followed by immediate medical consultation.

  >> Secondary Exposure to VALCHLOR

  Avoid direct skin contact with VALCHLOR in individuals other than the patient. Risks of secondary exposure include dermatitis, mucosal injury, and secondary cancers. Follow recommended application instructions to prevent secondary exposure.

  >> Dermatitis

  The most common adverse reaction was dermatitis, which occurred in 56% of the patients. Dermatitis was moderately severe or severe in 23% of patients. Monitor patients for redness, swelling, inflammation, itchiness, blisters, ulceration, and secondary skin infections. The face, genitalia, anus, and intertriginous skin are at increased risk of dermatitis. Follow dose modification instructions for dermatitis.

  >> Non-Melanoma Skin Cancer

  Four percent (4%, 11/255) of patients developed a non-melanoma skin cancer during the clinical trial or during one year of post-treatment follow-up: 2% (3/128) of patients receiving VALCHLOR and 6% (8/127) of patients receiving the mechlorethamine ointment comparator. Some of these non-melanoma skin cancers occurred in patients who had received prior therapies known to cause non-melanoma skin cancer. Monitor patients for non-melanoma skin cancers during and after treatment with VALCHLOR. Non-melanoma skin cancer may occur on any area of the skin, including untreated areas.

  >> Embryo-fetal Toxicity

  Based on its mechanism of action, case reports in humans, and findings in animals, VALCHLOR can cause fetal harm when administered to a pregnant woman. There are case reports of children born with malformations in pregnant women systemically administered mechlorethamine. Mechlorethamine was teratogenic and embryo-lethal after a single subcutaneous administration to animals. Advise women to avoid becoming pregnant while using VALCHLOR. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

  >> Flammable Gel

  Alcohol-based products, including VALCHLOR, are flammable. Follow recommended application instructions.

- **ADVERSE REACTIONS**

  In a randomized, observer-blinded, controlled trial, VALCHLOR 0.016% (equivalent to 0.02% mechlorethamine HCl) was compared to an Aquaphor®-based mechlorethamine HCl 0.02% ointment (Comparator). The maximum duration of treatment was 12 months. Sixty-three percent (63%) of patients in the VALCHLOR arm and 67% in the comparator arm completed 12 months of treatment.

  The body system associated with the most frequent adverse reactions was skin and subcutaneous tissue disorders. The most common adverse reactions (occurring in at least 5% of the patients) are shown in Table 1.

Table 1. Most Commonly Reported (≥5%) Cutaneous Adverse Reactions

	VALCHLOR N=128 % of patients		Comparator N=127 % of patients	
	Any Grade	Moderately-Severe or Severe	Any Grade	Moderately-Severe or Severe
Dermatitis	56	23	58	17
Pruritus	20	4	16	2
Bacterial skin infection	11	2	9	2
Skin ulceration or blistering	6	3	5	2
Skin hyperpigmentation	5	0	7	0

In the clinical trial, moderately-severe to severe skin-related adverse events were managed with treatment reduction, suspension, or discontinuation. Discontinuations due to adverse reactions occurred in 22% of patients treated with VALCHLOR and 18% of patients treated with the comparator. Sixty-seven percent (67%) of the discontinuations for adverse reactions occurred within the first 90 days of treatment. Temporary treatment suspension occurred in 34% of patients treated with VALCHLOR and 20% of patients treated with the comparator. Reductions in dosing frequency occurred in 23% of patients treated with VALCHLOR and 12% of patients treated with the comparator.

Reductions in hemoglobin, neutrophil count, or platelet count occurred in 13% of patients treated with VALCHLOR and 17% treated with Comparator.

- **DRUG INTERACTIONS**

  No drug interaction studies have been performed with VALCHLOR. Systemic exposure has not been observed with topical administration of VALCHLOR; therefore, systemic drug interactions are not likely.

- **USE IN SPECIFIC POPULATIONS**

  >> Pregnancy

  Pregnancy Category D

  Risk Summary

  Mechlorethamine can cause fetal harm when administered to a pregnant woman. There are case reports of children born with malformations to pregnant women systemically administered mechlorethamine. Mechlorethamine was teratogenic in animals after a single subcutaneous administration. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

  Animal Data

  Mechlorethamine caused fetal malformations in the rat and ferret when given as single subcutaneous injections of 1 mg/kg. Other findings in animals included embryolethality and growth retardation when administered as a single subcutaneous injection.

  >> Nursing Mothers

  It is not known if mechlorethamine is excreted in human milk. Due to the potential for topical or systemic exposure to VALCHLOR through exposure to the mother's skin, a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the mother.

  >> Pediatric Use

  Safety and effectiveness in pediatric patients have not been established.

  >> Geriatric Use

  A total of 79 patients age 65 and older (31% of the clinical trial population) were treated with either VALCHLOR or the comparator in the clinical trial. Forty-four percent (44%) of patients age 65 or older treated with VALCHLOR achieved a Composite Assessment of Index Lesion Severity (CAILS) response compared to 66% of patients below the age of 65. Seventy percent (70%) of patients age 65 and older experienced cutaneous adverse reactions and 38% discontinued treatment due to adverse reactions, compared to 58% and 14% in patients below the age of 65, respectively. Similar differences in discontinuation rates between age subgroups were observed in the comparator group.

Manufactured for:
Actelion Pharmaceuticals US, Inc.
South San Francisco, CA 94080, USA

ACTELION

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VENOUS DISEASE:

Successful treatment may require referral for vascular studies from page 1

but only for patients who have no underlying saphenous vein insufficiency (failure of valves within the vein that allows retrograde blood flow away from the heart). Correct technique includes treating feeding reticular veins before spider veins, he says. Agents approved by the Food and Drug Administration for this indication include sodium tetradecyl sulfate and polidocanol.

"Both are very effective and can be used as foams, which offer additional advantages for treating larger vessels," although the foam technique is an off-label use, Dr. Cartee says.

Because foamed sclerosants do not mix with blood, they push blood out of the way, increasing the time that the sclerosant is in contact with the endothelium, according to Dr. Cartee. This effectively doubles their sclerosing power compared to the liquid form; however, he says, foam may be too potent for fine telangiectasias, causing transparietal burns, extravasation of blood, and untoward side effects.

88 PERCENT
Closure rate after treatment with Varithena

Foam sclerotherapy, while in general very safe, has been associated with rare adverse neurologic events. A recent comprehensive review showed that foam sclerotherapy can produce temporary visual disturbances in 0.9 to two percent of patients (Willenberg T, Smith PC, Shepherd A, Davies AH. *Phlebology*. 2013;28(3):123-131). Experts previously blamed gas emboli for this side effect, Dr. Cartee says, but this review noted an additional, more satisfying explanation: systemic spread of locally induced vasoactive mediators, especially endothelin, which can trigger a migraine with aura in susceptible patients. No patients in the review experienced any lasting visual or neurologic effects.

SAPHENOUS VEIN INSUFFICIENCY

For patients with underlying saphenous vein insufficiency, he says, dermatologists can refer them to a phlebologist or, with proper training, treat this problem themselves. Dr. Cartee performs endovenous laser ablation, which seals up faulty veins from the inside and forces the body to reroute blood to healthy veins.

In this regard, he says that various lasers operating between 810 and 1,470 nm all have proven effective.

"Emerging evidence suggests that the water-selective lasers with wavelengths of 1,320 to 1,470 nm may produce less postoperative pain and quicker recovery," Dr. Cartee says.

Other effective techniques include radiofrequency ablation and ultrasound guided foam sclerotherapy.

"Recently, a foam sclerotherapy product became the first such agent to garner approval by the Food and Drug Administration. Varithena (injectable polidocanol foam, BTG) is now approved for the treatment of great saphenous incompetence and associated varicose veins," he says.

In phase 3 clinical trials, Varithena produced an ultrasound-confirmed closure rate of 88 percent, and a 64 percent reduction in symptoms (Todd KL 3rd, Wright D; for the VANISH-2 Investigator Group. *Phlebology*. 2013 Jul 17. [Epub ahead of print]).

"Presently, we have no data on long-term outcomes. But it appears to be effective in early results," Dr. Cartee says. "It offers the advantages of lower cost and near-painless administration, potentially without even using full sterile technique. This could make it faster and more user-friendly than the endovenous technologies currently used."

QUICK READ

Successfully treating venous disease requires knowing whom to refer for vascular studies, using proper sclerosing technique and choosing the right compression stocking strategy, an expert says.

Overall, Dr. Cartee says he looks forward to the arrival of new technologies, "But the techniques we have now are wonderful." They have supplanted surgical vein stripping, he says, largely because they are one-hour ambulatory procedures that are easier on patients.

> "Emerging evidence suggests that the water-selective lasers with wavelengths of 1,320 to 1,470 nm may produce less postoperative pain and quicker recovery."
>
> **Todd V. Cartee, M.D.**
> Hershey, Pa.

In all patients with symptomatic venous insufficiency, Dr. Cartee says, "We recommend graduated compression stockings." Donning two pairs of light (15 mm HG to 20 mm Hg) compression stockings doubles the compression, he notes, which can be a useful trick to achieve therapeutic compression levels (30 mm Hg to 40 mm Hg) in elderly patients.

Dr. Cartee says, however, that patients should avoid thromboembolic deterrent (TED) stockings, which they may have on hand from a prior surgery. These stockings are designed to prevent embolisms — in patients on operating tables and hospital beds. "In ambulatory patients, they can make vein disease worse. It's one of the most common mistakes I see from primary care physicians." **DT**

Disclosures: Dr. Cartee reports no relevant financial interests.

Researchers eye possible PAP link to bimatoprost

John Jesitus | Senior Staff Correspondent

LAS VEGAS — The first study attempting to quantify the impact of eyelid application of Latisse (bimatoprost 0.03 percent, Allergan) on periorbital fat is under way, its lead investigator said at the Cosmetic Surgery Forum, held here.

"Prostaglandin-associated periorbitopathy (PAP) is a hot topic in ophthalmology research right now," says Anupam Jayaram, M.D., a third-year resident in the department of ophthalmology at Northwestern University Feinberg School of Medicine, Chicago.

With Lumigan (bimatoprost 0.01 percent, Allergan) being a first-line treatment for open-angle glaucoma, "It's been well-documented that administering this eye drop into the eye causes an effect called PAP, basically an appearance of a sunken-in orbit (Filippopoulos T, Paula JS, Torun N, et al. *Ophthal Plast Reconstr Surg.* 2008;24(4):302-307)."

> "The effects of bimatoprost upon the eyelid reverse themselves rather quickly upon discontinuation of the drug."
>
> **Anupam Jayaram, M.D.**
> Chicago

CREATING NEW PROBLEMS?

The genesis for the current study came from the question of whether administering bimatoprost to the eyelid would produce the same effect, Dr. Jayaram says.

"There are currently no studies in the literature that examine what would happen with the administration of this drug onto the skin; namely, the eyelid surface," she says.

QUICK READ

An ongoing study will quantify the first time the impact on periorbital fat when patients apply Latisse to the eyelids, says its lead investigator.

Aesthetically, she says, "One thing that's been noted is that the administration of bimatoprost topically to the ocular surface for glaucoma causes an involution of dermatochalasis, a condition usually solved by surgical blepharoplasty. Some patients are reporting that their current dermatochalasis is resolving with the administration of this drug. It is perhaps something that could be looked into further. But typically, changes noted from the administration of bimatoprost are not cosmetically favorable."

While patients may experience a decrease in the amount of redundant eyelid skin, "Patients tend to describe the changes as the appearance of tired or sunken-in eyes. Though the product may be solving one problem, it is perhaps creating other problems," Dr. Jayaram says.

Although Dr. Jayaram declined to release specific study details, she says the protocol includes patients who have been using or recently began using Latisse for eyelash growth.

"Patients may not necessarily be coming back with complaints about their eyes," she says. Rather, to track any impacts of bimatoprost in a standardized, prospective fashion, investigators are using serial measurements of eyelid position, as well as photographs, exophthalmometry and subjective reporting of changes.

PATIENT COMPLIANCE

Along with measuring the degree of any periorbital changes, researchers hope to glean information about the time of onset of such changes, according to Dr. Jayaram. In 2011, the Food and Drug Administration required Allergan to add a warning regarding deepening of the eyelid sulcus to Lumigan's label. Latisse, however, currently carries no such warning.

Challenges that researchers face in such studies include patient compliance. In this regard, "Study instructions, as well as medication instructions, recommend once-nightly application of the product to the upper eyelid only," Dr. Jayaram says. Although patients receive regular reminders about these instructions, "It's still impossible to know exactly what they're doing at home with the drug — for example, how much of it is actually getting to the skin, versus the eyeball. These factors are difficult to control for but would be important to note for the study" if possible, she says.

> "The administration of bimatoprost topically to the ocular surface for glaucoma causes an involution of dermatochalasis."
>
> **Anupam Jayaram, M.D.**
> Chicago

As for a study completion date, Dr. Jayaram has not yet set one because she wants to accrue as many patients as possible to maximize the quantitative value of the study's results. But already, she has begun setting up additional study arms for the future.

Specifically, she said that based on current glaucoma case reports, "The effects of bimatoprost upon the eyelid reverse themselves rather quickly upon discontinuation of the drug. Some case reports have suggested resolution of effects within six week after discontinuation of Lumigan. We will be investigating whether reversal of effects after discontinuation of Latisse is similar." **DT**

Disclosures: Dr. Jayaram reported no relevant financial interests.

A CLASS 1, SUPER-POTENT SPRAY

For plaque psoriasis

Topicort®
(desoximetasone)
Topical Spray 0.25%

0.25%
SPRAY

Important Safety Information

- Topicort® Topical Spray is a topical corticosteroid indicated for the treatment of plaque psoriasis in patients 18 years of age or older.
- Topicort® Topical Spray is a topical corticosteroid that has been shown to suppress the hypothalamic-pituitary-adrenal (HPA) axis.
- Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of the topical corticosteroid.
- Because of the potential for systemic absorption, use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression.
- Local adverse reactions may be more likely to occur with occlusive use, prolonged use or use of higher potency corticosteroids. Reactions may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. Some local reactions may be irreversible.
- Safety and effectiveness of Topicort® Topical Spray in patients younger than 18 years of age have not been studied; therefore use in pediatric patients is not recommended.

TaroPharma®

See brief summary of Prescribing Information on reverse side.

AD100-0033 July 2013

TOPICORT® (desoximetasone) Topical Spray, 0.25%
Rx Only

BRIEF SUMMARY

1 INDICATIONS AND USAGE
Topicort® Topical Spray is a corticosteroid indicated for the treatment of plaque psoriasis in patients 18 years of age or older.

4 CONTRAINDICATIONS
None

5 WARNINGS AND PRECAUTIONS

5.1 Effect on Endocrine System
Topicort® Topical Spray is a topical corticosteroid that has been shown to suppress the hypothalamic-pituitary-adrenal (HPA) axis.

Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of the topical corticosteroid.

In a study including 21 evaluable subjects 18 years of age or older with moderate to severe plaque psoriasis, adrenal suppression was identified in 1 out of 12 subjects having involvement of 10-15% of body surface area (BSA) and 2 out of 9 subjects having involvement of >15% of BSA after treatment with Topicort® Topical Spray twice a day for 28 days. [*see Clinical Pharmacology (12.2)*]

Because of the potential for systemic absorption, use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the use of high potency steroids, larger treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure and young age.

An ACTH stimulation test may be helpful in evaluating patients for HPA axis suppression.

If HPA axis suppression is documented, an attempt should be made to gradually withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Manifestations of adrenal insufficiency may require supplemental systemic corticosteroids. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids.

Cushing's syndrome, hyperglycemia, and unmasking of latent diabetes mellitus can also result from systemic absorption of topical corticosteroids.
Use of more than one corticosteroid-containing product at the same time may increase the total systemic corticosteroid exposure.
Pediatric patients may be more susceptible to systemic toxicity from use of topical corticosteroids. [*see Use in Specific Populations (8.4)*]

5.2 Local Adverse Reactions with Topical Corticosteroids
Local adverse reactions may be more likely to occur with occlusive use, prolonged use or use of higher potency corticosteroids. Reactions may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. Some local adverse reactions may be irreversible.

5.3 Allergic Contact Dermatitis with Topical Corticosteroids
Allergic contact dermatitis to any component of topical corticosteroids is usually diagnosed by a failure to heal rather than a clinical exacerbation. Clinical diagnosis of allergic contact dermatitis can be confirmed by patch testing.

5.4 Concomitant Skin Infections
Concomitant skin infections should be treated with an appropriate antimicrobial agent.
If the infection persists, Topicort® Topical Spray should be discontinued until the infection has been adequately treated.

5.5 Flammable Contents
Topicort® Topical Spray is flammable; keep away from heat or flame.

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 practice.

In randomized, multicenter, prospective vehicle-controlled clinical trials, subjects with moderate to severe plaque psoriasis of the body applied Topicort® Topical Spray or vehicle spray twice daily for 4 weeks. A total of 149 subjects applied Topicort® Topical Spray.

Adverse reactions that occurred in ≥ 1% of subjects treated with Topicort® Topical Spray were application site dryness (2.7%), application site irritation (2.7%) and application site pruritus (2.0%).

Another less common adverse reaction (<1% but >0.1%) was folliculitis.

Table 1. Number (%) of Subjects with Adverse Reactions Occurring in ≥ 1%

	Topicort® Topical Spray, 0.25% b.i.d. (N = 149)	Vehicle spray b.i.d. (N = 135)
Number of Subjects with Adverse Reactions	13 (8.7%)	18 (13.3%)
Application site dryness	4 (2.7%)	7 (5.2%)
Application site irritation	4 (2.7%)	5 (3.7%)
Application site pruritus	3 (2.0%)	5 (3.7%)

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Teratogenic Effects: Pregnancy Category C
There are no adequate and well-controlled studies in pregnant women. Topicort® Topical Spray should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels.

Desoximetasone has been shown to be teratogenic and embryotoxic in mice, rats, and rabbits when given by subcutaneous or dermal routes of administration at doses 3 to 30 times the human dose of Topicort® Topical Spray based on a body surface area comparison.

8.3 Nursing Mothers
Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Because many drugs are excreted in human milk, caution should be exercised when Topicort® Topical Spray is administered to a nursing woman.

If used during lactation, Topicort® Topical Spray should not be applied on the chest to avoid accidental ingestion by the infant.

8.4 Pediatric Use
Safety and effectiveness of Topicort® Topical Spray in patients younger than 18 years of age have not been studied; therefore use in pediatric patients is not recommended. Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore at greater risk of adrenal insufficiency during and/or after withdrawal of treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children. [*see Warnings and Precautions (5.1)*]
HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. [*see Warnings and Precautions (5.1)*]

8.5 Geriatric Use
Clinical studies of Topicort® Topical Spray did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

10 OVERDOSAGE
Topicort® Topical Spray can be absorbed in sufficient amounts to produce systemic effects. [*see Warnings and Precautions (5.1)*]

17 PATIENT COUNSELING INFORMATION
See FDA-approved patient labeling (Patient Information and Instructions for Use)

Inform patients of the following:
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AD100-0030

Epinephrine may prolong neuromodulator results

John Jesitus | Senior Staff Correspondent

LAS VEGAS — Mixing neuromodulators with epinephrine may give patients the longer-lasting results they seek, according to an expert at Cosmetic Surgery Forum, held here. This combination, however, may not prove beneficial for everyone.


Dr. Rubin

The efficacy and prices patients pay for the three neuromodulators approved by the Food and Drug Administration are roughly equivalent, says Mark G. Rubin, M.D., a dermatologist in private practice in Beverly Hills, Calif. As such, he says, durability of results could provide a trump card.

"Anybody who comes out with a longer-lasting neuromodulator will take over the market, because that's what our patients complain about." Although filler results last six to eight months and sometimes longer, he says, "Patients have to come back every three months or so for their neuromodulators, so they start to get frustrated with that."

The concept of adding epinephrine to neuromodulators to achieve better and longer-lasting results first appeared in 2007 (Hantash BM, Gladstone HB. *Dermatol Surg.* 2007;33(4):461-468). "It's easy to do, and there's actually some very good science behind it."

NEUROMODULATORS WITH EPINEPHRINE

Very few dermatologists and dermatology residents, however, are aware of the publication, according to Dr. Rubin. In this study, investigators injected the periorbital rhytids on one side of 14 patients' faces with onabotulinumtoxinA (12 units, single injection site). They injected the other side with 12 units of onabotulinumtoxinA plus epinephrine (one part per 100,000). At all follow-up points through 90 days, the neuromodulator/epinephrine side showed better efficacy.

After the publication appeared, "I remember we started doing this for a while. And it worked. Then Dysport (abobotulinumtoxinA, Medicis) came out," Dr. Rubin says.

QUICK READ

A new study shows that adding epinephrine to neuromodulator injections may prolong results. However, an expert says, not all patients do well with the combination.

At the time, Dr. Rubin used epinephrine only in patients who did not respond normally to neuromodulators.

"I tell patients, if your results are lasting around three months, that's pretty much what you should be getting. If they last six weeks, something's wrong." Such patients generally did much better with the addition of epinephrine, he says.

"But when Dysport came out, we tried switching them to Dysport, and many of those patients responded. Now when I see patients who don't respond to Dysport or Botox (onabotulinumtoxinA, Allergan), I try Xeomin (incobotulinumtoxinA, Merz) as well. So I forgot about the adrenaline approach" until seeing two recent publications, Dr. Rubin says.

58 PERCENT
Of patients rated combination of onabotulinumtoxinA with lidocaine and epinephrine as superior

In the 2007 trial investigators injected only one site, which is uncommon in critical practice, Dr. Rubin says. However, a new 40-patient study involving crows' feet found that injecting one site (36 units abobotulinumtoxinA) per side of the face yields no statistical difference in results versus injecting three sites per side (12 units each) through 120 days of follow-up (Fabi SG, Sundaram H, Guiha I, Goldman MP. *J Drugs Dermatol.* 2013;12(8):932-937).

ADDING LIDOCAINE TO THE MIX

In another study, investigators gave injections of onabotulinumtoxin mixed with lidocaine and epinephrine to 181 patients who previously had been treated with onabotulinumtoxinA diluted with saline. Treatment sites included the glabella, the perioral and the periorbital areas.

"Wherever patients were being treated before, they were treated again, the only difference being the addition of lidocaine and epinephrine," Dr. Rubin says. Three months post-treatment, 58 percent of patients rated the combination treatment as superior (Kim A, Jung J, Pak A. *Cutis.* 2013;Suppl:13-18).

"It's always challenging when you retrospectively ask patients, 'How did you do with this last treatment?' There's a tendency for patients to like the last thing they had," he says. However, the study's large population at least suggests a trend toward better results with the combination.

"Intriguingly, 86 percent of patients thought the combination was better because they experienced immediate improvement due to the lidocaine, and the muscle paralysis associated with it," Dr. Rubin says. "Only 50.5 percent thought it lasted longer."

Future research should help to clarify what patients think of the treatment, according to Dr. Rubin.

POSITIVE VALUE

Based on current evidence, he says, the combination of neuromodulators and epinephrine appears to provide positive value.

"So why aren't we all doing this? One reason is that it's one more thing to do — we're juggling three neuromodulators, and how do you keep them separated?" he says. "Our office uses color-coded syringes."

Additionally, "Some patients don't do well with epinephrine — they develop palpitations and anxiety after injection."

Patients with ruddy complexions often develop significant vasoconstriction at treatment sites, resulting in the appearance of temporary white blotches, Dr. Rubin says. Additionally, the combination injection stings a little more than a traditional neuromodulator injection.

"In our experience, it worked really well in some patients and modestly well in others," he says. "It's easy to mix — just take 0.1 cc of 1:1000 epinephrine solution, inject it into 10 cc of saline and use that as your reconstituting solution." **DT**

Disclosures: Dr. Rubin is a consultant for Allergan and Merz and has performed clinical research for Medicis.

Comprehensive aesthetic consult boosts opportunity for positive outcomes

Ilya Petrou, M.D. | Senior Staff Correspondent

MAUI, HAWAII — Several factors play intertwining roles in achieving a successful aesthetic consult. Actively engaging and connecting with the patient and finding out the patient's real reasons for wanting to look more youthful are essential for improved aesthetic outcomes, according to an expert.

"The main focus in all of my aesthetic consults is to carefully seek out the real reason why the patient wants to look more youthful, not the stated reason," says Kent B. Remington, M.D., Remington Laser Dermatology Centre, Calgary, Alberta. He spoke at MauiDerm 2014. "In my experience, the stated reason usually has nothing to do with the real reason for aesthetic improvement and many patients will do almost anything to achieve that aesthetic goal."

Discovering a patient's real reasons for aesthetic improvement are almost always associated with an emotional moment in the clinical consult, Dr. Remington says. This could include personal reasons, such as the desire to remain an object of interest for a younger-looking partner, or to keep a youthful and vibrant appearance in a competitive job market.

"There are an increasing number of women who hold higher positions in the job market, such as CEOs and lawyers, and they know intuitively that the job market is a youthful arena," Dr. Remington says. "During their careers, some may have been bypassed for promotions or possibly have been as an older person. As a consequence of this, they want to look much younger because they know that they are in a very competitive youthful work environment, and seek to have that 'edge' over their competitors."

QUICK READ

Shifting from monotherapy toward performing full-face rejuvenation following a multi-therapeutic approach are essential in achieving excellent aesthetic outcomes.

POINT OUT POSITIVE FEATURES

Once the real reason for the patient's rejuvenation desires is established, Dr. Remington says he will refocus and identify the patient's most positive physical characteristics and attributes, and then try to support, build upon and enhance them.

> "The main focus in all of my aesthetic consults is to carefully seek out the real reason why the patient wants to look more youthful, not the stated reason."
>
> **Kent B. Remington, M.D.**
> Calgary, Alberta

With the help of a mirror, he will carefully ask the patient to point out what they think are their most positive features about their face and then with the permission of the patient, Dr. Remington will then point out to them where he sees possible aesthetic enhancements and improvements could be achieved, naturally all within the limits of realistic expectations.

"Very often, both the patient's and my own views and perspectives on what can be improved upon can be married together," he says. "There is always some middle ground that we can agree upon and this is the first step towards achieving good aesthetic outcomes."

Many patients will focus on a singular wrinkle or spot, Dr. Remington says, and falsely believe that addressing that particular cosmetic feature and/or performing a monotherapy on the aging face will result in a successful rejuvenation therapy to the face as a whole. According to Dr. Remington, it is absolutely paramount that the whole face of the patient be addressed when performing rejuvenation procedures in order to achieve a successful full-face rejuvenation outcome.

"All aesthetic physicians worldwide are plagued by patients who have a selective focus. One of my central goals during the aesthetic consult is to change the patient's selective focus on monotherapy and from one area of the face to a full-face restoration project with the correct recipe for that individual patient," he says.

SYMMETRY AND BALANCE

Beauty is often judged and evaluated on the basis of symmetry, balance and harmony. According to Dr. Remington, many patients will evaluate a certain face as "beautiful" because they view the face as a whole and do not concentrate on a specific characteristic of that face.

Along these lines, Dr. Remington performs rejuvenation procedures in

CONSULT see page **62**

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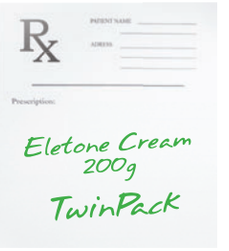

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CONSULT:

Establish why patients want rejuvenation procedures from page 60

his patients, which are typically multiple and include a mosaic of different fillers, neurotoxins and laser therapies. This allows him to comprehensively address the different aspects of the aging face, such as asymmetries, sagging skin, brow ptosis, dyschromias and general deflation of the facial skin and tissues.

Before any rejuvenation procedure is performed, all of Dr. Remington's patients will also have at least 10 photographs taken in his dedicated camera room. During the aesthetic consult, the photos are taken as the patient looks relaxed, animated, smiling, and smiling spontaneously. The photographs will not only take the focus off a particular line or wrinkle a patient sees, Dr. Remington says, but it also will help to point out the positive characteristics of the patient's face, and stress what can be done to support and enhance those good features. These concepts and issues are easy to show in the camera room's high-resolution monitor rather than just a mirror.

> "There is always some middle ground that we can agree upon and this is the first step towards achieving good aesthetic outcomes."
>
> **Kent B. Remington, M.D.**
> Calgary, Alberta

The aging face should not be treated all at once, Dr. Remington says, but instead it should be restored similar to an antique painting — in a piecemeal, progressive and caring fashion. Different approaches should be employed in multiple sessions over time that ultimately will result in a natural-looking, youthful patient.

"The big key is to give time to your aesthetic patients. You need to connect and engage with your patient, which will instill trust," Dr. Remington says. "Once you connect with them and understand what their genetics are, where they came from, what their job is and what they do, and what their real reasons are for desiring rejuvenation treatment, you can better address their concerns and achieve excellent aesthetic outcomes." **DT**

Disclosures: Dr. Remington reports no relevant financial interests.

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66 TREATMENT ADVANCES
Vismodegib useful for basal cell carcinoma where surgery is suboptimal approach

Fungal infections may mimic malignancies

Louise Gagnon | Staff Correspondent

QUEBEC CITY, QUEBEC — Common diseases can present in unusual ways, so treatment-resistant fungal infections on the skin should be biopsied, as these infections can mimic or coexist with malignancies, according to research presented at the annual meeting of the Canadian Dermatology Association.

Discussing three cases of skin cancers mimicking fungal infections, Afsaneh Alavi, M.D., F.R.C.P.C., a dermatologist at Women's College Hospital, Toronto and lecturer in the division of dermatology in the faculty of medicine, University of Toronto, stressed the need to avoid diagnosis delays.

"It is important to do a proper skin biopsy," Dr. Alavi says. "Early diagnosis of these conditions (cancers) can prevent future problems and the need for aggressive treatment of advanced disease. The detection of serious dermatological issues such as malignancies significantly affects patient's quality of life and the burden on healthcare system."

In selected cases, clinical criteria alone may not be sufficient to make a diagnosis of a fungal infection.

"A busy practice and cosmetic concerns regarding a scar may be a barrier to (performing) biopsies," says Dr. Alavi, who stresses that sometimes multiple biopsies are necessary.

"To detect a malignancy in a chronic ulcer, performing multiple and sometimes frequent biopsies from different clinical components of the skin eruption obviate a cancer," he says. "A negative biopsy for the cancer in a highly suspicious lesion does not rule out the cancer, for there could be a sampling error.

"Close observation of the patient is helpful," he says. "If it is an ulcer, you need to biopsy from the border and the center of ulcer, to make sure you cover all clinical components of the skin rash. In addition, appropriate biopsy technique avoids diagnostic uncertainties."

QUICK READ

Primary or metastatic malignancies can infiltrate the skin and can mimic cutaneous fungal infections, which highlights the significance of skin biopsies in arriving at accurate diagnoses.

PERFORMING BIOPSIES

Dr. Alavi recommends performing a punch biopsy to increase the accuracy of the diagnosis in most cases. If, however, the changes are in the deep dermis or subcutaneous fat, an incisional biopsy may be preferred. Ultimately, clinicians should have a high degree of suspicion and consider other possible diagnoses when a skin eruption appears as a fungus and does not respond to appropriate therapy, Dr. Alavi says.

In one case of cancer mimicking fungal infections, a woman with multiple annular skin eruptions over both breasts with discrete borders did not respond to topical antifungal therapy. She had a history of lung cancer that was believed to be in remission. A punch biopsy of the right breast showed cells compatible with metastatic lung carcinoma. The patient was then sent to an oncology center for treatment and was given a prognosis of limited survival, Dr. Alavi says.

Quotable

"Vismodegib has proven to be extremely useful in the treatment of metastatic BCC and locally advanced BCC."

George W. Monks, M.D.
Tulsa, Okla.

On therapies for basal cell carcinoma
See story, page 66

DTExtra

Educational how-to videos may prompt older men to monitor their skin either through self-examinations or clinical skin exams, thereby increasing earlier skin cancer diagnoses, according to the results of two new studies. In each study, one group received a video-based intervention with written materials while another received written-only material. Both groups saw increases in skin exam behaviors. "Our results support implementing behavioral interventions to encourage skin awareness among men aged at least 50 years," study authors wrote.

READ MORE: DERMATOLOGYTIMES.COM/SKINEXAMS

There may be other clues that suggest a lesion is not a neurotropic foot ulcer such as the fact that it is not located in a weight-bearing area, explains Dr. Alavi, referring to a case of an elderly diabetic patient who presented with a right foot ulcer in the fourth and fifth interdigital space that was complicated by a secondary bacterial infection and a coexisting fungal infection (tinea unguium).

"The ulcer location was not typical for the neurotropic diabetic foot ulcer and a local ulcer is not a common presentation for a fungal infection," Dr. Alavi says.

> "If it is an ulcer, you need to biopsy from the border and the center of ulcer, to make sure you cover all clinical components of the skin rash."
>
> **Afsaneh Alavi, M.D., F.R.C.P.C.**
> Toronto

Despite local, topical antifungal treatment and systemic antibiotic treatment for presumed secondary bacterial infection leading to the skin breakdown, the ulcer persisted, notes Dr. Alavi. A skin biopsy was then performed and revealed a squamous cell carcinoma. The patient was treated surgically, and there was full remission.

In the third case, a male patient presented with persistent asymptomatic erythematous patches in the axilla and groin that did not respond to several courses of topical antifungal medicine. A skin biopsy revealed cutaneous T-cell lymphoma, the mycosis fungoides type.

"As the population ages, the rate of cancers primarily involving or invading the skin is increasing overall, so we should be aware of this in our dermatological practices," she says.

Dr. Alavi notes several recent reviews in the literature have reported unsuspected malignant cancers presenting in 5 to 15 percent of leg ulcers. The most common malignancy is basal cell carcinoma and the second most common is squamous cell carcinoma, according to Dr. Alavi.[1-2] **DT**

References:
1. Tang JC, Vivas A, Rey A, et al. *Ostomy Wound Manage*. 2012;58(6):20-29
2. Senet P, Combemale P, Debure C, et al. Arch Dermatol. 2012;148(6):704-708
Disclosures: Dr. Alavi reports no relevant financial interests.

Vismodegib 'life-changing' for BCC patient populations

Ilya Petrou, M.D. | Senior Staff Correspondent

ORLANDO, FLA. — Vismodegib (Erivedge, Genentech) continues to demonstrate efficacy in treating patients with metastatic basal cell carcinoma (BCC) and locally advanced basal cell carcinoma (laBCC).


Dr. Monks

According to one dermatologist, the drug offers an excellent treatment alternative for this patient population that — until recently — had to undergo multiple surgeries and/or radiation therapy to control the progression of their sometimes-debilitating disease.

> "I would put vismodegib in the same life-changing category as the biologics for psoriasis and isotretinoin for acne."
>
> **George W. Monks, M.D.**
> Tulsa, Okla.

"Ever since receiving FDA (Food and Drug Administration) approval about two years ago, vismodegib has proven to be extremely useful in the treatment of metastatic BCC and locally advanced BCC. Prior to this drug, a lot of these patients would have needed major surgery resulting in significant morbidity, loss of function and possibly cranial nerve damage. In my opinion, vismodegib is a very welcome treatment option, and can be a life-changing drug for this patient population," said George W. Monks, M.D., Tulsa Dermatology Clinic, Tulsa, Okla., who discussed the drug at the Orlando Dermatology Aesthetic and Clinical Conference.

QUICK READ

Vismodegib is proving an effective treatment option for patients with metastatic and locally advanced basal cell carcinoma, and can be particularly useful for those patients in whom surgery and/or radiation therapy are considered suboptimal approaches.

HOW IT WORKS

Vismodegib is the first FDA-approved oral treatment for advanced BCC, Dr. Monks says, and it is also the first FDA-approved hedgehog pathway inhibitor. Patched (PTCH) is a membrane protein that blocks the translocation of smoothened (SMO), another membrane protein, to the cell surface. This translocation of SMO to the cell surface is required for intracellular signal transduction. In the presence of hedgehog ligand, PTCH inhibition of SMO is removed, and SMO is able to move to the cell membrane, resulting in intracellular signal transduction and expression of target genes.

Dysregulation of the hedgehog pathway — either through activation mutations in SMO or inactivating mutations in PTCH — can result in uncontrolled proliferation and tumorigenesis. Regardless of the exact mutation, the SMO receptor is activated, which is responsible for hedgehog pathway-mediated downstream BCC proliferation and survival signaling.

Metastatic BCC is extremely rare, Dr. Monks says, with rates ranging from 0.0028 to 0.55 percent of all BCCs. Advanced BCCs can be invasive and found in difficult-to-treat areas, such as next to cartilage or bone, or they can be recurrent. According to Dr. Monks, only a small subset of BCC patients can be classified as advanced.

> "Vismodegib can be a life-changing drug for this patient population."
>
> **George W. Monks, M.D.**
> Tulsa, Okla.

"The term 'locally advanced' has long been used in oncology in their staging system for cancer but is a fairly new term in our dermatology lexicon," he says. "The term really was introduced to our specialty when vismodegib was approved for the treatment of metastatic and laBCC. Many in our specialty are still unclear on what the true definition of a locally advanced basal cell carcinoma is."

ERIVANCE TRIAL

In the pivotal phase 2 ERIVANCE trial that led to the FDA approval of vismodegib, the definition of laBCC used the "S.E.L.E.C.T." acronym:

Size: ≥ 10 mm in diameter;

Extent: locally invasive BCC extending into underlying tissue, cartilage, bone, or nerve;

Location: surgery or radiation would result in significant disfigurement or loss of function;

VISMODEGIB see page 69


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REFERENCES: 1. Blecker, J. Double-blind comparison between two new topical steroids, halcinonide 0.1% and clobetasol propionate cream 0.05%. Curr Med Res Opin. 1975;3:225-228. 2. Bagatell FK. Halcinonide: a new potent anti-inflammatory drug. Cutis. 1974:14:459-462. 3. Thau P, Fox C. A new procedure for the preparation of polyethylene-mineral oil gels. J Soc Cosmet Chem. 1965;16:359-363.
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- 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.
- This medication is to be used as directed by the physician. It is for dermatologic use only. Avoid contact with the eyes.
- Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
- The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
- Patients should report any signs of local adverse reactions especially under occlusive dressing.
- **Pregnancy Category C:** 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.
- 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.

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.

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voice of the dermatologist

"We need to educate the general practitioners, and the guidelines can be a tool to make appropriate AK treatment further known to the medical community."

Eggert Stockfleth, M.D., Ph.D, on creation of actinic keratosis guidelines
See story, page 1

VISMODEGIB:

Side effect symptoms a trade-off for more invasive therapies

from page 66

Expected morbidity or deformity if surgery or radiation were to be performed;

Curative resection unlikely or contraindication to surgery;

Two or more recurrences in the same location after ≥ 2 surgical procedures.

Physicians can employ this useful acronym as a guideline, Dr. Monks says, to help them more accurately assess their BCC patients and see whether vismodegib might be the appropriate treatment choice in a given patient. Vismodegib treatment is, however, associated with some adverse events including muscle spasms and cramps, alopecia, dysgeusia and ageusia, weight loss, fatigue and nausea.

"Prior to starting this drug, I think it is very important to educate patients in what the most common side effects are. They will be much more compliant with the drug if they know what to expect," Dr. Monks says.

SIDE EFFECTS

Although the side effects associated with vismodegib are typically mild-to-moderate in severity, Dr. Monks says the trade-off of developing some of these symptoms compared to the multiple — and sometimes disfiguring — surgeries and/or radiation therapies and their associated morbidities is worth it.

"I've recommended vismodegib in select patients ever since its FDA approval, and in my experience, most patients tolerate the side effects relatively well. Many of them have had extreme tumor burden and have undergone hundreds of BCC surgeries resulting in significant surgical fatigue," he says. "After starting them on vismodegib, the vast majority stopped developing tumor and cleared their existing tumors within several months, circumventing the need for surgery and/or radiation."

The recommended dose for vismodegib is 150 mg/day. It remains unclear, however, how the use of the drug is going to play out in the long-term, for instance in patients with Gorlin syndrome (nevoid basal cell carcinoma syndrome), characterized by the development of multiple nonmelanoma skin cancers over a lifetime.

> Dysregulation of the hedgehog pathway can result in uncontrolled proliferation and tumorigenesis.

CONSIDERING COMBO THERAPIES

According to Dr. Monks, an interesting corollary can be made when looking at the beginnings of the biologics for the treatment of psoriasis. At first, physicians were not clear on how to exactly use biologics for psoriasis, so the main goal was to get patients cleared, he says, and when they were clear, drug holidays were recommended.

Physicians soon learned, however, that a drug holiday was perhaps not in the best interest of the patient in that it was difficult to recapture the efficacy of the biologic once the drug was restarted, as opposed to keeping patients on the drug. This is something that still needs to be learned with vismodegib, Dr. Monks says, in terms of exactly how the drug should be ideally administered over time, particularly in challenging cases such as Gorlin syndrome.

A combination therapy for metastatic and locally advanced BCC would also be theoretically possible, according to Dr. Monks, using vismodegib and topical imiquimod. Although this would be an off-label use, each individual drug is indicated for the treatment of BCC. As patients on vismodegib have little to no localized skin reactions, a combination therapy with vismodegib and a topical immunomodulator such as imiquimod could be possible. Imiquimod treatment could be initiated after response to vismodegib is determined, Dr. Monks suggests, making for an interesting future clinical trial.

"I would put vismodegib in the same life-changing category as the biologics for psoriasis and isotretinoin for acne. It is an exciting time for medical dermatologists as we continue to see more biologics introduced for psoriasis and new drugs for the treatment of melanoma and nonmelanoma skin cancer," Dr. Monks says. **DT**

Disclosures: Dr. Monks is a paid consultant for Genentech.

AK GUIDELINES:

Evidenced-based recommendations aim to improve quality of care

from page 1

The idea to develop evidence-based global treatment guidelines for AKs originated over two years ago in a discussion between Eggert Stockfleth, M.D., Ph.D., and George Martin, M.D. The project was undertaken by the Guideline Subcommittee of the European Dermatology Forum in collaboration with the International League of Dermatological Societies, and is now nearing completion.

Dr. Stockfleth, professor of dermatology, Charité University Medical Center, Berlin, chaired the guideline subcommittee. He reviewed the motivation, goals, and methodology used for developing the guidelines at MauiDerm 2014.

"This is the first global guideline for the treatment of AKs, and the recommendations in the guidelines are based on evidence, not eminence," Dr. Stockfleth says.

"By undertaking a systematic assessment of the efficacy and safety of available treatment options, the guidelines aim to ensure selection of appropriate treatment for specific clinical situations, thus improving quality of care and reducing the percentage of patients with AKs progressing to invasive squamous cell carcinoma (SCC)," he says.

EVIDENCE-BASED ASSESSMENT

The guidelines subcommittee was comprised of an international panel that included 15 dermatologists, three dermatopathologists, and one patient representative. An evidence-based assessment of the literature was undertaken. The literature review took advantage of the work recently completed by Gupta et al in their 2012 Cochrane Database Systematic Review of interventions for AKs, but also updated the latter research to identify subsequently published data.

The evidence was critically appraised for quality, the level of evidence for individual modalities was graded, and these assessments were taken into account in a consensus process for generating recommendations on the use of the various interventions for treatment of solitary lesions, multiple lesions (>5 AKs and field cancerization), and high risk AKs (e.g., immunosuppressed and/or high risk location).

QUICK READ

An international panel collaborated to create a set of evidence-based guidelines for treating patients with actinic keratoses.

Based on a variety of factors, the therapeutic recommendations are also given a strength weighting using the five-point GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach: 1. strong recommendation for use ("we recommend"), 2. weak recommendation for use ("we suggest"), 3. no recommendation ("we cannot make a recommendation with respect to"), 4. weak recommendation against ("we suggest not to"), 5. strong recommendation against ("we recommend not to").

The draft guidelines have already undergone internal review and have been sent out for consideration by external experts whose input will be used to craft the final document. To enable clinical decisions and optimize patient care, the guidelines will feature a flowchart of pathways for management of patients in specific clinical situations. The flowchart will depict the roles of specialists and general practitioners and treatments that may be offered by each category of providers. As highlighted in the flowchart, sun protection is recommended as part of the management for all patients.

Dr. Stockfleth explains that interest in developing global AK treatment guidelines derives from recognition that AK is the most common neoplastic skin lesion in the world and has the potential for progression to invasive SCC.

"AKs are part of a biologic continuum that begins with photodamaged skin followed by progression to subclinical AKs, clinical AKs, and SCC. Not all AKs will develop into invasive cancer, but we know they represent an early stage and that patients who present with multiple AKs in an area of field cancerization are at increased risk for developing all ultraviolet light-related skin tumors," Dr. Stockfleth says.

UNDERSTANDING AKS

Despite this knowledge, conceptions of AK vary internationally and are the basis for different perceptions about the importance of treatment.

"Development of international guidelines for the treatment of AK may further advance and standardize the perception of AKs," Dr. Stockfleth says.

In addition, there have been growing concerns about the adverse events and cosmetic outcomes associated with various treatments for AKs.

"An increase in the amount of available evidence pertaining to the different treatment options enabled a comparison of efficacy and safety," he says.

Considering the existence of varying conceptions about AKs, one of the goals of the AK management guidelines was to establish a more widely accepted definition for the lesion. In addition, it is hoped that the document will raise awareness among other physicians who see patients with AKs about the necessity of treatment. Dr. Stockfleth says that in some countries where there is a relatively small dermatology workforce, management of patients with AKs more likely falls under the purview of general practitioners.

"In Germany, for example, there are 4,000 dermatologists available to serve a population of 80 million people, whereas there are 62 million people living in England and only about 350 dermatologists. In England, there is a need for general practitioners who have a special interest in dermatology," he says.

"We need to educate the general practitioners, and the guidelines can be a tool to make appropriate AK treatment further known to the medical community." **DT**

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The final guidelines on management of AKs will be available online

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Dermatology Times

Mnemonic tool helps physicians increase patient satisfaction levels

Ilya Petrou, M.D. | Senior Staff Correspondent

WAIKOLOA, HAWAII — Fulfilling patients' expectations regarding cosmetic procedure outcomes can sometimes prove to be challenging. According to one physician, using two simple mnemonics can be instrumental in satisfying patients, and for diffusing potentially uncomfortable scenarios if expectations are not met.

"In order to keep patients happy, the physician must either meet or exceed their expectations. However, some patients may have unrealistic expectations and therefore it is paramount for the physician to clearly establish, together with the patient, the achievable goals of treatment," says Howard K. Steinman, M.D., DermOne Skin Cancer & Surgery Center, Irving, Texas. He spoke at the 38th annual Hawaii Dermatology Seminar in Waikoloa, Hawaii.

QUICK READ

Using mnemonic devices AIDET and BLAST are useful for physicians trying to keep patients happy, before, during and after aesthetic procedures, even when outcomes turn out less than optimal.

"This approach will help to keep patient satisfaction level high and leave little room for post-procedure surprises."

Beyond the prerequisite of fulfilling expectations, Dr. Steinman says keeping patients happy also requires knowledge, judgment, technical skills, diagnostic skills, interpersonal skills, favorable billing, and an effective and efficient staff and office.

AIDET METHOD

In order to help ensure that each patient receives the highest level of care and treatment, Dr. Steinman says he often will use AIDET, a mnemonic that stands for Acknowledge, Introduce, Duration, Explanation, and Thank You.

"This is a practical evidence-based method that is increasingly being taught at many medical centers and lectured on in many major hospital groups, and is used for effectively communicating with patients, families and staff. Ultimately, it serves as an important template for providing overall excellent customer service," Dr. Steinman says.

The AIDET mnemonic is a kind of scaffold for proper bedside manner, he says, and its use can help decrease patient anxiety and increase patient compliance — both of which can help lead to improved clinical outcomes and increased patient satisfaction.

MNEMONICS see page 75

Quotable

"The failure of health information technology to quickly deliver on its promise is ... because of the shortcomings in the design of the IT systems that are in place."

Art Kellermann, M.D., M.P.H.
RAND

On EHR efficacy
See story, page 80

DTExtra

A recent study confirms that because physicians spend so much time looking at electronic health records (EHRs), they miss out on nonverbal communication cues from patients. Overall, physicians with EHRs in their exam rooms spend one-third of their time looking at computer screens, compared with physicians who use paper charts who only spent about 9 percent of their time looking at them. "It's likely that the ability to listen, problem-solve and think creatively is not optimal when physicians' eyes are glued to the screen," says Enid Montague, Ph.D., first author of the study.

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Finacea® (azelaic acid) Gel, 15% is indicated for topical treatment of inflammatory papules and pustules of mild to moderate rosacea. Although some reduction of erythema which was present in patients with papules and pustules of rosacea occurred in clinical studies, efficacy for treatment of erythema in rosacea in the absence of papules and pustules has not been evaluated.

IMPORTANT SAFETY INFORMATION

Skin irritation (e.g. pruritus, burning or stinging) may occur during use with Finacea®, usually during the first few weeks of treatment. If sensitivity or severe irritation develops and persists during use with Finacea®, discontinue use and institute appropriate therapy. There have been isolated reports of hypopigmentation after use of azelaic acid. Since azelaic acid has not been well studied in patients with dark complexion, monitor these patients for early signs of hypopigmentation.

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Avoid use of alcoholic cleansers, tinctures and astringents, abrasives and peeling agents. Avoid the use of occlusive dressings or wrappings.

In clinical trials with Finacea®, the most common treatment-related adverse events (AE's) were: burning/stinging/tingling (29%), pruritus (11%), scaling/dry skin/xerosis (8%) and erythema/irritation (4%). Contact dermatitis, edema and acne were observed at frequencies of 1% or less.

Finacea® is for topical use only. It is not for ophthalmic, oral or intravaginal use. Patients should be reassessed if no improvement is observed upon completing 12 weeks of therapy.

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BRIEF SUMMARY
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1 INDICATIONS AND USAGE
FINACEA® Gel is indicated for topical treatment of the inflammatory papules and pustules of mild to moderate rosacea. Although some reduction of erythema which was present in patients with papules and pustules of rosacea occurred in clinical studies, efficacy for treatment of erythema in rosacea in the absence of papules and pustules has not been evaluated.

5 WARNINGS AND PRECAUTIONS
5.1 Skin Reactions
Skin irritation (i.e. pruritus, burning or stinging) may occur during use of FINACEA Gel, usually during the first few weeks of treatment. If sensitivity or severe irritation develops and persists, discontinue treatment and institute appropriate therapy.

There have been isolated reports of hypopigmentation after use of azelaic acid. Since azelaic acid has not been well studied in patients with dark complexion, monitor these patients for early signs of hypopigmentation.

5.2 Eye and Mucous Membranes Irritation
Avoid contact with the eyes, mouth and other mucous membranes. If FINACEA Gel does come in contact with the eyes, wash the eyes with large amounts of water and consult a physician if eye irritation persists *[see Adverse Reactions (6.2)]*.

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 practice.

In two vehicle-controlled and one active-controlled U.S. clinical trials, treatment safety was monitored in 788 subjects who used twice-daily FINACEA Gel for 12 weeks (N=333) or 15 weeks (N=124), or the gel vehicle (N=331) for 12 weeks. In all three trials, the most common treatment-related adverse events were: burning/stinging/tingling (29%), pruritus (11%), scaling/dry skin/xerosis (8%) and erythema/irritation (4%). In the active-controlled trial, overall adverse reactions (including burning, stinging/tingling, dryness/tightness/ scaling, itching, and erythema/irritation/redness) were 19.4% (24/124) for FINACEA Gel compared to 7.1% (9/127) for the active comparator gel at 15 weeks.

Table 1: Adverse Events Occurring in ≥1% of Subjects in the Rosacea Trials by Treatment Group and Maximum Intensity*

	FINACEA Gel, 15% N=457 (100%)			Vehicle N=331 (100%)		
	Mild n=99 (22%)	Moderate n=61 (13%)	Severe n=27 (6%)	Mild n=46 (14%)	Moderate n=30 (9%)	Severe n=5 (2%)
Burning/ stinging/ tingling	71 (16%)	42 (9%)	17 (4%)	8 (2%)	6 (2%)	2 (1%)
Pruritus	29 (6%)	18 (4%)	5 (1%)	9 (3%)	6 (2%)	0 (0%)
Scaling/ dry skin/ xerosis	21 (5%)	10 (2%)	5 (1%)	31 (9%)	14 (4%)	1 (<1%)
Erythema/ irritation	6 (1%)	7 (2%)	2 (<1%)	8 (2%)	4 (1%)	2 (1%)
Contact dermatitis	2 (<1%)	3 (1%)	0 (0%)	1 (<1%)	0 (0%)	0 (0%)
Edema	3 (1%)	2 (<1%)	0 (0%)	3 (1%)	0 (0%)	0 (0%)
Acne	3 (1%)	1 (<1%)	0 (0%)	1 (<1%)	0 (0%)	0 (0%)

* Subjects may have >1 cutaneous adverse event; thus, the sum of the frequencies of preferred terms may exceed the number of subjects with at least 1 cutaneous adverse event.

In patients using azelaic acid formulations, the following adverse events have been reported: worsening of asthma, vitiligo, depigmentation, small depigmented spots, hypertrichosis, reddening (signs of keratosis pilaris) and exacerbation of recurrent herpes labialis.

Local Tolerability Studies
FINACEA Gel and its vehicle caused irritant reactions at the application site in human dermal safety studies. FINACEA Gel caused significantly more irritation than its vehicle in a cumulative irritation study. Some improvement in irritation was demonstrated over the course of the clinical trials, but this improvement might be attributed to subject dropouts. No phototoxicity or photoallergenicity were reported in human dermal safety studies.

6.2 Post-Marketing Experience
The following adverse reactions have been identified post approval of FINACEA Gel. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate the frequency or establish a causal relationship to drug exposure:

Eyes: iridocyclitis upon accidental exposure of the eyes to FINACEA Gel

7 DRUG INTERACTIONS
There have been no formal studies of the interaction of FINACEA Gel with other drugs.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Teratogenic Effects: Pregnancy Category B
There are no adequate and well-controlled studies in pregnant women. Therefore, FINACEA Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Dermal embryofetal developmental toxicology studies have not been performed with azelaic acid, 15% gel. Oral embryofetal developmental studies were conducted with azelaic acid in rats, rabbits, and cynomolgus monkeys. Azelaic acid was administered during the period of organogenesis in all three animal species. Embryotoxicity was observed in rats, rabbits, and monkeys at oral doses of azelaic acid that generated some maternal toxicity. Embryotoxicity was observed in rats given 2500 mg/kg/day [162 times the maximum recommended human dose (MRHD) based on body surface area (BSA)], rabbits given 150 or 500 mg/kg/day (19 or 65 times the MRHD based on BSA) and cynomolgus monkeys given 500 mg/kg/day (65 times the MRHD based on BSA) azelaic acid. No teratogenic effects were observed in the oral embryofetal developmental studies conducted in rats, rabbits and cynomolgus monkeys.

An oral peri- and post-natal developmental study was conducted in rats. Azelaic acid was administered from gestational day 15 through day 21 postpartum up to a dose level of 2500 mg/kg/day. Embryotoxicity was observed in rats at an oral dose of 2500 mg/kg/day (162 times the MRHD based on BSA) that generated some maternal toxicity. In addition, slight disturbances in the post-natal development of fetuses was noted in rats at oral doses that generated some maternal toxicity (500 and 2500 mg/kg/day; 32 and 162 times the MRHD based on BSA). No effects on sexual maturation of the fetuses were noted in this study.

8.3 Nursing Mothers
It is not known whether azelaic acid is excreted in human milk; however, *in vitro* studies using equilibrium dialysis were conducted to assess the potential for human milk partitioning. The studies demonstrated that, at an azelaic acid concentration of 25 µg/mL, the milk/plasma distribution coefficient was 0.7 and the milk/buffer distribution was 1.0. These data indicate that passage of drug into maternal milk may occur. Since less than 4% of a topically applied dose of 20% azelaic acid cream is systemically absorbed, the uptake of azelaic acid into maternal milk is not expected to cause a significant change from baseline azelaic acid levels in the milk. Nevertheless, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

8.4 Pediatric Use
Safety and effectiveness of FINACEA Gel in pediatric patients have not been established.

8.5 Geriatric Use
Clinical studies of FINACEA Gel did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

17 PATIENT COUNSELING INFORMATION
Inform patients using FINACEA Gel of the following information and instructions:

Use only as directed by your physician.

- For external use only.
- Before applying FINACEA Gel, cleanse affected area(s) with a very mild soap or a soapless cleansing lotion and pat dry with a soft towel.
- Avoid use of alcoholic cleansers, tinctures and astringents, abrasives and peeling agents.
- Avoid contact with the eyes, mouth and other mucous membranes. If FINACEA Gel does come in contact with the eyes, wash the eyes with large amounts of water and consult your physician if eye irritation persists.
- Wash hands immediately following application of FINACEA Gel.
- Cosmetics may be applied after the application of FINACEA Gel has dried.
- Avoid the use of occlusive dressings or wrappings.
- Skin irritation (e.g., pruritus, burning, or stinging) may occur during use of FINACEA Gel, usually during the first few weeks of treatment. If irritation is excessive or persists, discontinue use and consult your physician.
- Report abnormal changes in skin color to your physician.
- To help manage rosacea, avoid any triggers that may provoke erythema, flushing, and blushing. These triggers can include spicy and thermally hot food and drinks such as hot coffee, tea, or alcoholic beverages.

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MNEMONICS:

Evidence shows mnemonic reminders help physicians improve bedside manner from page 72

Following AIDET, physicians should always clearly acknowledge the patient's presence — as well as anyone accompanying the patient — upon entering the examination room, using eye contact and a smile. Physicians should introduce themselves and describe their role, background and experience.

The physician should also be very clear on the expected duration of a procedure and common time frame estimates, such when the results could be expected, how long until resolution of a given condition, or how long until the patient can resume normal activities. The physician needs to listen to the patient and explain each step of the procedure, and try to identify any areas of concern that the patient may have before the commencement of treatment.

According to Dr. Steinman, keeping the patient informed along every step of the way before, during and after a procedure is equally essential, and can help to calm those patients who may be apprehensive regarding the office visit and/or procedure performed. At the end of the visit, the physician should always thank the patient for their trust and the opportunity to provide care for them.

"AIDET can help prevent the patient from being unhappy, because unhappiness nearly always comes from unmet expectations," he says. "If you continually let people know what to expect on all different levels of patient care, then they are going to be 'happy' and satisfied because their expectations have been met."

BLAST APPROACH

In contrast, Dr. Steinman said that the BLAST (Believe, Listen, Apologize, Satisfy, Thank) mnemonic can be extremely useful when treatments, procedures and outcomes do not go as expected or intended. The brainchild of Albert Barneto, a consultant to the restaurant industry, BLAST was originally developed to train cashiers and young receptionists at restaurants to help them better deal with unhappy customers, and retain them as customers. In the medical arena, the technique can help physicians and their staff much better manage uncomfortable scenarios in which the patient is unhappy regarding treatment and outcomes.

"For the past three years, we have incorporated the BLAST technique in my practice — training residents, dermatologists and office staff — and have found the technique to work very well. 'BLASTing' patients only takes about five minutes or so, in which time you can build, repair and maintain a good relationship with dissatisfied patients," Dr. Steinman says.

All aspects of the BLAST mnemonic are critical in diffusing an uncomfortable situation and soothing the unhappy patient however, Dr. Steinman says the *belief* that the physician should show in the patient's expressed concerns regarding their problem is perhaps the most crucial aspect of the mnemonic and the cornerstone of the "healing" process.

"Many physicians may want to avoid dealing with unhappy patients. The BLAST mnemonic is a human relations technique that provides structure, confidence and effectiveness to an uncomfortable situation/conversation," he says.

CONVEY EMPATHY

According to Dr. Steinman, it is crucial that the physician sit down with patients and evoke belief in what they are expressing about their dissatisfaction or grievances regarding outcomes, regardless of whether they are exaggerating, lying, incorrect, or acting overly emotional or irrational.

"It is important to remember that an unhappy patient believes that you have harmed or wronged them, and physicians must refrain from trivializing the patient's feelings," Dr. Steinman says. "Expressing belief in their worry and disappointment will convey understanding, support and empathy. This, in turn engenders trust, and trust will eliminate adversarial feelings and any need to argue."

Actively listening to the patient (the "L" in BLAST) will not only prevent facial expressions and postures of disbelief, but will allow time for the patient to vent his or her frustrations. Here, the physician must remain calm and relaxed, maintain eye contact, and be attentive to the patient's concerns, while offering expressions of understanding and agreement.

After carefully listening to the patient's grievances, Dr. Steinman says the physician can then clarify and repeat back to the patient his or her concerns without trying to defend or justify — as the patient is in search of solutions, not excuses. The physician should listen and clarify (i.e. actively listen) more than once to convince the patient they understand their concerns.

OFFERING APOLOGIES

The physician should then apologize (the "A" in BLAST) for what the patient is experiencing and for their unmet expectations, even if the physician did not do anything wrong. Apologizing is not an acceptance of responsibility, Dr. Steinman says, but merely a gesture conveying empathy and understanding.

"The apology is the avenue for explaining without appearing defensive or accusatory. Although it may seem counterintuitive and unwise, a sincere apology will help diffuse fear, frustration and anger that the patient may be feeling. It also builds trust and strengthens relationships, and mitigates the likelihood of litigation," Dr. Steinman says.

The physician must then try to satisfy the patient (the "S" in BLAST) by offering two or three solutions that are convenient and amenable to the patient, and finish off by thanking the patient for giving them a second chance, presenting an opportunity to maintain a good reputation.

"When dealing with upset patients, we often become anxious, defensive or angry. BLAST is a very effective technique for diffusing, redirecting and correcting these situations, while keeping you calm and in control," Dr. Steinman says. "It creates a harmony in the room within a few minutes, and transforms a bad situation into an advantage and an opportunity to fix it for both parties." **DT**

Disclosures: Dr. Steinman reports no relevant financial interests.

Patricia Redsicker is a healthcare content marketing consultant and principal at Wordview Editing in Baltimore

6 social media marketing success tips for aesthetic practices

Are you interested in learning how content and social media marketing can help grow your aesthetic practice?

Most aesthetic practices are still using costly, outdated channels of advertising to build their brands. The problem with this approach is that patients have tuned out to these channels. According to *Aesthetic Medicine News*, today's patients get most of their information about cosmetic procedures from social media.

You're probably wondering, "What is the relationship between content marketing and social media?"

Social media marketing isn't just about putting up a Facebook page or a Twitter profile.

It's about educating people, answering their questions about aesthetics, and sharing interesting news about your practice. This is actually content marketing, and it is done primarily on your blog or website.

But that's not enough.

Social media promotion is critical to online content marketing success. Because there are millions of users on Facebook, Twitter, Google+ and other social sites, it is very likely that people who need your aesthetic services (yet don't know that your blog exists!) are hanging out there.

The best way to reach them is by taking the stories that you've posted on your blog and placing them in these sites.

It's that easy? Well, yes and no. Yes, because once you have all your content ready, all you have to do is promote it on your social media networks. But preparation is key.

Social media is a very active space. There are a lot of interesting conversations taking place at the same time and since your target audience has a short attention span, they can get distracted very easily.

The challenge for you as a dermatologist using social media, is that you have to be more interesting and more creative than the other people or brands in your target audience's network! How do you that?

Here are six content marketing and social media success tips for your aesthetic practice.

> The "About" section of your Facebook page should be optimized with keyword-rich names, categories and descriptions.

1 Tell stories

Use your blog to tell stories about your industry, practice, people and events. Each story should be unique and interesting enough to create appeal and draw new audiences on Facebook, Twitter and other social sites that you use.

Human-interest stories are very popular on social media. Aesthetic practices are fortunate to be able to leverage "show and tell" story-telling strategies. Using images and patient stories you can illustrate how your practice is impacting people's lives, by improving their appearance, and making them feel wonderful about themselves.

2 Blog often

If you don't already have one, develop an editorial calendar to help you blog regularly and consistently. Remember, too, that social media content benefits from planning and regular updating.

You need to plan for the interesting stories that you will share on Facebook, Twitter, Google+ or Pinterest. Of course many of these stories will be inspired from your blog, but once in a while you may also need to add other content (photos, video, podcasts, etc.) to engage audiences within those specific networks.

3 Execute well

Even though the dermatology and aesthetic industry is interesting by nature, how you execute stories about your category on social media is very important.

For example, on Facebook and Pinterest, posting visually appealing and well-edited photos will go much farther than posting links to your blog. On Twitter you will need different executions skills such as how to craft a compelling tweet with 140 characters, or how to use relevant hashtags to make it easy for people to find your content.

Every social media platform is different. It's important for you to learn those environments and leverage their unique features to reach a wider audience with your message.

4 Include location

One of your primary marketing goals is to attract more patients to

your practice. Create or update your Facebook page, Twitter profile and Pinterest account with your physical location and your contact information.

When patients come in for their appointment, encourage them to "check-in" to your location using Facebook Places.

Checking-in on Facebook has the same effect as word-of-mouth marketing. When a Facebook user sees (on her Newsfeed) that her friend (your patient) has checked into your location, she'll be curious to learn more about your practice and will probably click through to your Facebook Page for more information.

5 Work on your 'About' section

The "About" section of your Facebook page should be optimized with keyword-rich names, categories and descriptions. The words you use to describe your practice should reflect the natural conversational language that your audience uses. This will increase the likelihood of appearing on Facebook's Graph Search results.

Similarly, the About page of your website should not just focus on keywords such as aesthetics, but rather on answering questions that typical patients would ask. Think about some of the common questions that your patients have asked in the past and update your practice's About page with content that provides those answers.

6 Consider contests, promotions and giveaways

Contests, promotions and giveaways are very effective ways of acquiring new clients via social media. Because contests can produce outstanding results, it's important that you make yours stand out by offering a prize that will create excitement and enthusiasm among your audience. Giving away a free iPad has nothing to do with your practice, so don't bother.

You can give away a specific skin product with a "limited time only" message to create a sense of urgency and interest. Avoid giving away free services as this might encourage people not to buy until they find out if they've won. To ensure high participation encourage Facebook fans to submit photos of themselves, or share stories for a chance to win. **DT**

Which of these content and social media tips have you used to market your practice?

Share your experience with us:
editor@dermatologytimes.com

H.L. Greenberg, M.D., is a board-certified dermatologist in private practice at Las Vegas Dermatology

How to use social media to make your practice known

SOCIAL MEDIA is about being social. When I started Las Vegas Dermatology, I thought, "I'm a great physician, I just completed 11 years of schooling after college (medical school, an internal medicine residency, a dermatology research year and a dermatology residency), I have a sophisticated electronic medical record (EMR) and a patient-first philosophy. I should be busy right from day one."

Sadly, the problem and truth of the matter was — and is — when you start out, no one knows who you are, and no one cares. You have no name, no reputation, and no word-of-mouth. As a new dermatology graduate and business owner, you are an unknown quantity despite your impressive credentials. You could have the best website in the world, but if no one ever visits that site, it's a waste of resources.

That said, once someone has met you or is searching for you online, you need to have a great website — get help with this and choose a URL (website name) that is your practice's name. Mine is http://lasvegasdermatology.com, and I own shortened (lvderm.com) and related websites, such as the .org and .net.

GET YOUR NAME OUT

Pound the pavement, shake hands and give cards to everyone! The most effective thing that I did to get patients in the door when I started Las Vegas Dermatology was networking. I would visit other physician's offices who were working in my building, introduce myself and hand out business cards and brochures.

Although I have now met all of the physicians in my building, I continue attending networking events like the Vegas Young Professionals, various charity events and Las Vegas Chamber of Commerce events. My business needs patients, and I consistently hand out cards to everyone I meet, whether they are a billionaire, busboy, business owner, colleague, cocktail server, or valet — you never know whose going to need a dermatologist.

USE SOCIAL MEDIA

You can also get your name out by using social networking sites. Facebook is a part of people's daily routines and a means by which we can keep track of family and friends. It is possible to have your business or personal Facebook postings linked to your Twitter account; this is an easy way to kill two birds with one stone.

My office staff and I collaborate on all of our social media postings. Typically, my staff writes Facebook content, and I review, alter and then sign off on it. If, during the course of a day or week, I come across something relevant or newsworthy, I will post that on my business or personal Facebook or Twitter feed, depending on the content. Because posted content is a reflection of you and your practice, it is imperative that you are in control and aware of that message. At Las Vegas Dermatology, I review all social media postings because spelling errors, factual errors and unsubstantiated claims could be detrimental to a practice; it is important to ensure that your message is consistent and appropriate.

WATCH WHAT YOU POST

Don't be creepy online. If your website, Facebook or Twitter posts are all about selling, no one is going to be interested in following what you've got to say. Many times, price isn't even the issue; most people aren't even aware of the services and products you have in the office.

I can't tell you how many times I've been disappointed to discover that a patient I have been treating for years has been getting a service or product that we provide at another establishment because they didn't know that we offered it — this includes Botox (onabotulinumtoxinA, Allergan), fillers, laser hair removal, laser tattoo removal, chemical peels, microdermabrasion, etc.

Making your patients aware of your services is a key first step in getting them to use your services. How many times have people told you, "I didn't know that I needed it, but now I can't live without it?" Educating a patient about the benefits of a product or service will go a much longer way then "selling" them on it.

YouTube is another avenue of expression that has the potential to drive business to your practice and educate would-be patients. YouTube is a video site where you can post original content or add already posted content to playlists. Las Vegas Dermatology's YouTube channel has more than 80 videos posted, with the majority demonstrating original content.

Videos on our site include academic lectures I have given, patient videomonials and real patient surgical videos. I have had many patients explain to me that they chose me as their physician after watching a surgery I performed online. Claim your YouTube channel now; it should be the same name as your practice. Even if you post no videos, add videos to your playlist from the American Academy of Dermatology and my award-winning American Society for Dermatologic Surgery video on why you should choose a dermatologist for skincare problems.

Figure out what are you hoping to achieve with the messages you are putting out there, and make the magic happen. **DT**

PROVEN RESULTS YOU CAN TRUST.

- Evaluated in **7 studies**, on over **1,800 patients** across 5 countries [1-7]
- After four weeks use of the moisturizing cream, patients used **39%** less corticosteroids as skin conditions improved [1]
- **67%** reduction in EASI scores at week 8 [5]
- **72%** improvement in Quality of Life scores at 12 weeks[1]

Studies conducted on patients 2 months to 65 years of age

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1. Assessment of AVEENO® Eczema Therapy Moisturizing Cream through a Multi-centric Clinical Study on Infants, Children and Adults with Atopic Dermatitis. (n=71 patients in total aged 6 months to adult ; topical steroid data based on n=19 patients who previously used topical steroids during the washout period; improvement of QOL based on n=18 children (CDLQI). 2. Clinical assessment of AVEENO® Eczema Therapy to Alleviate the Eczema Signs of Dry to Very Dry Skin/Skin Prone to Atopic Dermatitis and to Improve the Patient's Quality of Life. (n=75) Studies sponsored by Johnson & Johnson do Brazilind.com. Prod. Para Saúde Ltda. Principal Investigator. Dr. Lucia Helena Favaro de Arruda. Preliminary data presented by Dr. Maria João Lopes at the ESPD Congress, Istanbul 2012. 3. Gr eek Observational Study of AVEENO® Eczema Therapy Moisturizing Cream and Cleansing Therapy Moisturizing Wash. (n=1607) Preliminary data presented Dr. Kyriakos Volonakis at the ESPD Congress, Istanbul 2012. 4. Comparing the Effectiveness of AVEENO® Eczema Therapy Moisturizing Cream and EpiCeram® Skin Barrier Emulsion in Improving Skin Moisturization and Barrier Function in Moderate to Severe Dry Skin. (n=27) Nebus J, Nystrand G, Schmalenberg K, et al. J Am A cad Dermatol. 2011;6 4:AB71. 5. A Daily Oat Based Skin Care Regimen for Atopic Skin. (n=25) Nebus J, Nystrand G, Fowler J, Wallo W. J Am A cad Dermatol. 2009; 60:AB67. 6. Evaluating the Tolerance and Safety of AVEENO® Eczema Therapy Moisturizing Cream and AVEENO® Baby Cleansing Therapy Moisturizing Wash in Babies and Children with Atopic Dermatitis. (n=23) Nebus J, Wallo W, Eichenfeld L, MD; Poster presented at the 34th Annual Meeting of the Society of Pediatric Dermatology. July 2008. 7. Evaluating the Safety and Tolerance of AVEENO® Eczema Therapy Moisturizing Cream and AVEENO® Baby Cleansing Therapy Moisturizing Wash in Patients with Atopic Dermatitis. (n=21) Judith Nebus, Warren Wallo, Joseph Fowler Jr., MD; J Am A cad Dermatol. 2007; 56:AB71.

EHRs: The real story

Daniel R. Verdon | Group Content Director

DESPITE THE government's bribe of nearly $27 billion to digitize patient records, nearly 70 percent of physicians say electronic health record (EHR) systems have not been worth it. It's a sobering statistic backed by newly released data from marketing and research firm MPI Group and *Medical Economics* that suggest nearly two-thirds of doctors would not purchase their current EHR system again because of poor functionality and high costs. (See Tables 1-2.)

In a surprise finding, nearly 45 percent of physicians from the national survey report spending more than $100,000 on an EHR. About 77 percent of the largest practices spent nearly $200,000 on their systems. (See Table 3)

While physicians can receive $44,000 through the Medicare EHR Meaningful Use (MU) incentive program, and $63,750 through Medicaid's MU program, some physicians say it's not nearly enough to cover the increasing costs of implementation, training, annual licensing fees, hardware and associated services. But the most dramatic unanticipated costs were associated with the need to increase staff, coupled with a loss in physician productivity.

"We used to see 32 patients a day with one tech, and now we struggle to see 24 patients a day with four techs. And we provide worse care," said one survey respondent.

While some physicians cited benefits of accessing patient data, availability of practice metrics, and e-prescribing conveniences for patients, most physicians do not believe these systems come close to creating new efficiencies or sharing data with multiple providers or improving patient care.

In fact, when doctors were asked if their EHR investment was worth the effort, resources and cost, "no" was the reply given by nearly 79 percent of respondents in practices with more than 10 physicians. (See Table 1)

Medical Economics' survey results, based on responses from nearly

EHR see page **82**

About the survey

Medical Economics' State of EHR Survey was conducted by the research firm The MPI Group and used an online questionnaire. There were 967 total respondents, with surveys received in November and December 2013. Respondents answers to the survey are either anonymous (no contact information provided) or confidential (contact information provided and the respondent willing to discuss the survey with *Medical Economics*.) The margin of error for most questions on the survey is approximately ± 3.2 percent at a confidence level of 95 percent.

About MPI Group

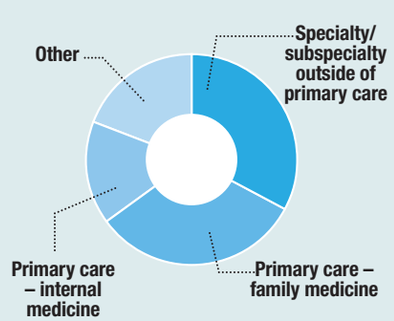
The MPI Group offers thought leadership and research, that help create insight, understanding, affinity, and market awareness. Based in Shaker Heights, Ohio, MPI also maintains one of the world's largest databases of detailed financial, operational, and strategic performance metrics collected from thousands of facilities and firms around the globe. For more information, go to mpi-group.com.

About *Medical Economics*

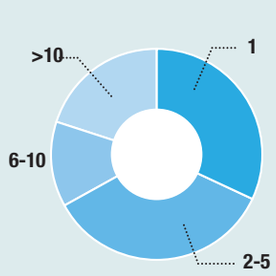
Medical Economics is the leading business media brand for physicians in the United States. *Medical Economics* engages physicians 945,000 times every month in print, in digital editions, online, e-newsletters and through our iPad app. **DT**

Survey respondents

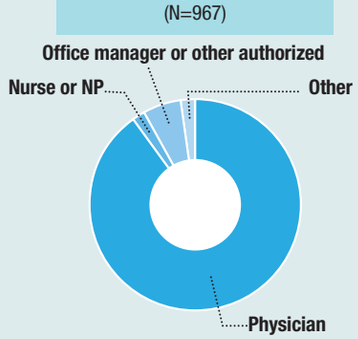
Practice description
(N=967)



Number of physicians
(N=967)



Participant title
(N=967)



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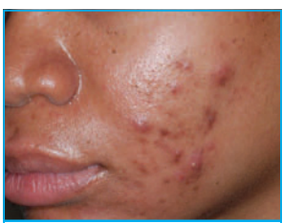
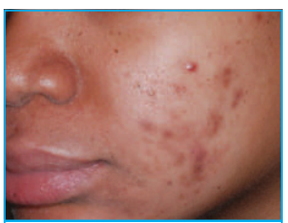
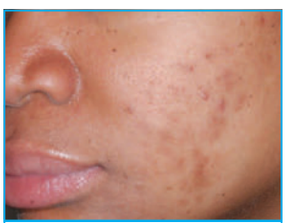
Clinically tested to be as effective as the leading acne prescription cream.[2]


Baseline

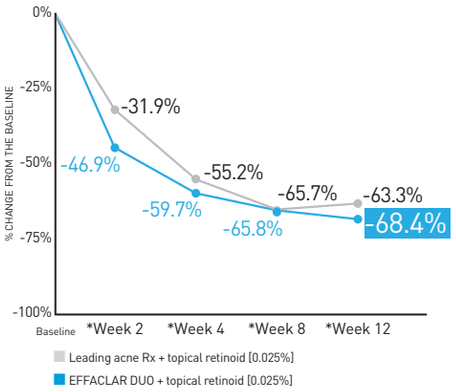

Week 2


Week 12

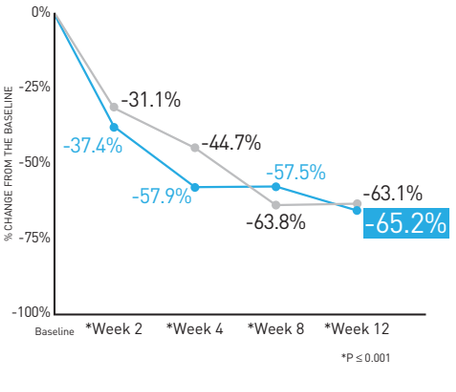
- 5.5% Micronized Benzoyl Peroxide reduces inflammation while minimizing irritation
- 0.4% Micro-exfoliating LHA (derivative of Salicylic Acid) for precise cell-by-cell exfoliation
- Minimum Irritation. Non-comedogenic. Fragrance-free. Tested on sensitive skin.

Significant improvement in reduction of acne lesions

INFLAMMATORY LESION COUNTS[2]



NON-INFLAMMATORY LESION COUNTS[2]



*P ≤ 0.001

(1) Dual action acne treatment stems from Benzoyl peroxide.
(2) Protocol: A 12 week dermatologist controlled, multi-center study: double blind clinical trial to evaluate safety and efficacy of two acne creams in subjects with mild to moderate acne vulgaris. 61 patients, ages 18–50, multi-ethnic skin, all skin types. 2 cell study: Cell 1, 27 patients, [EFFACLAR DUO]+ 0.025% Topical Retinoid vs. Cell 2, 34 patients, [a leading topical Benzoyl peroxide prescription] + 0.025% Topical Retinoid. Results measured at mean % change from baseline at 12 weeks of use. Application of topical retinoid applied once a day in PM and application of Effaclar DUO or a leading topical prescription Benzoyl peroxide twice a day. Inclusion criteria: 15 inflammatory lesions and 20 non-inflammatory lesions.

EHR:

Many doctors say technology shortcomings negatively impact patient care from page 80

1,000 physicians, were corroborated by the findings of a January 2013 RAND Corp. study, detailed in *Health Affairs, The New York Times, USA Today*, and other national media organizations, criticizing the usability and interconnectedness of current EHR systems.

"The failure of health information technology to quickly deliver on its promise is not caused by its lack of potential, but rather because of the shortcomings in the design of the IT systems that are currently in place," says Art Kellermann, M.D., M.P.H., the study's senior author and the Paul O'Neill Alcoa Chair in Policy Analysis at RAND.

Another 2013 RAND report, titled "Physician Professional Satisfaction and their Implications for Patient Care," concludes that frustrations related to EHRs are negatively influencing physician attitudes about their careers.

"Poor EHR usability, time-consuming data entry, interference with face-to-face patient care, inefficient and less fulfilling work content, inability to exchange health information between EHR products, and degradation of clinical documentation were prominent sources of professional dissatisfaction," the report says.

The most recent data from MPI Group and *Medical Economics* not only corroborates these physician sentiments related to EHRs, but calls on software developers to build solutions that help physicians improve patient care, not obstruct it.

CLOSER LOOK AT THE RESULTS

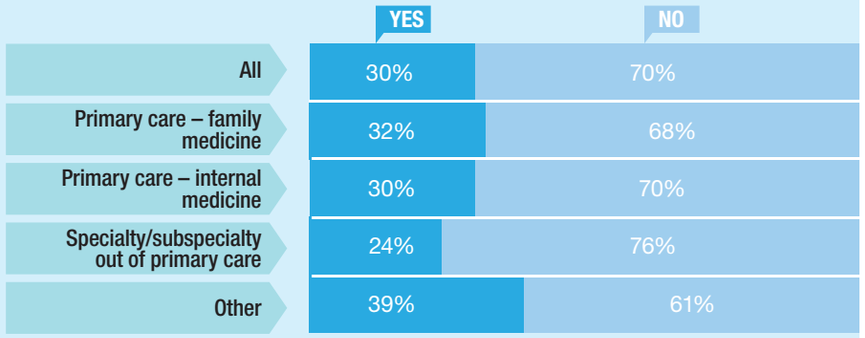
Here are other key findings from the national survey:

- 73 percent of the largest practices would not purchase their current EHR system. The data show that 66 percent of internal medicine specialists would not purchase their current system. About 60 percent of respondents in family medicine would also make another EHR choice.

EHR see page 86

TABLE 1 70% say EHRs *not worth it*

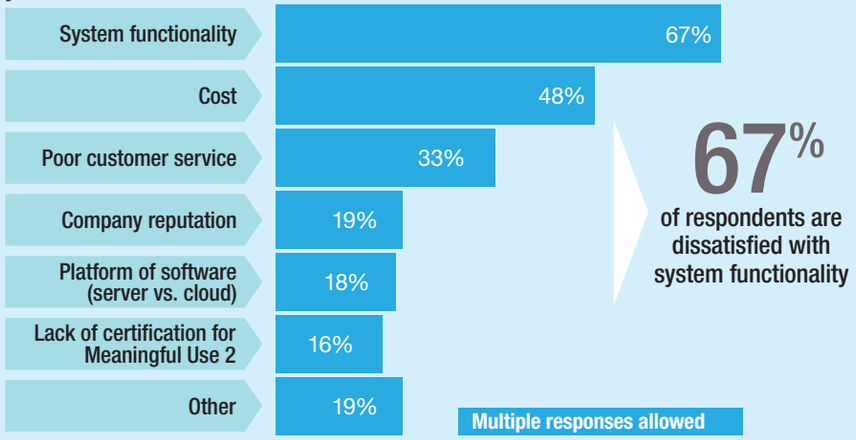
Has your EHR investment been worth the effort, resources and costs?



Source: 2014 Exclusive EHR Study Survey; MPI Group, Medical Economics N=952

TABLE 2 Practices dislike EHR functionality and cost

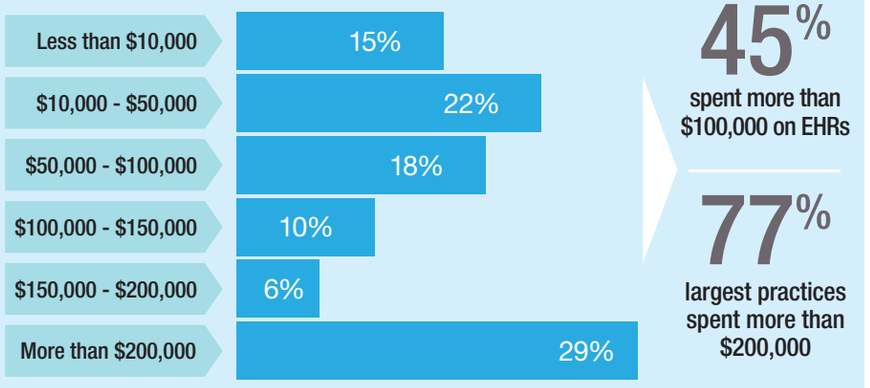
If you are planning to switch EHR systems, which factors are influencing your decision?



Source: 2014 Exclusive EHR Study Survey; MPI Group/Medical Economics N=606

TABLE 3 EHR implementations have been costly

How much have you invested today in your EHR system, including hardware, software, training, consulting, etc.?



Source: 2014 Exclusive EHR Study Survey; MPI Group/Medical Economics N=925

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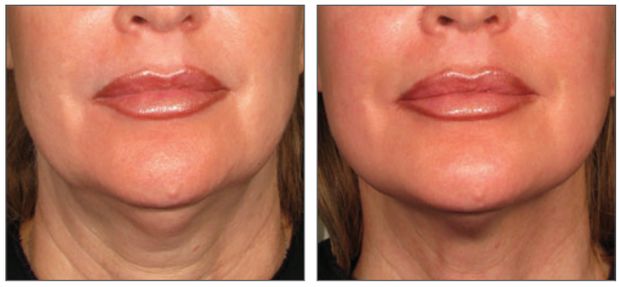
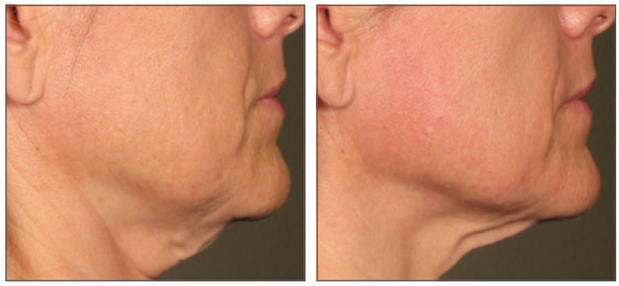
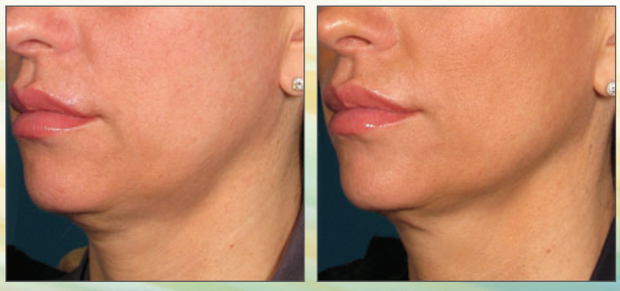


PRE-TREATMENT | DAY 90, *Single Treatment*



PRE-TREATMENT | DAY 180, *Single Treatment*



PRE-TREATMENT | DAY 360, *Single Treatment*

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EHR:

Many doctors say technology shortcomings negatively impact patient care from page 82

- 67 percent of physicians dislike the functionality of their EHR systems.
- Nearly half of physicians believe the cost of these systems is too high.
- 45 percent of respondents say patient care is worse since implementing an EHR. Nearly 23 percent of internists say patient care is significantly worse.
- 65 percent of respondents say their EHR systems result in financial losses for the practice. About 43 percent of internists and other specialists/subspecialists outside of primary care characterized the losses as significant.
- About 69 percent of respondents said that coordination of care with hospitals has not improved.
- Nearly 38 percent of respondents doubt their system will be viable in five years.
- 74 percent of respondents believe their vendors will be in business over the next five years.

MAJOR DISCONNECT

The *Medical Economics* survey was conducted to gauge physician attitudes about EHRs and benchmark data gathered during a separate and novel two-year EHR Best Practices Study of 29 U.S. physicians in independent practices (nearly all were in solo practice).

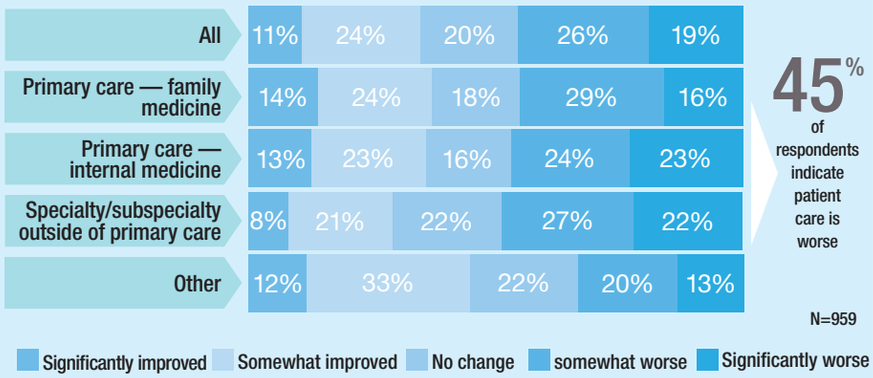
While this two-year study concluded at the end of 2013, some of the same physician attitudes and frustrations related to the implementation and use of EHRs were documented in the national survey. Common frustrations cited by physicians in both projects included a decrease in patient visits, reports of efficiency declines, and unanticipated costs associated with implementing and using EHR systems.

The national survey underscores the major disconnect between the current state of EHR software and the needs of physicians. **DT**

Questions? Comments?
Give **Dermatology Times** your feedback by contacting us at editor@dermatologytimes.com.

TABLE 4 **Impact on patient care**

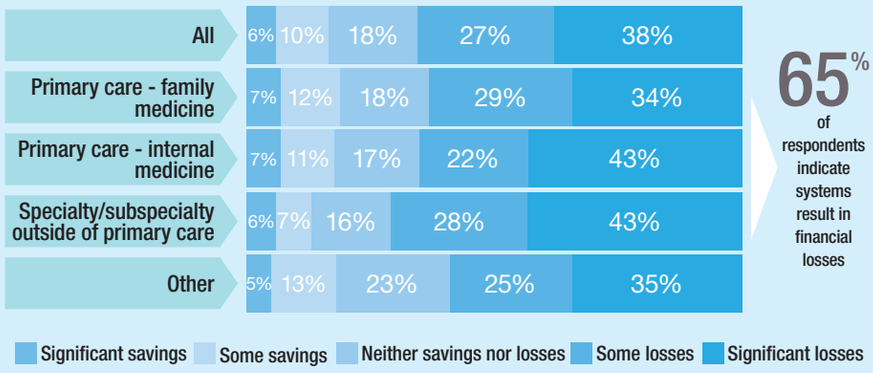
To what extent has your EHR system improved the quality of patient care?*



Source: 2014 Exclusive EHR Study Survey; MPI Group/Medical Economics * Categories may not sum to 100% due to rounding

TABLE 5 **EHR systems and financial losses**

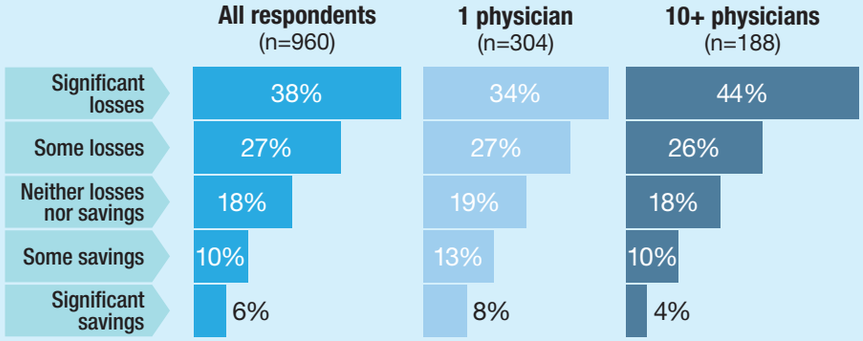
To what extent has your EHR system saved you money?



Source: 2014 Exclusive EHR Study Survey; MPI Group/Medical Economics N=960

TABLE 6 **The escalating costs associated with EHRs**

To what extent has your EHR system saved you money?*



Source: 2014 Exclusive EHR Study Survey; MPI Group/Medical Economics * Categories may not sum to 100% due to rounding.

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Security risk analysis: How to protect patient records and remain HIPAA-compliant

Mark Norris | Contributing Author

PROBABLY THE least understood and greatest exposure and risk for practices attesting to meaningful use (MU) is the need to complete a security risk analysis. When it comes to the technical concepts like firewalls, routers and security protocols, most offices just do not know where to begin. You trust your vendors and business associates to keep you compliant, but what if they do not?

The use of health information technology continues to expand in healthcare. Although these new technologies provide many opportunities and benefits for consumers, they also pose new risks to consumer privacy.

Because of these increased risks, the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) include national standards for the privacy of protected health information, the security of electronic protected health information, and for breach notification to consumers. HITECH also requires Health and Human Services (HHS) to perform periodic audits of covered entity and business associate compliance with the HIPAA Privacy, Security, and Breach Notification Rules.

Many of the MU measures are already familiar to practices. Actions such as gathering vitals, demographic documentation, and medication histories physicians can perform in their sleep. While learning the interface of their new electronic health record (EHR) system is a very real obstacle, in time, staff learn what button to push and box to click to be compliant.

But the technical issues can be much trickier for physicians, who aren't necessarily IT experts.

An example: In a recent visit at a rural practice, a national telecommunications provider had been onsite to upgrade the practice's broadband connection. In the process, they disconnected the firewall because they could not configure it correctly, and left it unplugged. They did not notify the practice of their actions and left after assuming completion of the job.

It was not until a week later, when the practice network went down and they called in their local hardware vendor, that they discovered the potential breach situation. The practice, through no fault of its own, was completely exposed. In a follow-up call to the vendor, they responded, "We don't know what you are talking about." Really? This time everyone got lucky.

Here is what medical practices attesting to meaningful use stage 1 need to know about completing a security risk analysis.

Mitigate security risks to your medical practice

The five components to risk management

The security infrastructure of a medical practice should have five components, according to the HIPAA security rule. The following table briefly outlines each component and provides examples.

5 security components for risk management

Security Components	Examples	Examples of Security Measures
Physical safeguards	• Your facility and other places where patient data is accessed • Computer equipment • Portable devices	• Building alarm systems • Locked offices • Screens shielded from secondary viewers
Administrative safeguards	• Designated security officer • Workforce training and oversight • Controlling information access • Periodic security reassessment	• Staff training • Monthly review of user activities • Policy enforcement
Technical safeguards	• Controls on access to EHR • Use of audit logs to monitor users and other EHR activities • Measures that keep electronic patient data from improper changes • Secure, authorized electronic exchanges of patient information	• Secure passwords • Backing-up data • Virus checks • Data encryption
Policies and procedures	• Written policies and procedures to assure HIPAA security compliance • Documentation of security measures	• Written protocols on authorizing users • Record retention
Organizational requirements	• Breach notification and associated policies • Business associate agreements	• Agreement review and updates

Source: The Office of the National Coordinator for Health Information Technology

RISK ANALYSIS EXPLAINED

The Centers for Medicare and Medicaid Services (CMS) defines the requirement this way: The practice must "Protect electronic health information created or maintained by the

SECURITY see page **90**

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SECURITY:

Technology offers opportunity and risk from page 88

certified EHR technology through the implementation of appropriate technical capabilities and conduct or review a security risk analysis per 45 CFR 164.308(a)(1), implement updates as necessary and correct identified security deficiencies as part of the eligible providers risk management process..."

Do you really understand what that means? If not, you are not alone. A lack of technology expertise is the problem. You are not an IT guru and must depend on others, who may not be protecting your best interests.

Privacy and security are like **chronic diseases** that require **treatment, ongoing monitoring** and evaluation, and periodic adjustment.

To make a simplistic medical analogy, a security risk analysis is the examination and testing you do to assess clinical risk and diagnose a clinical condition applied to your practice's information technology infrastructure and operations. Just as you use a diagnosis and other clinical data to plan treatment, you will use the risk analysis to create an action plan to make your practice better at protecting patient information. Further, privacy and security are like chronic diseases that require treatment, ongoing monitoring and evaluation, and periodic adjustment. A security risk analysis is a systematic and ongoing process of both:

- Identifying and examining potential threats and vulnerabilities to protected health information in your medical practice.
- Implementing changes to make patient health information more secure than at present, then monitoring results (i.e., risk management).

The HIPAA Security Rule requires covered entities to conduct a risk analysis to identify risks and vulnerabilities to electronic protected health information (EPHI). Risk analysis is the first step in an organization's Security Rule compliance efforts. Following HIPAA risk analysis guidelines will help you to establish the safeguards you need to implement based on the unique circumstances of your healthcare practice.

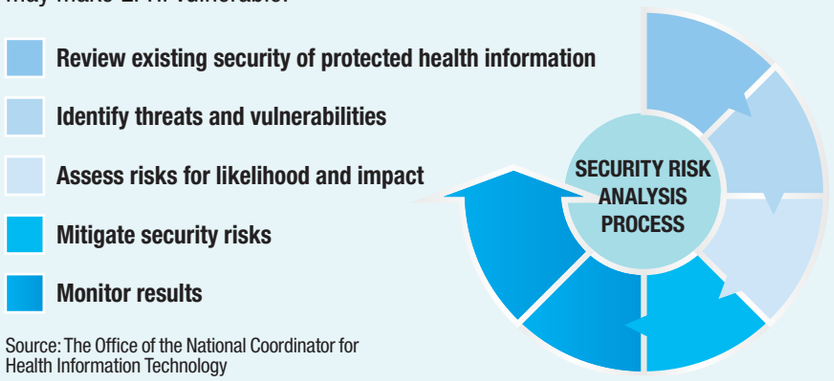
After completing a risk analysis, which will identify your areas of risk, policies and procedures must be put in place to document and mitigate these risks. Risk analysis is an ongoing process that should provide your medical practice with a detailed understanding of the risks to the confidentiality, integrity and availability of EPHI.

HIPAA requires that covered entities "implement policies and procedures to prevent, detect, contain, and correct security violations" by conducting "an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of EPHI held by the (organization)."

Providers should develop a risk analysis that addresses these criteria by evaluating the impact and likelihood of potential breaches, implementing security features, cataloguing security features, and maintaining security protections.

What is a security risk analysis?

A security risk analysis involves analyzing vulnerabilities and threats to your system to safeguard electronic protected health information (EPHI). It means reviewing your policies, practices, and systems and correct any issues that may make EPHI vulnerable.



Source: The Office of the National Coordinator for Health Information Technology

HIPAA OMNIBUS FINAL RULE SUMMARY

There are three areas that physicians will need to focus on to comply with the new HIPAA rules:

- Privacy, security, and breach notification policies and procedures (and in some cases, new work flows and forms);
- notice of privacy practices; and
- business associate agreements.

All of these forms must be updated. This updated documentation to identify your risks and how you will address them must be dated during the attestation period, not after.

The bottom line is this: If you do not document it, you did not do it. **DT**

Mark Norris is CEO of Medical Record Services, which works with practices on meaningful use compliance, privacy and security, and attestation. He is former executive director of NEO HealthConnect, one of The Ohio Health Information Partnership's (OHIP) seven Regional Extension Centers (REC). He oversaw 350 primary care physicians on issues of meaningful use compliance and attestation.

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Dermatologists have been challenged by the limits of existing treatments for hyperpigmentation. The unmet medical need has fueled research to develop more effective alternatives. Recently, a distinguished panel of dermatologists convened to discuss the potential of a novel addition to the various modalities available for treating the spectrum of hyperpigmentary disorders.

This exclusive supplement to the November 2013 issue of ***Dermatology Times*** summarizes the panel's discussion of their clinical experiences and variety of approaches to skin discoloration, including utilization of Lytera® Skin Brightening Complex—a nonprescription, hydroquinone-free topical cosmetic product which targets four key mechanisms involved in the development of hyperpigmentation.

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The panel's instructive exchange includes photo vignettes of some of their most challenging cases and reports the clinical data supporting the innovative Lytera® Skin Brightening Complex—both as monotherapy and in sequence with adjunctive topical and laser treatment regimens.

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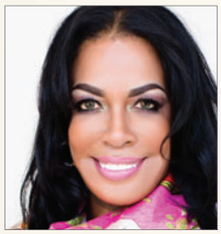

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RVUs: A valuable tool for aiding practice management

Jeffrey Bendix | Senior Editor

WHEN IT COMES to managing practice finances, physicians have few better tools at their disposal than the relative value unit (RVU). RVUs can be used for everything from helping to determine compensation in a multi-physician practice to deciding whether to take a buyout offer from a hospital system.

WHAT ARE RVUS?

RVUs are part of the system Medicare uses to decide how much it will reimburse physicians for each of the 9,000-plus services and procedures covered under its Physician Fee Schedule, and which are assigned current procedural terminology (CPT) code numbers. The dollar amount for each service is determined by three components: physician's work, practice expenses, and malpractice insurance.

Physician's work, in turn, is divided into four subcomponents: the time it takes to perform the service, the technical skill and/or physical effort required to perform the service, the amount of mental effort and judgment required, and the stress arising from any potential risk to the patient from performing the service.

Each of these three components is assigned an RVU. Then, to account for variations in living and business costs across the country, each of the three components is multiplied by a factor known as the Geographic Practice Cost Index, or GPCI.

The three components are added together, and the resulting sum is then multiplied by a dollar amount known as the conversion factor to arrive at the reimbursement dollar figure: The dollar amount of the conversion factor is established each year by Congress. The RVUs themselves are determined as part of what's known as the Resource-based Relative Value Scale (RBRVS), a system for describing, quantifying, and reimbursing physician services relative to one another.

Using RVUs to calculate productivity bonus

Income Calculations	Physician
RVU's (Professional)	2,800
RVU %	0.2000
Professional Income	176,998.85
Ancillary	34,998.85
Imaging Income Allocation	—
Lab Income Allocation	—
Gross Income Distribution	**211,997.70**
LESS: Direct Expenses	
Auto and Travel	(1,661.45)
Professional Dues	(2,700.82)
Health Insurance — Physician	—
Disability Insurance — Group Physician	—
Professional Liability Insurance — Physician	(31,272.82)
Journals and Publications	(393.27)
Net Income Distributable	**175,969.34**
LESS: Distributions Made (salary)	**120,000.00**
Net Bonus Payable	**55,969.34**

Source: Z Management Group Ltd

WHY THEY WERE CREATED

The RVU/RBRVS system was created as a way of bringing more uniformity to Medicare's reimbursement systems while also trying to rein in spiraling medical spending, explains H. Christopher Zaenger, principal of Z Management Group in Barrington, Ill. Until then, Medicare based its reimbursements on what it determined were the "uniform, customary and reasonable" fees for a service in a given market.

In 1988, the Centers for Medicare and Medicaid Services commissioned a study from the Harvard School of Public Health to look at the resources and costs associated with the services that doctors provide. That study led to the introduction of the RBRVS system in 1992. It has been in use ever since, although not without controversy.

RVUS IN PRACTICE MANAGEMENT

Understanding RVUs is important because "they are the language the payers speak when contracting with practices, and for reimbursing doctors for the work they do," says Jeffrey Milburn M.B.A., C.M.P.E., an independent national practice consultant with the Medical Group Management Association (MGMA.) "It's kind of a national standard, and like it or not, doctors need to be familiar with the system."

The reimbursement impact of the RVU system is not limited to Medicare. "If you look at most contracts today, you see that virtually every commercial carrier benchmarks its fee schedule to the Medicare fee schedule," says Mr. Zaenger. "Historically it's always been higher than what Medicare pays, but over the last three to five years that has

changed, and now there are some plans that actually pay less than Medicare."

The percentage of the Medicare fee schedule a commercial insurer will pay often is a function of the supply of, and demand for, the type of service a practice provides. If you're the only dermatologist in town, you have not only a geographic monopoly but a specialty monopoly, giving you a lot of leverage with the insurance company, which means it will pay much more than Medicare, Mr. Milburn says.

Conversely, if many practices are providing the same service in a community — or if only one commercial payer includes the community's physicians in its panel, the doctors will have to accept whatever rate the payer sets, even if it's less than Medicare, or risk losing patients.

Along the same lines, RVUs are a useful way of comparing how well payers reimburse for the same service or procedure, says Frank Cohen, principal of the Frank Cohen Group, a medical consulting firm in Clearwater, Fla. To do so, Mr. Cohen says, first divide the practice's total expenses for the year by the practice's RVUs, to produce a dollar cost per RVU.

Armed with that information, "you can go to a payer and say 'I do so much better with these other payers that it's not worth it for me to see your patients anymore.'" And while practices sometimes balk at the idea of giving up any patients, "sometimes the best thing you can do for your business is to send the bad payers to your competitors," Mr. Cohen says.

In most cases, costs and revenues tend to increase relative to each other. But occasionally a practice may encounter certain procedures where, for whatever reason, the cost-to-revenue ratio is much higher than in others. In those cases, Mr. Cohen says, he advises practices to try to negotiate a "carve out," whereby the payer reimburses at a higher rate for those procedures.

He also advises clients to measure their providers' productivity per RVU relative to one another. That can be done by calculating each provider's revenue and RVUs as a percentage of the practice's total revenue and RVUs, and then dividing the results. (See table, "Using RVUs to calculate productivity bonus).

He cautions, however, that there may be valid reasons for a provider's low ratio, such as his or her willingness to see more Medicaid patients than others in the practice.

RVUS AND PHYSICIAN COMPENSATION

Another potential function for RVUs is as a tool to help multiphysician practices determine how much to pay their physicians. Practices typically use them for this purpose in one of two ways, Mr. Milburn says. The first is straight productivity, whereby the practice multiplies the number of work RVUs the doctor generates by its own conversion factor to arrive at a compensation figure.

The conversion factor typically is determined by dividing the national median compensation for a specialty by the median number of work RVUs for that specialty, data for which can be obtained from the MGMA or American Medical Group Association. That conversion factor acts as a "market rate" for doctors in that specialty for each RVU they produce, Mr. Milburn says.

The second approach is to pay each physician a salary plus a bonus tied to the number of work RVUs generated over a base number, such as 2,000 RVUs. "When a practice wants to put in a productivity incentive, that's typically how they will do it," he says.

With hospital systems across the country looking to grow, RVUs can be among the tools a practice uses to decide whether to sell, Mr. Zaenger says. That's because most large systems use RVUs to set physician compensation and productivity bonuses.

"They really need to analyze their practice from an RVU standpoint, so if the hospital says they will be benchmarked at, say, 4,600 RVUs per year for their evaluation and management services, they know if that's a realistic number for them to attain," Mr. Zaenger says. **DT**

Medicare's new transparency rule triggers privacy concerns

Donna Marbury | Contributing Author

Will reimbursement data on individual physicians lead to better healthcare or leave doctors exposed?

In an attempt to be more open with the public, the Centers for Medicare and Medicaid Services (CMS) may have allowed insurance companies, watchdogs, and competitors to access data on individual physicians' reimbursements. Amid concerns that the data can be presented completely out of context, will this new policy portray solo practitioners in an unfair light?

Due to a policy change that CMS announced in January, it will be easier for insurance companies, patients and watchdogs to get payment information about individual physicians. According to a post on CMS' blog, the agency will start evaluating requests for physician pay information in the same way as other Freedom of Information Act (FOIA) requests. CMS will also begin creating and publishing data sets of physician pay and services.

Reid Blackwelder, M.D., F.A.A.F.P., president of the American Academy of Family Physicians (AAFP), says he worries that the data will be used without proper context and give a distorted view of how much money physicians make.

"It is a limited database on payments to physicians for only one payer. Again, the context of that data is critical to allow for proper interpretation of Medicare as part of the physicians revenue. Regardless, this data does not really relate to the actual overall pay of any physician, especially as it does not include a physician's expenses, overall demographic data, and so on," Dr. Blackwelder says.

CMS says the move is in response to more than 130 comments from more than 300 organizations about making payment data available. "Given the advantages of releasing information on Medicare payment to physicians and the agency's commitment to data transparency, we believe replacing the prior policy with a new policy in which CMS will make case-by-case determinations is the best next step for the agency," said Jonathan Blum, CMS principal deputy administrator, in the blog post announcing the change.

But will making payment information for individual physicians available mislead the public and cause privacy issues for physicians?

"The disclosure of payment data from government healthcare programs must be balanced against the confidentiality and personal privacy interests of physicians and patients who may be unfairly impacted by disclosures," says Ardis Dee Hoven, M.D., president of the American Medical Association (AMA). "The unfettered release of raw data will result in inaccurate and misleading information. Because of this, the AMA strongly urges HHS (the Department of Health and Human Services) to ensure that physician payment information is released only

TRANSPARENCY see page **96**

CMS' new transparency provision versus the Sunshine Act

Information about physicians will be more accessible to the public through the Sunshine Act, because data will be available online this fall. However, the Centers for Medicare and Medicaid Services' (CMS) new Medicare transparency provision requires filing a Freedom of Information Act (FOIA) request, which can be complicated and must be approved before any information is released to the public. The details of the provision will be published this spring.

The Sunshine Act is the portion of the Affordable Care Act that requires drug and medical device manufacturers to report any payments they make to physicians. Information about how much physicians are being paid by these companies is available for review by physicians on the Open Payment website and a mobile app, both operated by CMS. Information gathering started in August 2013, and will be released to the public on the Open Payment website and app this September.

"Taken together (Sunshine Law and Medicare payment information), this transparency approach may have some impact as consumers look to see a physician's 'profile' — from whom she or he has accepted payments, what his Medicare performance may have been, etc. I think it remains to be seen if this information is really utilized by the public in choosing their physicians," says Judith A. Waltz, partner with Foley & Lardner LLP.

Reid Blackwelder, M.D., F.A.A.F.P., president of the American Association of Family Physicians, says these new laws shouldn't taint the physician profession, but those who are committing fraud have a lot to worry about.

"It depends on the number of FOIA requests and whether or not patients choose to go into the Open Payment website and look up a physician's information," Dr. Blackwelder says. "It is more likely to change perception of an individual physician rather than physicians as a whole, if it has any impact at all." **DT**

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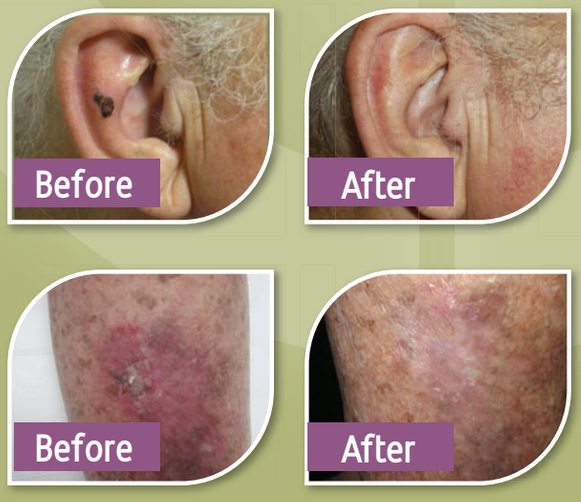

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TRANSPARENCY:

Some physicians fear new policy will distort pay without proper context from page 94

for efforts aimed at improving the quality of healthcare services and with appropriate safeguards."

PAYMENT DATA RELEASED ON 'CASE-BY-CASE' BASIS

Because the policy must undergo a 60-day review process before being published in the 2014 *Federal Register*, how the requests will be made and processed is yet to be determined.

Mr. Blum mentioned physician privacy issues in the post, ensuring that each request for information would be evaluated on a "case-by-case basis.

"As CMS makes a determination about how and when to disclose any information on a physician's Medicare payment, we intend to consider the importance of protecting physicians' privacy and ensuring the accuracy of any data released as well as appropriate protections to limit potential misuse of the information," Mr. Blum wrote.

Shari Erickson, M.P.H., vice president of governmental and regulatory affairs for the American College of Physicians, says the organization will be recommending that CMS establish a review process so that physicians can know if information about them is requested and can review those requests.

"There has to be an appropriate limitation of data. And physicians should be able to review any data before it is published, and any issues concerns should be noted. There should be a lot of safeguards, and we will be advocating for these with CMS," Ms. Erickson says.

However, Judith A. Waltz, partner with Foley & Lardner LLP in San Francisco, says physicians should assume that CMS' new stance on transparency means that it is unlikely information

TRANSPARENCY see page **98**

The rich doctor myth

SOME PHYSICIANS worry that inaccurate use of Medicare payment data will increase the perception that doctors are overpaid and contribute to driving up healthcare costs. Here are some facts on physician pay.

$173,000 - $185,000

Primary care physicians earn barely more annually than the amount they accumulated in debt from medical school, between $173,000 and $185,000

SOURCE: CBS News

$11

During the three to seven years of medical residency, physicians in training who abide by the maximum 80-hour work week mandated by the Joint Commission make about $11 per hour before taxes. Some residents work more than 100 hours per week, making their hourly wage even lower

SOURCE: Philly.com

40,000

"Physicians spend about 40,000 hours training and more than $300,000 on their education, yet the amount of money they earn per hour is only a few dollars more than a high school teacher." — Benjamin Brown, M.D., author, *The Deceptive Income of Physicians*

SOURCE: 85th Medical Economics Continuing Study

32%

When it comes to diabetes care, nearly one-third of physicians say they are unable to provide comprehensive care because of low reimbursement

SOURCE: American Health & Drug Benefits.

6%

Physician practice owners' income decreased by 6 percent between 2011 and 2012

SOURCE: 85th Medical Economics Continuing Study

65%

On average, nonprimary care doctors earn $116,000, or 65 percent more, than primary care doctors

SOURCE: NerdWallet Health

20%

Family physicians spend one-fifth of their time performing activities outside of office visits that are not reimbursed

SOURCE: National Center for Biotechnology Information

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TRANSPARENCY:

Some physicians fear new policy will distort pay without proper context from page 96

requests will be denied. CMS' recent steps towards increasing public transparency include releasing information about the 100 most common inpatient services in May 2013 and average charges for the top 30 outpatient procedures in June 2013.

"In appropriate cases, an agency may give a party whose information is being requested for release a chance to file an objection to the release of information prior to its being released," Ms. Waltz says. "If this opportunity is provided, the party whose information is requested must be able to establish why the requested information fits into an exemption or is otherwise not appropriate for release."

HEALTH PLANS, WATCHDOGS — AND COMPETITORS?

The startup of the Affordable Care Act has brought about swift changes in how insurance companies determine their patient panels. For example, UnitedHealthcare is aiming to narrow its Medicare Advantage network by 15 percent by the end of 2014, and has already attempted to cut 2,250 physicians from its networks in Connecticut alone. Because it isn't clear to physicians why these cuts are being made, some fear that CMS data on individual physicians could become additional fodder for insurance companies looking to narrow their networks.

Dr. Blackwelder says that the AAFP has expressed concern about the "well-documented history of private insurers misusing claims data to profile physicians, deny them reasonable reimbursement, or subject patients to higher out-of-pocket costs." He hopes CMS will release the data to improve quality measures and assist with clinical research.

"If used correctly, this data can provide accurate and meaningful information to patients, physicians, and other stakeholders that can improve quality at the point of care. However, data is just data, and requires appropriate context and interpretation," Dr. Blackwelder says.

There is also the possibility that information about physicians could be requested by competitors, malpractice lawyers or employers to determine the value of a practices, assets, future income, and experience, Ms. Waltz says. It is unlikely that patients themselves will file requests for information, but Ms. Waltz expects that patient advocacy groups, journalists and other whistle-blowers will have the ability to file multiple requests at once to present information to the public.

> "There is also the possibility that information about physicians could be requested by competitors, malpractice lawyers, or employers to determine the value of a practices, assets, future income and experience."
>
> **Judith A. Waltz**
> Foley & Lardner LLP

"Since CMS is going to make individual determinations as to whether to release the information, it seems likely that legal issues going forward will include allegations that CMS has made a wrong call in response to a FOIA request in releasing the information, or that use of the information obtained is somehow improper by whomever is trying to use it," Ms. Waltz says.

MEANINGFUL TRANSPARENCY

A convergence of government agencies aiming to be more transparent, along with more access to physicians through social media and the web ultimately means that physicians will have less privacy from now on.

In some cases, transparency can be helpful to physicians, Ms. Erickson says, citing the trend among practices to have up front pricing for services. According to a 2013 survey by Mass Insight Survey Research Group, 89 percent of Massachusetts patients want to know medical costs up front and more than 70 percent want "useful information" about out-of-pocket costs. Ms. Erickson says this works because physicians have more control over how the data is presented, and it makes a difference to patients.

"It all depends on how well shared and usefully displayed the information is," Ms. Erickson says. "There's a lot of data that is not usable or if it is used by patients, it's not presented in a meaningful way."

Hopefully, information on individual physicians' reimbursement from Medicare won't be used to paint a broader picture that implies that physicians are somehow milking the healthcare system, Dr. Blackwelder says.

"Medicare payment alone does not capture or convey other expenses, including a physician's student loan debt from attending medical school, office rents, malpractice insurance, staff salaries, and energy bills," he says. "Margins are often very thin, and looking at income only does not portray the complete picture, especially from only one payer. And it leaves out expenses, the critical second half of the equation."

Physicians shouldn't fear that the new policy will change the way their patients view them, Dr. Blackwelder says, overall all they want is better care.

"Ultimately, we must ensure that all such policies are part of improving the quality of care patients receive," Dr. Blackwelder says. "We should all be focusing on ensuring that patients get the right care, from the right person in the right place at the right time. If we do this, patients will likely not care too much about this policy." **DT**

Disclosures: Donna Marbury is a content specialist for *Medical Economics*.

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Ways to stay HIPAA-compliant when using mobile devices

Zachary B. Cohen, J.D., and Michael G. DiFiore, J.D.
Contributing Authors

In today's era of smartphones and tablets, the question is no longer whether physicians and their staff members should send text messages containing protected health information (PHI), but rather what is the safest way to do so. Here are some tips practices should consider.

Texting, as compared to emailing, may be very useful in addressing immediate healthcare questions and needs, but it also allows for the flow of fairly unprotected information. Text messages can be forwarded to anyone and, unless deleted, the text message will remain both on the sender's and receiver's devices permanently. Another problem is simple user error, such as choosing the wrong contact in the device's stored contact list.

Practices can take action to prevent unauthorized disclosures. See "Security options," below, for a list of protective measures from the Office of the National Coordinator for Health Information Technology.

OTHER PRECAUTIONS

It is not only prudent, but required, to limit messages to only the information absolutely necessary to accomplish the objective.

> The penalty for one HIPAA violation can result in a fine of up to $50,000, and identical violations can lead to a maximum of $1.5 million in a year.

Furthermore, large database files should never be attached to text messages because these can greatly increase the number of individuals whose information is exposed, which, in turn, greatly increases the potential financial consequences.

Providers are well advised to implement these safeguards when they transfer PHI electronically.

STEEP FINES FOR HIPAA VIOLATIONS

The penalty for one Health Information Portability and Accountability Act (HIPAA) violation can result in a fine of up to $50,000, and identical violations can lead to a maximum fine of $1.5 million in a year. There have been a number of recent enforcement actions against both providers and payers, big and small.

In addition, with the HIPAA rules now applying directly to business associates, the field for potential violations has broadened. In many instances, the violations resulted from loss or misuse of portable devices. The Office for Civil Rights expects full compliance on HIPAA security. Providers should consider themselves on notice. **DT**

Disclosures: Zachary B. Cohen, J.D., and Michael G. DiFiore, J.D., are associates at Garfunkel Wild, P.C. in Great Neck, N.Y.

Security options

Passwords: A simple and inexpensive way to prevent unauthorized access to or use of any device. Merely password-protecting the device does not negate certain reporting obligations that may arise under federal or state law if the device is lost or stolen.

Remote wiping: There are a variety of applications and software that can be installed on a device that allow the device owner to erase data from the device remotely in the event it is lost or stolen. Remote wiping may obviate the state and federal reporting obligations depending on how quickly the device is wiped.

Encryption: This technique adds an additional layer of security. Under the Health Information Portability and Accountability Act (HIPAA), entities have various obligations regarding an unsecured breach of PHI. However, if the PHI is correctly encrypted, the PHI is secured and the same obligations no longer apply.

Secured networks: This avoids interception by unauthorized users.

Delete PHI: Immediate removal of PHI from devices clearly avoids access by unintended recipients. Additionally, when discarding or returning the device to a telecommunications provider, all PHI stored on the device must be erased. **DT**

A Cure for Common ICD-10-dinitis

ICD-10-dinitis: A stress-related disease afflicting doctors and caused by inadequate solutions for ICD-10, resulting in lost reimbursements and time. Symptoms include number fatigue, extension nausea, crosswalk vertigo, diagnosis pointer pain and superbill depression.

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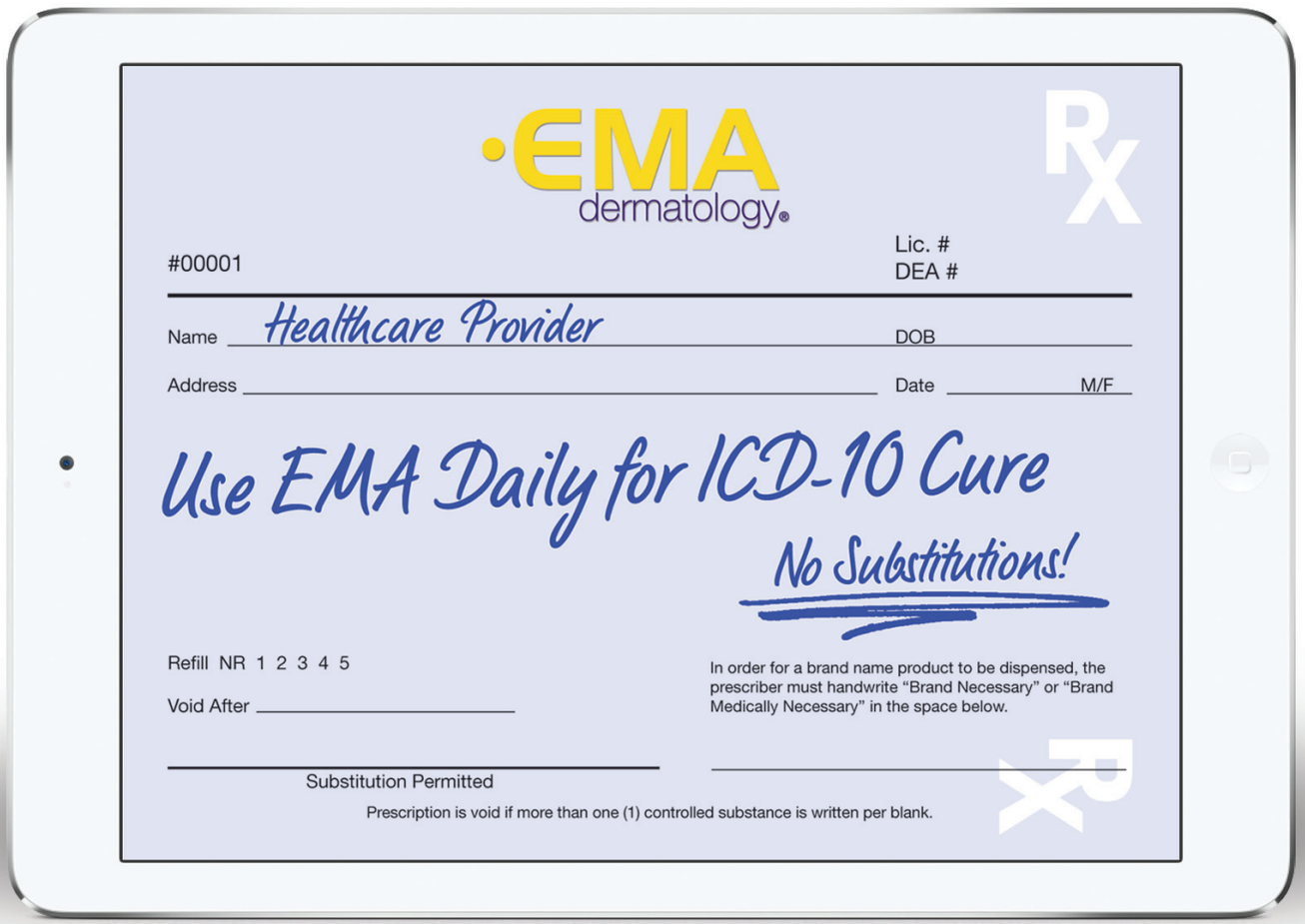

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Jan Mohamed, C.F.P. is president, ConfidentVision. Michael Berry, Ch.F.C., is principal, Flagpole Capital LLC & MSF LLC and director of financial service, Daktori. They are founding members of the Daktori Financial Fellowship and co-authors of the 2014 update to "The Physician's Money Manual" (available in June). Mr. Mohamed lives in Dallas. Mr. Berry lives in Western Connecticut. They can both be reached at (855) 325-8674.

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Income above this specific amount (it changes annually, and with other circumstances. Consult an adviser) is disregarded for calculating retirement plan contributions you may make. If you are a high earner, would like to save more than thousands per year for your post-retirement living expenses? There are choices available.

CATCH-UP PLAN

Defined benefit pension plans and *cash balance plans* offer high-income taxpayers an opportunity to contribute $200,000 to $300,000 per year under certain circumstances. The idea behind this type of planning is that it allows for larger contributions for people who need to "catch up"[1] on post-retirement saving.

A defined benefit catch-up plan could work for you if:

- You are at least 45 years old; or
- You started saving for retirement very recently (or are about to start); or
- You lost some or all of your retirement plan in a divorce; or
- You had to take a withdrawal from your retirement plan for any reason; or
- You converted your old retirement plan to an IRA or Roth IRA; or
- You made some bad investments and lost money in your retirement plan; or
- You had to file bankruptcy; or
- You lost a lawsuit and judgment (including a divorce).

There are many reasons to utilize the retirement catch-up provisions.[1] For instance, the increased retirement plan contributions not only help save for retirement, but they also reduce taxable income and put your funds into a vehicle that is statutorily protected from creditors.

NUMBERS DON'T LIE

In 2014, someone under age 50 can defer $17,500 into a 401(k) plan and someone over 50 can put away $23,000[2]. With matching and profit-sharing plan contributions, the total can be increased to $52,000 for someone under 50 and as much as $57,500 for taxpayers who are over 50.

In comparison, a doctor in her mid-50s could contribute and deduct more than $200,000 in a properly designed defined benefit or cash balance plan. This provides an opportunity for the soon-to-be-retiree to turbo-charge his or her retirement.

Defined benefit and cash balance plans have become much more popular since the Pension Protection Act of 2006. The act did several things to help make these plans more appealing. First, the act clarified the legality of cash balance plans. Secondly, the Pension Protection Act explained how a company, such as a medical practice, might be able to sponsor both a 401(k) profit sharing and a defined benefit

Plan and take advantage of the unique characteristics of each scenario, and benefit from the combination of the two. With the help of a financial adviser, the Pension Protection Act of 2006 (PPA) can help you to cross test the benefit from both types of plans and be able to weight the contributions in a way that most significantly supports the plan beneficiaries.

ADDITIONAL BENEFITS

For families that purchase term life insurance with after-tax dollars, there is an additional savings opportunity. Many retirement plans allow the participant to buy insurance with pre-tax dollars and only pay a small tax each year. The advantage is that the death benefit from the insurance will go to the spouse *income tax-free*.

This is a great way to create an instant estate and to provide tax-free dollars to a surviving spouse from your retirement plan. Additional tax-efficient opportunities with retirement plans, nonqualified plans, and risk-management arrangements are more popular than ever, but those are outside the scope of this article. Find physician-focused adviser in your area at www.daktori.com/contact-us.

To learn more ways to reduce unnecessary taxes while improving your retirement and risk management planning, consider ordering the authors' new book, *The Physician's Money Manual*, at Amazon.com or iBookstore.com for $49. You may also receive a free copy of the book by subscribing to the authors' newsletter at www.daktori.com/free-book/today. **DT**

References

1. Actuarial calculations provided by Senex.
2. Limits are under IRC 415 of the code. See: http://www.irs.gov/uac/IRS-Announces-2014-Pension-Plan-Limitations;-Taxpayers-May-Contribute-up-to-$17,500-to-their-401(k)-plans-in-2014 (as of 2/13/14) for more information

FREE CME offer: Dermatologists can receive 7.5 hours of category I CME credits in risk management by signing up for the financial fellowship newsletter at www.daktori.com/free-book/. *Michael Berry is a co-author of* The Physician's Money Manual. *Along with Mr. Berry (of Connecticut), Jan Mohamed (of Texas) and four other members of the Daktori Financial Fellowship have been named "2013 Best Financial Advisers for Physicians" by* Medical Economics. *Jan Mohamed is a registered investment adviser of securities and advisory services offered through Brokers International Financial Services are offered through Brokers International Financial Services, Panora, IA, Member FINRA/SIPC. Mr. Mohamed of Dallas has more than 30 years of experience working with physicians and high-income business owners. Brokers International Financial Services, and Daktori are not affiliated companies. For more information about speaking engagements or consulting services, contact Daktori communications director, John Henry Dreyfuss at 917-520-4192.*

Aczone® (dapsone) gel, 5%

Start with ACZONE®

Because there's strength in balance

Discover the efficacy and tolerability of ACZONE® Gel for acne

Patients saw continued improvement in their acne through week 12[1,2]

Less than 1% of patients had severe erythema, dryness, or oiliness/peeling in studies that evaluated safety[2]

BASELINE

WEEK 12*

Day 1
Prescribe ACZONE® Gel twice daily at first visit

Week 4
Their acne didn't get worse before it got better[1]

Week 12
Patients stayed on treatment (1% discontinued due to treatment-related factors)[1]

*Illustration of clearing. Actual results may vary.

INDICATION

ACZONE® (dapsone) Gel 5% is indicated for the topical treatment of acne vulgaris.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hematological effects: Oral dapsone treatment has produced dose-related hemolysis and hemolytic anemia. Individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency are more prone to hemolysis with the use of certain drugs. There was no evidence of clinically relevant hemolysis or anemia in patients treated with ACZONE® Gel 5%, including patients who were G6PD deficient. Some subjects with G6PD deficiency using ACZONE® Gel 5% developed laboratory changes suggestive of mild hemolysis.

If signs and symptoms suggestive of hemolytic anemia occur, ACZONE® Gel 5% should be discontinued. ACZONE® Gel 5% should not be used in patients who are taking oral dapsone or antimalarial medications because of the potential for hemolytic reactions. Combination of ACZONE® Gel 5% with trimethoprim/sulfamethoxazole (TMP/SMX) may increase the likelihood of hemolysis in patients with G6PD deficiency.

Peripheral neuropathy: Peripheral neuropathy (motor loss and muscle weakness) has been reported with oral dapsone treatment. No events of peripheral neuropathy were observed in clinical trials with topical ACZONE® Gel 5% treatment.

Skin: Skin reactions (toxic epidermal necrolysis, erythema multiforme, morbilliform and scarlatiniform reactions, bullous and exfoliative dermatitis, erythema nodosum, and urticaria) have been reported with oral dapsone treatment. These types of skin reactions were not observed in clinical trials with topical ACZONE® Gel 5% treatment.

ADVERSE REACTIONS

The most common adverse reactions of ACZONE® Gel 5% (incidence ≥ 10%) are oiliness/peeling, dryness, and erythema at the application site.

DRUG INTERACTIONS

Topical application of ACZONE® Gel followed by benzoyl peroxide in subjects with acne vulgaris resulted in a temporary local yellow or orange discoloration of the skin and facial hair (reported by 7 out of 95 subjects in a clinical study) with resolution in 4 to 57 days.

Please see Brief Summary of full Prescribing Information on the reverse page.

References: 1. Draelos ZD, Carter E, Maloney JM, et al; for United States /Canada Dapsone Gel Study Group. Two randomized studies demonstrate the efficacy and safety of dapsone gel, 5% for the treatment of acne vulgaris. *J Am Acad Dermatol.* 2007;56(3):439.e1-439.e10. **2.** ACZONE® Prescribing Information.

ALLERGAN Medical Dermatology

www.aczone.com APC45DP14 | 133187

ACZONE® (dapsone) Gel 5%

INDICATIONS AND USAGE

ACZONE® Gel, 5%, is indicated for the topical treatment of acne vulgaris.

DOSAGE AND ADMINISTRATION

For topical use only. Not for oral, ophthalmic, or intravaginal use. After the skin is gently washed and patted dry, apply approximately a pea-sized amount of **ACZONE®** Gel, 5%, in a thin layer to the acne affected areas twice daily. Rub in **ACZONE®** Gel, 5%, gently and completely. **ACZONE®** Gel, 5%, is gritty with visible drug substance particles. Wash hands after application of **ACZONE®** Gel, 5%.

If there is no improvement after 12 weeks, treatment with **ACZONE®** Gel, 5%, should be reassessed.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Hematological Effects

Oral dapsone treatment has produced dose-related hemolysis and hemolytic anemia. Individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency are more prone to hemolysis with the use of certain drugs. G6PD deficiency is most prevalent in populations of African, South Asian, Middle Eastern, and Mediterranean ancestry.

There was no evidence of clinically relevant hemolysis or anemia in patients treated with **ACZONE®** Gel, 5%, including patients who were G6PD deficient. Some subjects with G6PD deficiency using **ACZONE®** Gel developed laboratory changes suggestive of mild hemolysis.

If signs and symptoms suggestive of hemolytic anemia occur, **ACZONE®** Gel, 5% should be discontinued. **ACZONE®** Gel, 5% should not be used in patients who are taking oral dapsone or antimalarial medications because of the potential for hemolytic reactions. Combination of **ACZONE®** Gel, 5%, with trimethoprim/sulfamethoxazole (TMP/SMX) may increase the likelihood of hemolysis in patients with G6PD deficiency.

Peripheral Neuropathy

Peripheral neuropathy (motor loss and muscle weakness) has been reported with oral dapsone treatment. No events of peripheral neuropathy were observed in clinical trials with topical **ACZONE®** Gel, 5% treatment.

Skin

Skin reactions (toxic epidermal necrolysis, erythema multiforme, morbilliform and scarlatiniform reactions, bullous and exfoliative dermatitis, erythema nodosum, and urticaria) have been reported with oral dapsone treatment. These types of skin reactions were not observed in clinical trials with topical **ACZONE®** Gel, 5% treatment.

ADVERSE REACTIONS

Clinical Studies Experience

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

Serious adverse reactions reported in patients treated with **ACZONE®** Gel, 5%, during clinical trials included but were not limited to the following:

- Nervous system/Psychiatric – Suicide attempt, tonic clonic movements.
- Gastrointestinal – Abdominal pain, severe vomiting, pancreatitis.
- Other – Severe pharyngitis

In the clinical trials, a total of 12 out of 4032 patients were reported to have depression (3 of 1660 treated with vehicle and 9 of 2372 treated with **ACZONE®** Gel, 5%). Psychosis was reported in 2 of 2372 patients treated with **ACZONE®** Gel, 5%, and in 0 of 1660 patients treated with vehicle.

Combined contact sensitization/irritation studies with **ACZONE®** Gel, 5%, in 253 healthy subjects resulted in at least 3 subjects with moderate erythema. **ACZONE®** Gel, 5%, did not induce phototoxicity or photoallergy in human dermal safety studies.

ACZONE® Gel, 5%, was evaluated for 12 weeks in four controlled studies for local cutaneous events in 1819 patients. The most common events reported from these studies include oiliness/peeling, dryness, and erythema.

One patient treated with **ACZONE®** Gel in the clinical trials had facial swelling which led to discontinuation of medication.

In addition, 486 patients were evaluated in a 12 month safety study. The adverse event profile in this study was consistent with that observed in the vehicle-controlled studies.

Experience with Oral Use of Dapsone

Although not observed in the clinical trials with **ACZONE®** Gel (topical dapsone) serious adverse reactions have been reported with oral use of dapsone, including agranulocytosis, hemolytic anemia, peripheral neuropathy (motor loss and muscle weakness), and skin reactions (toxic epidermal necrolysis, erythema multiforme, morbilliform and scarlatiniform reactions, bullous and exfoliative dermatitis, erythema nodosum, and urticaria).

DRUG INTERACTIONS

Trimethoprim-Sulfamethoxazole

A drug-drug interaction study evaluated the effect of the use of **ACZONE®** Gel, 5%, in combination with double strength (160 mg/800 mg) trimethoprim-sulfamethoxazole (TMP/SMX). During co-administration, systemic levels of TMP and SMX were essentially unchanged. However, levels of dapsone and its metabolites increased in the presence of TMP/SMX. Systemic exposure (AUC_{0-12}) of dapsone and N-acetyl-dapsone (NAD) were increased by about 40% and 20% respectively in the presence of TMP/SMX. Notably, systemic exposure (AUC_{0-12}) of dapsone hydroxylamine (DHA) was more than doubled in the presence of TMP/SMX. Exposure from the proposed topical dose is about 1% of that from the 100 mg oral dose, even when co-administered with TMP/SMX.

Topical Benzoyl Peroxide

Topical application of **ACZONE®** Gel followed by benzoyl peroxide in subjects with acne vulgaris resulted in a temporary local yellow or orange discoloration of the skin and facial hair (reported by 7 out of 95 subjects in a clinical study) with resolution in 4 to 57 days.

Drug Interactions with Oral Dapsone

Certain concomitant medications (such as rifampin, anticonvulsants, St. John's wort) may increase the formation of dapsone hydroxylamine, a metabolite of dapsone associated with hemolysis. With oral dapsone treatment, folic acid antagonists such as pyrimethamine have been noted to possibly increase the likelihood of hematologic reactions.

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic Effects: Pregnancy Category C

There are no adequate and well controlled studies in pregnant women. Dapsone has been shown to have an embryocidal effect in rats and rabbits when administered orally in doses of 75 mg/kg/day and 150 mg/kg/day (approximately 800 and 500 times the systemic exposure observed in human females as a result of use of the maximum recommended topical dose, based on AUC comparisons), respectively. These effects were probably secondary to maternal toxicity. **ACZONE®** Gel, 5%, should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Although systemic absorption of dapsone following topical application of **ACZONE®** Gel, 5%, is minimal relative to oral dapsone administration, it is known that dapsone is excreted in human milk. Because of the potential for oral dapsone to cause adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue **ACZONE®** Gel, 5%, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and efficacy was evaluated in 1169 children aged 12-17 years old treated with **ACZONE®** Gel, 5%, in the clinical studies. The adverse event rate for **ACZONE®** Gel, 5%, was similar to the vehicle control group. Safety and efficacy was not studied in pediatric patients less than 12 years of age, therefore **ACZONE®** Gel, 5%, is not recommended for use in this age group.

Geriatric Use

Clinical studies of **ACZONE®** Gel, 5%, did not include sufficient number of patients aged 65 and over to determine whether they respond differently from younger patients.

G6PD Deficiency

ACZONE® Gel, 5% and vehicle were evaluated in a randomized, double-blind, cross-over design clinical study of 64 patients with G6PD deficiency and acne vulgaris. Subjects were Black (88%), Asian (6%), Hispanic (2%) or of other racial origin (5%). Blood samples were taken at Baseline, Week 2, and Week 12 during both vehicle and **ACZONE®** Gel, 5% treatment periods. There were 56 out of 64 subjects who had a Week 2 blood draw and applied at least 50% of treatment applications. **ACZONE®** Gel was associated with a 0.32 g/dL drop in hemoglobin after two weeks of treatment, but hemoglobin levels generally returned to baseline levels at Week 12.

There were no changes from baseline in haptoglobin or lactate dehydrogenase during **ACZONE®** or vehicle treatment at either the 2-week or 12-week time point.

The proportion of subjects who experienced decreases in hemoglobin ≥1 g/dL was similar between **ACZONE®** Gel, 5% and vehicle treatment (8 of 58 subjects had such decreases during **ACZONE®** treatment compared to 7 of 56 subjects during vehicle treatment among subjects with at least one on-treatment hemoglobin assessment). Subgroups based on gender, race, or G6PD enzyme activity did not display any differences in laboratory results from the overall study group. There was no evidence of clinically significant hemolytic anemia in this study. Some of these subjects developed laboratory changes suggestive of mild hemolysis.

OVERDOSAGE

ACZONE® Gel, 5%, is not for oral use. If oral ingestion occurs, medical advice should be sought.

Rx ONLY

U.S. Patents 5,863,560; 6,060,085; and 6,620,435
Based on 72205US13

Analyze cost, usability features carefully when considering EHR switch

Derek Kosiorek, CPEHR, CPHIT | Contributing author

USE THE EXPERIENCE your practice gained during its first EHR implementation to make your new system work for you.

Once upon a time, a practice management system was the major software purchase for a medical practice. It required significant money, a detailed analysis of work flows, lots of interfaces, extensive training, and a genuine fear of such a system controlling so much information that was vital to the practice. And that was just for the billing system.

Now that we have electronic health record (EHR) systems, the game has changed dramatically. There are very few areas of a medical practice that aren't completely reliant on EHR systems. This makes it vital to have one that works well.

With EHR satisfaction falling at an alarming rate (see "EHRs: The real story," page 80), it's no surprise that practices are beginning to look at replacing their systems. An EHR is nothing more than a tool to manage information. If the tool doesn't do it's job, it's time to get a new one.

Of course, dissatisfaction is only one of many reasons that a practice may need or desire to change its EHR system. Mergers and acquisitions often result in vendors phasing out or reducing support for existing software. A practice's growth can render a system unusable. Organizational relationships with a new group or hospital may make a change more attractive or beneficial to a practice.

Still, the main reason why practices change systems is because the current software is deemed too difficult or impractical to use, and it is hurting productivity or substantially increasing physician time to process patient data.

If you are thinking of changing EHR systems, let's look at some questions you'll need to ask to ensure a successful new EHR implementation.

WHERE IS THE DATA?

A current industry buzzword is "cloud computing," which is the practice of keeping your practice's data and information off-site somewhere and accessible via the Internet. But even that term can mean different things depending on various factors. Your system will take on one of three different profiles.

The first is the traditional practice of installing a server or servers in your office and having all computers and locations work with the data on that server. With this method, it is the practice's responsibility to maintain the hardware and all connections to that hardware, including from remote sites and employees working from home. Many practices prefer the inherent security that comes with this setup.

In most cases, however, EHR systems are "cloud-hosted," which means the server equipment is located at a facility approved by the vendor. All computers and devices connect to this server remotely, whether they are in your office, at home, or on the road.

Responsibility for maintaining the servers varies depending on the nature of the contract, but most vendors will take on this role. The benefit of this setup is the ability to free up physical space on site and allow the IT staff to focus on other areas of need, or simply reduce the need for IT staff.

A more complicated way to use the cloud is referred to as Software as a Service (SaaS). This is currently the most common way software is built in other industries and for consumer needs. The software is usually run through an Internet Web browser, which means access is achieved from any device on the Internet by entering a user name and password. A good example is Internet-based email. Your username/password gets you access, and the user interface is through a Web browser.

The best setup depends on your preferences and needs. Most software experts agree that SaaS is where all software is moving, but very few EHR vendors offer this arrangement now.

WHAT WILL IT COST?

Costs vary greatly and depend on many factors, including the number of staff and office locations and the unique circumstances of your technical infrastructure needs.

SWITCH see page **106**

Ensuring a successful EHR switch

☑ SET GOALS:
Practices switching EHR systems must have clear expectations for what the system will do. Set specific goals for what you want to be happening with your software in the coming 12 to 18 months.

☑ LESSON LEARNED:
What could be improved from the last install? Did your staff receive enough training? Were the right computers and equipment purchased? Were alerts set properly?

☑ NEW TECHNOLOGIES
Analyze new ways of doing things when making major changes to your practice. From cloud solutions to mobile devices to remote access, make sure you do the research, and find the most efficient methods to operate your practice.

SWITCH:

How to implement your new EHR successfully from page 105

I have seen a great many EHR contracts, and I'm convinced that vendors like the fact that pricing structures vary so much. For example, some are based on licenses per doctor, some based on licenses per user, and others are based on how many devices or workstations are accessing the product.

The best way to compare pricing in an "apples to apples" way is to group the various proposals you are considering into four areas: software costs, third party costs, implementation costs, and annual maintenance costs.

Putting all costs and fees into these groups will enable you to make a much more accurate comparison of what the final costs to your practice will be.

If you are looking at a subscription-based model for one of your vendor candidates, add up the total cost over five or seven years, then compare it to the total cost for the other systems.

HOW DO I AVOID THE SAME PROBLEMS?

Many medical groups go into an EHR implementation without having clear expectations of what the EHR will do. If you were building a house, you wouldn't start throwing bricks on the ground and hope a functional house is the result. So why do it for software that may cost just as much as the house?

The most important step is to set specific goals for what you want your software to accomplish in the coming 12 to 18 months. Do you want a system that will help you improve productivity levels? Do you want to reduce patient wait times? Do you want to improve physician satisfaction? How about fewer errors? It may even be that you want employees complaining less.

The point is to set measurable goals so you can revisit them after the implementation so you can decide if the system is meeting your expectations. If you can measure the outcomes, you can determine the level of success after the project is over.

Other questions that should be asked about your last installation include whether your staff received enough training, whether the right computers and equipment were purchased, and whether the alerts were set to trigger at the right times and frequency.

Remember, it is just as important to keep in mind what went right as it is what went wrong. What functionality do you want to preserve in the next generation of your EHR?

Shopping for an EHR system

Use the following tips as you evaluate systems:

Vet the vendor

- Check referrals and references.
- What is the vendor's experience? How many installs and client types? How many providers and sites per business entity?
- Does the vendor have certified products for 2011 and 2014?

Vet the system

- Identify the number of installs (business entities) and physicians and nonphysician practitioners that have used the system.
- Break out the numbers by specialty and ownership type (private owned, hospital/IDS owned).
- Is this an integrated EHR with a practice management (PM) component? Or is the PM interfaced with an EHR (were these two separate products that are "married"?)
- If considering just an EHR product, get the details on what PM products interface with the EHR and what is required (cost- and process-wise) to implement and maintain bi-directional integration.
- Find out how long the EHR system has been in in active use

Ownership history

- Any mergers?
- Does the company own other products? What are they?
- Is the EHR product the owner's primary source of business?

See the EHR in action

- Observe in as much detail as possible other practices (at least three practices, if possible) using the system.

Source: Gail Levy, M.A., and Kathryn Moghadas, RN, CLRM, CHBC, CHCC, CPC

The true costs of EHR systems

Experts advise physicians to analyze all of the costs associated with a new system if they are implementing for the first time or changing vendors.

The analysis should include:

- **Hardware:** desktop computers, tablets/laptops, database servers, printers, and scanners
- **EHR software:** Potential costs include EHR application, interface modules, and upgrades.
- **IT support:** Implementation assistance costs could include an IT contractor, attorney, electrician, and/or consultant support; chart conversion; hardware/network installation; and workflow redesign support.
- **Training in how to use the EHR** and associated hardware, and how the EHR will create new work flows.
- **Ongoing network fees and maintenance:** Potential ongoing costs include hardware and software license maintenance agreements, contining staff education, telecom fees, and IT support fees. Some practices may need to hire IT operations staff, clinical data analysts, or application analysts. There may also be associated fees to access or transfer your data.

voice of the dermatologist

"Making patients aware of your services is a key first step in getting them to use your services."

H.L. Greenberg, M.D., Las Vegas
See story, page 78

BE AWARE OF NEW TECHNOLOGIES

By it's nature, technology evolves quickly. When looking at making major changes to your practice, it's important to consider the newer ways of doing things.

The cloud is offering benefits that were not conceived just a few years ago. Do your doctors or nurses want touchscreen tablets to carry around the office rather than laptops or fixed PCs? It's possible now. What method of remote access will you need to gain access to the system? Do the research and find the most efficient methods.

Whatever system you select, make sure that you plan to open your Internet portal so that patients can access their personal health information. There are many reasons to do this, because not having a portal will be a detriment to your practice in the coming years.

If you don't yet have a patient portal, you can be sure your competitors will.

IT GETS EASIER

Considering the effort you put into implementing your first EHR, you may think that doing it the second time around will be difficult.

Believe it or not, however, it may actually be easier on your practice and your staff members. Your employees are now used to the changes that came from moving from paper to computer, so that hurdle has been overcome. Having a first go-around with an EHR system means your practice will be more knowledgeable about what it needs in an EHR system, and what questions need answers before committing to a new vendor. **DT**

Derek Kosiorek, CPEHR, CPHIT, is a principal consultant for MGMA Health Care Consulting Group. He specializes in evaluating and implementing technology solutions for healthcare organizations.

A sample of what your colleagues learned at MauiDerm 2014

5 CLINICAL PEARLS FOR TREATING FACIAL ACTINIC KERATOSES

At the MauiDerm 2014 meeting, conference organizer George Martin, M.D., shared five clinical pearls for treating facial actinic keratosis (AK).

1 Phase 3 data on 0.5 percent 5-fluorouracil (5-FU) showed that one week of daily use of 0.5 percent 5-FU cleared nearly 75 percent of individual AKs. Try: 0.5 percent 5-FU QD x one week, wait one month, then follow with two to three weeks QD application to "clean up" remaining AKs. This regiment has gained widespread acceptance by patients and physicians as a more tolerable field therapy. The 5 percent 5-FU BID is equivalent to 0.5 percent 5-FU and can be used interchangeably.

2 Ingenol mebutate 0.015 percent applied nightly x3 has been a remarkably effective therapy with great patient compliance. However, its Food and Drug Administration approval was for limited areas (25 cm^2). As a full-face therapy, it appears very effective; however, controlled studies on "full-face" clearance/efficacy is lacking. Patients need to be counseled that they will experience a "chemical peel" effect with burning and stinging beginning four hours after application. This is due to its MOA, which includes a direct cytotoxic effect. Analgesia is generally required. Clinically, we have observed while treating full-face, a selectivity of ingenol mebutate for AKs with minimally affected areas between the AK lesions.

3 If you perform photodynamic therapy (PDT) in your practice and use one- to three-hour aminolevulinic acid (ALA) incubation periods, recent phase 2 studies from DUSA Pharmaceuticals show that one-, two- or three-hour incubation periods are roughly equally efficacious but require two treatments eight weeks apart for most patients to achieve > 70 percent individual lesion clearance. To maximize the efficacy of a one-hour incubation, consider pretreating with 5-FU for one week to the face or 10 days to the scalp, and then perform a one-hour ALA incubation.

This combination will eliminate the need for a second PDT. For those patients with refractory facial AKs, consider pretreating for seven days with 3.75 percent imiquimod followed by ALA PDT (one- to three-hour incubation). Excellent long-term results (18 months) have been observed when destructive techniques such as PDT are combined with immune modulators.

4 Can ALA PDT be painless? Try incubating for 15 minutes with ALA and then place the patient under the blue light for one hour. Preliminary results (G. Martin MD) demonstrate that ALA PDT as monotherapy or in combination with 5-FU or 3.75 percent imiquimod is, in fact, "painless." Large-scale studies are warranted to determine efficacy.

5 The use of 3.75 percent imiquimod for diffuse facial AKs while effective, results in substantial downtime of nearly six weeks. Consider 3.75 percent imiquimod QD x7 days, two weeks' rest, then Q weekly. There will be some initial unsightliness but chronic immune stimulation (> 1 year) appears to be helpful in limiting AK recurrences and may prove over time to inhibit the development of invasive squamous cell carcinoma

BEWARE OF FAKE TOXINS

Michael Gold, M.D., at the MauiDerm 2014 conference shared his insight into the world of fake botulinum toxins. There is a huge counterfeit market, he said. It behooves dermatologists to be aware, because the phony products are easily acquired over the Internet or purchased overseas and carried into the United States. These fake products look exactly like their legitimate counterparts, and the consequences of acquiring and using such products can be highly detrimental to patients — not to mention, it's illegal to use fake products.


Dr. Gold

While the United States does not have the most incidents of pharmaceutical crime, it ranks high, according to a new Pharmaceutical Security Institute that is studying the threat of counterfeit products and how to control the problem.

Risks clinicians can take with fake products include:

- Contamination — products could carry unknown, harmful pathogens;
- Unknown origination — products are untraceable to any manufacturer;
- Uncontrolled — there is no quality assurance;
- Fluctuant potency — products are not standardized, which could lead to unwanted side effects and death;
- It's illegal.

NEUROMODULATORS NOT EQUAL

Joel Cohen, M.D., explained to attendees at MauiDerm 2014 the differences among the three approved botulinum toxin products and how to use them successfully to take advantage of their unique properties.


Dr. Cohen

Dr. Cohen recommended that doctors really think about these products as unique and begin to use them for their individual properties. They're not interchangeable, he said. Conversion factors are inadequate, studies have found, so there's no perfect conversion ratio. And it's very difficult to make direct comparisons between products because studies have been designed differently, there has been an evolution of endpoints and study design may lead to limitations in how you are able to interpret the data.

In comparing studies, clinicians run into challenges in that endpoints are changing. The Food and Drug Administration now requires a two-grade composite improvement in which both the physician and the patient agree there is a two-grade improvement.

So there are different criteria being used, according to Dr. Cohen, director of AboutSkin Dermatology and Derm-Surgery, Englewood Colo. Also, there are differences in technique between what is used in FDA pivotal studies and what physicians probably do in their practices, he said. Often the studies stick to very specific dosing, but in a medical practice, a study dose may not

MAUIDERM 2014 see page 110

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MAUIDERM 2014:

A sample of what your colleagues learned from page 108

be warranted for a particular patient. Dr. Cohen said he tapers according to the patient's musculature.

Additionally, he advised dermatologists to:

- Avoid multiple modalities in the same day because side effects of one treatment may impact the results of another.
- Avoid combining products in one syringe due to a lack of standardization in the reconstitution process, which could lead to unwanted effects.
- There is good data on combination therapies on different days, however, and these can be very effective, he said.
- Approach each patient differently. Treat by region for a specific goal, rather than by a standardized treatment protocol.

When used properly, studies have shown that neuromodulators can improve a person's quality of life through improved self-esteem. Educating yourself on the properties of the individual products, the data and then using that information to make educated decisions in how you approach your practice can make for successful outcomes.

THE PURPOSE OF AESTHETICS

We're learning more about the aging process and how it occurs at different levels: from the surface of the skin, all the way down to the bony structure. Our purpose in aesthetics is to understand this process and to work with it to highlight the natural beauty of an individual, Ava Shamban, M.D., told attendees at the MauiDerm 2014 meeting.

Beauty is an experience of sight, smell and sound. We, as purveyors of beauty, want to make sure that everything that we do on the face makes the face memorable, Dr. Shamban said. She explained her concept of the Signature Feature and how to use it for a successful aesthetic outcome.

Culturally, our concept of aging is being redefined, Dr. Shamban said. Our ideas have changed about what is normal, possible and expected of our health and quality of life. People want to look and feel better longer. And a lot of literature exists to support that the way a person looks really affects how they feel.

So the purpose of aesthetics is to enhance an individual's natural beauty, said Dr. Shamban, assistant clinical professor of dermatology at the UCLA-Geffen School of Medicine, and owner and director of AVA MD, Santa Monica and Beverly Hills, Calif. We can do that by individually assessing each patient based on his or her natural attributes, combining that with cultural aesthetics, and marrying that with the universal aesthetic.

These ideas form the basis of what Dr. Shamban calls the Signature Feature concept.

Everyone has a signature feature:

- It's a natural feature of the face that's particularly arresting: eyes, mouth, nose, hair, etc. It's the first thing you notice about someone and you can use the blink test to pick it out, she said.
- The signature feature ties to who the person is; their persona.
- Increasing the signal to noise ratio by reducing the background noise, you can highlight that natural feature.

Follow more coverage at: dermatologytimes.com/mauiderm-2014

upcoming events

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

34th Annual ASLMS Conference
www.aslms.org
April 2-6, 2014
Phoenix Convention Center
Phoenix

State-of-the-Art in Facial Aesthetics 2014
www.ffasurg.org
April 9-13, 2014
Intercontinental Hotel Buckhead
Atlanta

South Carolina Dermatological Association Annual Meeting
www.scda-assn.org
April 11-12, 2014
DoubleTree Hotel
Charleston, S.C.

Icahn School of Medicine Advances in Facial Reconstruction & Cosmetic Surgery
cosmeticcadaverworkshop.com
April 12-13, 2014
Mount Sinai Medical Center
New York

ASDS - The Art & Science of Soft-Tissue Fillers and Neuromodulators
www.asds.net/Fillers
April 12-13, 2014
Loews Philadelphia Hotel
Philadelphia

European Workshop on Skin Immune Mediated Inflammatory Diseases
www.simid2014.org
April 24-26, 2014
Conference Centre Veronafiere
Verona, Italy

FSDDS 2014 Annual Meeting
www.fsdds.org
April 25-27, 2014
Disney's Contemporary Resort
Lake Buena Vista, Fla.

American College of Mohs Surgery 46th Annual Meeting
www.mohscollege.com
May 1-4, 2014
JW Marriott Desert Ridge
Phoenix

Society for Investigative Dermatology Annual Meeting
www.sidnet.org
May 7-10, 2014
Albuquerque Convention Center
Albuquerque, N.M.

Montreal Dermatological Society 91st Atlantic Dermatological Conference
www.atlanticderm.org/ad/
May 9-11, 2014
Le Centre Sheraton Montreal
Montreal

Australasian College of Dermatologists Annual Scientific Meeting
www.dermcoll.asn.au
May 18-21, 2014
Melbourne Convention and Exhibition Centre
Melbourne, Australia

Alabama Dermatology Society Seminar in the City
alabamaderm.org
May 23-26, 2014
Hilton Hotel at Times Square
New York

Summit in Aesthetic Medicine 2014
www.globalacademycme.com
June 6-7, 2014
St. Regis Monarch Beach Resort
Dana Point, Calif.

Georgia Society of Dermatology and Dermatological Surgery 59th Annual Meeting
www.gaderm.org
June 6-8, 2014
Grove Park Inn
Asheville, N.C.

Cosmetic Bootcamp Summer Meeting
www.cosmeticbootcamp.com
June 12-15, 2014
St. Regis Aspen Resort
Aspen, Colo.

European Society of Pediatric Dermatology 12th ESPD Congress
www.espd2014.com
June 12-14, 2014
Kieler Schloss
Kiel, Germany

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API HD camera provides streaming capabilities

THE V.I.O. STREAM camera combines a native high-defnition (HD) sensor with advanced exposure controls and settings to create high-quality video under both optimal and challenging light conditions, the company states. Designed for seamless integration, the V.I.O. Stream is a RTSP-(real-time streaming protocol) enabled device capable of streaming full HD 1080 wirelessly or via IP over USB. The device is waterproof, dustproof, and shockproof — ideal for monitoring, surgery and checkups. Complete control of Stream and its features is possible from any browser-based device. It can also be configured as an access point or client to existing networks, and meld with other devices. Stream is both wearable and capable of being integrated, offering a variety of static or body-worn mounting options.

EXTREME TECHNOLOGIES
vio-pov.com/stream

NIGHT CONCENTRATE BOOSTS SKIN'S DEFENSE SYSTEM

RESVERATROL B E by SkinCeuticals is an antioxidant night concentrate that works to repair and prevent accumulated damage in the skin, the company states. It contains a maximized concentration of 1 percent pure soluble resveratrol that is enhanced with baicalin and vitamin E, to allow for greater antioxidant protection.

The company says its has developed an innovative, patent-pending delivery system to solubilizes a high concentration of resveratrol in an aqueous formulation. The product has undergone testing in 55 female patients with mild-to-moderate hyperpigmentation, skin laxity, lines and wrinkles. Resveratrol B E reportedly improved skin radiance, elasticity, firmness and smoothness after 12 weeks. The product will be available at physician offices.

SKINCEUTICALS
www.skinceuticals.com

PLATFORM GIVES PAYMENT SOLUTION FOR PATIENTS

VECNA,a provider of patient self-service solutions, and Meridian Medical Management (M3) — a provider of revenue cycle and system integration services — have partnered up to deliver a complete end-to-end patient registration and payment solution.

Vecna's Patient Information Exchange platform allows patients to pay bills online through any Web-enabled device, including tablets and smartphones, as well as through onsite self-service registration kiosks, according to the company.

Of those patients who access the patient information exchange, Vecna's customers have seen 85 percent make payments on past due balances. In addition, the Patient Information Exchange gives patients the ability to update demographics information including those required for Meaningful Use, as well as mailing addresses and contact information.

VECNA AND MERIDIAN MEDICAL MANAGEMENT
www.vecna.com | www.m3meridian.com

SILICONE SHEETS IMPROVE APPEARANCE OF SCARS

SCARAWAY SILICONE SCAR SHEETS are a noninvasive and drug-free scar treatment designed to improve the appearance of new and old scars. The sheets mimic the natural barrier function of healthy skin and therefore soften scars, according to the company.

The thin, flexible sheets deliver slight direct pressure to the scar and effectively and safely improve the thickness, color and texture of keloids and hypertrophic scars, studies show. According to the company, significant results can be seen in as little as four weeks.

ScarAway has been approved by the Food and Drug Administration as a class 1 medical device, the company says. The sheets are now available over-the-counter.

SCARAWAY
www.myscaraway.com

TRETIN-X CREAM FOR ACNE AVAILABLE NATIONWIDE

TRETIN-X (tretinoin, USP) Cream 0.075 percent is now available nationwide through Onset Dermatologics, the company recently announced.

Tretin-X Cream 0.075 percent was approved by the Food and Drug Administration in 2013 and has been available in limited geographic areas since November 2013. It is indicated for topical application in the treatment of acne vulgaris.

While the cream vehicle is free of known irritants, such as parabens, alcohol, and propylene glycol, it is recommended that patients protect their skin from sun, sunlamps, extreme wind or cold as well as harsh skincare products when using this product to prevent irritation.

ONSET DERMATOLOGICS
www.onsetdermatologics.com

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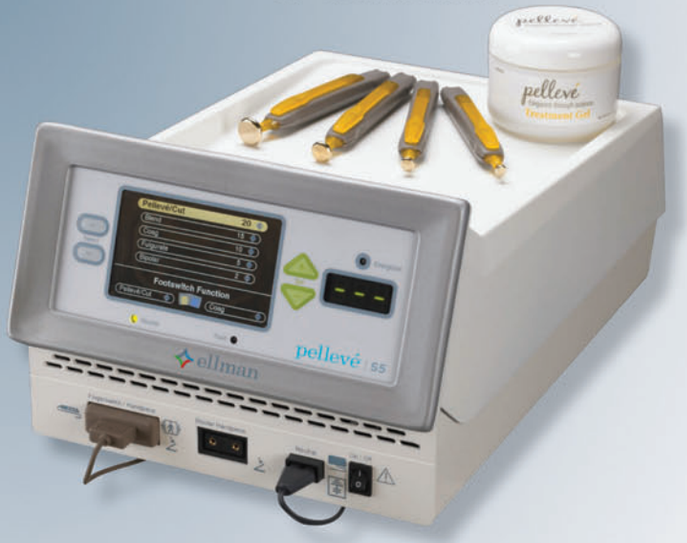

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Procedures table enhances patient comfort

THE MIDMARK 360 HUMANFORM procedures table was designed to promote more efficient outcomes and enhance patient comfort, according to the company. It allows unobstructed access to the patient, clear views of surgical sites, and more precise positioning.

The table's Active Sensing Technology helps to avoid impact during movement, such as objects getting caught under the footrest or seat. The Barrier-Free Design has an 18-inch low seat height and 650-pound patient capacity. There is optional programmability that stores up to four "favorite" positions, plus an optional rotation allowing the table to be rotated to bring both the patient and any necessary instruments or devices to the point of care. Power height, back, foot and tilt allow clinicians to quickly and precisely move the patient into the most ideal position for medical treatment.

MIDMARK
midmark.com/humanform

NIGHT TIME SCAR TREATMENT AIDS NATURAL REPAIR

MEDERMA PM Intensive Overnight Scar Cream is now available from Merz North America.

In clinical studies, subjects who used Mederma PM for eight weeks as directed saw a 50 percent reduction in the size of the scars after 8 weeks with noticeable improvement in as little as 2-4 weeks, the company said. The scar cream is formulated with peptides, collagen, and antioxidants to complement natural nighttime skin regeneration.

Text, email, calendar reminders and an iPhone app aid effective use and allow users to monitor scar improvement over time.

MERZ NORTH AMERICA
www.mederma.com

OINTMENT TREATS INFLAMMATION, IRRITATION

BENSAL HP topical ointment is now available from Valeant Dermatology in a 30 gm tube. The ointment is ideal for use on external inflammation and irritation associated with common forms of dermatitis, according to the company.

The product also can be used to treat certain eczematoid conditions, including complications associated with pyodermas, the company states. It is also indicated for the treatment of insect bites, burns and fungal infections.

Bensal HP is contraindicated for use in patients who are hypersensitive to topical polyethylene glycols. Use of Bensal HP with other topical agents has not been studied, the company states. A small percentage of patients may experience a temporary burning sensation upon applying the ointment. The safety and efficacy of the ointment in pediatric patients has not been established.

VALEANT DERMATOLOGY
www.bensalhprx.com

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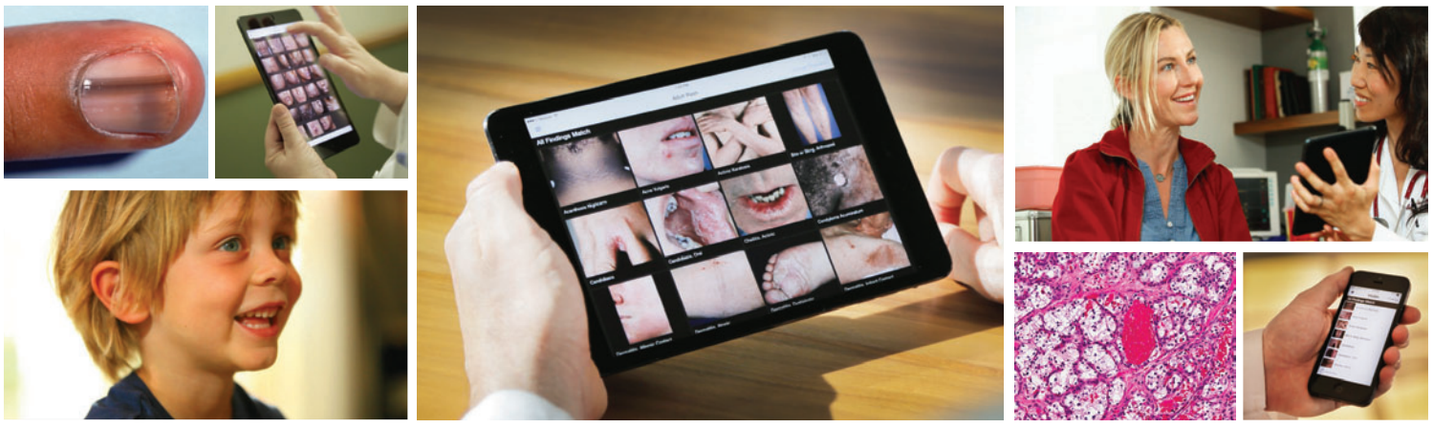

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DOES GLUTEN DRIVE SKIN DISEASE?

Q&A

NORMAN LEVINE, M.D.

Gluten and gluten-sensitive enteropathy have become hot topics among the lay public and in medical practices. We dermatologists have historically concerned ourselves with gluten only as it relates to dermatitis herpetiformis. This may be changing. John Zone, M.D., from the University of Utah, Salt Lake City, discusses how gluten sensitive enteropathy may impact many areas of our specialty.

Dr. Levine: Exactly what is gluten and what is a gluten-sensitive enteropathy?

A. John Zone, M.D.: Gluten is really a group of proteins that is in various grains: rye, barley and wheat. There are specific substances in them called prolamins that are responsible for the immune response. That group of proteins is not present in rice or oats; it is just present in rye, barley and wheat. These proteins are large enough to produce an immune response, and that's what they do in celiac disease and possibly in other conditions.

Dr. Levine: So when we talk about gluten-sensitive enteropathy, what does that mean?

A. Gluten-sensitive enteropathy and celiac disease are synonymous. Gluten-sensitive enteropathy means that there is damage to the intestinal mucosa that is induced by gluten, and when gluten is withdrawn from the diet, the damaged mucosa heals over in a matter of months. So that's gluten-sensitive enteropathy. There, of course, are other enteropathies that aren't sensitive to gluten.

Dr. Levine: All of a sudden, it seems like people are talking about this and it seems like the incidence of this has become tremendously high. What happened?

A. The first thing that made celiac disease more common was better testing and identification of occult disease.

I started studying celiac disease and gluten sensitivity back in the 1970s, and it was deemed to be very rare. At that time, the only way that people could be diagnosed was with a small intestinal biopsy or with a skin biopsy if they had dermatitis herpetiformis.

We got better blood tests in the 1990s and a lot of work was done on establishing the reliability of various blood tests in predicting the intestinal abnormality. So with the availability of a blood test, it was first found in about 2000 that about one in 100 people in the United States had a positive blood test for celiac disease, and if you go ahead and biopsy their intestine, you will find out that indeed they have gluten-sensitive enteropathy or celiac disease of the intestine.

We used to think that people only had celiac disease if they had a lot of symptoms: crampy abdominal pain, diarrhea, etc. Now we know from our blood test that up to two-thirds of the people do not have abdominal symptoms, but they may have secondary complications such as malabsorption of iron and osteoporosis.

"The first thing that made celiac disease more common was better testing and identification of occult disease."

John Zone, M.D.
Salt Lake City

The question of whether or not the incidence of celiac disease is actually increasing with time is an interesting one. There is only one study that I know of that actually has dealt with that.

Joseph Murray, M.D., a researcher at Mayo Clinic, took serum that had been stored since the 1960s or '50s, I am not sure, for military recruit and established their serum positivity. It was much lower than a comparable group today. It may well be that the incidence of celiac disease and gluten sensitivity is increasing for reasons other than better testing, we don't know what those reasons might be (Murray JA, Van Dyke C, Plevak MF, et al. *Clin Gastroenterol Hepatol*. 2003;1(1):19-27).

Dr. Levine: Could it have anything to do with our diet and how it changed over time?

A. In the long run, yes. Prior to 10,000 years ago, and then grain was a relatively new thing in the human diet 5,000 years ago or thereabouts. That change in diet over time — where men started to eat more grain — has likely produced a population that reacts to dietary gluten. As far as change in diet in the past 20 years, there is no evidence that I am aware of that this has been a factor. Some people have considered the possibility that gluten sensitivity has been increased by viral infections and other things that have precipitated it, but no one knows the answer.

Dr. Levine: Let's move on to the disease that all of us grew up thinking about in relation to gluten, and that is dermatitis herpetiformis. Has the incidence of this disease changed over the past 30 to 40 years?

A. The only incidence study done in the United States, we did in Utah in 1987, and we haven't repeated the incidence study. To me, it seems about the same as it has always been: approximately 11 new cases per 100,000 population per year. (Smith JB, Tulloch JE, Meyer LJ, Zone JJ. *Arch Dermatol*. 1992;128(12):1608-1610). Those

GLUTEN see page 119

Sunscreens: Beyond Broad Spectrum
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Photobiologist and industry veteran Curt Cole, Ph.D., takes a science-based look at photoprotection, sunscreen formulations and emerging priorities under the new FDA Sun Monograph.

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GLUTEN:

How does gluten-sensitive enteropathy impact dermatology practice?

from page 116

numbers have ranged as low as three or four and as high as 12 in different reports, but there doesn't seem to be any difference.

Dr. Levine: Why are there so few cases of dermatitis herpetiformis while so many people have gluten sensitivity?

A. Well it's interesting, because in Finland, Timo Reunala, M.D., at the University of Tampere, Finland, who is a colleague, has been investigating this for many years. In a large population study, he found that one out of every six patients with celiac disease had dermatitis herpetiformis (Salmi TT, Hervonen K, Kautiainen H, Collin P, Reunala T. *Br J Dermatol*. 2011;165(2):354-359). That's relatively common. Most of these people when they were diagnosed with celiac disease went on a gluten-free diet and their dermatitis cleared relatively rapidly. So the incidence of dermatitis herpetiformis is much higher than we think. When one really goes after it, you will find a reasonable number of new cases. But I think today, a lot of them are rapidly treated with gluten-free diet.

Plus an interesting thing has happened in society now, of course, and that is that 20 years ago gluten restriction was not very popular, but it has become almost a fad now. So you can go to any restaurant and get a gluten-free diet. I see patients all the time who have had dermatitis herpetiformis, who will say, "Oh yeah, I figured that it was related to celiac disease and I went on a gluten-free diet." For every one of those, there are probably 10 other people who had gone on gluten-free diets for no particular reason and have not gotten better, but a gluten-free diet has become very popular.

Dr. Levine: Is that your treatment of choice for dermatitis herpetiformis?

A. Yes. I think the best treatment for dermatitis herpetiformis is a gluten-free diet. Traditionally when we were started in dermatology, we treated everyone with dapsone. Dapsone, if the patient tolerates it, clears the skin and suppresses the disease. However, dermatitis herpetiformis recurs if a regular diet is instituted again. If managed correctly in the right doses, it will suppress the disease indefinitely.

I just had a patient of mine pass away who had been on dapsone since 1943 and tolerated it pretty well. Now what we do know from some recent studies from Hungary, about 60 percent of the people have osteoporosis because of malabsorption — and they are subject to other malabsorptive problems also.

GLUTEN see page 128


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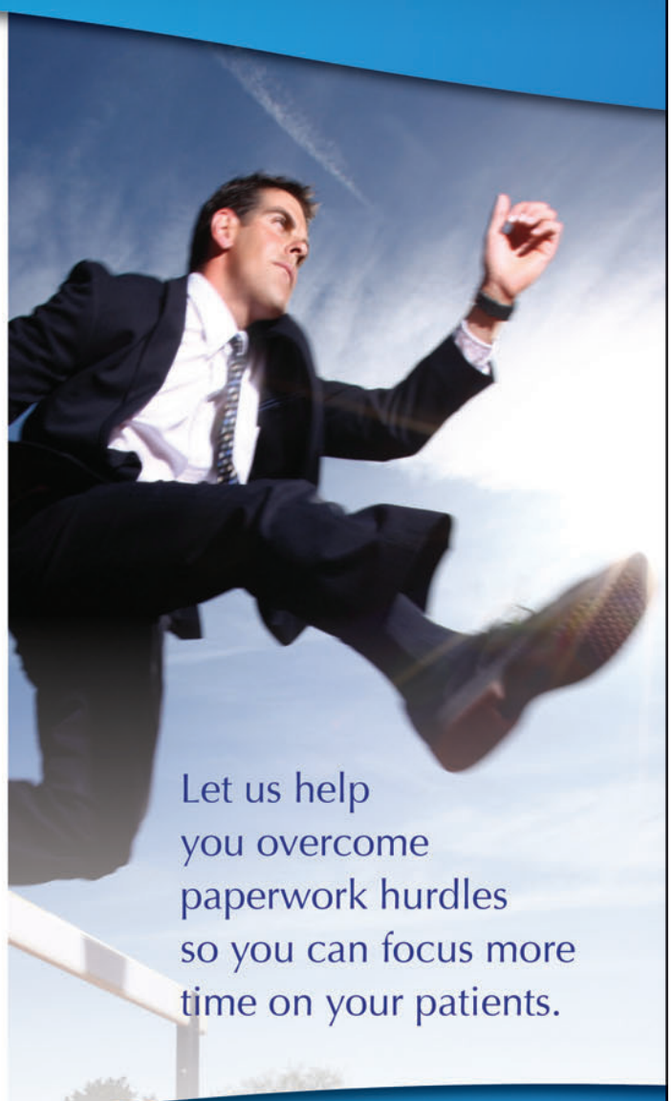

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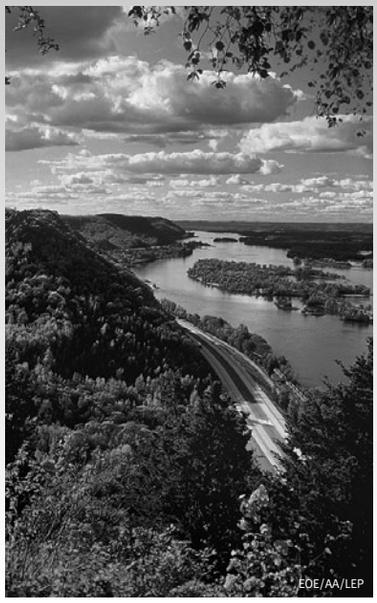

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GLUTEN:

How does gluten-sensitive enteropathy impact dermatology practice? from page 119

(Sárdy M, Kárpáti S, Merkl B, et al. *J Exp Med*. 2002;195(6):747-757). So, gluten-free diet is probably the best treatment since it may ultimately reduce the incidence of osteopenia.

What I do now is start patients on a gluten-free diet and a small dose of dapsone to make them comfortable and then gradually try to taper their dapsone and maintain them on a gluten-free diet. Of course there are number of people who just once they find out how well dapsone works, don't want any part of a gluten-free diet, and I just explain to them that they are at an increased risk for osteoporosis and possibly secondary lymphoma.

Dr. Levine: How do you specifically guide them in terms of avoiding gluten?

A. I used to have a detailed handout that I had made with a dietitian, and I used to refer them to dietitians. With the Internet now, I tell them particular Internet sites and organizations that I know have good quality information. In our region, I used the Celiac Disease Foundation of Los Angeles that I work with, and I know that its information is first-class — or the Gluten Intolerance Group of Seattle. All the information is online. There is also the advantage that many of the patients become part of the self-help groups of these organizations and stay much more current on the details of the diet than I do, actually.

Dr. Levine: Let's move on to other possible associations of a gluten-sensitive enteropathy and other dermatoses that have been proposed to be related to celiac disease. Could you address the association of psoriasis and gluten sensitivity?

A. There are multiple diseases that have been said to be associated with gluten sensitivity. It appears that when people have celiac disease, they have a heightened immune response. They are very flared up from an immunologic standpoint. If a person with celiac disease happens to have psoriasis, — both of those diseases are fairly common; so if one in 100 people has celiac disease and one in 100 people has psoriasis, you can imagine that a number of people have both diseases.

Those people who have both diseases have been reported repeatedly to improve their psoriasis on a gluten-free diet; however, because the coexistence of the two is relatively rare, we don't routinely test psoriatics for celiac disease. Those papers have come mostly from Sweden, where, of course, they have a much better control of their population and can document associations easily in the population In the United States, we don't have the population studies available.

Dr. Levine: Is there a situation where you would ever take a person with psoriasis and somehow determine whether they have gluten-sensitive enteropathy?

A. Gluten-sensitive enteropathy, of course, is familial. In our studies of 2,000 first-degree relatives, we found that one in eight (12 percent) of the first-degree relatives of celiac patients turned out to have celiac disease. So if a person with psoriasis had a family history of celiac disease, I would definitely test that person for celiac disease. If they didn't have a family history of celiac disease, then there is a one in 100 chance that a psoriatic has celiac disease. I am not saying that psoriasis is caused by celiac disease in selected cases.

Dr. Levine: In like fashion, the controversy of atopic dermatitis and any kind of dietary issues have been raised in the literature; what's your view of atopic dermatitis and gluten-sensitive enteropathy?

A. Luigi Greco, M.D., at the University of Naples Federico II, Naples, Italy, has looked into this in detail and the story is the same. The incidence of celiac disease was not higher in those with atopic dermatitis. It's still just 1 in 100. So 1 in 100 patients with atopic dermatitis will have celiac disease, just like 1 in 100 Caucasians will have celiac disease. If that particular person has celiac disease, his/her atopic dermatitis will likely improve on a gluten-free diet. It's a relatively rare event, but when there is coexistence of the two diseases, once again this hyperactive immune state that is produced by celiac disease or gluten-sensitive enteropathy seems to act as a stimulant. Indeed, I have treated several patients who had hand dermatitis — what we all would have considered atopic dermatitis in adults, at least that's what I have called them — and turned out to have celiac disease and totally cleared on a gluten-free diet.

I have had people from around the country contact me about such cases, and it does happen. They are relatively rare. On the other hand, somewhere around 5 percent of patients with aphthous stomatitis in adulthood has celiac disease. So if patients who have aphthous stomatitis also have occult celiac disease, the mouth lesions likely will respond to gluten restriction. That's what is called non-celiac gluten sensitivity. We are seeing a phenomenon especially in United States where up to 5 percent of the population is saying that they are gluten sensitive. Now we know that the incidence of celiac disease is 1 percent when we really go after people. That means that four out of five people who claim they are been gluten sensitive don't have celiac disease. There is an interesting literature developing on non-celiac gluten sensitivity, which is called NCGS in the literature. We usually start out by testing them for celiac disease, we tell them they don't have celiac disease, but they say, "No, no, I am gluten sensitive."

Indeed, in some blinded studies, they have been able to show that some of these people will get symptoms when given gluten as opposed to placebo. That's probably right now the most controversial area in gluten sensitivity. The thing that I ask myself is do the people who have non-celiac gluten sensitivity have skin disease that is driven by gluten, and the answer is we really don't know. The problem with non-celiac gluten sensitivity is we have no good test for it, so we can't separate the people who really do have gluten sensitive disease from the people who don't have gluten sensitive disease other than by blinded challenge. **DT**

IMPORTANT INFORMATION ABOUT

Mirvaso®

(Brimonidine) Topical Gel, 0.33%*

*Each gram of gel contains 5 mg of brimonidine tartrate, equivalent to 3.3 mg of brimonidine free base

BRIEF SUMMARY

This summary contains important information about MIRVASO (Mer-VAY-Soe) Gel. It is not meant to take the place of the full Prescribing Information. Read this information carefully before you prescribe MIRVASO Gel. For full Prescribing Information and Patient Information please see package insert.

WHAT IS MIRVASO GEL?

MIRVASO (brimonidine) Topical Gel, 0.33% is a prescription medicine that is used on the skin (topical) to treat facial redness due to rosacea that does not go away (persistent).

WHO IS MIRVASO GEL FOR?

MIRVASO Gel is for use in adults ages 18 years and older.

WHAT WARNINGS AND PRECAUTIONS SHOULD I BE AWARE OF?

MIRVASO Gel should be used with caution in patients that:

- have depression
- have heart or blood vessel problems
- have dizziness or blood pressure problems
- have problems with blood circulation or have had a stroke
- have dry mouth or Sjögren's Syndrome
- have skin tightening or Scleroderma
- have Raynaud's phenomenon
- have irritated skin or open sores
- are pregnant or plan to become pregnant. It is not known if MIRVASO Gel will harm an unborn baby.
- are breastfeeding. It is not known if MIRVASO Gel passes into breast milk. You and your female patient should decide if she will use MIRVASO Gel or breastfeed. She should not do both.

Ask your patient about all the medicines they take, including prescription and over-the-counter medicines, skin products, vitamins and herbal supplements. Using MIRVASO Gel with certain other medicines may affect each other and can cause serious side effects.

Keep MIRVASO Gel out of the reach of children.

If anyone, especially a child, accidentally swallows MIRVASO Gel, they may have serious side effects and need to be treated in a hospital. Get medical help right away if you, your patient, a child, or anyone else swallows MIRVASO Gel and has any of these symptoms:

- **Lack of energy, trouble breathing or stops breathing, a slow heart beat, confusion, sweating, restlessness, muscle spasms or twitching.**

WHAT ARE THE POSSIBLE SIDE EFFECTS OF MIRVASO GEL?

The most common side effects of using MIRVASO Gel include:

- redness, flushing, burning sensation of the skin, skin irritation

Skin redness and flushing may happen about 3 to 4 hours after applying MIRVASO Gel. Ask your patients to tell you if they get skin redness and flushing that is uncomfortable.

MIRVASO Gel can lower blood pressure in people with certain heart or blood vessel problems. See **"What warnings and precautions should I be aware of?"**

These are not all of the possible side effects of MIRVASO Gel. Remind your patients to call you for medical advice about side effects.

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

HOW SHOULD MIRVASO GEL BE APPLIED?

- Remind your patients to use MIRVASO Gel exactly as you instruct them. They should not use more MIRVASO Gel than prescribed.
- Patients should not apply MIRVASO Gel to irritated skin or open wounds.
- **Important**: MIRVASO Gel is for use on the face only. Patients should not use MIRVASO Gel in their eyes, mouth, or vagina. They should also avoid contact with the lips and eyes.
- Instruct your patients to see the detailed Instructions for Use that come with MIRVASO Gel for information about how to apply MIRVASO Gel correctly.

GENERAL INFORMATION ABOUT THE SAFE AND EFFECTIVE USE OF MIRVASO GEL

Remind your patients not to use MIRVASO Gel for a condition for which it was not prescribed and to not give MIRVASO Gel to other people, even if they have the same symptoms. It may harm them.

WHAT ARE THE INGREDIENTS IN MIRVASO GEL?

Active Ingredient: brimonidine tartrate
Inactive Ingredients: carbomer homopolymer type B, glycerin, methylparaben, phenoxyethanol, propylene glycol, purified water, sodium hydroxide, titanium dioxide.

WHERE SHOULD I GO FOR MORE INFORMATION ABOUT MIRVASO GEL?

- Go to **www.mirvaso.com** or call **1-866-735-4137**

GALDERMA LABORATORIES, L.P.
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Revised: August, 2013
HCP

MIRVASO® (brimonidine) topical gel, 0.33%

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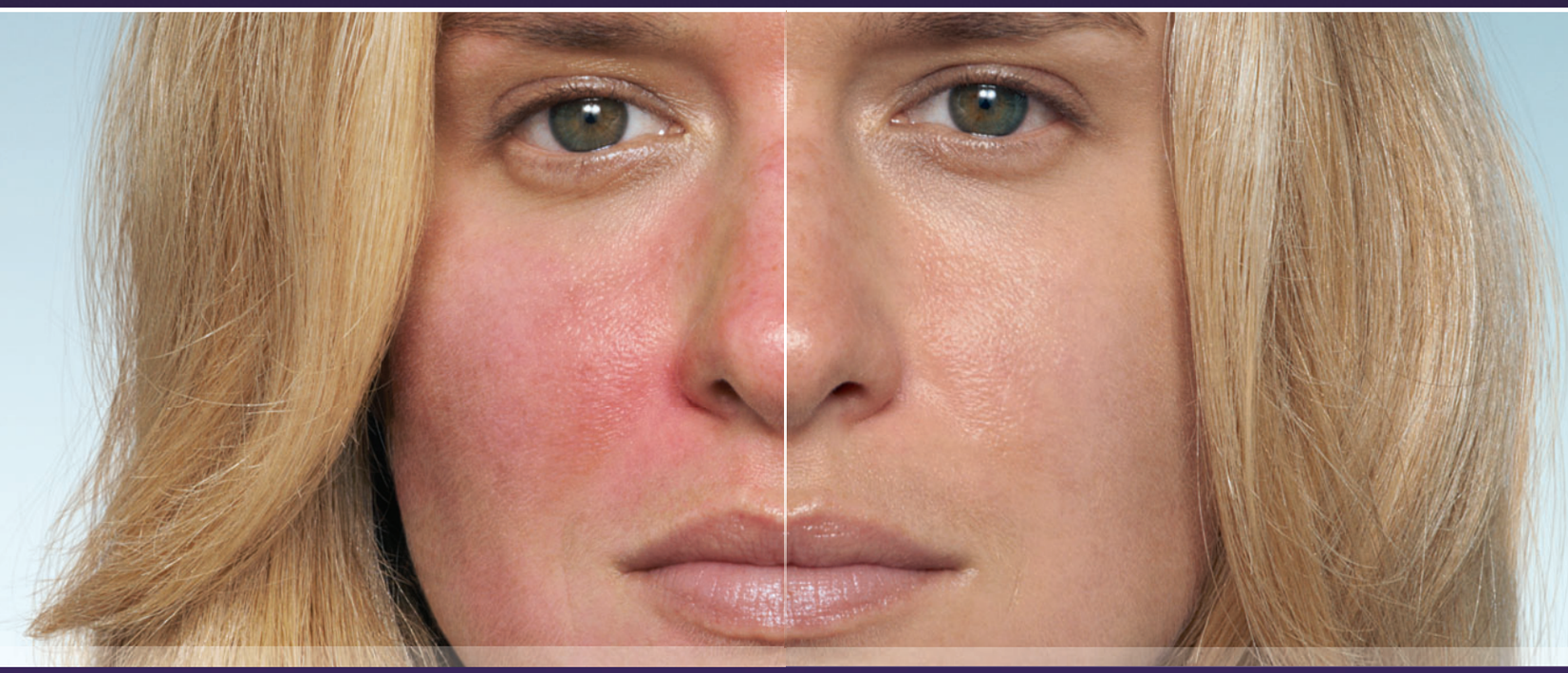
References: 1. Fowler J Jr, Jackson JM, Moore A, et al; Brimonidine Phase III Study Group. Efficacy and safety of once-daily topical brimonidine tartrate gel 0.5% for the treatment of moderate to severe facial erythema of rosacea: results of two randomized, double-blind, vehicle-controlled pivotal studies. *J Drugs Dermatol.* 2013;12(6):650-656. **2.** Mirvaso [package insert]. Galderma Laboratories, L.P. Fort Worth, TX; 2013.

Help your patients with facial erythema of rosacea experience...

THE MIRVASO EFFECT



Not an actual patient. Individual results may vary. Results are simulated to show a 2-grade improvement of erythema. At hour 12 on day 29, 22% of subjects using Mirvaso Gel experienced a 2-grade improvement of erythema compared with 9% of subjects using the vehicle gel.*

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- The **first** and **only** FDA-approved topical treatment specifically developed and indicated for the facial erythema of rosacea[1]
- Fast results that last up to **12 hours**[1]
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Important Safety Information

Indication: Mirvaso® (brimonidine) topical gel, 0.33% is an alpha-2 adrenergic agonist indicated for the topical treatment of persistent (nontransient) facial erythema of rosacea in adults 18 years of age or older. **Adverse Events:** In clinical trials, the most common adverse reactions (≥1%) included erythema, flushing, skin-burning sensation, and contact dermatitis. **Warnings/Precautions:** Mirvaso Gel should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, thromboangiitis obliterans, scleroderma, or Sjögren's syndrome. Alpha-2 adrenergic agents can lower blood pressure. Mirvaso Gel should be used with caution in patients with severe or unstable or uncontrolled cardiovascular disease. Serious adverse reactions following accidental ingestion of Mirvaso Gel by children have been reported. **Keep Mirvaso Gel out of the reach of children.** Not for oral, ophthalmic, or intravaginal use.

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 the following page.

See for yourself. Visit **www.mirvaso.com/hcp**.

MIRVASO®
(brimonidine) topical gel, 0.33%

*Phase 3 clinical studies of 553 subjects 18 and older. Subjects were randomized 1:1 to either Mirvaso Gel or vehicle for 29 days. Subjects and clinicians were asked to grade the improvement they saw at 30 minutes and hours 3, 6, 9, and 12 following application.

†Each gram of gel contains 5 mg of brimonidine tartrate equivalent to 3.3 mg of brimonidine free base.