"Physicians love devices. It's not the technology hurdle. It's not the device hurdle. It just has to be built the right way." — Gopal Chopra, M.D.

TOP 3 Patient Care Apps

page 76

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ANTIMICROBIAL STEWARDSHIP

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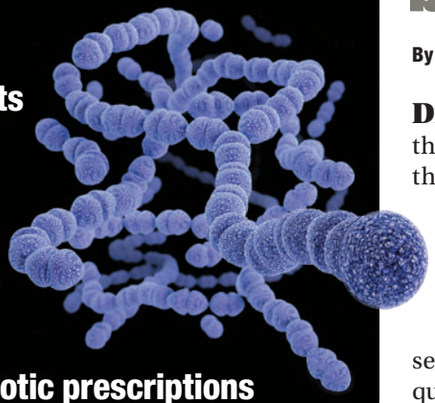
ANTIMICROBIAL STEWARDSHIP

How dermatologists can be part of the solution

Although dermatologists represent 1% or less of the U.S. physician population,

dermatologists prescribe almost

5% of all antibiotic prescriptions



By John Jesitus | Senior Staff Correspondent

DERMATOLOGISTS generally know that the sensitivity of many pathogens to the antibiotics used to treat them is decreasing, experts say. But many dermatologists may not appreciate their specialty's role in potentially fueling the problem.

Regarding changes in pathogens' sensitivity to antibiotics, "There's no question we have a global public health issue," says James J. Leyden, M.D., emeritus professor of dermatology at the University of Pennsylvania School of Medicine, Philadelphia. Rather than "antibiotic resistance," he prefers the term "change in antibiotic sensitivity." Resistance implies interference with clinical outcomes, he explains, which doesn't always happen when a pathogen's antibiotic sensitivity decreases.

According to a World Health Organization (WHO) fact sheet, antimicrobial resistance impacts patients with

ANTIBIOTICS see page 17

Combination therapies evolve to address countless dermatologic conditions

By Lisette Hilton | Staff Correspondent

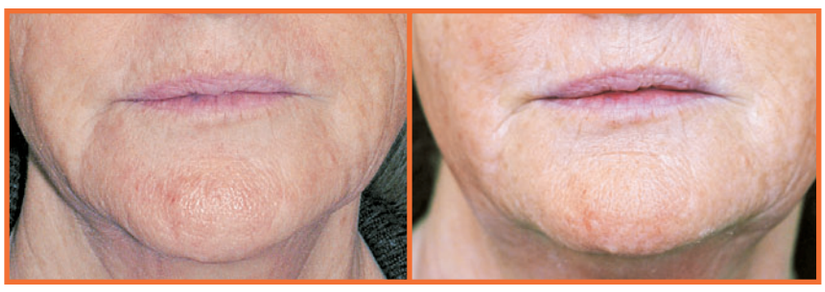
DERMATOLOGISTS are using an evolving collection of combination therapies designed to address different aspects of disease, monotherapy limitations and failures, as well as enhance treatment.

Combination therapies are pivotal when treating skin cancer patients using the field cancerization approach, according to Alexandra Zhang, M.D., associate staff in the department of dermatology, Cleveland Clinic, Cleveland.

Dr. Zhang, a Mohs surgeon, says field therapy involves addressing not only skin

COMBO see page 24

A female patient before (left) and one month after three monthly laser treatments with the Alma Harmony Near Infrared Devic at a setting of 50 W, 30 kJ per treatment.



Photos: Macrene Alexiades-Armenakas, M.D., Ph.D.

Are you prepared for meaningful use mandates?

By John Jesitus | Senior Staff Correspondent

AMONG THE MOST troublesome stage 2 requirements of the Medicare and Medicaid EHR Incentive Programs is the requirement that 5 percent of patients use the Internet to communicate with practices, an expert says.

Mark D. Kaufmann, M.D., says, "The most onerous change by far in stage 2 is that you're no longer judged only on what you're doing — your patients have to start participating with you in order for your practice to comply with stage 2." Dr. Kaufmann is an associate clinical

MEANINGFUL USE see page 64

CLINICAL DERMATOLOGY

16 Advanced genetic testing paves way for personalized medicine

22 Guidelines clarify controversies of vitamin D

COSMETIC DERMATOLOGY

34 Can telomere manipulation stop skin's biologic clock?

41 Hyaluronic filler products dominate filler market in Europe

BUSINESS OF DERMATOLOGY

52 Simplify, conceptualize for effective presentations

55 What to know when negotiating a medical practice sale or merger

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

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RESOURCES IN DERMATOLOGY

Access resources that will aid in successful and efficient adoption of electronic health records systems and attest to meaningful use, stage 1.
dermatologytimes.com/EHRinvestments

Review a broad range of clinical, CME and digital information about conditions like psoriasis, rosacea and melanoma. Learn emerging treatment options to help patients reduce symptoms.
dermatologytimes.com/fragileskintherapies

Trending FROM September

Studies that help aesthetic practitioners understand what is happening functionally in the skin, aid in refining injection techniques with BoNT-A and individualizing treatment strategies to optimize treatment results.
dermatologytimes.com/technique

Pregnant women can use topical corticosteroids for short periods of time and in normal doses without posing a risk to the fetus, recent research suggests.
dermatologytimes.com/corticosteroids

The Food and Drug Administration has approved Galderma's topical gel Mirvaso (brimonidine 0.33 percent) for the treatment of facial erythema from rosacea. Two phase 3 clinical studies demonstrated an improvement in facial redness of rosacea with Mirvaso versus vehicle gel.
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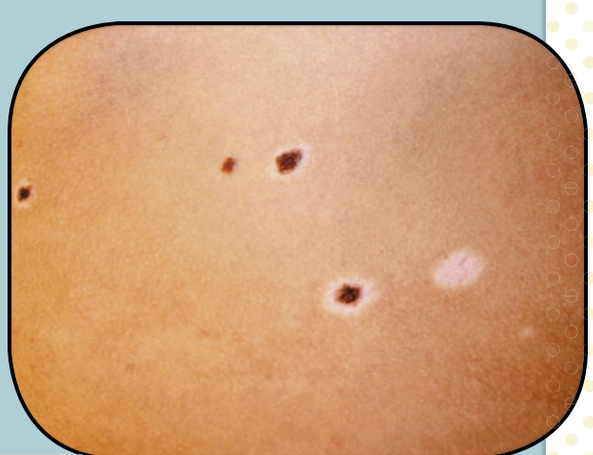
What's your diagnosis?

A panicked mother of an 11-year-old girl brings her daughter to your office for evaluation of changing moles that she discovered when they returned from the family beach vacation last weekend. What's your diagnosis?



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The Business of Dermatology

Grasp entrepreneurial mindset to survive

With healthcare law uncertainties looming, it's time to stop worrying and reformat your practice, one doctor says. Doctors must adapt to a new environment. Offer your services for cash and bypass the system. Form alliances with your peers. Stop taking insurance and government dole, he says.

dermatologytimes.com/newbusiness

How to find the best bank for your bucks

Whether you need credit for new equipment or want to simplify daily financial tasks, it is important to find a bank that understands the needs of your practice. Here are some of the most important things to consider when choosing a bank.

dermatologytimes.com/cash

ACA: It's not what the doctor (or voters) ordered

What some American voters thought they wanted was a socialized health insurance safety net for all citizens. What they got was the Affordable Care Act, aka "Obamacare." Rather than the government owning and operating the healthcare system, as it is done in Canada, this system has been sold to private corporate interests but with rules by government law. What are the consequences of the ACA?

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Are physicians being forced to focus on data over patient care?

Tanya Feke, M.D. | Guest Contributor

I have never met a physician who went to medical school to become a business person. The unfortunate truth, however, is that physicians are put into business-minded situations everyday, whether hospital-employed or in private practice, and many without proper training. Despite the best intentions of medical schools, graduates have little preparation for the fiscal realities of medicine and the real world of numbers.

So, how high can you count? Formulas and calculations. Hours and minutes. Dollars and cents. Numbers keep us moving, pushing us to do more in less time, all in the name of productivity. This numeric world may be tantalizing for mathematicians and accountants, but for the practicing physician those numbers threaten the foundation of what we do:

- How many hours do you work? Does your professional life compromise your home life?
- How many relative value units do you generate per session? Is this above or below preset expectations?
- Did you use the correct International Classification of Diseases, Ninth Revision (ICD-9) code for billing purposes? How will you adapt to ICD-10 when it kicks into gear in 2014?
- Did you use proper Current Procedural Terminology codes to bill your office visits? Are you secure from an audit and the possible fines that could result from one?
- Have you met percentage thresholds for meaningful use? Pay-for-performance criteria? How will they affect your revenue?

Every aspect of medical care has become consumed in numeric jargon. While it is important to acknowledge these factors — our financial viability depends on them — focusing too much on these matters in the moment threatens to weaken the stronghold of medical practice, the patient-physician relationship. Distracted from the job at hand, many physicians cannot separate the cacophony of numbers from the person sitting before them.

WHEN IT DOESN'T ADD UP

Physicians practice in different specialties but they all share the same goal — helping people. If only that task were as easy as it sounds. Certain business models prevent a physician from doing what he or she feels will most benefit patients. Add to that the reality that some patients refuse services, while others demand what is unnecessary and you have a real quandary.

Faced with these challenges regularly, medical providers can become disheartened. Too often, a fistful of minutes allotted to a patient visit evaporates and an opportunity to improve the lives of everyone in the exam room — the patient, his or her family, and the physician — dissolves into nothingness. The sad results often are burnout, cynicism, job turnover and early retirement.

I once had a patient, Joe, complain about a bill he received for services rendered. To have someone challenge my work ethic and accuse me of overcharging insulted me to the core. Review of his chart showed that he was a new patient and his chart documented a detailed history — medical, surgical, family, and

GUEST COMMENTARY see page 10

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

FTC can challenge practice mergers

Dr. Derm owns 15 dermatology practices. Dr. Skin owns 12 similar practices. Recently a venture capitalist bought all 27 practices, merging them as one practice. All dermatologists were given a 20-mile, two-year restrictive covenant.

The goal of these businessmen was to purse a strategy of acquiring and integrating physician group dermatology practices. Though aware of the Stark Law and Anti-Kickback Statute issues tied to such business transactions, when they received a Federal Trade Commission (FTC) challenge to the merger, everybody was shocked.

Can the FTC challenge such mergers if it believes that competition has been significantly adversely affected? Recently a similar challenge occurred in Nevada. Renown Health ("Renown") of Reno, Nev., is an integrated healthcare delivery system serving a 17-county area including northern Nevada, Lake Tahoe and northeastern California. It owns and operates four general acute care hospitals, a children's hospital and eight urgent care centers, and it employs numerous physicians, servicing out of 16 medical group offices.

The FTC complaint arose from the acquisition by Renown of two cardiology practices in Reno. The FTC alleged that the acquisition and employment of the physicians substantially lessened competition for cardiology services in and around Reno.

Non-compete covenants

Before these transactions, Sierra Nevada Cardiology Associates Inc. ("SNCA") and Reno Heart Physicians Inc. ("RHP") were the two largest cardiology practices in the Reno area. Renown closed the acquisition of SNCA on Nov. 24, 2010. In connection with the acquisition of the assets of SNCA, 15 SNCA physicians entered into employment agreements with Renown.

The employment agreements included non-competition, non-solicitation and non-interference restrictive covenants. The non-competition covenant prohibited the employed physician from providing professional and medical services specializing in cardiology as an employee of a hospital, medical practice or other medical facility within a 50-mile radius of the physician's principal place of practice for two years after the expiration or termination of his or her employment agreement.

In connection with the acquisition of the assets of RHP, 17 physicians associated with RHP entered into employment agreements with Renown. Those employment agreements included restrictive covenants identical to or substantially similar to restrictive covenants in the employment agreements with the former SNCA physicians.

The FTC reviewed the transactions and the impact that the consolidation of the SNCA and RHP physicians into the Renown physician group had on competition in the relevant market. The FTC defined the relevant product market as "cardiology services" and the relevant geographic market as the "Reno area," including Warshoe County, Nev., but not Carson City, Nev.

Eliminating competition

The FTC noted that, after consummation of the RHP acquisition, Renown employed 97 percent of cardiologists in the relevant market. After the RHP transaction closed, two Renown cardiologists terminated employment agreements and left Reno. Also, three new physicians commenced private practice in the Reno area. After these market departures and additions, the FTC alleged Renown controlled 88 percent of the cardiologists in the Reno area.

The FTC noted that, before the transactions, SNCA and RHP were competitors for cardiology services. After Renown purchased SNCA, RHP was the only significant competitor for cardiology services in the Reno market. The FTC alleged that Renown's acquisition of RHP eliminated all competition for cardiology services in the Reno market based on price, quality and other terms. Health plans had no bargaining power in negotiating with Renown for cardiology services because there were no competitors for these services in Reno.

The facts of the Renown case are extreme. Rarely will a hospital or healthcare system in a competitive market employ 88 percent of physicians in a specific specialty. The case should, however, serve as a cautionary tale for dermatologists as they begin to merge into larger practices in this competitive market.

A healthcare system that controls almost 90 percent of the market in a particular medical specialty obviously runs a significant risk that the system's contracting activities may be challenged by the FTC on antitrust grounds. Significant antitrust concerns may be raised even if a system controls a much lower percentage of the physicians in a single specialty in a given market, such as dermatology.

The lesson of Renown is that healthcare systems executing an aggressive physician practice acquisition and integration strategy must remain sensitive to the unique competitive features of its service area, and it should engage in a rigorous antitrust analysis of a proposed transaction. **DT**

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GUEST COMMENTARY from page 6

social histories, along with a review of medical records from his former primary care provider. His blood pressure was acutely elevated. As a result, medications had been prescribed and a one-week follow-up arranged. Coding guidelines showed that I had qualified for the level of visit I had billed, but to him this was still excessive.

Reflection led me to realize that Joe had a different set of numbers guiding his expectations. He had no understanding of ICD-9; he was not faced with 99214 or modifier 25s. For him, the cost of the office visit in relation to paying his other bills took center stage, the unpaid time he took off from work to attend the office visit. His personal experience had given him a unique set of priorities. For him, the numbers simply did not add up.

Similar feelings of frustration erupt when physicians interact with insurance companies and other payers. Government regulations and the ever-controversial sustainable growth rate formula have kept us up in arms for years. We are no different than Joe. The numbers do not always meet what we deem to be fair, and that is what ignites the need for healthcare reform.

One of the difficulties in modern medicine is its frequent lack of transparency. Patients do not always realize all we are doing and why we are doing it. Likewise, many providers have not been educated on business models beyond a quick briefing on coding. They are being guided in the direction of accountable care organizations, not necessarily knowing if these organizations will generate long-term success for their practices. Meaningful use is changing the fundamental dynamics of practice, adding to the already demanding numbers crunch. Many providers simply jump through hoops now so they do not risk financial penalty later.

No one can understand the reasons until the process is explained to them. As providers, we need to be more transparent with our patients to improve medical outcomes and patient satisfaction. As professionals, we need to seek information that justifies our business models and exemplifies best practices. As gatekeepers for healthcare in America, we need to be advocates on both ends. Unfortunately, we often feel too rushed and pressured to do just that. We are so exhausted we sometimes feel like we are drowning in the numbers. The distraction leads to more patient encounters that heighten anxiety levels for both providers and patients.

FINDING THE ONE

We are only human. There will be times when we are overwhelmed by our patients and the external pressures that we face not only in medicine but in every aspect of our lives. What we need to learn is how to spin those unsavory situations in ways that bring us back to our origins, our altruism.

My inspiration first came to me by way of a 14-year-old girl, a sparkly teenager who bubbled with energy. Her name was Jenny. When we met as freshmen in high school, we had no idea her adolescent years would be tarnished by the cruel diagnosis of leukemia six months later.

I watched her bravely face chemotherapy, watched her lose her flowing locks of hair, watched her oncologist support the family through each stage of treatment, and watched her victory into remission after a bone marrow transplant. Unfortunately, her dream of graduating high school never came to fruition. On Dec. 1, 1992, Jenny passed away.

Many physicians have a story that inspired them to pursue the long years of medical school, the rigors of residency, and beyond. For me, Jenny provoked that instinct to be more than I thought I could be. She brought that out in people. She was not a number. She was the number, the only number that matters — one of a kind. If I could find a way to focus on the one, to release the other numbers when I was with a patient, I knew I could make a world of difference. **DT**

Tanya Feke, M.D., is a board certified family practitioner in practice with Middlesex Hospital Primary Care in Durham, Conn.

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NAFTIN GEL, 2% INDICATIONS AND USAGE

NAFTIN Gel, 2% is an allylamine antifungal indicated for the treatment of interdigital tinea pedis caused by the organisms *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum* in patients 18 years of age or older.

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

In clinical trials with NAFTIN Gel, 2%, the most common adverse reactions (2%) were application site reactions.

WARNINGS AND PRECAUTIONS

If redness or irritation develops with the use of NAFTIN Gel, 2%, treatment should be discontinued.

NAFTIN CREAM, 2% INDICATIONS AND USAGE

NAFTIN Cream, 2% is indicated for the treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organism *Trichophyton rubrum* in adult patients ≥18 years of age.

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

In clinical trials with NAFTIN Cream, 2%, the most common adverse reaction (≥1%) was pruritus.

WARNINGS AND PRECAUTIONS

If redness or irritation develops with the use of NAFTIN Cream, 2%, treatment should be discontinued.

Please see brief summary of Full Prescribing Information on adjacent page(s).

References: 1. PHAST Monthly Prescription Data through July 2013. **2.** Data on file, Merz Pharmaceuticals. **3.** NAFTIN Cream, 2% [package insert]. Greensboro, NC: Merz Pharmaceuticals, LLC; January 2012. **4.** NAFTIN Gel, 2% [package insert]. Greensboro, NC: Merz Pharmaceuticals, LLC; June 2013. **5.** Brennan B, Leyden JJ. *J Am Acad Dermatol*. 1997;36(2 pt 1):S3-S8.

MERZ

NAFTIN® CREAM 2% (Naftifine HCl)

Rx ONLY

INDICATIONS AND USAGE: NAFTIN (naftifine hydrochloride) Cream, 2% is an allylamine antifungal indicated for the treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organism *Trichophyton rubrum* in adult patients ≥18 years of age.

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS: If redness or irritation develops with the use of NAFTIN Cream, 2% treatment should be discontinued.

Information for Patients:

1. NAFTIN (naftifine hydrochloride) Cream, 2% is for topical use only. NAFTIN (naftifine hydrochloride) Cream, 2% is not intended for intravaginal or ophthalmic use.

2. If irritation or sensitivity develops with the use of NAFTIN (naftifine hydrochloride) Cream, 2% treatment should be discontinued and appropriate therapy instituted. Patients should be directed to contact their physician if these conditions develop following use of NAFTIN (naftifine hydrochloride) Cream, 2%.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies to evaluate the carcinogenic potential of NAFTIN (naftifine hydrochloride) Cream, 2% have not been performed.

Pregnancy: Pregnancy Category B. There are no adequate and well-controlled studies of NAFTIN (naftifine hydrochloride) Cream, 2% in pregnant women. Because animal reproduction studies are not always predictive of human response, NAFTIN (naftifine hydrochloride) Cream, 2% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when NAFTIN (naftifine hydrochloride) Cream, 2% is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established. The number of pediatric patients ≥12 years of age studied was too small to adequately assess safety and efficacy.

ADVERSE REACTIONS: In clinical trials with NAFTIN (naftifine hydrochloride) Cream, 2% the most common adverse reaction (≥1%) was pruritus.

NAFTIN (naftifine hydrochloride) Cream, 2% is manufactured for Merz Pharmaceuticals, LLC, Greensboro, NC 27410.

NAFTIN® GEL 2% (Naftifine HCl)

Rx ONLY

INDICATIONS AND USAGE: NAFTIN (naftifine hydrochloride) Gel, 2% is an allylamine antifungal indicated for the treatment of interdigital tinea pedis caused by the organisms *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum* in patients 18 years of age and older.

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS: If redness or irritation develops with the use of NAFTIN Gel, 2% treatment should be discontinued.

Information for Patients:

1. Inform patients that NAFTIN (naftifine hydrochloride) Gel, 2% is for topical use only. NAFTIN (naftifine hydrochloride) Gel, 2% is not intended for ophthalmic, oral, or intravaginal use.

2. Patients should be directed to contact their physician if irritation develops with the use of NAFTIN (naftifine hydrochloride) Gel, 2%.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies to evaluate the carcinogenic potential of NAFTIN (naftifine hydrochloride) Gel, 2% have not been performed.

Pregnancy: Pregnancy Category B. There are no adequate and well-controlled trials of NAFTIN (naftifine hydrochloride) Gel, 2% in pregnant women. Because animal reproduction studies are not always predictive of human response, NAFTIN (naftifine hydrochloride) Gel, 2% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when NAFTIN (naftifine hydrochloride) Gel, 2% is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established. The number of pediatric subjects ≤12 years of age studied was too small to adequately assess safety and efficacy.

ADVERSE REACTIONS: In clinical trials with NAFTIN (naftifine hydrochloride) Gel, 2%, the most common adverse reactions (2%) were application site reactions.

NAFTIN (naftifine hydrochloride) Gel, 2% is manufactured for Merz Pharmaceuticals, LLC, Greensboro, NC 27410.

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Cavities may influence cancer risk

JAMA Otolaryngology-Head and Neck Surgery
September 2013

archotol.jamanetwork.com/article.aspx?articleid=1736930

PEOPLE WITH more dental cavities have less risk of being diagnosed with head and neck squamous cell carcinoma (HNSCC) than patients with few or no cavities, according to a study published online Sept. 12 in *JAMA Otolaryngology-Head and Neck Surgery*.

For the case-control study conducted in a comprehensive cancer center, researchers from the University at Buffalo, N.Y., evaluated 399 patients and 212 controls with a new diagnosis of HNSCC, and 221 participants without the cancer from 1999 to 2007. Researchers analyzed the dental history of all patients, especially history of dental cavities, by measuring the number of decayed, missing and filled teeth.

Study results showed that 146 of the total HNSCC patients (36.6 percent) had oral cavity squamous cell carcinoma (SCC). Oropharyngeal SCC was detected in 151 patients (37.8 percent), and 102 (25.6 percent) had laryngeal SCC.

After making adjustments for age at diagnosis, sex, marital status, smoking status and alcohol use, those falling in the upper tertiles of caries (odds ratio [OR], 0.32 [95 percent CI, 0.19-0.55]; P for trend=0.001), crowns (OR, 0.46 [95 percent CI, 0.26-0.84]; P for trend=0.03), and endodontic treatments (OR, 0.55 [95 percent CI, 0.30-1.01]; P for trend=0.15) were less likely to have HNSCC than those in the lower tertiles.

"We observed an inverse association between dental caries and HNSCC, which persisted among never smokers and never drinkers," study authors concluded. "Besides untreated caries, two other objective measures of long-standing caries history (endodontic treatments and crowns) were also inversely associated with HNSCC with similar effect sizes."

The study was funded by grants from the National Cancer Institute and the National Institute of Dental and Craniofacial Research. **DT**

Tests ID cancer markers in dermatomyositis

Arthritis & Rheumatism
September 2013

onlinelibrary.wiley.com/doi/10.1002/art.38093/abstract

RESEARCHERS have developed new assays to identify cancer biomarker antibodies against anti-transcriptional intermediary factor-1 (TIF-1 gamma) and nuclear matrix protein NXP-2 in patients with dermatomyositis, according to new findings published online Sept. 3.

Using immunoblotting and immunoprecipitation techniques, researchers detected antibodies against TIF-1 gamma and NXP-2 proteins. Researchers conducted blood analyses on 111 patients from Stanford University Dermatology Clinic and 102 patients from the Johns Hopkins University Myositis Center.

Results indicated 17 and 38 percent of patients in the two cohorts combined had antibodies against NXP-2 and TIF-1 gamma, respectively. Using the specific tests, approximately 83 percent of dermatomyositis patients with cancer reacted to NXP-2 or TIF-1 gamma. Additionally, factors such as cancer, older age and male gender appear to be associated with NXP-2 or TIF-1 gamma antibodies, with anti-NXP-2 especially linked with cancer in men.

Study authors suggested the results show that NXP-2 and TIF-1 gamma antibodies are typically dermatomyositis specificities (in 53 percent of patients) and are detected in most patients with cancer-related dermatomyositis.

Age appears to play a role in identifying patients with the highest cancer prevalence. In patients under age 60 without TIF-1 gamma or NXP-2 antibodies, the frequency of cancer is low (2.6 percent). Cancer frequency climbs to 11 percent in patients under age 60 with either TIF-1 gamma or NXP-2 antibodies. Over age 60, six out of 11 patients (55 percent) with NXP-2 antibodies had cancer. The frequency was nine out of 29 in patients with TIF-1 gamma antibodies and only three of 18 (17 percent) in patients without either of the antibodies. **DT**

Vaccination rates up, but so is measles incidence, CDC reports

Morbidity and Mortality Weekly Report
September 2013

www.cdc.gov/mmwr/preview/mmwrhtml/mm6236a1.htm

THOUGH IMMUNIZATION rates among children in the United States are high, there appears to be a rebirth of measles among unvaccinated children and adults, according to a Sept. 13, 2013 update from the Centers for Disease Control and Prevention (CDC).

The 2012 National Immunization survey shows that vaccination for many diseases is at or above 90 percent for children ages 19 months to 35 months.

Yet, as of late August, the CDC indicated reports of 159 known cases of measles in 2013. It's reportedly the second largest number of measles cases in the country since measles was eliminated in 2000.

Three outbreaks make up most of the 2013 cases — 65 cases in New York, 23 in North Carolina, and 20 in Texas. The disease has been detected in 16 states, and has targeted newborns to senior citizens. Thirty-six percent of patients were younger than 5 years, and 11 percent younger than 1 year, the latter of which were too young to be vaccinated. No deaths have been reported this year.Most cases were among unvaccinated people or those with unknown vaccination status.

According to the new data, vaccination rates for children born between 2009 and May 2011 for measles, mumps and rubella (MMR) was almost 91 percent; for polio, nearly 93 percent; and for hepatitis B and varicella/chickenpox, about 90 percent.

Coverage was lower for diphtheria, tetanus and pertussis (DTaP), at 83 percent; the full series of *Haemophilus influenzae* (Hib), at 81 percent; and four doses of pneumococcal conjugate vaccine (PCV), at less than 82 percent.

The CDC currently recommends that children get a measles/mumps/rubella vaccine at 12 months and again at 4 to 6 years of age. **DT**

Airport screeners may hold potential for cancer detection

Presented at the 246th National Meeting & Exposition of the American Chemical Society in Indianapolis

TECHNOLOGY in devices being used for airport security could lead to the development of more advanced skin cancer screening, recent research suggests.

The terahertz radiation (T-rays) used in airport security checkpoints can be used to detect the early signs of melanoma, according to research presented at the 246th National Meeting & Exposition of the American Chemical Society in Indianapolis.

T-rays can penetrate only a few millimeters through skin, cloth and other non-metallic materials. Research teams are harnessing T-rays to test their effectiveness for cancer diagnostics.

"T-rays are a form of non-ionizing radiation, like ordinary visible light, but they can be focused harmlessly below into the body and capture biochemical signatures of events like the start of cancer," Anis Rahman, Ph.D., president and chief technology officer, Applied Research & Photonics, Harrisburg, Pa., said of the technology.

Biochemical changes from chancer occur in the melanocytes before melanomas appear on the skin, investigators noted. **DT**

Lack of sleep may speed skin aging

Presented at the International Investigative Dermatology Meeting in Edinburgh, Scotland

SLEEP DEPRIVATION can increase the signs of aging in the skin and decrease the skin's ability to recover after sun exposure, a recent clinical trial indicates.

Researchers at University Hospitals Case Medical Center, Cleveland, examined 60 premenopausal women between the ages of 30 and 49, with half of the participants categorized as having poor sleep quality, according to a news release. This classification was made based on average duration of sleep and the Pittsburgh Sleep Quality Index.

Participants were given a visual skin evaluation and noninvasive skin tests such as UV light exposure and skin barrier disruption. Participants also completed sleep logs for one week to quantify sleep duration.

Poor quality sleepers demonstrated increased signs of intrinsic skin aging such as fine lines, uneven pigmentation and reduced elasticity. Good quality sleepers recovered more efficiently from skin stressors. Sunburn recovery was slower in those who got poor quality sleep, with erythema remaining higher over 72 hours.

Using a transepidermal water loss test at various points, good quality sleepers had recovery 30 percent higher than poor quality sleepers.

"Sleep deprived women show signs of premature skin aging and a decrease in their skin's ability to recovery after sun exposure," Elma Baron, M.D., the study's primary investigator, said in the news release.

The study was commissioned by Estée Lauder. **DT**

Risk of rosacea higher in females with migraines

Journal of the American Academy of Dermatology
September 2013

www.jaad.org/article/S0190-9622(13)00308-3/abstract

WOMEN who suffer from migraines may have a slightly higher risk of rosacea, a study suggests.

Investigators from the University of Basel, Switzerland, studied 53,927 participants with incident rosacea between 1995 and 2009. Participants were identified from the General Practice Research Database in the United Kingdom. They were matched with the same number of control participants who did not have rosacea, according to the study abstract.

There was a small overall association between rosacea and migraines in women (adjusted odds ratio [OR] 1.22, 95 percent confidence interval 1.16-1.29) but not in men. The effect was more pronounced in female migraine sufferers ages 50 to 59 (adjusted OR, 1.36).

"Female triptan users also revealed slightly increasing risk estimates with increasing age, with the highest odds ratio of 1.66 (95 percent confidence interval 1.30-2.10) in women ages 60 years or older," study authors noted.

The findings were published in the September issue of the *Journal of the American Academy of Dermatology*. **DT**

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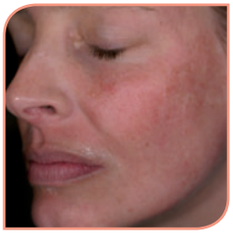

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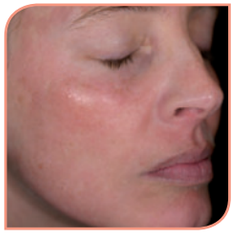

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*Barolet D, Lussier I, Mery S, Merial-Kieny C. Beneficial effects of spraying low mineral content thermal spring water after fractional photothermolysis in patients with dermal melasma. Journal of Cosmetic Dermatology 2009; 8:109-113. Individual results may vary.

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Dermatology Times

22 VITAMIN D
IOM research guidelines help to clarify controversies

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Advanced genetic testing paves way for personalized medicine

By Ilya Petrou, M.D. | Senior Staff Correspondent

WASHINGTON — New genetic testing methods may not only help identify the potential risk for individuals to develop certain diseases but may also open the door for more targeted therapies and management strategies, which could be of particular benefit in higher risk patient populations.

"Recent advances made in genetic mapping techniques, such as the development of whole exome and genome sequencing are allowing us to better and more quickly identify hereditary diseases ranging from genodermatoses, such as hidradenitis suppurativa and familial disseminated superficial actinic porokeratosis (DSAP) to a variety of cancers and other inheritable diseases," Jorge R. Toro, M.D., said at the 90th Atlantic Dermatological Conference in Washington. He is chief of the department of dermatology, Washington DC VA Medical Center. "These breakthrough technologies can help forge a more personalized medicine approach for our patients."

Putting the new genetic testing technology to work, researchers recently investigated the genetic basis of DSAP, a rare genetic variant of porokeratosis, in a group of Han Chinese families with extensive pedigrees (Zhang S-Q, Jiang T, Li M, et al. *Nat Genet*. 2012;44(10):1156-1160). Employing whole exome sequencing, researchers were able to specifically identify mutations in the MVK (mevalonate kinase) gene responsible for the autosomal dominant disease.

According to Dr. Toro, the identification of the susceptibility gene for DSAP can help advance the understanding of the molecular pathogenesis of the disease, which could lead to more targeted therapies and treatment strategies in the future.

"This is a powerful study based on the considerably large pedigrees and the exome sequencing technique used. After you do linkage analysis, the probability of identifying a gene is considerably high, and the ascertained genetic information is very strong," Dr. Toro says.

QUICK READ

The recent scientific advances in genetic mapping technologies can help in better understanding the genetic basis of inherited skin diseases, which may lead to more targeted future treatment strategies and management of patients with genetic skin diseases.

EVOLUTION OF TECHNIQUES

Gene testing has undergone significant evolution, progressing from single variant, full sequence of individual genes, and selected gene panel, to the now increasingly popular whole exome sequencing and whole genome sequencing techniques.

GENETIC MAPPING see page **21**

Quotable

"Risks of taking too much vitamin D are not well defined. We need to better understand what those risks are and at what levels of vitamin D they start to apply."

Martin A. Weinstock, M.D.
Providence, R.I.

See story, page 22

DTExtra

Vitamin D supplements can lower atopic dermatitis (AD) index scores, a study published in the August issue of the *Journal of the American Academy of Dermatology* suggests. Researchers studied vitamin D concentrations and a variety of factors in a cohort of 95 patients with AD and 58 controls. Patients with AD who had lower 25-hydroxyvitamin D3 levels had a higher frequency of bacterial skin infections. There were no significant correlations for vitamin D levels with other laboratory and clinical parameters.

SOURCE: HEALTHDAY NEWS

ANTIBIOTICS:

Limit orals, combine with topicals, experts advise from page 1

infections ranging from HIV to *Staphylococcus aureus* (*S. aureus*). Resistant infections increase the length and cost of treatment, the WHO says, and the time when patients remain infectious. Versus nonresistant infections, the fact sheet adds, resistant infections are twice as likely to kill.

CONTRIBUTING TO THE PROBLEM

In dermatology, says Whitney P. Bowe, M.D., studies show that resistant *Propionibacterium acnes* (*P. acnes*) makes patients more likely to fail treatment, although research has not yet established how much more likely. She is a dermatologist based in New York City and Westchester, N.Y., and clinical assistant professor of dermatology at the State University of New York Downstate Medical Center.

For all the above reasons, says Guy F. Webster, M.D., Ph.D., "We must maintain antibiotics' antibiotic activity," or more specifically, antibiotics' ability to kill microorganisms by interfering with key processes such as protein synthesis or cell wall formation. He is a dermatologist in private practice in Hockessin, Del.

Antimicrobials including benzoyl peroxide, on the other hand, are directly toxic to microorganisms — a distinction many dermatologists don't realize, Dr. Leyden says.

Dermatologists also may not fully appreciate their specialty's contribution to overall antibiotic use, he says. Although dermatologists represent 1 percent or less of the U.S. physician population, Dr. Leyden says that based on unpublished pharmaceutical industry monitoring data, "We prescribe almost 5 percent of antibiotic prescriptions. That means we are not the problem, but we are at least contributing potentially to it."

P. ACNES RESISTANCE

Much more than other physicians, Dr. Leyden explains, dermatologists tend to prescribe antibiotics chronically — particularly for acne and rosacea. Meanwhile, he says, "There's absolutely no controversy over the fact that *P. acnes*' sensitivity has changed drastically."

In the 1970s, Dr. Leyden and co-authors found no evidence of changes in *P. acnes*' antibiotic sensitivity in approximately 1,000 patients (Leyden JJ, Marples RR, Mills OH, Kligman AM. *South Med J*. 1974;67(1):20-25). Following the introduction of topical clindamycin and erythromycin in the United States, "By the late '80s, it was very difficult not to find microorganisms that had very different antibiotic sensitivity patterns" than they originally had. Similar patterns emerged in England (Eady EA, Cove JH, Holland KT, Cunliffe WJ. *Br J Dermatol*. 1989;121(1):51-57).

Overall, Dr. Bowe says that according to a systematic review, the prevalence of antibiotic resistant *P. acnes* grew from 20

ANTIBIOTICS see page **18**

ANTIBIOTICS:

Limit orals, combine with topicals, experts advise

from page 17

percent in 1978 to 62 percent in 1996. (Cooper AJ. *Med J Aust*. 1998;169(5):259-261).

Regarding specific drugs, Dr. Leyden says that worldwide, "Changes in *P. acnes* sensitivity to erythromycin have rendered that drug basically useless."

Resistance rates of *P. acnes* to topical erythromycin vary regionally, Dr. Webster says ranging from 30 to 50 percent.

"Clindamycin, when it first came out, was an excellent topical drug for acne," Dr. Webster says. "Now it's pretty much worthless, at least as monotherapy."

Conversely, Dr. Leyden says, "*P. acnes* still remains most sensitive to minocycline," followed by doxycycline, then tetracyclines.

Dr. Webster adds, "*S. aureus* is largely resistant to erythromycin. I don't know that anyone has correlated that with the use of topical erythromycin for acne for 30 years, but that's certainly a possibility."

INCREASED VULNERABILITY

Somewhat similarly, Dr. Bowe notes that antibiotics' ability to kill the body's normal protective flora may leave cell-surface receptors vulnerable to colonization with pathogens such as methicillin-resistant *S. aureus* (MRSA).

Since the 1970s, Dr. Leyden says, several papers have shown that antibiotics can be linked with increased carriage of Streptococcus pyogenes in the oropharynx, and with higher rates of upper respiratory tract infections.

Theodore Rosen, M.D., speaking at the American Academy of Dermatology Summer Academy meeting, warned, "Bacteria will conjugate with just about anything." And the *P. acnes* genome contains every known mechanism for passing on mutations that may confer resistance to other organisms in the microbiome, he said.

Moreover, even two weeks of oral antibiotics can alter the body's internal flora for weeks, months or years to come, Dr. Rosen says (Jernberg C, Löfmark S, Edlund C, Jansson JK. *Microbiology*. F010 Nov;156(Pt 11):3216-3223). Dr. Rosen is a professor of dermatology at Baylor College of Medicine, Houston.

The development of acne in increasingly younger children also may be contributing to changes in pathogens' sensitivity to antibiotics, says Lawrence F. Eichenfield, M.D., chief of pediatric and adolescent dermatology at Rady Children's Hospital and professor of pediatrics and medicine (dermatology) at the University of California, San Diego.

"We're seeing a fair amount of acne in younger children, as puberty has come earlier over time," Dr. Eichenfield says.

The presence of acne in younger children also correlates with development of more severe acne over time (Lucky AW. *Dermatology*. 1998;196(1):95-97), Dr. Leyden says. With more children being treated, Dr. Eichenfield says, "It's even more important to adhere to responsible antibiotic use."

GUIDELINES LIMIT ANTIBIOTIC USE

Instead of extended antibiotic use, several studies — and new pediatric acne guidelines (Eichenfield LF, Krakowski AC, Piggott C, et al. *Pediatrics*. 2013;131(Suppl 3):S163-S186) — support the concept of briefer courses of systemic antibiotics, used in combination with topical antimicrobials and retinoids.

In the former area, Dr. Webster says, "Benzoyl peroxide is broadly antimicrobial. It doesn't appear to exert a microbiologic stress, or select out one bacteria versus another, unlike topical clindamycin."

"A decade ago," Dr. Eichenfield says, "it was standard for dermatologists to prescribe 12 or 18 months — or much longer — of doxycycline or minocycline. Now the recommendation is to institute oral antibiotics along with topical therapy, in an attempt to limit the course of antibiotic therapy to two to four months, followed by topical maintenance. For difficult cases, one can include other systemic therapy" such as hormonal therapy or, in severe, resistant cases, isotretinoin.

Dr. Leyden says that the longest study that supports limited antibiotic courses for acne involved doxycycline plus an adapalene-benzoyl peroxide combination product, versus doxycycline plus placebo gel, for 12 weeks. Researchers then randomized patients who had reached 50 percent improvement into treatment with adapalene and benzoyl peroxide or antibiotic alone for 24 weeks. At that point, the group that used doxycycline followed by adapalene and benzoyl peroxide posted a 76 percent reduction in total lesion counts.

"This study clearly showed that one could maintain treatment results without systemic antibiotics after the initial 12 weeks, Dr. Leyden says (Tan J, Stein Gold L, Schlessinger J, et al. *J Drugs Dermatol*. 2012;11(2):174-180)."

Two prior studies showed similar results (Leyden J, Thiboutot DM, Shalita AR, et al. *Arch Dermatol*. 2006;142(5):605-612; Thiboutot DM, Shalita AR, Yamauchi PS, et al. *Arch Dermatol*. 2006;142(5):597-602).

Henceforth, Dr. Leyden says, "Someone needs to market these concepts." People may not read or remember journal articles, he says. "And they may not understand or believe everything in them. Then the publications are gone."

EXPANDING EDUCATION

Accordingly, Dr. Rosen recommends broad campaigns to educate both prescribers and patients that antibiotics are a precious, limited resource.

"Campaigns like that actually work (Ranji SR, Steinman MA, Shojania KG, Gonzales R. *Med Care*. 2008;46(8):847-862). I wish we would do that in our offices," Dr. Rosen says. Additionally, he tells dermatologists, "If there's an alternative to an antibiotic, consider it. If you think it's an infection, don't guess — culture it." And if using an antibiotic, "Make sure you use the right dose and duration."

Inculcating such habits will take time, Dr. Leyden says. "I wrote the first paper on the combination of a topical retinoid — tretinoin — and tetracycline antibiotics in 1973." However, he adds, it took dermatologists 25 years to broadly embrace the concept. Ultimately, he says, "It's up to dermatologists to accept the evidence." **DT**

Disclosures: Drs. Leyden and Webster are consultants for all manufacturers of acne drugs. Dr. Eichenfield served as co-chair for the American Acne and Rosacea Society guideline committee with Diane Thiboutot, M.D. He has received research support from Galderma. Dr. Rosen reports no relevant financial interests. Dr. Bowe is a consultant for Procter & Gamble, Johnson & Johnson Consumer Products, and Galderma.

NEW

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:
- Use this medication as directed by the physician.
- Topicort® Topical Spray is for external use only. Avoid use on the face, axilla or groin.
- Do not use this medication for any disorder other than that for which it was prescribed.
- Do not bandage or otherwise cover or wrap the treated skin so as to be occlusive.
- Report any signs of local or systemic adverse reactions to the physician.
- Do not use other corticosteroid-containing products with Topicort® Topical Spray without first consulting with the physician.
- Discontinue therapy when control is achieved. If no improvement is seen within 4 weeks, contact the physician.
- This medication is flammable; avoid heat, flame, or smoking when applying this product.
- Discard this product 30 days after dispensed by pharmacist.

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voice of the dermatologist

"Given the amount of continued research regarding the effects of vitamin D, it is certainly plausible that these recommendations may change over time."

Martin Weinstock, M.D.,
Providence, R.I. **page 22**

GENETIC MAPPING:

Technology advances may lead to targeted treatment strategies from page 16

Whole exome sequencing involves capturing the exons using array-based or liquid-phase hybridization (using DNA or RNA), and sequencing using next-generation technology. According to Dr. Toro, ideal candidates for whole exome sequencing would be those patients in whom individual gene tests and targeted gene panels are negative, with no molecular basis identified, and/or in those patients with a clinical phenotype of a disease that could be explained by one of many genes.

"The whole exome sequencing technique allows you to generate a massive amount of data, which needs to be filtered to find potential 'smoking guns.' In many cases, the novel technique can help further elucidate the genetic basis of a disease," Dr. Toro says.

Patients who request gene testing typically undergo an extensive diagnostic odyssey, he says, and whole exome and whole genome sequencing could facilitate the search for the responsible gene of the disease investigated. Moreover, these newer techniques also offer much more efficient, cost-effective and less time-consuming testing options when performing gene mapping.

"Whole exome and genome sequencing are allowing us to better and more quickly identify hereditary diseases."
Jorge Toro, M.D.
Washington

WEALTH OF INFORMATION

When looking for a specific condition or disease, Dr. Toro says that a single gene mapping approach could prove to be the appropriate testing technique. However, whole exome or whole genome testing approaches using next-generation technology could be ideal for more complex diseases, as these techniques enable the evaluation of millions of sequences concurrently.

"Whole exome and whole genome sequencing will typically give you a wealth of genetic information that may be associated with the investigated condition or disease. The tests may also give you other genetic data such as information regarding BRCA1 or BRCA2 gene mutations, which are associated with a higher risk for developing breast and ovarian cancers," Dr. Toro says.

According to Dr. Toro, whole genome sequencing, in particular, represents a very real view into the future of genetic testing and what personalized medicine will look like. The fledgling technique allows one to look at coding sequences of an individual's genome.

"Whole genome testing personifies the true meaning of personalized medicine. It allows you to look at the changes occurring in the chromosomes of an individual, and these changes as they relate to a condition or disease are going to indicate whether one should proceed with precautionary measures, such as the surveillance of certain diseases, drug therapy and prevention surgery," Dr. Toro says. **DT**

Disclosures: Dr. Toro reports no relevant financial interests.

Guidelines clarify controversies surrounding vitamin D

By Ilya Petrou, M.D. | senior staff correspondent

Miami Beach, Fla. — Vitamin D has been in and out of favor with physicians and their patients over the years. Controversies over the embattled vitamin still continue regarding its safe, beneficial daily allowance. According to recent research, however, and guidelines from the Institute of Medicine (IOM), the majority of Americans are taking enough vitamin D.

These guidelines advise that a sufficient vitamin D level is at or above 20 ng/mL, in contrast to older guidelines that put it above 30 ng/mL.

The investigatory panel also set new guidelines regarding the recommended daily allowance (RDA) of vitamin D and found that 400 IU for infants under 12 months old, 600 international units (IU) for children and adults younger than 70, and 800 IU for those older than 70 are not only safe, but beneficial in maintaining musculoskeletal health.

"Many people can benefit from supplements. According to the IOM report, a vitamin D supplement dosed at 600 IU a day is safe, and I think the data is pretty strong to support that," says Martin A. Weinstock, M.D., department of dermatology, Rhode Island Hospital, Brown University, Providence, R.I.

FULFILLING DAILY INTAKE

The three sources of vitamin D include skin synthesis after exposure to ultraviolet light, certain foods, and supplements.

The official recommended daily intake of 600 IU of vitamin D may be achieved through fortified food sources, particularly milk, but, according to Dr. Weinstock, most people today do not get anywhere near the recommended daily allowance this way.

"The main source of vitamin D is via ultraviolet light exposure from the sun. Clearly, we do not recommend for people to increasingly expose themselves to the sun for the sake of vitamin D synthesis because of the increased risk of developing skin cancer," Dr. Weinstock says. "However, under normal circumstances, people are not completely protected from the ultraviolet rays of the sun and they do get a certain amount of sun during normal activities, boosting vitamin D synthesis and vitamin D levels."

QUICK READ

Recent research and guidelines issued by the Institute of Medicine may help clarify the ongoing controversies regarding vitamin D.

In those patients who are concerned about their vitamin D levels, Dr. Weinstock advises that vitamin D dietary supplements could be taken according to the new IOM guidelines, or vitamin D-fortified foods could be added and/or increased in their diet.

> "Under normal circumstances, people … do get a certain amount of sun during normal activities, boosting vitamin D synthesis and vitamin D levels."
>
> **Martin A. Weinstock, M.D.**
> Providence, R.I.

Patients who are concerned about potentially low levels of vitamin D have the option of taking a blood test to check their serum levels of 25-hydroxyvitamin D, the common measure of vitamin D status. Accordingly, the clinician can recommend dietary supplements or other methods to achieve normal levels of the vitamin.

EXCESS RISK UNDEFINED

The main risk related to vitamin D excess would be supplementing with doses well above the RDA, Dr. Weinstock says.

According to the guidelines, the "upper limit" for safe daily vitamin D intake is 4,000 IU. Concerns regarding excess could include hypercalcemia and hypercalciuria, potential renal stones, increased cancer risk, or other adverse health outcomes, he says.

"Unfortunately, risks of taking too much vitamin D are not very well defined. We need to better understand what those risks are and at what levels of vitamin D they start to apply in each patient," he says.

The primary known benefit of vitamin D supplements is musculoskeletal health. Supplementation reduces risk of falls and fractures, particularly among the elderly, he says. In concurrence with the IOM research, however, Dr. Weinstock says there is no strong evidence linking low vitamin D with various cancers, heart disease, diabetes and other conditions.

"This is an ever-changing field and I would suggest that physicians remain attentive regarding the newest literature on vitamin D. Given the amount of continued research regarding the effects of vitamin D, it is certainly plausible that these recommendations may change over time," Dr. Weinstock says. **DT**

Disclosures: Dr. Weinstock reports no relevant financial interests.

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COMBO THERAPIES:

Treatments evolve for countless dermatologic conditions from page 1

cancers, but also surrounding actinic keratoses.

"Field cancerization sometimes makes surgical therapy difficult because if the tumor is ill-defined and sits in a field of precancerous and cancerous background, it is difficult for us to get clear margins. And it is difficult for us to treat the cancer completely. Therefore, combination therapies in that situation provide help," Dr. Zhang says.

SKIN CANCER OPTIONS

While surgical modalities remain the mainstay treatment for primary nonmelanoma skin cancer and melanoma, other options often help to clear the field of cancerization. Such options include electrodesiccation and curettage, cryotherapy, chemical peels and laser treatments, photodynamic therapy and topical modalities, according to Dr. Zhang.

"Topical modalities are more frequently used today," she says.

Among the topical options: immunomodulators, such as imiquimod; chemotherapy agents, including 5 fluorouracil (5-FU); diclofenac (a nonsteroidal anti-inflammatory), topical retinoids and, a plant extract approved by the Food and Drug Administration in January 2012, ingenol mebutate.

Imiquimod, which is FDA-approved to treat actinic keratosis, has also been shown in studies to be an effective adjunct to surgery in the treatment of melanoma in situ, according to Dr. Zhang.

"There also are case reports indicating topical imiquimod in the treatment of melanoma in situ and melanoma cutaneous metastases. So that is potentially another important component ... in combination with surgery for the treatment of melanoma in situ or possibly as part of the treatment regimen for metastatic melanoma in conjunction with BRAF inhibitors or targeted immunotherapy. Further studies need to be done to confirm this as a viable treatment modality," she says.

EMERGING MODALITIES

Emerging nonsurgical modalities to treat precancerous and cancerous skin lesions include chemical peels and laser ablation, using a CO_2 laser or photodynamic therapy, she says.

Dr. Zhang also uses systemic medications in conjunction with surgery in the treatment of high-risk squamous cell carcinoma. These include oral retinoids and, on the horizon, oral capecitabine.

"Articles published have been using low dose capecitabine in the fashion of oral retinoids, for chemoprevention," Dr. Zhang says. "Of course, the new revolution in the treatment of basal cell carcinoma is the new biologic medication, vismodegib, which is indicated to treat locally advanced basal cell carcinoma, metastatic basal cell carcinoma and ... nevoid basal cell syndrome."

> "We have a lot of data now showing that what we eat and drink is impacting our skin."
>
> **Whitney Bowe, M.D.**
> New York

While researchers have yet to publish studies on combination therapies using biologics, combinations in this realm are probably in the future, Dr. Zhang says.

In essence, if a dermatologic surgeon sees a skin cancer lesion is ill-defined, sitting in a field of a precancerous or actinic damaged background, Dr. Zhang says it can be a good approach to first give the patient a course of topical therapy or other combination therapy to treat the field prior to surgery.

"Photodynamic therapy is the emerging nonsurgical modality. We've been using it more often because it can treat a large field of actinic damage," she says. "Photodynamic therapy has also been effective in reducing the incidence of new skin cancers."

STANDARD FOR ACNE

Using combinations of therapies is standard practice in acne treatment, according to Whitney Bowe, M.D., assistant clinical professor of dermatology, SUNY Downstate Medical Center, New York.

"There are multiple factors that lead to acne lesions and multiple contributors to acne pathogenesis. So, if you can attack acne from multiple perspectives and attack it at different points in that cascade that leads to acne, you're more successful with therapy," she says.

There are important advantages to using combination acne treatments. Using retinoids, for example, in combination with other treatments speeds acne's response to the retinoids, she says.

Dr. Bowe, who has published and lectured extensively on acne, says the most critical combination therapy in acne continues to be the use of benzoyl peroxide with any oral or topical antibiotic. The combination approach is especially important given that bacterial and antibiotic resistance has become a major issue, she says.

"Nowadays, there are very high resistance rates. Erythromycin is barely effective anymore, and there is a lot of resistance to topical clindamycin, oral tetracycline and doxycycline," Dr. Bowe says. "The least amount of resistance is with oral minocycline, but even with oral minocycline, there are increasing levels of resistance."

COMBO see page 26

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COMBO THERAPIES:

Treatments evolve for countless dermatologic conditions from page 24

For acne on the face, chest and back, dermatologists often use oral antibiotics and benzoyl peroxide, in addition to a retinoid. And for acne in adult females who are experiencing flares that seem to be hormonal in nature, it's important to consider adding an oral contraceptive or an oral androgen antagonist (spironolactone) to the topical retinoid and benzoyl peroxide regimen.

One of the newer acne combination therapies is Epiduo (Galderma), a combination of benzoyl peroxide and adapalene.

"Adapalene is a retinoid molecule, whereas, benzoyl peroxide has an antibacterial mechanism of action, where it actually kills bacteria rather than slowing its growth (it's bactericidal, not simply bacteriostatic)," Dr. Bowe says. "The fact that this company was able to stabilize this molecule, adapalene, alongside benzoyl peroxide is very promising. Dermatologists would use it as a combination treatment topically, for people struggling with mild-to-moderate acne, or they would use it in combination with an oral antibiotic for people struggling with moderate-to-severe acne."

NEW APPROACHES

What's new? A more holistic approach to acne treatment, according to Dr. Bowe.

"Stress reduction and diet modifications are meant to be used in conjunction with the tried-and-true prescription therapies for acne, so they can potentially help us to wean our patients off the prescriptions faster and maintain clearance longer in between flares," she says. "We have a lot of data now showing that what we eat and drink is impacting our skin."

The two strongest recommendations when it comes to diet, according to the dermatologist, are to avoid high glycemic index foods and dairy. High glycemic index foods have high amounts of refined carbohydrates and include white bread, white pasta, cornflakes and chips. Dr. Bowe recommends replacing these and other high glycemic index foods with low glycemic foods, such as barley, multigrain bread, sweet potatoes, nuts, vegetables and lean protein.

Another combination therapy outside the prescribing box is stress reduction.

"We have a lot of basic science studies showing that certain stress hormones, like corticotropin releasing hormones and substance P, are actually able to bind directly to oil glands and promote acne flairs," Dr. Bowe says. "... meditation, yoga, deep breathing, talking to friends, any of those things can be beneficial for people who have acne."

COMBINATIONS SHOW PROMISE

There's no question, combination approaches are important in psoriasis, says Johann E. Gudjonsson, M.D., Ph.D., assistant professor of dermatology, University of Michigan, Ann Arbor.

"Using combination therapies is something we've been doing for a very long time, most commonly with different combinations of topical treatments and UV phototherapy," he says.

"With the advent of whole new classes of therapeutics, including the biologics, it has opened up the possibility of combining different therapies, both old and new, for increased therapeutic effect," he says. "When we combine treatments, we can often get by with a lower dose of either agent that we use. By using a lower dose (of agents) with no or minimal overlapping of side effects, you can often offer a pretty safe treatment for psoriasis."

SEVERE CASES ONLY

When using systemic drugs, dermatologists treating psoriasis patients should reserve combination therapies for more severe cases, where monotherapy isn't achieving full control, Dr. Gudjonsson says.

Among the combinations used commonly in patients with more severe disease: systemic medication, such as methotrexate, with light treatment, or methotrexate with biologics.

"We often 'rescue' them, so to speak. They might be beginning to fail biologic treatment, then we use the combination to kind of get the effect back," Dr. Gudjonsson says. "The other reason we often use combination of systemic therapies — especially with methotrexate — is to prevent development of anti-drug antibodies that may, with time, neutralize the biologic that we have been using."

In recent years, dermatologists have been combining anti-tumor necrosis factor (anti-TNF) agents, such as adalimumab, infliximab, with methotrexate either at the start of treatment, or when patients begin to fail biologic monotherapies. Dr. Gudjonsson says the newest psoriasis combination treatment that he has been using has been Stelara (ustekinumab, Janssen Biotech) and methotrexate.

"Again, it comes down to having a patient who is not fully controlled on biologic monotherapy, and we're trying to maintain the therapeutic response or preventing treatment failure by adding another agent that has minimal overlap in side effects," he says.

While data on combining different biologic treatments for psoriasis is lacking, there is limited data indicating the efficacy of combining biologic treatments with older, traditional systemic medications such as methotrexate or acitretin, or UV phototherapy.

PAYING IT FORWARD

One of the most important combinations in cosmetic dermatology, says dermatologist Christopher B.

COMBO see page 28

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COMBO THERAPIES:

Treatments evolve for countless dermatologic conditions from page 26

Harmon, M.D., of Birmingham, Ala., is that of neurotoxins and fillers. Dermatologists have long known neurotoxins are best for the upper third of the face and fillers for the lower third, he says.

"We've also known there are lots of exceptions. There are great uses for neurotoxins around the mouth. But the neurotoxin combined with the filler often gives greater longevity to the filler," he says.

Combining neurotoxins with laser resurfacing or medium-depth chemical peels also helps enhance those laser treatments or peels. According to Dr. Harmon, new combined ablative and nonablative fractionated devices offer a significant improvement in the treatment of rhytids.

"When you combine (these devices) with a neurotoxin, then, it multiplies the long-term benefit of the resurfacing procedure," he says.

The benefit of adding a neurotoxin to a medium-depth chemical peel is the skin peels and remodels when muscles are adynamic, preventing the muscle from reforming nearby lines. Essentially, the peel does its job to even the skin tone and texture, while the neurotoxin helps diminish rhytids.

"(Adding a neurotoxin) prolongs and maximizes the impact of the resurfacing treatment, whether it's a chemical peel or light and laser," he says. "Ideally you want to do it two or three weeks ahead of the resurfacing, so during the wound-healing phase those muscles and that skin are inactive."

COSMETIC APPROACHES

Another trend is ushering a cosmetic-medical dermatology combination approach for acne. Thinner fillers, such as Belotero Balance (Merz Aesthetics), are becoming increasingly popular because clinicians can place these superficially in the papillary dermis and not worry about inflammatory papules occurring. These thinner fillers are ideal for filling in acne scars, Dr. Harmon says.

Macrene Alexiades-Armenakas, M.D., Ph.D., assistant clinical professor, Yale University School of Medicine, New Haven, Conn., says there are other combination approaches that can boost therapeutic efficacy from cosmetic procedures. One example: The combination of devices that treat rhytids and photodamage, such as intense pulsed light or fractional CO_2, with devices that treat skin laxity, such as infrared or radiofrequency.

"Another example is combining devices with topical anti-aging actives. Currently, I am conducting an IRB trial combining topical application of 37 Extreme Actives, an anti-aging cream ... with an ultrasound device, the Alma Impact (Alma Lasers), which has been shown to increase penetration of topically applied agents into the skin," Dr. Armenakas says. "This is a new area of research that is sure to open up new vistas in our field." **DT**

Disclosures: Dr. Gudjonsson has conducted clinical trials with Amgen. Dr. Bowe has served as a consultant for Johnson & Johnson consumer products, Proctor & Gamble, L'Oreal and Galderma. Dr. Alexiades-Armenakas has a research grant from Alma and is finishing a funded study with Syneron. Drs. Bowe, Harmon and Zhang report no relevant financial interests.

Warts in children may self-resolve

Leiden, Netherlands — As many of half of the warts in children ages 4 to 12 will resolve without treatment, a recent study published in the September/October issue of *Annals of Family Medicine* indicates.

If the warts measured at least 1 cm in diameter, children were more likely to pursue treatment (odds ratio = 3.2; 95 percent confidence interval [CI], 1.9-5.3), researchers noted. This was especially true when parents reported that their child's warts caused inconvenience (odds ratio = 38; 95 percent CI, 16-90).

At one year, the complete resolution rate was 52 per 100 person-years at risk. For each year of age decrease, the likelihood of resolution increased by about 10 percent.

"Patients and family physicians should weigh the benign natural course, the adverse effects of treatments, and the costs on the one hand, and the effectiveness of treatments and the risk of spreading untreated warts on the other," study authors stated. "Future research needs to more precisely establish the time to resolution of warts and identify subgroups of patients with relatively low natural resolution rates and high treatment response rates." **DT**

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

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

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

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

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

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

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

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

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

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

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

CONTRAINDICATIONS
None.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

* All Grades: mild, moderate or severe

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

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

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

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

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

* Mild, Moderate, or Severe

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

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

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

Clinical Trials Experience: External Genital Warts

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

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

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

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

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

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

Postmarketing Experience

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

Application Site Disorders: tingling at the application site

Body as a Whole: angioedema

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

Endocrine: thyroiditis

Gastro-Intestinal System Disorders: abdominal pain

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

Hepatic: abnormal liver function

Infections and Infestations: herpes simplex

Musculo-Skeletal System Disorders: arthralgia

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

Respiratory: dyspnea

Urinary System Disorders: proteinuria, urinary retention, dysuria

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

Vascular: Henoch-Schonlein purpura syndrome

OVERDOSAGE

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

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

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

April 2012 19110248

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

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

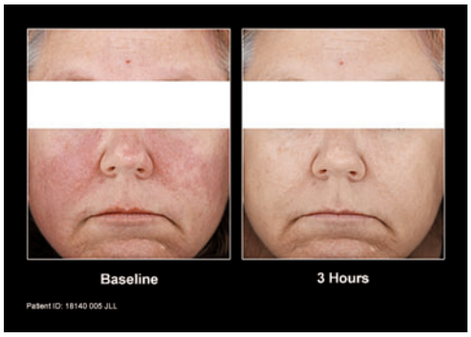
Flu-like signs and symptoms may accompany, or even precede, local skin reactions and may include fatigue, nausea, fever, myalgias, arthralgias, malaise and chills.

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

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

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

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



GALDERMA LABORATORIES

Topical gel indicated for facial erythema of rosacea

Mirvaso (brimonidine 0.33 percent) topical gel has been approved by the Food and Drug Administration for the treatment of facial erythema of rosacea in adults ages 18 and older. Applied once daily, Mirvaso gel works to reduce rosacea redness and lasts for up to 12 hours, according to the company.

Two phase 3 studies showed that adults who used Mirvaso gel had a greater improvement in facial redness of rosacea than vehicle gel. The topical gel constricts dilated facial blood vessels to reduce rosacea redness. Mirvaso gel should be applied in a pea-sized amount, once daily to five facial regions: forehead, chin, nose, and each cheek.

Mirvaso gel is safe and well-tolerated, according to the company. In controlled trials common adverse reactions included erythema, flushing, skin burning sensation and contact dermatitis.

FOR MORE INFORMATION:
www.galderma.com

TOPMD SKIN CARE

Body wash reduces eczema symptoms

CLn BodyWash is designed to help ease symptoms of eczema and atopic dermatitis. The non-drying wash helps to cleanse skin prone to eczema, acne, infection and folliculitis, according to the company.

The non-irritating gel cleanser has the benefits of a bleach bath, but the convenience and portability of a gel cleanser. The over-the-counter body wash has a sodium hypochlorite base and has been clinically tested to be safe and effective in children ages 6 months and older. The product can be used in the shower or bath. Complementary products include the CLn SportWash and CLn Facial Cleanser.

FOR MORE INFORMATION:
www.clnwash.com

CALIBER IMAGING & DIAGNOSTICS

Imaging device offers noninvasive skin biopsy

The VivaScope 1500 Multilaser system, the newest device in the company's VivaScope confocal microscope product line, enables the opportunity for a painless, noninvasive optical skin biopsy, the company states.

The new VivaScope 1500 Multilaser systems include three lasers of different wavelengths that can be used in fluorescence-mode imaging to enhance image contrast when combined with dyes that are approved for human use by the Food and Drug Administration. With the VivaScope 1500 Multilaser system, changes in living skin are viewed at the cellular level, and because the imaging is noninvasive, cellular changes can be monitored over time without damage to the tissue, according to the company.

FOR MORE INFORMATION:
www.caliberid.com

TACTILE MEDICAL

Woundcare device manages venous leg ulcers

The ACTitouch Adaptive Compression Therapy system is an ambulatory device for patients with chronic wounds. The device combines intermittent and sustained compression therapies to help heal venous leg ulcers, according to the company.

The ACTitouch system's lightweight, wraparound sleeve can be removed for bathing or sleeping. Air-filled chambers and a padded undersock provide a comfortable fit and the device can be worn discreetly beneath clothing and with regular shoes, the company states.

The ACTitouch system includes a Therapy Tracker to further support and improve patient utilization. The tracker automatically records and displays average daily use in each of the two compression modes, generating data clinicians can use to reinforce patient therapy goals.

FOR MORE INFORMATION:
www.tactilemedical.com

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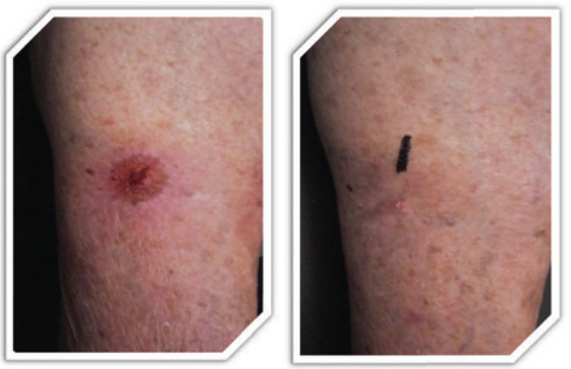

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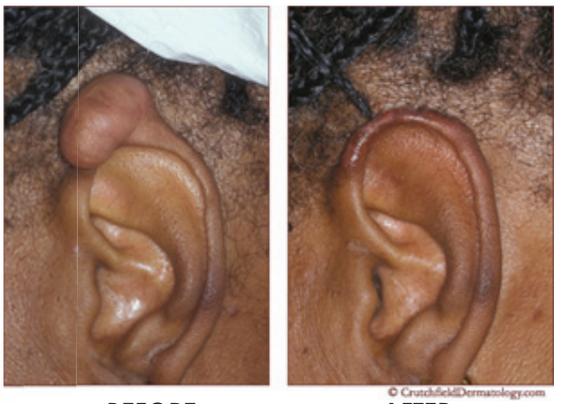

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41 **HA PRODUCTS IN EUROPE**
European physicians have access to a broader range of hyaluronic acid fillers than those in U.S.

48 **EXPLORING NEURON DEATH**
Certain botulinum toxin types cleave proteins that can result in blocking neurotransmitter release

Can telomere manipulation stop the biological clock?

John Jesitus | Senior Staff Correspondent

WAILEA, HAWAII — Factors including UV exposure and psychological stress can accelerate the aging process, partly through their influence on telomeres, an expert says. Research is beginning to uncover strategies to counter these forces, however.

Telomeres are critical for protecting the genome, preventing cancers and regulating the aging process, says Barbara A. Gilchrest, M.D., professor and chair emeritus, department of dermatology, Boston University School of Medicine.

"Aging is nature's way of protecting organisms from alterations in the genome. Nature doesn't care if our skin looks awful. It only cares that the genome is protected. When cells divide, there is a tiny but known, constant risk of mistakes being made in replicating the genome. That's one of the reasons cancer risk increases with age," Dr. Gilchrest, who spoke at MauiDerm 2013, says. "Additionally, sun exposure is known to cause DNA damage."

Rather than allow cells that are becoming mutated and dysregulated due to accumulated DNA damage to replicate, she says, aging shuts these cells down.

"It's been well documented that with repeated cell division, the cells ultimately will undergo either senescence (the cells simply stop dividing) or apoptosis (cell suicide)," she says.

Along with cumulative DNA damage, she says that over the past decade, research has identified telomere shortening as another major aging mechanism.

"Currently, telomere biology is perhaps the hottest topic in our attempts to understand aging skin and other tissues," she says.

QUICK READ

The aging process prevents replication of cells whose DNA is potentially damaged, an expert says. Within this process, she adds, stress, UV radiation and exercise have been shown to impact the length of telomeres.

LOOKING DEEPER AT DNA

In the DNA replication process, "At the tip of each chromosome reside approximately 10,000 base pairs of telomeric DNA," all of which repeat the TTAGGG (thymine, adenine, guanine) sequence and form a loop at the end of each chromosome. "The very end of the telomere tucks into the proximal part of the telomere, making a closed loop that essentially hides the TTAGGG sequence within the double-stranded DNA. Thus, the cell never sees this TTAGGG sequence — except when the chromosomes must straighten out in order to be replicated, or at times of major damage, when the telomeric strands may separate because of bulky adducts or to accommodate repair proteins."

Without telomeres, Dr. Gilchrest says, any cell will die.

TELOMERE MANIPULATION see page 44

Quotable

"We have high-cohesivity HAs, as well as very low-cohesivity HAs, that are not available in the United States."

Patrick Trevidic, M.D.
Paris

See story, page 41

DTExtra

Low-level laser therapy (LLLT) appears to be a safe and effective option for treating hair loss, according to a study published in *Lasers in Surgery and Medicine*. Investigators with Massachusetts General Hospital, Boston, reviewed medical literature and found that LLLT stimulated hair growth in mice that had chemotherapy-induced alopecia and in mice with alopecia areata. LLLT also demonstrated hair growth stimulation in controlled clinical trials in men and women. The therapy helped to move follicles to the anagen phase, according to the study.

SOURCE: HEALTHDAY NEWS

Hyaluronic acid products dominate filler market in Europe

By John Jesitus | Senior Staff Correspondent

LAS VEGAS — In the European Union (EU), a simple approval process for hyaluronic acid (HA) products has yielded a broader array of offerings than what's available in the United States, an expert says. Easier EU approvals also have given HA a virtual lock on the European filler market, he adds.

"The European Commission considers fillers to be medical devices, and it is easier to obtain a CE mark than FDA (Food and Drug Administration) approval," says Patrick Trevidic, M.D., a Paris-based plastic, reconstructive and cosmetic surgeon in private practice. "That's why HA has 95 percent of the filler market in Europe."

These conditions also explain why the European filler market includes a broader spectrum of HA cohesivity.

QUICK READ

European physicians use a broader range of hyaluronic acid fillers than those available stateside, says an expert. European consensus guidelines suggest injecting HA with needles or cannulas, depending on the indication.

"We have high-cohesivity HAs, as well as very low-cohesivity HAs, that are not available in the United States," he says.

HA INDICATIONS

Indications for the former include body and buttocks remodeling, versus facial and fine line filling for the low-cohesivity fillers, which generally use non-cross-linked HA.

In 2012, after conferring with European authorities, Galderma subsidiary Q-Med stopped marketing the highly cohesive Macrolane (HA) for breast augmentation because radiologists say it can make reading mammograms difficult, and because HA degradation stimulates neovascularization, Dr. Trevidic says. Presently, he adds, "We are waiting for more clinical and radiological

HA FILLERS IN EUROPE see page 42

HA FILLERS IN EUROPE:

Broader range of hyaluronic acid products available overseas

from page 41

studies to be completed." Recent research includes a two-year follow-up study that he and several colleagues recently completed (submitted for publication).

Regulators are looking for longer-term data, Dr. Trevidic says, but he expresses confidence that in time, research will show that Macrolane is safe for breast augmentation. All forms of breast augmentation can make reading mammograms more challenging, says a Q-Med press release. Macrolane is still available for body contouring in the EU, Dr. Trevidic says.

CANNULAS' ADVANTAGES

As for injection tools, "In Europe, we were first to launch the cannula, starting more than five years ago with the Pix'L Micro Cannula (Q-Med). We began using it for some specific areas such as the periorbital area and the perioral/lip area. And now we use the cannula for virtually all injection areas" because cannulas cause less pain and bruising and fewer hematomas.

"Also, because the cannula has a blunt tip, we have fewer adverse events like embolisms. Cannulas are a little more expensive, but they are a step forward for our patients," he says.

97 PERCENT

A 2010 study of 32 patients demonstrated that HA with lidocaine resulted in decreased pain for this percentage of patients.

For superficial injections using low-cohesivity HA, Dr. Trevidic recommends using 30- to 27-gauge flexible cannulas, versus 25-, 23- or 21-gauge rigid cannulas for deeper injections designed to replace volume and lift skin, such as in the periorbital area. Additionally, Expert2 Expert (E2e), a Paris-based organization offering education in aesthetic medicine and dermatology, provides the following consensus recommendations:

The temporal area — "We use bolus injections deep on the bone when we want to lift an area, and there is no anatomical danger in the area," Dr. Trevidic says. Conversely, a needle might pierce a blood vessel or other structure in areas such as the periorbital region. Additional areas suitable for bolus injections include the malar and chin areas, including the mandibular ligament, he says.

The middle third of the face — Here, he says, E2e recommends injecting in two planes: deep bolus injections, plus superficial injections performed with lighter cannulas to spread low-cohesivity HA throughout the malar region.

The mandibular line — deep cannula injections; **the nasolabial and marionette lines** — needle or cannula injections; **the lips** — cannula for augmentation, needle for Cupid's bow and fine lines.

INCORPORATING LIDOCAINE

Regarding injection-site pain, he says, Allergan was the first HA filler manufacturer to incorporate lidocaine into its products in Europe. Conversely, European law prohibits physicians from mixing other filler materials such as calcium hydroxylapatite with lidocaine. Accordingly, "CHA is not used often in Europe. We prefer HA, which is now mixed with lidocaine in all manufacturers' prepackaged syringes."

In 2010, Dr. Trevidic was a co-investigator with Paris-based plastic surgeon Flavio Facchini, M.D., on a double-blinded, randomized, controlled trial involving 32 patients. It showed that lidocaine decreases pain for 97 percent of patients (data on file with manufacturer). Other studies assessing pain during injections of HA combined with lidocaine revealed similar results: greater comfort for patients, he says.

In contrast, Dr. Trevidic says that much of the EU excludes silicone and other permanent fillers. In France's experience, he says, such fillers may not pose dangers immediately, but they may at two to four years after implantation, when granulomas may form.

For similar reasons, the EU suspended its approval of DermaLive (acrylic hydrogel, HA; Dermatech) in 2003. People may have called this product a semi-permanent filler, he says, "But that means nothing." Because it included silicone, Dr. Trevidic says, any problems the material created were likely to last a lifetime. **DT**

Disclosures: Dr. Trevidic is a consultant for Merz, Teoxane, Galderma, Ipsen/Galderma and TSK Laboratory but owns no stock in these companies. He is also a member of E2e.

Consensus recommendations

- **THE TEMPORAL AREA**
  Bolus injections deep on the bone to lift an area when there is no anatomical danger in the area.
- **THE MIDDLE THIRD OF THE FACE**
  Inject in two planes: deep bolus injections, plus superficial injections performed with lighter cannulas to spread low-cohesivity HA throughout the malar region.
- **THE MANDIBULAR LINE**
  Deep cannula injections.
- **THE NASOLABIAL & MARIONETTE LINES**
  Needle or cannula injections.
- **THE LIPS**
  Cannula for augmentation, needle for Cupid's bow and fine lines.

— Expert2Expert (E2e)

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TELOMERE MANIPULATION:

Slowing the aging process through telomere manipulation

from page 44

"It's also been shown that the telomeres shorten with each round of replication. Therefore, telomeres have been called the biological clock. They tell a cell how old it is, and if it's time to enter senescence or apoptosis," she says.

"If one experimentally disrupts telomeres and exposes the TTAGGG sequence, the cell responds as if it had experienced DNA damage. It will turn on all of its DNA damage response pathways, which include the p53 protein, also called the Guardian of the Genome."

The cell responds strongly to environmental insults, Dr. Gilchrest says, because within the TTAGGG sequence, "The thymidines are where UV causes most of its damage. It dimerizes or hooks together adjacent thymidine residues. That explains about 80 percent of the damage that results from sun exposure. Guanine residues are the site of oxidative damage, and chemical carcinogens also target guanines and, less often, adjacent guanine-adenine residues. Therefore, the telomeres are a superb target for DNA damage."

> "Nature doesn't care if our skin looks awful. It only cares that the genome is protected."
>
> **Barbara Gilchrest, M.D.**
> Boston

RESPONSE TO DAMAGE

Research has shown that any DNA-damaging agent that injures cells creates damage throughout the genome, she adds. "But you get far more damage in the telomere. With UV, for example, you get about seven times more damage in the telomere than in the rest of the DNA. To me, it suggests that one of the functions of telomeres is to recognize that damage is occurring, and to help the cells respond appropriately. One appropriate mutation-avoidance response might be aging."

80 PERCENT

of the damage that results from sun exposure is due to the UV that dimerizes or hooks together adjacent thymidine residues.

Moreover, "Telomere lengths have been strongly implicated in human aging," she says.

In people age 60 and older, Dr. Gilchrest says, telomere length correlates with longevity (Cawthon RM, Smith KR, O'Brien E, et al. *Lancet.* 2003;361(9355):393-395). Conversely, extremely short telomeres characterize rare diseases marked by accelerated aging, such as Werner syndrome and progeria.

IMPACT OF STRESS

Other factors that contribute to aging include stress. A study co-authored by Nobel Prize laureate Elizabeth Blackburn, Ph.D., showed that mothers dealing with the stress of chronically ill children had shorter telomeres and decreased telomerase activity versus mothers with healthy children (Epel ES, Blackburn EH, Lin J, et al. *Proc Natl Acad Sci U S A.* 2004;101(49):17312-17315). However, physical activity appears to prevent telomere shortening caused by psychological stress (Puterman E, Lin J, Blackburn E, et al. *PLoS One.* 2010;5(5):e10837).

More recently, a study showed that endogenously reactivating telomerase activity in telomerase-deficient mice extends telomeres, reduces DNA damage signaling and prevents age-associated degeneration of multiple organs (Jaskelioff M, Muller FL, Paik JH, et al. *Nature.* 2011;469(7328):102-106). Accordingly, study authors write that their results "support the development of regenerative strategies designed to restore telomere integrity."

No one knows when these insights might generate anti-aging therapies for the skin or other organs, Dr. Gilchrest says, but many efforts are being harnessed toward this goal.

"For now," she says, "we must still rely on minimizing environmental DNA damage from sun exposure, cigarette smoke, air pollution, and other carcinogens." **DT**

Disclosures: Dr. Gilchrest reports no relevant financial interests.

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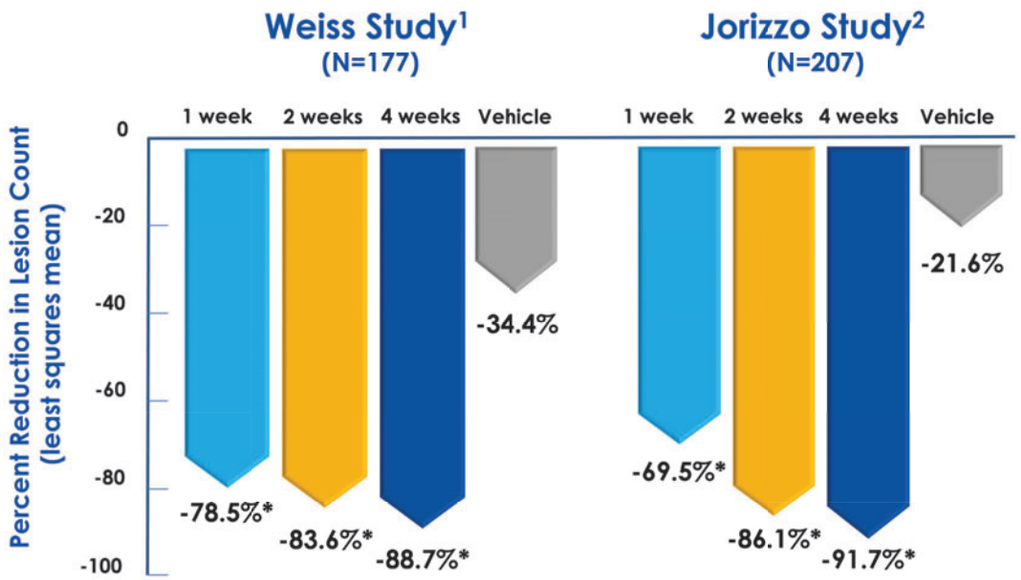
Significant AK lesion reduction at 1, 2, and 4 weeks



*P<.001 vs vehicle.

Results from two Phase 3 vehicle-controlled, randomized, double-blind, multicenter studies of patients (N=384) with actinic keratoses. Secondary endpoint of percent reduction (least squares mean) in AK lesions at 1, 2 and 4 weeks compared active to vehicle.

Significant mean reduction in the number of AK lesions with 1 week of treatment compared to vehicle[1,2]

- Flexibility to prescribe for as little as 1 week or as long as 4 weeks, depending on tolerability and treatment goals.

Carac is indicated for the topical treatment of multiple actinic or solar keratoses of the face and anterior scalp.

Important Safety Information

Carac is contraindicated in women who are nursing, pregnant or may become pregnant as fluorouracil may cause fetal harm.

Carac should not be used in patients with dihydropyrimidine dehydrogenase (DPD) enzyme deficiency.

Rarely, unexpected, systemic toxicity (e.g., stomatitis, diarrhea, neutropenia, and neurotoxicity) associated with parenteral administration of fluorouracil has been attributed to deficiency of dihydropyrimidine dehydrogenase "DPD" activity. Symptoms included severe abdominal pain, bloody diarrhea, vomiting, fever, and chills.

Carac should be discontinued if severe abdominal pain, bloody diarrhea, vomiting, fever, or chills develop when using the product.

Application of Carac to mucous membranes should be avoided due to the possibility of local inflammation and ulceration.

In clinical trials, the most common drug-related adverse events were application site reactions (94.6%), which included: erythema, dryness, burning, erosion, pain, and edema, and eye irritation (5.4%).

Patients using Carac should avoid prolonged exposure to sunlight or other forms of ultraviolet irradiation during treatment, as the intensity of the reaction maybe increased.

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

References: 1. Weiss J, Menter A, Hevia O, et al. Effective treatment of actinic keratosis with 0.5% fluorouracil cream for 1, 2, or 4 weeks. *Cutis.* 2002;70(suppl 2):2229. **2.** Jorizzo J, Stewart D, Bucko A, et al. Randomized trial evaluating a new 0.5% fluorouracil formulation demonstrates efficacy after 1-, 2-, or 4-week treatment in patients with actinic keratosis. *Cutis.* 2002;70:335-339.

MEDICIS®
A DIVISION OF VALEANT PHARMACEUTICALS

Carac® Cream, 0.5%

Rx Only

(fluorouracil cream)

BRIEF SUMMARY

IMPORTANT NOTE: This information is a BRIEF SUMMARY of the complete prescribing information provided with the product and therefore should not be used as the basis for prescribing the product. This summary has been prepared by deleting information from the complete prescribing information such as certain text, tables, and references. The physician should be thoroughly familiar with the complete prescribing information before prescribing the product.

FOR TOPICAL DERMATOLOGICAL USE ONLY (NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE)

INDICATIONS AND USAGE

Carac is indicated for the topical treatment of multiple actinic or solar keratoses of the face and anterior scalp.

CONTRAINDICATIONS

Fluorouracil may cause fetal harm when administered to a pregnant woman. Fluorouracil is contraindicated in women who are or may become pregnant. 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 the fetus.

No adequate and well-controlled studies have been conducted in pregnant women with either topical or parenteral forms of fluorouracil. One birth defect (ventricular septal defect) and cases of miscarriage have been reported when fluorouracil was applied to mucous membrane areas. Multiple birth defects have been reported in the fetus of a patient treated with intravenous fluorouracil.

Animal reproduction studies have not been conducted with Carac. Fluorouracil, the active ingredient, has been shown to be teratogenic in mice, rats, and hamsters when administered parenterally at doses greater than or equal to 10, 15 and 33 mg/kg/day, respectively, [4X, 11X and 20X, respectively, the Maximum Recommended Human Dose (MRHD) based on body surface area (BSA)]. Fluorouracil was administered during the period of organogenesis for each species. Embryolethal effects occurred in monkeys at parenteral doses greater than 40 mg/kg/day (65X the MRHD based on BSA) administered during the period of organogenesis.

Carac should not be used in patients with dihydropyrimidine dehydrogenase (DPD) enzyme deficiency. A large percentage of fluorouracil is catabolized by the enzyme dihydropyrimidine dehydrogenase (DPD). DPD enzyme deficiency can result in shunting of fluorouracil to the anabolic pathway, leading to cytotoxic activity and potential toxicities.

Carac is contraindicated in patients with known hypersensitivity to any of its components.

WARNINGS

The potential for a delayed hypersensitivity reaction to fluorouracil exists. Patch testing to prove hypersensitivity may be inconclusive.

Patients should discontinue therapy with Carac if symptoms of DPD enzyme deficiency develop.

Rarely, unexpected, systemic toxicity (e.g. stomatitis, diarrhea, neutropenia, and neurotoxicity) associated with parenteral administration of fluorouracil has been attributed to deficiency of dihydropyrimidine dehydrogenase "DPD" activity. One case of life threatening systemic toxicity has been reported with the topical use of 5% fluorouracil in a patient with a complete absence of DPD enzyme activity. Symptoms included severe abdominal pain, bloody diarrhea, vomiting, fever, and chills. Physical examination revealed stomatitis, erythematous skin rash, neutropenia, thrombocytopenia, inflammation of the esophagus, stomach, and small bowel. Although this case was observed with 5% fluorouracil cream, it is unknown whether patients with profound DPD enzyme deficiency would develop systemic toxicity with lower concentrations of topically applied fluorouracil.

Applications to mucous membranes should be avoided due to the possibility of local inflammation and ulceration.

PRECAUTIONS

General

There is a possibility of increased absorption through ulcerated or inflamed skin.

Information for the Patient

Patients using Carac should receive the following information and instructions:

1. This medication is to be used as directed.
2. This medication should not be used for any disorder other than that for which it was prescribed.
3. It is for external use only.
4. Avoid contact with the eyes, eyelids, nostrils, and mouth.
5. Cleanse affected area and wait 10 minutes before applying Carac.
6. Wash hands immediately after applying Carac.
7. Avoid prolonged exposure to sunlight or other forms of ultraviolet irradiation during treatment, as the intensity of the reaction may be increased.
8. Most patients using Carac get skin reactions where the medicine is used. These reactions include redness, dryness, burning, pain, erosion (loss of the upper layer of skin), and swelling. Irritation at the application site may persist for two or more weeks after therapy is discontinued. Treated areas may be unsightly during and after therapy.
9. If you develop abdominal pain, bloody diarrhea, vomiting, fever, or chills while on Carac therapy, stop the medication and contact your physician and/or pharmacist.
10. Report any side effects to the physician and/or pharmacist.

Laboratory Tests

To rule out the presence of a frank neoplasm, a biopsy may be considered for those areas failing to respond to treatment or recurring after treatment.

Carcinogenesis, Mutagenesis and Impairment of Fertility

Adequate long-term studies in animals to evaluate carcinogenic potential have not been conducted with fluorouracil. Studies with the active ingredient of Carac, fluorouracil, have shown positive effects in *in vitro* and *in vivo* tests for mutagenicity and on impairment of fertility in *in vivo* animal studies. *Fluorouracil* produced morphological transformation of cells in *in vitro* cell transformation assays. Morphological transformation was also produced in an *in vitro* assay by a metabolite of fluorouracil, and the transformed cells produced malignant tumors when injected into immunosuppressed syngeneic mice.

Fluorouracil has been shown to exert mutagenic activity in yeast cells, *Bacillus subtilis*, and *Drosophila* assays. In addition, fluorouracil has produced chromosome damage at concentrations of 1.0 and 2.0 mcg/mL in an *in vitro* hamster fibroblast assay, was positive in a microwell mouse lymphoma assay, and was positive in *in vivo* micronucleus assays in rats and mice following intraperitoneal administration. Some patients receiving cumulative doses of 0.24 to 1.0 g of fluorouracil parenterally have shown an increase in numerical and structural chromosome aberrations in peripheral blood lymphocytes.

Fluorouracil has been shown to impair fertility after parenteral administration in rats. Fluorouracil administered at intraperitoneal doses of 125 and 250 mg/kg has been shown to induce chromosomal aberrations and changes in chromosome organization of spermatogonia in rats. In mice, single-dose intravenous and intraperitoneal injections of fluorouracil have been reported to kill differentiated spermatogonia and spermatocytes at a dose of 500 mg/kg and produce abnormalities in spermatids at 50 mg/kg.

Pediatric Use

Actinic keratosis is not a condition seen within the pediatric population, except in association with rare genetic diseases. Carac should not be used in children. The safety and effectiveness of Carac have not been established in patients less than 18 years old.

Geriatric Use

No significant differences in safety and efficacy measures were demonstrated in patients age 65 and older compared to all other patients.

Pregnancy

Teratogenic Effects: Pregnancy Category X

See CONTRAINDICATIONS

Nursing Women

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

ADVERSE REACTIONS

The following were adverse events considered to be drug-related and occurring with a frequency of ≥1% with Carac: application site reaction (94.6%), and eye irritation (5.4%). The signs and symptoms of facial irritation (application site reaction) are presented below.

Summary of Facial Irritation Signs and Symptoms - Pooled Phase 3 Studies

Clinical Sign or Symptom	Active One Week N=85	Active Two Week N=87	Active Four Week N=85	ALL Active Treatments N=257	Vehicle Treatments N=127
	n (%)	n (%)	n (%)	n (%)	n (%)
Erythema	76 (89.4)	82 (94.3)	82 (96.5)	240 (93.4)	76 (59.8)
Dryness	59 (69.4)	76 (87.4)	79 (92.9)	214 (83.3)	60 (47.2)
Burning	51 (60.0)	70 (80.5)	71 (83.5)	192 (74.7)	28 (22.0)
Erosion	21 (24.7)	38 (43.7)	54 (63.5)	113 (44.0)	17 (13.4)
Pain	26 (30.6)	34 (39.1)	52 (61.2)	112 (43.6)	7 (5.5)
Edema	12 (14.1)	28 (32.2)	51 (60.0)	91 (35.4)	6 (4.7)

During clinical trials, irritation generally began on day 4 and persisted for the remainder of treatment. Severity of facial irritation at the last treatment visit was slightly below baseline for the vehicle group, mild to moderate for the 1 week active treatment group, and moderate for the 2 and 4 week active treatment groups. Mean severity declined rapidly for each active group after completion of treatment and was below baseline for each group at the week 2 post-treatment follow-up visit.

Thirty-one patients (12% of those treated with Carac in the Phase 3 clinical studies) discontinued study treatment early due to facial irritation. Except for three patients, discontinuation of treatment occurred on or after day 11 of treatment.

Eye irritation adverse events, described as mild to moderate in intensity, were characterized as burning, watering, sensitivity, stinging and itching. These adverse events occurred across all treatment arms in one of the two Phase 3 studies.

Summary of All Adverse Events Reported in ≥ 1% of Patients in the Combined Active Treatment and Vehicle Groups - Pooled Phase 3 Studies

	9721 and 9722 Combined				
Adverse Event	Active One Week N=85	Active Two Week N=87	Active Four Week N=85	ALL Active Treatments N=257	Vehicle Treatments N=127
	n (%)	n (%)	n (%)	n (%)	n (%)
BODY AS A WHOLE	7 (8.2)	6 (6.9)	12 (14.1)	25 (9.7)	15 (11.8)
Headache	3 (3.5)	2 (2.3)	3 (3.5)	8 (3.1)	3 (2.4)
Common Cold	4 (4.7)	0	2 (2.4)	6 (2.3)	3 (2.4)
Allergy	0	2 (2.3)	1 (1.2)	3 (1.2)	2 (1.6)
Infection Upper Respiratory	0	0	0	0	2 (1.6)
MUSCULOSKELETAL	1 (1.2)	1 (1.1)	1 (1.2)	3 (1.2)	5 (3.9)
Muscle Soreness	0	0	0	0	2 (1.6)
RESPIRATORY	5 (5.9)	0	1 (1.2)	6 (2.3)	6 (4.7)
Sinusitis	4 (4.7)	0	0	4 (1.6)	2 (1.6)
SKIN & APPENDAGES	78 (91.8)	83 (95.4)	82 (96.5)	243 (94.6)	85 (66.9)
Application Site Reaction	78 (91.8)	83 (95.4)	82 (96.5)	243 (94.6)	83 (65.4)
Irritation Skin	1 (1.2)	0	2 (2.4)	3 (1.2)	0
SPECIAL SENSES	6 (7.1)	4 (4.6)	6 (7.1)	16 (6.2)	6 (4.7)
Eye Irritation	5 (5.9)	3 (3.4)	6 (7.1)	14 (5.4)	3 (2.4)

Adverse Experiences Reported by Body System

In the Phase 3 studies, no serious adverse event was considered related to study drug. A total of five patients, three in the active treatment groups and two in the vehicle group, experienced at least one serious adverse event. Three patients died as a result of adverse event(s) considered unrelated to study drug (stomach cancer, myocardial infarction and cardiac failure).

Post-treatment clinical laboratory tests other than pregnancy tests were not performed during the Phase 3 clinical studies. Clinical laboratory tests were performed during conduct of a Phase 2 study of 104 patients and 21 patients in a Phase 1 study. No abnormal serum chemistry, hematology, or urinalysis results in these studies were considered clinically significant.

DOSAGE AND ADMINISTRATION

Carac cream should be applied once a day to the skin where actinic keratosis lesions appear, using enough to cover the entire area with a thin film. Carac cream should not be applied near the eyes, nostrils or mouth. Carac cream should be applied ten minutes after thoroughly washing, rinsing, and drying the entire area. Carac cream may be applied using the fingertips. Immediately after application, the hands should be thoroughly washed. Carac should be applied up to 4 weeks as tolerated. Continued treatment up to 4 weeks results in greater lesion reduction. Local irritation is not markedly increased by extending treatment from 2 to 4 weeks, and is generally resolved within 2 weeks of cessation of treatment.

OVERDOSE

Ordinarily, topical overdosage will not cause acute problems. If Carac is accidentally ingested, induce emesis and gastric lavage. Administer symptomatic and supportive care as needed. If contact is made with the eye, flush with copious amounts of water.

HOW SUPPLIED

Cream - 30 gram tube NDC 0187-5200-30

Store at Controlled Room Temperature 20° to 25° C (68° to 77° F) [see USP].

Prescribing Information as of November 2012

Keep out of the reach of children. Rx Only

Distributed by:
Valeant Pharmaceuticals North America LLC
Bridgewater, NJ 08807

CRC-006

GOLDFADEN SKINCARE

Product smooths creases in facial skin

Liquid Face Lift fills in facial skin creases, allowing for makeup to smooth over without traces of skin imperfections, according to the company.

Combined with Dr. Goldfaden's Velvety Serum, the products provide crease relief and firmness for a nonsurgical quick fix. Antioxidants and skin-firming ingredients reduce the appearance of fine lines and loose skin. Hyaluronic acid helps to plump skin and delivers moisture. This formula restores smoothness and lifts the skin within seconds of application, promoting a more youthful appearance, the company claims.

FOR MORE INFORMATION:
www.goldfadenmd.com

NEOCUTIS

Antioxidant defense system protects skin from oxidative stress

RéACTIVE antioxidant serum is powered by Vitaplex C, a technology platform. Vitaplex C provides an advanced, synergistic shield against free radicals, to help protect skin from oxidative stress, the company claims. Targeted antioxidants include a high and optimal strength of 15 percent micronized vitamin C, stabilized in a silicone-based formulation.

A mix of five antioxidants addresses multiple-levels of free radical activity to help preserve skin's biomolecules: tocopherol (vitamin E); vitamin C, epigallocatechin gallate, dimethylmethoxy chromanol, and creatine.

RéACTIVE Antioxidant Serum helps to protect skin from oxidative stress, both internally and externally, to form a strong defensive shield against skin aging, according to the company. It also neutralizes free radicals at multiple levels to help minimize collagen, elastin and other skin biomolecule alterations due to oxidative stress.

FOR MORE INFORMATION:
www.neocutis.com

NIA 24

Intensive retinol repair fights UV damage

With a formula of Pro-Niacin molecule plus retinol, NIA 24 Intensive Retinol Repair rapidly fights signs of UV damage including deep-set wrinkles, fine lines, dark spots, sun spots, and lack of skin firmness.

NIA 24 Intensive Retinol Repair helps repair existing sun damage while protecting against future damage without side effects associated with retinol usage such as dryness, redness, itchiness and flakiness.

Other key features include: Pro-Niacin, which helps repair damaged DNA within skin cells; retinol, which increases cell turnover and collagen to improve texture, tone, smoothness, firmness; botanical complex of seaweed and Tara tree extracts, which promote a stronger dermal matrix that minimizes wrinkles; sodium hyaluronate, which hydrates skin; and hexapeptide, which stimulates collagen to fight wrinkles.

FOR MORE INFORMATION:
www.NIA24.com

LA ROCHE-POSAY

Anti-aging serum firms skin

The Substiane [+] Serum is an anti-aging concentrate that helps to plump the skin, visibly giving it volume and elasticity, according to the company. Substiane [+] Serum combines 2 percent LR 2412 with 3 percent Pro-Xylane to combat skin's loss of firmness without irritation. La Roche-Posay says LR 2412 is an ingredient that fills in the gaps between lipid layers and corneocytes on the skin's surface for visible plumping. Pro-Xylane helps to retain several times its weight in water and helps to replenish volume and protect skin's support structure, the company claims.

The moisturizing texture of Substiane [+] Serum imparts a smoothing effect, revitalizing the complexion, according to the company. Substiane [+] Serum is paraben-free, tested on sensitive skin and dermatologist-tested.

FOR MORE INFORMATION:
www.laroche-posay.us

Certain botulinum toxin types may **cause neuron death**

QUICK READ

According to one researcher, some botulinum toxin types cleave proteins that may result in blocking neurotransmitter release and inducing neuron death. However, this is seen in the clinical setting using a high level of toxin. Still, an expert warns that a rare patient with a mild mutation in the SNAP-25 sequence might be susceptible to losing neuron function.

By Lisette Hilton | Staff Correspondent

Boston — Not all botulinum toxins are equally safe for neurons, according to a new study by Harvard researchers.

According to the study's senior author, Harvard Medical School researcher Min Dong, Ph.D., two of seven of the botulinum toxins, types C and E, cause neuron death. And while generally safe for healthy neurons, botulinum toxin type A, used in Botox (onabotulintumtoxinA, Allergan) and Dysport (abobotulinumtoxinA, Medicis), causes neuron death in the laboratory when scientists introduce mutations to a key neuron protein.

Dr. Dong and colleagues published the study Feb. 12 in *Nature Communications*.

"We investigated the seven types of toxins," Dr. Dong says. "All seven relax muscles by blocking synaptic vesicle exocytosis. This is very well established. We looked at whether any of them, in addition to blocking synaptic vesicle exocytosis, might cause damage to survival of neurons."

Dr. Dong says he was intrigued by earlier research suggesting botulinum toxin type C caused neuron death. His study, which looked at both rats' neurons cultured from embryonic rat brains and human motor neurons differentiated from human embryonic stem cells, not only confirms that research but also exposes potential dangers of using type E toxin and helps to establish a cellular mechanism.

It is known that all botulinum toxins shut down signals from neurons to muscles by attacking a complex composed of three

proteins inside neurons. The researchers have discovered that two of these three proteins, known as syntaxin 1 and SNAP-25, not only release signals from neurons, but also perform the essential housekeeping process of recycling the neuron's plasma membranes. Type C toxin attacks syntaxin 1, while type E toxin attacks SNAP-25. The resulting blockage of plasma membrane recycling leads to death of neurons.

"You have types A, C, and E that cleave … SNAP-25. Then, you have type C that cleaves two proteins: SNAP-25 and syntaxin 1," Dr. Dong says.

In essence, cleavage of SNAP-25 and syntaxin 1 not only block neurotransmitter release but also induce neuron death. Why? Dr. Dong explains SNAP-25 and syntaxin 1 have a secondary role: to mediate the recycling of the plasma membrane of neurons. Recycling of the plasma membrane is essential for neuron survival.

In contrast to syntaxin 1 and SNAP-25, the third protein in the complex, known as synaptobrevin, is not involved in the recycling process. This explains why type B, D, F and G toxins, all of which attack synaptobrevin, do not cause neuron death, according to this study.

WHAT ABOUT TYPE A?

Researchers suggest that unlike types C and E, type A does not generally cause neuron death, despite cleaving SNAP-25. Type E cleaves a larger fragment from SNAP-25 than type A, causing extensive damage to the function of SNAP-25. In contrast, SNAP-25 cleaved by type A can still support the neuron's essential recycling of plasma membranes.

But the safety of type A toxin is not absolute, scientists found. Once SNAP-25 has been cleaved by type A, its ability to tolerate more mutations and defects in neurons is reduced. When Dr. Dong and team introduced a mild mutation into SNAP-25, which under normal conditions is tolerated, and introduced botulinum toxin type A, the neuron died.

"Whether this can occur in rare cases in patients needs to be studied further," he says.

USING INFORMATION IN PRACTICE

The use of botulinum toxin type A in clinical applications is quite safe, although, questions remain about whether a patient with a mild mutation in the SNAP-25 sequence might be susceptible to losing neuron function after being treated with botulinum toxin A. If such a patient exists, it would be a rare occurrence, Dr. Dong says.

Another comfort regarding the use of type A for cosmetic purposes, according to Dr. Dong, is that the cytotoxicity effect is dose dependent.

"In order to observe this effect, even for types C and E, we have to use a relatively higher level of toxin to treat the neurons and get rid of basically every molecule of SNAP-25 and syntaxin 1 in neurons. The level of toxin we used under experimental conditions is much higher than what is used in the clinic, especially by dermatologists," Dr. Dong says.

Dermatologists, however, should be cautious of using types C and E to treat patients, according to Dr. Dong. While the toxins are not yet used commercially by dermatologists, there are small-scale studies looking at the use of type C for muscle relaxing, the researcher says. **DT**

Disclosure: Dr. Dong reports no disclosures related to this study; however he has received funding from IPSEN for an unrelated study.

Q&A PATIENT PREP

Disinfection is an important part of any procedure involving piercing the skin. Here, our expert panel discusses approaches to sterilization and cleansing, as well as the odds of serious infections.

Q: How do you approach prepping a patient prior to an injection procedure?

Susan Weinkle, M.D.
Dermatologist, Bradenton, Fla.

Amy Taub, M.D., dermatologist, Chicago: I clean the skin area to be treated with Hibiclens (antiseptic, MöInlycke Health Care) and then follow that with alcohol.

Michael Persky, M.D., plastic surgeon, Encino Calif.: It depends what I'm doing. I think with Sculptra (Aesthetic, injectable poly-L-lactic acid, Valeant) or Radiesse (calcium hydroxylapatite, Merz Aesthetics), if we're doing a lot of injections on the face, we do Hibiclens and I think probably everybody should be cleaning with that. We don't have time usually for a little poke of Botox (onabotulinumtoxinA, Allergan) here or there (and studies have shown that the infection rate with filler injections is the same with or without cleansing the skin), or a little filler here or there, and we'll just use alcohol to disinfect the skin.

Rebecca Fitzgerald, M.D., dermatologist, Los Angeles: I think that's a great question and it's a very, very, important one. And if you look at the line sepsis literature in hospitals, they've studied what you can clean the face with to really reduce the incidence of infections. And it's 2 percent chlorhexidine and 70 percent alcohol. And we use sterile water — we just pour it in a cup to clean faces because there are biofilms of *Mycobacterium* in tap water. And if you're doing a ton of injections, the odds are that something's not going to happen to you — it's not very common, but you can reduce that even further by using sterile water.

Welf Prager, M.D., dermatologist, Hamburg, Germany: The disinfection is a very important part of the procedure. I always do it myself. The other point I want to mention is that when you're using a blunt cannula don't even think about touching the cannulas or anything you put into the patient's face. When I want to reuse it or put it aside, I have a sterile gauze and I put then the syringe with the cannula on the sterile gauze.

Derek Jones, M.D., dermatologist, Los Angeles: In my office I analyze the patient first and use a white waxy marker. The patient has a mirror. We're marking out the areas where we agree that product is needed. And then we have the patient washing with chlorhexidine. There is some debate as to whether or not chlorhexidine could be damaging if you get it in the eye. I tell patients to be quite careful not to get in their eye when they're doing the facial wash with it. And then I come back around with an alcohol swab — alcohol remains a really excellent antimicrobial. I wipe the area and it dries very quickly. And then I replace my markings and start injecting

Michael Kane, M.D., plastic surgeon, New York: I think the most important thing is simple face washing. Just like cutting down nosocomial infections, it's simple hand washing in a hospital. For me the choice of which agent is much less important as mechanically cleaning that skin. Almost no one comes in with clean skin. They've got some sort of moisturizer or makeup on, filled with bacteria crammed into their pores. And it doesn't really matter unless you mechanically cleanse their skin and get all that junk out of there.

So we have them scrub with a facial scrub — patients rarely wash their face very well — and then I will sit there with an old-fashioned gauze and alcohol and keep rubbing until that gauze is completely white. It takes a long time and

Dermatology Times **presents a panel discussion (right) at the annual Vegas Cosmetic Surgery and Aesthetic Dermatology annual meeting. Here, panel members discuss best practices for prepping patients prior to injection procedures.**

VIDEO **dermatologytimes.com/patientprep**

they don't like it. But I think it's by far the most important thing rather than choice of agent.

Susan Weinkle, M.D., Bradenton, Fla.: I have my assistant go in and prep the skin with Hibiclens. Then she applies the topical anesthetic. I don't like to cause pain. I like to try to make things gentle. So she applies the topical anesthetic. I'm always running behind so that gets to sit for a while. And then I go in and with my assistant we take the gauze and alcohol, which I think not only helps in terms of removing bacteria and is bacteriostatic but I think that it degreases the skin. So I really like using the alcohol after the Hibiclens and that degreases the skin.

Then I use my marking pen. I don't inject with sterile glove. I inject with a clean glove. I try not to put my hand on the needle or the cannula. And I think that's been one potential concern with using the long cannulas — is sometimes with the difficulty getting them in the skin, we're putting that non-sterile gloved hand down on the shaft of that cannula trying to work it into the skin and manipulate it. I think that we really have to look at good, clean technique, especially going forward as we have longer-lasting types of implants that we're going to putting in faces.

It's sort of like if you develop good technique for what we have now hopefully then that will relate to less problems going forward. **DT**

Q. *Has anyone ever had a patient who developed an infection from a filler or a botulinum toxin injection? Because I've never had one and I wonder what the reason for that is.*

Amy Taub, M.D.
Dermatologist, Chicago.

Michael Persky, M.D., plastic surgeon, Encino, Calif.: I think the vascularity of the face is so great; that is probably the reason why there is such a very low rate of infection from injectable fillers, because we're putting a tiny number of skin bacteria into the face when we do injections. The only time I've had an infection from injectables — and this is a pearl — was a woman I was injecting with Sculptra and it wasn't the Sculptra, it could have been any filler. It was a patient who failed in her history to tell us that she had a chin implant, although we ask everybody. When the needle got down to the chin I hit something that felt unlike bone with the 25-gauge needle. I didn't even inject any filler but the needle had violated the capsule around the chin implant.

Three days later she called — it was over Thanksgiving weekend and she said, "My chin is swelling." I put her on antibiotics. She didn't want her husband to know about the injections so she had started taking steroids on her own. Another day later she called and said, "It's getting really big." I drove home from San Diego where my girls were in a soccer tournament and met her at the office. Her chin and the implant was infected. I told her, "We really have to put you in the hospital for IV antibiotics."

She refused at that point and after more antibiotics, she came back the next day with her husband now who's very angry. We hospitalized her for five days of IV antibiotics followed by another two weeks of IV antibiotics at home through a central line. We finally convinced her to take the implant out.

So the pearl here is I would warn everybody not to violate the capsule of an implant because it's an avascular space and one bacteria cell transferred from the skin, despite washing and antiseptics can sometimes cause a huge problem there. **DT**

55 NAVIGATING NEGOTIATIONS
What to know before embarking on a medical practice sale or merger

56 REDUCE PORTFOLIO RISK
How to adjust investment strategies to mitigate loss

Simplify, conceptualize for **effective presentations**

John Jesitus | Senior staff Correspondent

MIAMI BEACH, FLA. — Nobody likes overly busy presentation slides — especially the audience members who must decipher them on the fly, an expert says.

"Communicating medical ideas is an essential part of medicine," says Wilson Liao, M.D., assistant professor of dermatology, University of California, San Francisco (UCSF). But when he and three colleagues began considering this matter, they realized that "We weren't providing our residents with much guidance as to how to give medical presentations." Results included presentations that went over the heads of their audience, or shoehorned in too much material, he says.

Fortunately, Dr. Liao says that to a large degree, "Presentation skills are teachable." So he, along with Kelly Cordoro, M.D., Ilona Frieden, M.D., and Kanade Shinkai, M.D., and all of the UCSF dermatology department, crafted a series of speaker development guidelines to help not only their residents, but also other dermatologists at the American Academy of Dermatology annual and summer meetings.

KNOW YOUR AUDIENCE

"Before you even create your talk," Dr. Liao says, "determine your audience's knowledge level, and what are the main things you can teach them that would be helpful or interesting to them. Those knowledge gaps should be the two or three things you continually reinforce during your presentation." This way, he says, after leaving the talk, attendees should be able to tell colleagues, "The talk was about X, and I learned Y and Z."

When creating slides, Dr. Liao says, "The key is to simplify. One common shortcoming we see is that people feel the need to put everything on the slides that they're going to say. But it's much more powerful to show an image" or another abbreviated version of the main idea, while leaving the details to the speaker.

By the same token, Dr. Liao recommends limiting one's slide total to the minutes allotted for the presentation.

"If you have 15 minutes, generally you shouldn't have more than 15 slides," unless several of them are images that will flip by rather quickly, he says.

"We've noticed that it takes a person looking at a slide about 20 to 30 seconds just to figure out what's going on. Few things are more frustrating" than watching a speaker advance slides too quickly. Conversely, "Leaving the slides up for at least a minute and going through the content helps audience members orient" and digest each slide's contents.

Briefly stating each slide's main idea across the top of the slide (or the appropriate diagnosis on each clinical image) also helps orient an audience. During any presentation, Dr. Liao says, "It's natural for audience members' attention to drift in and out." This prevents them from feeling lost when they refocus on the talk.

EFFECTIVE PRESENTATIONS see page **63**

Quotable

"Approach investing with the goal of diversifying risk through non-correlated assets, allowing funds to compound over time."

Jason M. O'Dell, M.S., C.W.M., and Andrew Taylor, C.F.P.
OJM Group

See story, page 56

DT**Extra**

A new government website is providing guidance for patients about their rights and choices for releasing their health information. The site, called **Meaningful Consent, describes which portions of patient information are restricted from access.** The website builds upon recommendations from a committee of the Office of the National Coordinator for Health Information Technology (ONC) that directed ONC to inform, collect and evaluate the information patients require to make an informed choice about electronic health information exchanges.

SOURCE: MEDICAL ECONOMICS

Finacea® (azelaic acid) Gel, 15% is a topical prescription medication used to treat inflammatory papules and pustules of mild to moderate rosacea.

Rosacea is with her wherever she goes. So is Finacea®.

It's true. Rosacea is complex and it's with them for life. Finacea® treats the papules and pustules with associated erythema 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.

You have made Finacea® the #1 Dermatologist-prescribed topical brand.[1]

Finacea®
(azelaic acid) Gel, 15%

INDICATION & USAGE

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.

Avoid contact with the eyes, mouth, and other mucous membranes. In case of eye exposure, wash eyes with large amounts of water. Wash hands immediately following application of Finacea®.

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.

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

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.

1. According to IMS NPATM (National Prescription Audit) July 2010-August 2013

Finacea®
(azelaic acid) Gel, 15%

For Dermatologic Use Only–Not for Ophthalmic, Oral, or Intravaginal Use
Rx only

BRIEF SUMMARY
CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

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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What you need to know when negotiating a medical practice sale or merger

By Debra Beaulieu | Staff Correspondent

Among the major challenges posed by the Affordable Care Act, there's an undeniable trend: Practice owners are looking to sell or merge with other organizations as a means to adapt and thrive in today's healthcare environment. However, it can take years to identify the partners and circumstances that best meet your practice's needs.

According to a July 2013 report from Wolters Kluwer Health, 34 percent of primary care, family medicine and internal medicine physicians said that over the next three to five years they would be "exploring different business models," which could include "mergers (or) becoming part of a hospital system."

For practitioners who are part of this statistic, there is far more work involved beyond deciding if alignment or consolidation is the right choice.

"This is not the kind of thing you can do on the fly," says Kenneth T. Hertz, F.A.C.M.P.E., a principal consultant with the Medical Group Management Association. "There are so many details and so much complexity involved that unless you take the time to put together a comprehensive checklist and check it twice, you're going to run into problems. It's virtually guaranteed," he says.

START PLANNING EARLY

With so much legwork to be done, practices can put themselves at an advantage by thinking about their alignment strategy even before finding a specific partner, Mr. Hertz says.

To start with, your practice needs to identify what its goals are in joining another, potentially larger, organization. "This means deciding what you're trying to achieve, what the deal breakers are to you, and understanding your practice and what you're looking for in a partner," he says.

In addition, you can use this preplanning phase to prepare for the due diligence process that will start once you begin discussions with a potential buyer or partner. For example, how current is your list of assets? Do you have documentation for your software and hardware? Can you easily access information about malpractice suits and insurance coverage?

GAIN TRUST

Once you identify a potential partner and begin talks, one of the keys to gaining the other party's trust is to be as open and transparent with information about your organization as possible says Tejas Mehta, M.D., who took over his father's primary care practice, Mehta Medical Group in Humble, Texas, 15 months ago.

As part of his growth strategy for the business, Dr. Mehta merged with a nearby solo physician in March 2013. However, prior to the actual merger both practices engaged in talks for more than four years, Dr. Mehta says.

The biggest challenge to making the deal finally happen, according to Dr. Mehta, was gaining the other physician's trust.

"This guy was an independent physician, but even groups are leery of joining somebody else," he says. "There are a lot of docs out there, unfortunately, who sort of gloss over the numbers. There's a lot of opacity in the structure of the company and the finances of the company, so at the end of the day, there's very little faith to push the company or those working for him."

To prove that he would make a trustworthy and valuable partner, Dr. Mehta promised the other practitioner upfront full transparency of numbers and operations, as well as assuring him that he would be treated the same as the other primary care physicians in the group.

"And I think that helped sell him," Dr. Mehta says, adding that the materials he provided also proved to the other doctor that he would be coming into an organization that was professional and well-run.

"I've got the appropriate managers in place and we pay attention to our finances; we watch every single penny," he says. "At the end of the day, they (potential partners) need to know that they're coming to an organization that's accountable to them as the group moves forward."

While also advocating for honesty and transparency, healthcare attorney Bill Kalogredis, J.D., C.H.B.C., of Kalogredis, Sansweet, Dearden and Burke Ltd., in Wayne, Pa., warns that both parties should sign confidentiality agreements before opening their books to each other (which Dr. Mehta did).

Mr. Kalogredis recommends that the parties agree not to tell anyone that they are talking, and that they will return all documentation to each other should the deal not go through.

"The one thing you don't want to have happen, especially if you're a practice that is looking to sell or merge with a bigger group, hospital, or hospital system, is that you don't want them to take advantage of what they learned about your practice," he says.

COMMON DISCUSSION POINTS

Once both parties' information is on the table and there is a shared interest in moving forward, there are still numerous potential sticking points the buyer and seller or merging entities will need to work through.

This is the current task before Richard Morgan, administrator of Augusta GYN, P.C., in Augusta, Ga., whose group is in the early stages of exploring a merger with a nearby practice.

At this point, he is confident that, "the personalities and blending of the practices really shouldn't be a problem," Mr. Morgan says. "It's just some of the hot topic items we have to work out." These topics will

NEGOTIATING MERGERS see page 58

Jason M. O'Dell, M.S., C.W.M., is a financial consultant, author of a number of national books for doctors, and a principal of OJM Group (www.ojmgroup.com).

Andrew Taylor, C.F.P., is a portfolio manager with the financial consulting OJM Group.

Reduce portfolio risk

If you are like most investors, you have significant concerns about the global economy. The financial crisis of 2008 remains fresh in the minds of affluent Americans, even though our stock markets have come back. Sluggish growth has inhibited job creation and the recovery has been slower than anticipated.

Central banks and governments throughout the globe have implemented an array of measures to stimulate growth in their respective local economies. The financial markets have responded favorably to a four-year trend of government spending. However, the days of artificial stimulus will have to come to an end at some point in the near future. Once the market's safety net is removed, volatility will return and global economies will have to stand on their own. For these reasons and many others, it is crucial that well-informed investors, including physicians, adjust their investment behavior accordingly. This article touches on a few ideas.

INVESTMENT THEORY FOR PHYSICIANS

Most savvy doctor investors understand that portfolio diversification is a key consideration to reducing some of the risk of loss in a portfolio. In historically volatile markets, mitigation of loss is not a luxury — it is a necessity. Though most educated investors who thought they were "adequately diversified" still lost nearly half their portfolio value in 2008 and 2009 — how did this happen? Most investors were diversified within the stock market with holdings in various sectors. What these investors suffered was "market risk." The entire market came crashing down, and so did all investors within the market.

Affluent individuals should approach investing with the goal of diversifying risk through non-correlated assets, allowing their funds to compound over time by achieving positive returns net of taxes and inflation with reduced volatility. This strategy does not suggest opportunity should be ignored, it simply states that risk must be properly managed and allocated. Generally speaking, this strategy is suitable for physicians of all ages for different reasons. An established physician less than 10 years from retirement has likely accumulated significant assets and now needs to limit the range of possible outcomes for his or her established wealth. A young or middle-aged physician's greatest asset is their ability to generate future earnings. While a higher risk tolerance is appropriate for a doctor in this demographic, the income earned will be significant enough that with proper savings and risk management, the younger physician has no need to participate in speculative investments. Consistent after-tax returns and proper planning will be sufficient to allow a young physician to retire comfortably and maintain an appropriate standard of living. What investors should understand is that diversification need not be limited to securities like traditional stock and bond investments or bank deposits. Proper diversification must be across investment classes and not just within a class (such as securities or real estate) — especially in volatile markets that return periodically throughout an individual's lifetime. A balance of domestic and foreign securities, real estate, small businesses, commodities, and other alternative investments would prove to be much less risky than holding the majority of your investments in real estate and securities (which is what most doctors do).

Most doctors who contact us are either affluent and want to fine-tune their planning or they are getting more involved in their financial planning. Subsequently, many of our physician clients have taken a more active interest in surgery centers, medical office buildings and other healthcare related real estate. This strategy contradicts the idea of achieving portfolio diversification, by having a disproportionate amount of capital dependent upon the success of a single industry. One strategy of portfolio diversification for doctors is to avoid all healthcare related investments. The theory is that doctors already have a large portion of their income related to healthcare.

ALTERNATIVE INVESTMENTS

According to results of a recent world wealth report , the 2012 allocation of the world's high net worth individuals by investment class is expected to be as follows: 38 percent equities, 29 percent fixed income, 15 percent real estate, 11 percent cash, and 8 percent alternative investments. A key benefit of alternative investments is the low correlation to broad equity markets. Non-traded alternative investments can provide a variety of roles in a physician's portfolio.

Certain categories of alternatives have successfully served as a hedge in client portfolios in the past. In 2008, when multiple stock indices declined by nearly 50 percent from their peak values, a majority of managed futures strategies offered positive returns. Past performance does not provide assurance of future success. However, a hedging technique that successfully minimized damage during the worst financial crisis most of us have experienced in our lifetime certainly warrants consideration.

For doctors who can't build or participate in surgery centers or other profitable healthcare investments, a popular investment strategy is to take advantage of different investment programs that are not traded on a public exchange. non-traded real estate investment Trusts (REITs), leasing funds and oil and gas drilling programs are a few examples. As with any investment, there are pros and cons for each type of offering.

Given recent market conditions, many physician investors have been attracted to non-traded programs because they offer a sense of stability. Most of these programs are available to investors at a flat price, for example $10 per share, during the offering period. An advantage to these programs is that their performance is not correlated with any particular market or index, making them an additional form of diversification. Holding non-correlated offerings may help reduce the "volatility roller coaster" of a traditional portfolio. They should be an additional allocation in your portfolio, not a substitute for proper allocation.

Another significant benefit for physicians in the higher income tax brackets is the potential tax benefit an alternative program can offer. Some programs offer tax deductions on the initial invest-

ment. Others pay tax-efficient dividends. Some programs offer both. For example, there are oil and gas drilling programs that offer tax deductions on the initial investment due to intangible drilling costs and tax deductions on the program's cash flow due to depreciation and depletion allowances. REITs' and leasing funds' dividends are often only partially taxable to the investor. These tax efficiencies vary by program and from year-to-year.

WORD OF CAUTION

It is important to note that one of the advantages of a non-traded offering is also a disadvantage. There is typically no market for shares of these programs. As an investor, you are expected to hang on to the security for the life of the investment that can be as long as four to 10 years. This makes your investment essentially illiquid. In addition, these programs are not without risk. You could invest in an oil and gas drilling program that finds no oil. You will get a deduction, but you may not get much of the initial money back. Like any other investment class, some offerings are more aggressive than others, and none make any guarantee about future performance. As with any investment, you run the risk of losing the principal investment — make sure you understand the investment and how it fits within your portfolio before committing to the strategy.

THE TIME IS NOW

There has never been a better time to focus on investment risk management and tax reduction planning. For physician-investors seeking ways to diversify traditional stock and bond portfolios and reduce portfolio volatility while possibly reducing unnecessary taxes, non-traded investments are an attractive alternative. Please contact the authors to see if alternative investments or other planning strategies might possibly reduce your investment risk, reduce your taxes and increase the total after tax return of your portfolio. **DT**

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voice from the industry

"The advantage to offering financing yourself is that it can be **more profitable than using finance companies**, because you earn higher interest."

Keith Borglum, C.H.B.C.,
from **page 60**

NEGOTIATING MERGERS:

Know what questions to ask before selling or merging your practice from page 55

vary by practice, but some common discussion points may include:

- **Governance** — Who will have decision-making authority? What will be the new group's track to partnership?
- **Distribution of earnings and expenses** — Will previous arrangements made for one group's part-time doctors be honored? How will fixed and variable expenses be allocated? How might physicians' compensation formulas change?
- **Electronic health records** — If the two entities are using different systems, will one migrate to the other, or will they adopt another system altogether?
- **Staffing** — Will each practice's administrator still have a role? How will absences, such as maternity leave, be handled? Will employees with overlapping responsibilities be let go or transferred to different positions? How will employees' benefits, payroll, and policies be affected? What information about the transaction will be shared with staff and when?
- **Physical location** — Will either or both parties be moving locations? Will a new owner have the right to move physicians to practice in another location after the sale?

Practices should discuss with potential partners their concerns and expectations regarding patient access, volume, and physician workloads, Mr. Hertz says. "Those are going to be the big issues because there's going to be this kind of tsunami (with healthcare reform). The question is whether there is a thoughtful plan for the practice in terms of how to address that."

MAKE AGREEMENTS CLEAR

Even when the parties are extremely careful to address the myriad implications of a sale or merger, practitioners should be sure to read over their final contract or employment agreement thoroughly before signing, warns Owen Dahl, M.B.A., F.A.C.H.E., a consultant based in The Woodlands, Texas.

"More often than not I find a few changes in that final agreement," he says. "So I would suggest that with the last final agreement, don't assume that all the terms are the same as you discussed. Make sure you read with a fine tooth comb because that's where the surprises are."

When it comes to negotiating contracts in general, be especially mindful of avoiding provisions that are vague or subject to later interpretation, Mr. Kalogredis adds.

"The biggest advice I can give is to clearly define what the deal is," Mr. Kalogredis says. "I don't like vagueness from either side if I can help it. Nobody's going to come up with the perfect document every time, but you try to at least address the issues. And by addressing the issues, you're at least saying, 'Yes, I agree' or 'No, I don't.'" DT

Have you sold or merged your practice? Tell us about it: twitter.com/DermTimesNow or facebook.com/DermatologyTimes

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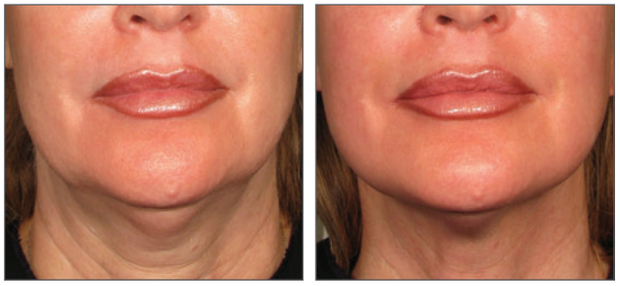

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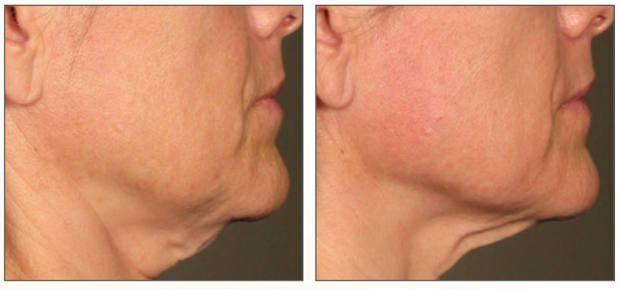

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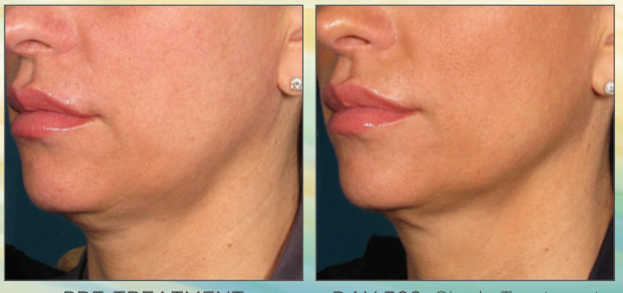

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Keith Borglum, C.H.B.C. is a practice management consultant, appraiser and broker in Santa Rosa, Calif.

How to make payment plans work for patients

MANY more patients are now uninsured due to the recession, layoffs, and working part-time jobs without health insurance. Others are underinsured or have high-deductible plans such as Health Saving Accounts.

The Affordable Care Act (ACA) is suffering delays, and even when ready, many people and companies are expected to opt out and pay the minor penalties instead. The ACA plans may have deductibles in the thousands of dollars, an amount well beyond the means of many people.

> Providing financing lets the patient get medical care, and lets the provider get paid.

Providing financing through your office is one way of enabling your patients to move forward in getting the medical care they need. More patients can afford small monthly payments, than can afford a single large payment. Providing financing lets the patient get medical care, and lets the providers get paid; a win-win, at least as far as getting and delivering care is concerned. What you don't want to create are patient debts for which you won't ever get paid.

FINANCING OPTIONS

There are two major ways to provide financing for patients. The first is to be a conduit for a finance company, and the second is to offer your own financing, direct to patients, out of your own pocket.

Finance companies are eager to install lending programs in your practice. These operate similar to financing through purveyors of appliances, furniture, automobiles, etc. The finance companies provide loans to patients, just like a credit card, but limited to medical care. These loans can often be obtained by patients whose credit cards are maxed-out or patients who are less creditworthy, but often at the price of much higher interest rates than regular credit cards. The patient can be qualified for the loan on the spot in your office, and you get paid right away.

Within these financing company plans, two flavors exist: recourse and nonrecourse. In recourse loans, the patient pays lower interest, but if they don't pay, you will be required to repay the money the finance company paid you. In nonrecourse loans, the interest is higher, but if the patient doesn't pay, you don't need to pay the money back. Research popular finance companies, which may include some of the world's biggest banks, but be aware that many won't finance primary care. They will provide you glossy posters and brochures and forms for your reception area, and make it easy for you. You can check with your current bank and medical association first to see what they offer.

The second approach is to finance payment plans for patients on your own. This involves more work, including setting up the protocols, creating financing forms, processing the payments, collecting past-due payments, and training staff. You also need to comply with federal and state Truth in Lending Act requirements. Some patients might not be as responsible with payments when paying you directly, rather than to a finance company.

MAXIMIZING PROFITS

The advantage to offering financing yourself is that it can be more profitable than using the finance companies, because you earn the higher interest (sometimes 9 percent or more). I know of a cosmetic practice that earns almost as much by bundling and selling its consumer loans on the banking secondary-market as it earns through surgeries.

Another option is using companies such as DocPay.com, which will set up monthly payment plans for patients and deduct payments from patient accounts. Rather than charging interest to the patient, DocPay charges you or the patient a small per-payment fee.

While no one type of financing plan is perfect, every practice can find a plan that fits its needs. Before implementing a plan, check with your accountant or attorney about state and federal compliance requirements in your location. **DT**

Are you offering patients financing? What plan formats are working for you? E-mail sthuerk@advanstar.com

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4 ways Obamacare insurance exchanges could change healthcare

By Brandon Glenn | Staff Correspondent

THE OFFICIAL kick-off date for the Affordable Care Act (ACA), often known as "Obamacare," was Oct. 1.

On that date, consumers began shopping for insurance via one of the ACA's key components — health insurance exchanges. The exchanges will be open to individuals, families, and businesses with 50 or fewer employees.

As of early September, 16 states and Washington, D.C., are planning to run their own exchanges, seven states are planning partnership exchanges with the federal government and 27 states will default to federally run exchanges, according to the Kaiser Family Foundation.

Health insurance exchanges — and more broadly the ACA — will bring big changes for consumers and insurers, according to a recent viewpoint in the *New England Journal of Medicine* written by Henry Aaron, Ph.D., of the Brookings Institution, and Kevin Lucia, J.D., of Georgetown University.

> Exchanges "will become an instrument that can reshape the healthcare delivery system.
>
> **Henry Aaron, Ph.D., Brookings Institution and Kevin Lucia, J.D., Georgetown University**

For individuals, the ACA will result in millions more Americans gaining access to insurance coverage. For insurers, the ACA "changes the rules" in that they must sell to all willing buyers, and that policies must provide a specified minimum level of coverage, Dr. Aaron and Mr. Lucia write.

But exchanges have the potential to do much more in subsequent years once the initial kinks are worked out. After they're implemented, exchanges may be forced — or have the option — to adopt policies that could reshape the financing and delivery of healthcare, according to Dr. Aaron and Mr. Lucia. Here are four ways that could happen:

1 EXCHANGES' SCOPE OF COVERAGE WILL GROW: In 2016, exchanges will be required to offer insurance to businesses with 51 to 100 employees. Further, exchanges have the option of allowing larger employers like state and local governments to contract with them for insurance beginning in 2017.

2 EXCHANGES CAN BAR INSURANCE SALES TO INDIVIDUAL AND SMALL BUSINESSES OUTSIDE THE EXCHANGES: So far only Vermont and Washington, D.C., have exercised this option. The idea behind this provision of the legislation is that by barring sales outside the exchanges, states will create a "single, unified market" and discourage insurers from trying to siphon younger, healthier individuals out of the exchanges. If Vermont and Washington, D.C., have success with this, expect other states to follow suit.

3 EXCHANGES COULD IMPROVE PRICE TRANSPARENCY: There are numerous efforts underway to improve the availability of information on the prices hospitals and physicians charge, and exchanges could help further this effort by advertising this information and making it more widely available. Exchanges could get even more aggressive by offering incentives for insurers to encourage or require providers to apply research findings from analyses of comparative effectiveness.

4 SOME EXCHANGES CAN SELECTIVELY CONTRACT WITH INSURERS: Currently, only six exchanges are requiring insurers to offer standardized plans, and some of the minority of states that are limiting the number of plan offerings have set the cap so high that consumers are likely to experience information overload, Dr. Aaron and Mr. Lucia say. But in the future, exchanges could begin to embrace these types of regulatory tools, such as restricting the number of plans for sale if consumers become overwhelmed with lots of options.

Exchanges are likely to focus on "mundane administrative tasks" in the first year or two after implementation, but after those glitches are ironed out, exchanges "will become an instrument that can reshape the healthcare delivery system," according to Dr. Aaron and Mr. Lucia. DT

Have you seen changes resulting from the ACA?
Tell us your thoughts: sthuerk@advanstar.com.

EFFECTIVE PRESENTATIONS:

Slide presentations need to be focused, easy to understand from page 52

Keys for successful presentations

- Know your audience
- Limit slide total to number of minutes allotted for presentation
- Leave slides up for at least a minute
- Use simple charts or bar graphs
- Organize slides so they tell a story
- Build from more familiar information to less familiar information

KEEP IT SIMPLE

Medical research, he says, often produces dense, detailed tables that aren't necessarily ready for prime time. Such tables may be appropriate in a book, Dr. Liao says. "But in a presentation, no one's going to have time to look through all the different compartments." Incorporating this information into simple charts or bar graphs communicates more efficiently, he says.

"Create your slides so that they tell a story. Human beings are wired to respond to stories," Dr. Liao says. "Take the listener through a journey — whether it's your personal journey learning the topic, or the journey of a patient."

If starting with a case study, he advises inserting an image upfront.

"If you don't grab the audience's attention within the first 60 seconds, you've lost them. There's nothing more powerful than a visual."

Structurally, he adds, building from familiar to less familiar details can aid in engaging an audience.

"Jumping right into unfamiliar territory can turn people off. The idea is, somewhere near the beginning of the presentation, engage the listener," he says. "Maybe give people a few ideas they're familiar with so that they feel comfortable, and then slowly lead them to the new information."

Other "story" arcs may entail moving from case presentation to case management. "By the end of the talk, audience members will know what steps to take to take care of those patients in the future," Dr. Liao says. Starting with an unsolved clinical problem and leading an audience to a solution works the same way, he says. **DT**

Disclosures: Dr. Liao reports no relevant financial interests.

MEANINGFUL USE:

How to prepare for and meet stage 2 mandates from page 1

professor, department of dermatology, Icahn School of Medicine at Mount Sinai, New York. He spoke at the summer meeting of the American Academy of Dermatology.

"And this communication has to be something other than, 'Can I make an appointment?'" Meeting this mark requires a patient to check a pathology report online, for example, and then request a callback to discuss it.

"That sticks in the throat of many physicians. It's one thing to tell us what we have to do. It's another thing to tell us we must convince our patients to do something they may not want to do. This will be a difficult obstacle people have to confront in stage 2," and many of them don't know it.

Fortunately, Dr. Kaufmann adds, acceptable solutions include installing a kiosk in one's waiting room and asking patients on their way out to send a query via this technology.

"Additionally, there's no rule against physicians initiating the contact. If a pathology report comes in, someone on your staff could go through the patient portal and say, 'Mr. Jones, if you log into the portal, you'll see your pathology report from last week. Please verify (online) that you've seen the report, and contact us if you have any questions,'" Dr. Kaufmann says.

Takeaways about stage 2 requirements:

- 5 percent of patients must use Internet to communicate with practices;
- In a practice's first year under stage 2, the 90 days of meaningful use required to qualify for incentive payments must constitute a consecutive calendar quarter;
- Physicians can skip height and weight documentation if they believe these data are irrelevant to their practices.

CONFUSING SUBTLETIES

Requirements for stage 2 of meaningful EHR use also contain potentially confusing subtleties, Dr. Kaufmann says. For 2014, he explains, any practices that have done two years or more under stage 1 of the program automatically will be considered stage 2. And in a practice's first year under stage 2, he says, the 90 days of meaningful use required to qualify for incentive payments must constitute a consecutive calendar quarter, which was not the case in stage 1.

Additionally, "A lot of what was optional in stage 1 becomes mandatory in stage 2." More specifically, the number of required measures remains 20, as in stage 1. But in stage 2, the number of mandatory core measurements rises from 15 to 17. The percentage targets that practices must hit in these areas also increase, as do the number of quality measures required (from six of 64 in stage 1, to nine in stage 2).

Overall, Dr. Kaufmann says that with the amount of blowback from physicians, vendors and others that these changes have generated, "There's still a chance we won't see full stage 2 implementation on time." It's already been delayed once, he adds.

CHANGES TO WATCH FOR

Other key stage 1 changes include alterations to requirements for recording patients' vital signs. Most relevant to dermatologists, Dr. Kaufmann says, is the provision that physicians can skip height and weight documentation if they believe these data are irrelevant to their practices. "Many dermatologists — especially surgical dermatologists — take blood pressure on many patients, but never height and weight."

Previously, Dr. Kaufmann says, physicians who failed to provide height and weight along with blood pressure (for at least half their patients) would have failed the vital sign requirement.

"For 2013 and beyond, the Centers for Medicare and Medicaid Services (CMS) have allowed specialists to parse out which vital signs are relevant to their practice and which are not," he says.

Regarding recent CMS data, Dr. Kaufmann says he finds it shocking that 17 percent of practices that qualified for meaningful use incentives in 2011 dropped out of the program in 2012.

"That doesn't bode well for stage 2, as it is a major leap from stage 1," he says. As more practices reach stage 2, he adds, the dropout rate likely will surge.

Meanwhile, Dr. Kaufmann advises caution in attesting to Medicare's physician quality system (PQRS), as well. CMS data show that in 2011, 22 percent of dermatologists met these goals, earning average bonuses of nearly $4,000 — among the highest for any specialty. However, "The intent of the PQRS program was not to make dermatologists richer. Be aware that these numbers are going to be on CMS' radar screen, and measures may be adjusted," especially if the number of participating dermatologists increases and their average bonus remains relatively high. **DT**

Disclosures: Dr. Kaufmann is a medical advisory board member for Modernizing Medicine Inc.

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COSMETIC SURGERY FORUM Las Vegas | Dec. 5-7, 2013

THE COSMETIC SURGERY FORUM, slated for Dec. 5-7, 2013, at the Aria Resort and Casino in Las Vegas, is billed as a multispecialty educational event where it's fun to learn the latest in research, treatments and techniques in dermatology and cosmetic surgery. Attendees can expect ample interactive and hands-on demonstrations and discussions. The forum, headed by course director and certified dermatologist and cosmetic surgeon, Joel Schlessinger, M.D., who is also president of *LovelySkin.com,* targets dermatologists, cosmetic surgeons, residents and fellows.

Attendees can earn up to 21.75 CME credits. Session highlights include marketing and social media tips when starting a new practice, best ways to spend $100,000 in your practice, top 10 cosmeceuticals, and a Q&A with key opinion leaders.

Dr. Schlessinger's philosophy is that continuing education plays a primary role in practice of cosmetic dermatology and cosmetic surgery, and how the forum presents this information is unique.

"Cosmetic Surgery Forum is unlike any other conference because it is set up as a discursive, rather than didactic event. This means the material is always new as the discussions form the basis for the topics and they can go in any direction the audience or panelists take them," Dr. Schlessinger says.

"Additionally, each panelist is allowed only five to seven slides and five to seven minutes of 'talk time,' so discussion is allowed, rather than tolerated. Microphones are placed on each table and audience members are encouraged to participate. This leads to interesting and informative interchanges," he says.

WHILE IN VEGAS, don't miss one of the widely acclaimed Cirque du Soleil shows. Check out the "O" show (*www.cirquedusoleil.com/en/shows/o/default.aspx*) at the "O" Theatre at Bellagio. Want to be a bit more adventurous? Venture to the Mandalay Bay's Shark Reef (*www.mandalaybay.com/shark-reef*) or free fall from Las Vegas' very own Sky Jump (*www.stratospherehotel.com/Tower/Rides/SkyJump*). When ready to grab a bite, consider. D.O.C.G. (*www.cosmopolitanlasvegas.com/taste/restaurant-collection/d-o-c-g.aspx*), a Las Vegas Italian restaurant/wine bar, or Tacos and Tequila at the Luxor hotel (*www.luxor.com/restaurants/t_and_t.aspx*).

For more information: www.cosmeticsurgeryforum.com.

upcoming events

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

International Society of Hair Restoration Surgery Annual Scientific Meeting
www.ishrs.org
Oct. 23-26, 2013
Hyatt Regency, San Francisco

Hampton University Skin of Color Research Institute - 2013 Skin of Color Symposium
www.huscri.org
Oct. 25-27, 2013
Royal Sonesta Harbor Court Hotel, Baltimore

Ohio Dermatological Association 30th Annual Meeting
www.ohioderm.org
Oct. 25-27, 2013
Hilton Columbus at Easton, Columbus, Ohio

ASDS - The Art and Science of Soft-Tissue Fillers and Neuromodulators
www.asds.net/fillers/
Oct. 26-27, 2013
Grand Hyatt, New York, New York

American Society for Mohs Surgery Closure Course
www.mohssurgery.org
Oct. 28-30, 2013
DoubleTree San Diego/Mission Valley
San Diego

Skin Disease Education Foundation 14th Las Vegas Dermatology Seminar
www.globalacademycme.com
Oct. 31-Nov. 2, 2013
The Cosmopolitan, Las Vegas

Society of Dermatology Physician Assistants 11th Annual Fall Conference
www.dermpa.org
Nov. 13-16, 2013
InterContinental Buckhead, Atlanta

Global Controversies and Advances in Skin Cancer
www.gc-sc.org
Nov. 21-24, 2013
Brisbane Convention and Exhibition Centre
Brisbane, Australia

Mount Sinai School of Medicine 16th Annual Winter Symposium
www.icahn.mssm.edu/education
Dec. 6-8, 2013
Mount Sinai Medical Center, Stern Auditorium
New York

Mayo Clinic Arizona 8th Annual Practical Course on Dermoscopy & Update on Malignant Melanoma
www.mayo.edu/cme/dermatology-2013s959
Dec. 6-8, 2013
Wesin Kierland Resort, Scottsdale, Ariz.

International Hyperhidrosis Society Master Class in Hyperhidrosis Patient Care & Practice Efficiency
www.sweathelp.org
Dec. 7, 2013
FireSky Resort & Spa, Scottsdale, Ariz.

ad index

ADVERTISER	PRODUCT	WEBSITE	PAGE
ABBOTT LABORATORIES	HUMIRA	www.humira.com	35-41
BAYER HEALTHCARE PHARMACEUTICALS	FINACEA	www.finacea.com	53-54
CEPTARIS THERAPEUTICS INC	VALCHLOR	www.valchlor.com	CV2
COSMETIC SURGERY FORUM		www.cosmeticsurgeryforum.com	43
DERMATOLOGY FOUNDATION		www.dermatologyfoundation.org	COVER TIP
GALDERMA LABORATORIES	MIRVASO	www.galderma.com	CV3-CV4
GENENTECH	ERIVEDGE	www.erivedge.com	48-49
KAO USA INC	CUREL	www.curel.com	7
MEDICAL TECHNOLOGY INDUSTRIES		www.mti.net	57
MERZ PHARMACEUTICALS	NAFTIN	www.naftin.com	11-12
MIDMARK CORPORATION		www.midmark.com	65
MISSION PHARMACAL	ELETONE	www.missionpharmacal.com	5-6
THE NEOSTRATA COMPANY	SKIN ACTIVE	www.neostratapro.com	25
PALOMAR MEDICAL TECHNOLOGIES	PICOSURE	www.palomarmedical.com	61
PIERRE FABRE DERMOCOSMITIQUE	AVENE	www.pierre-fabre.com/fr	15
SENSUS HEALTHCARE	SRT - 100	www.sensushealthcare.com	33
STIEFEL, A GSK COMPANY	FABIOR FOAM	www.fabiorfoam.com	67-68
SUN PRODUCTS CORP	AFC	www.allfreeclear.com/samples	17
TARO PHARMACEUTICALS	ACCENT	www.tarousa.com	27
TARO PHARMACEUTICALS	TOPICORT SPRAY	www.tarousa.com	9-10, 19-20
ULTHERA INC	ULTHERAPY	www.ultherapy.com/physicians	59
UNILEVER	DOVE	www.doveprofessional.com/care	23
VALEANT PHARMACEUTICALS	CARAC	www.carac.info	45-46
VALEANT PHARMACEUTICALS	ZYCLARA	www.medicis.com	29-31
VISCOT MEDICAL	DERMARKER	www.viscot.com	51
WEXLER HEALTHCARE PROPERTIES		www.healthcare-properties.com	63

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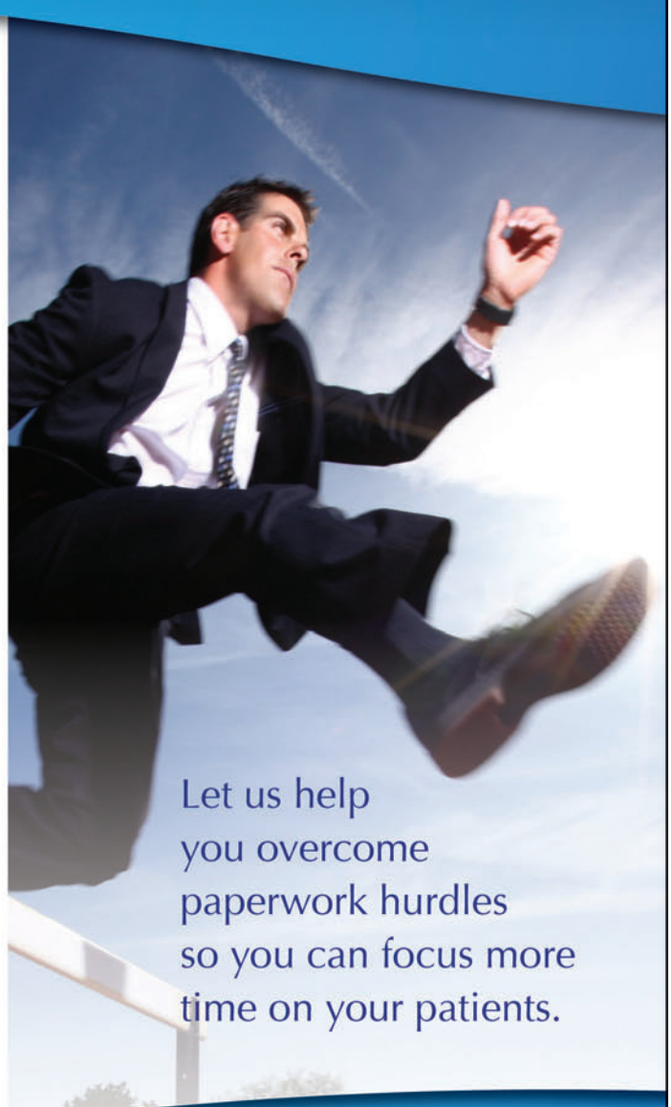

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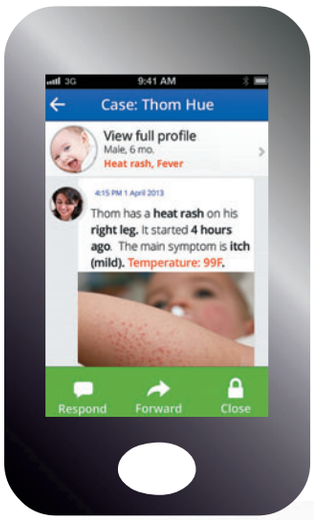

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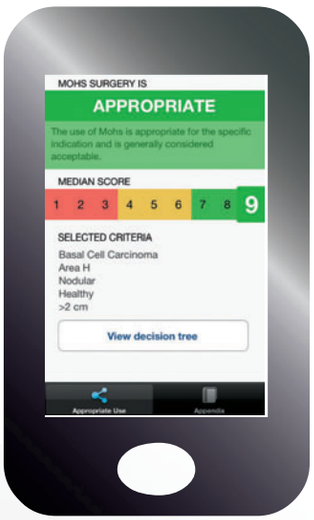
- supplemental clinical algorithms, and;
- a sharable quick reference section.



"Physicians must consider a variety of factors ... when determining whether to use Mohs surgery for the treatment of skin cancer. This new app is a great tool that will help dermatologists and other physicians provide the highest level of care to the patients who will benefit the most from this specialized surgery," says Dirk M. Elston, M.D., F.A.A.D., president of the American Academy of Dermatology.

www.aad.org/MohsAUC

MEDSNAP

MEDSNAP ID uses computer vision technology allowing physicians to use an iPhone to quickly identify an entire set of patient pills and screen them for safety. It allows patients to demonstrate what prescriptions they're taking and quickly generates an accurate list with drug-drug and drug-disease interactions. The app can also export reports through print and email.

www.medsnap.com

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.
Fort Worth, Texas 76177 USA
Revised: August, 2013
HCP

MIRVASO® (brimonidine) topical gel, 0.33%

GALDERMA Committed to the future of dermatology

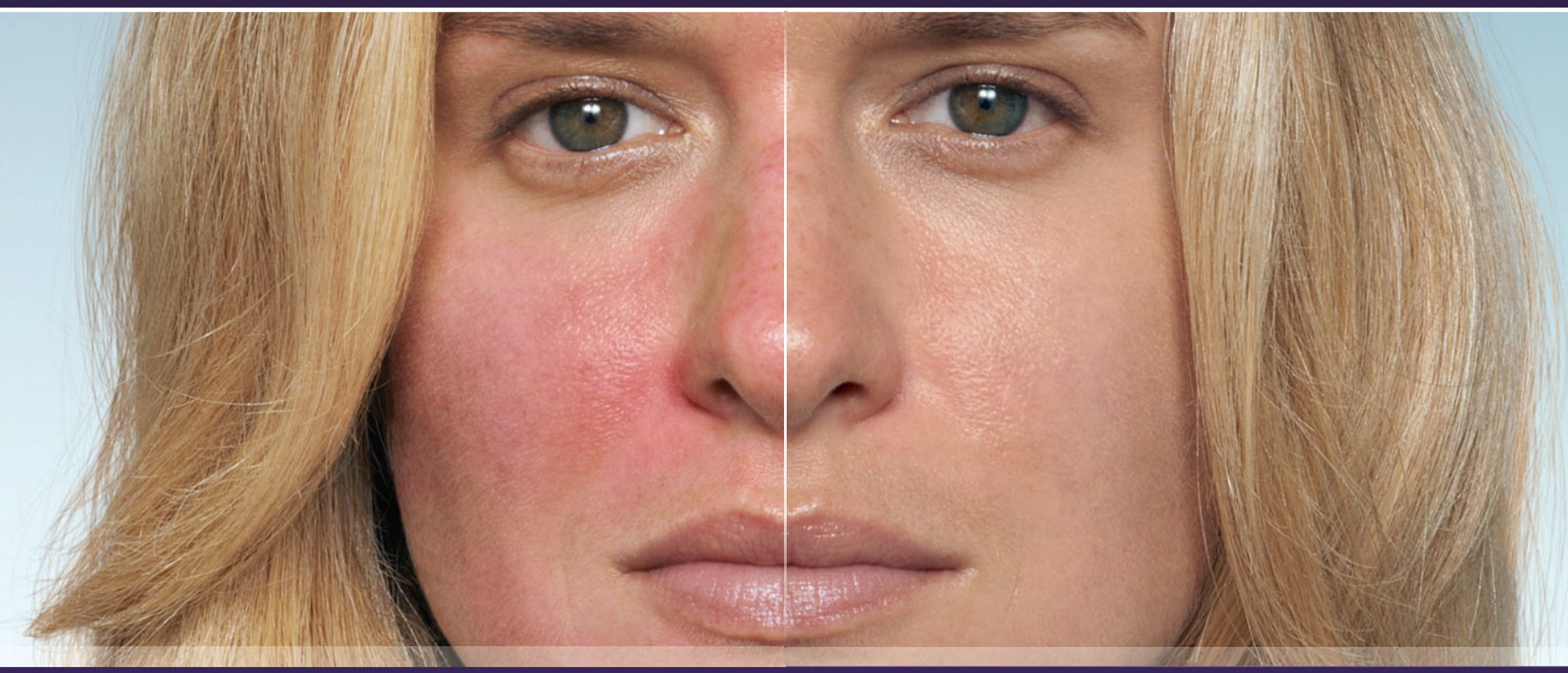
Galderma Laboratories, L.P.
14501 N. Freeway
Fort Worth, TX 76177
MIR-164B Printed in USA 08/13

GALDERMA Committed to the future of dermatology

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.*

RAPID AND SUSTAINED ERYTHEMA REDUCTION BROUGHT TO YOU BY MIRVASO® (brimonidine) TOPICAL GEL, 0.33%†

- 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]
- The most commonly reported adverse events in controlled clinical studies included erythema (4%), flushing (2%), skin-burning sensation (2%), and contact dermatitis (1%)[2]

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.