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Distinctions
Male-female skin differences drive Tx choices

AMY REYES | Managing Editor

Should men and women be treated with the same facial products in the same way? A literature review by an international group of physicians shows that the physiological skin parameters of hydration, transepidermal water loss, sebum, microcirculation, pigmentation and thickness differ among men and women, suggesting that treatment choices should differ as well.

“Understanding the physiological, chemical, and biophysical characteristics of the skin helps us develop a proper approach for the management of skin diseases,” wrote the authors of a review that focuses on sex differences of skin. The review appears in the September issue of the International Journal of Women’s Dermatology.

The review, which included 57 studies, was led by Alireza Firooz, M.D. of the Center for Research and Training in Skin Disease and Leprosy at Tehran University of Medical Sciences in Iran. “The studies show that the skin parameters of hydration, transepidermal water loss, sebum, microcirculation, pigmentation, and thickness are generally higher in men but skin pH is higher in women,” she and her colleagues wrote.

Developing a deeper understanding of the skin in this way could be useful in developing facial products and cosmetic treatments that are truly sex-specific.

“The knowledge of sex-linked cutaneous differences might help in study planning and the development of female-specific products for more appropriate dermatological treatments or cosmetic interventions,” the authors wrote.

There are established sex differences in anatomy (see “Optimize injections in men,” page 40), male-female 35.

Oral contraceptives for acne
Ethical dilemmas for physicians in Catholic healthcare organizations

INGRID TORJESEN | Staff Correspondent

Clinicians working for Catholic healthcare organizations are generally barred from prescribing contraceptives for birth control, but where does the clinician stand when a woman requests a prescription for oral contraceptive pills for acne?

The Catholic Church views contraception as separating sex from the purpose of procreation within a marriage and therefore does not approve of contraceptive methods. Catholic health institutions in the United States are explicitly prohibited from promoting or condoning contraceptive practices under the Ethical and Religious Direc-

tives for Catholic Health Care Services, established by the United States Conference of Catholic Bishops that sets rules for Catholic-affiliated health care organizations in the United States.

The treatment of acne is a well-known non-contraceptive benefit of birth control pills, so female patients may attend Catholic health institutions asking for a prescription for birth control pills as a treatment for acne, when they may really want the prescription to prevent pregnancy. The patient may even go so far as to state that she wants the prescription primarily for contraception and to...
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“...oversimplification can result in stereotyping, as well as medical mismanagement.”

A framework for better medical management

by DR. ELAINE SIEGFRIED
Dr. Siegfried is professor of pediatrics & dermatology, Saint Louis University Health Sciences Center, St. Louis, Mo.

The change in social norms seems to be faster, wider and more furious than ever. Watching old movies is a good way to appreciate them. Racism and sexism are obvious in memorable caricatures in classics like “Gone with the Wind,” but even relatively recent films like “Grease,” “Pretty Woman” and “The Little Mermaid” feature a glaring lack of diversity, and sexism that is uncomfortable to view in the wake of the #MeToo movement. Questioning these norms also raises many discomforting issues about how we view and understand our social, and even our medical worlds.

Like most women, I have been a victim of sexism and sexual harassment on many occasions, starting in high school. One memorable episode was during my first medical school clerkship in 1983 — 135 years after Elizabeth Blackwell graduated from the only medical school to accept women and 20 years after Gloria Steinem published her Playboy Bunny expose. By that time, significant advancements had been made toward equal rights for women. Slightly more than 50% of my graduating classmates were women. I even recall a few female professors. But harassment was still an accepted norm, while protest was not.

My surgery rotation was marred by a resident who frequently commented on my appearance and invaded my physical space. Disturbed by his behavior, I wrote a letter to the surgery department chairman, who called me into his office and reprimanded me to keep my mouth shut and get my work done.

I have always considered myself a liberal, and so I have been baffled when my adult offspring scorn my occasional comments about the inexplicable biology of gender-neutral individuals by accusing me of stereotyping. Like many millennials, they instinctively object to generalizations involving some social groups and argue that categorization carries only negative connotations.

CATEGORIZATION CAN BE MISLEADING
But as a physician, I have been trained to observe and categorize information presented by history and physical exam in order to develop a differential diagnosis. Unfortunately, categorization is imprecise and misinterpretation — information considered out of context — can be misleading. The “science” of phrenology is an excellent example.

What about race? Centuries ago there were many more social and geographic limitations to mingling, and it was easier to group humans into one of three general racial classifications that are now considered offensive. Race is an undeniably crude marker, but an honest scientific attempt at understanding human variation. So are other, easily identifiable markers, such as gender, age and weight. Perhaps environmental factors like recent exposures, diet, stress and socioeconomic status are more clinically significant.

What about fertility? Do those with a lot of children differ from the child-free? How about habitat? Categorizing (and stereotyping) human traits is not difficult based on living in rural, suburban or urban locations, or for Americans from northern, southern, eastern, or midwestern regions.

Globalization and the Human Genome Project are gradually redefining the concept of race. The online genealogical databases now include the genetic blueprints of over seven million people, many of whom have unexpected ancestry, identifying them as mutts, rather than purebreds. Although these popular molecular genotyping techniques more accurately inform heritage than medical risk, it is not surprising that canine purebreds are at higher risk than mutts for specific autosomal recessive disorders, just as sickle cell disease is more common in blacks and cystic fibrosis in whites.

Race and ethnicity are important to medical science in many ways, despite their inherent biases. Attention to race undoubtedly raises concerns about inequality and discrimination. One example is that black patients are less likely than white patients to receive treatment for pain. This discrepancy may also explain why the opioid epidemic disproportionately affects higher income-level white patients.

Similarly, genetic traits can confer both benefit and risk — e.g. hemoglobin S causing sickle cell disease while conferring protection against malaria, and Apolipoprotein L1 predisposing one to glomerulosclerosis but decreasing the risk of African trypanosomiasis.

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has stressed the importance of assessing the impact of race and ethnicity in drug development strategies to help detect pharmacogenetic variation. Science writer and TED speaker Moises Velasquez-Manoff, has countered that doctors should ignore race, because it is an inaccurate clinical feature with socioeconomic implications. He advocates use of a more specific...
While the inclination has been that EHRs would reduce liability, it is still not clear.

The burden of EHR implementation

by DAVID J. GOLDBERG, M.D., J.D.

Dr. Goldberg is director of Skin Laser and Surgery Specialists of New York and New Jersey, past director of Mohs and Laser Research, Icahn School of Medicine at Mt. Sinai; and, adjunct professor of law, Fordham Law School in New York City.

As more dermatologists implement EHR systems, many have seen an increase in workload. Dermatologists are now concerned that implementing new information systems may initially increase, rather than decrease their malpractice risk as described in a 2010 article published in the New England Journal of Medicine. 1

As we have all seen with any new device, the risk of complication increases during the early period of use. And, moving from paper records to electronic systems has been no exception. As the authors of the NEJM article point out, studies have documented increases in computer-related errors following the implementation of computerized physician order entry systems. Mortalities may not be the major issue in the dermatology office, but the move from paper documentation to electronic records can affect the daily care of patients in many ways.

In illustrating this, the authors of the NEJM article cited a study that showed a higher rate of failure to inform patients of abnormal test results in outpatient practices when both paper and electronic records were used compared with the use of paper or electronic records alone. There is no reason to think such problems would not exist in a dermatology office.

Time spent training staff and optimizing EHR systems for use in a dermatology office will decrease the possibility of human-based errors, as those dermatology offices that have taken this approach will attest. Yet, it may not prevent mistakes entirely.

As with any system, problems may be delayed in appearing following the implementation, and a provider may not become aware until even later.

The authors of the NEJM article noted that a federal court held that a hospital that switched from a paper to an electronic system for delivering test results had a duty to “implement a reasonable procedure during the transition phase” to ensure the timely delivery of test results to doctors. While the court did not elaborate on the requirements that constitute a reasonable procedure, it found that the hospital had met its duty by establishing a training protocol for the period before all physicians had completed training on the new system. 2

While the inclination has been that EHRs would reduce liability, it is still not clear. The use of EHR systems creates new legal issues, by increasing more extensive written documentation, and the additional data recorded can be used to track physician activity, such that it could support proof of negligence.

As a critical mass of dermatologists adopt and implement EHR systems, failure on the part of the new minority of non-adopters to follow may be considered a deviation from the standard of care.

If Dr. EMR did not eventually purchase an EHR, he could be found to have deviated from the standard of care for that non-purchase.

References
“Truly breakthrough innovation starts with a clear problem statement.”

A critical first step to defining great problems

by STEVE XU, M.D. & WILLIAM JU, M.D., FAAD

Dr. Xu is an instructor in dermatology at Northwestern University Feinberg School of Medicine; medical director, Center for Bio-Integrated Electronics, Simpson Querrey Institute for Bionanotechnology, Northwestern University; and, co-founder, Advancing Innovation in Dermatology Accelerator Fund. Dr. Ju is co-founder of Advancing Innovation in Dermatology, Inc. and co-founder of the Advancing Innovation in Dermatology Accelerator Fund.

When it comes to innovation in healthcare, dermatology has a unique advantage. More often than not, the problems that afflict our patients and the problems that frustrate us as physicians and other healthcare providers are right in front of our eyes. We have a visual, tactile and visceral connection to the problem, which is something much more powerful than any CT image could ever do.

This front row seat and multi-sensory connection to patient suffering allows more profound insights into the clinical, psychological, pathophysiologic and socioeconomic drivers of the problem.

Why focus on this problem? Isn’t innovation about new solutions? Too often in biomedical innovation, new and exciting technologies with incredible capabilities and features are simply targeting the wrong problem leading to an eventual loss of resources and time, and failure. Truly breakthrough and successful innovation often starts with a clear and compelling problem statement.

THE RISKS OF FAILURE

In biomedical innovation, there are many risks of failure. These can be categorized in different ways (e.g. scientific, medical, regulatory, payor, financing, skills of the team, etc.).

1. TECHNICAL RISKS Broadly, we think of risk in two main ways for innovations. The first risk is a technical risk. Is the medical device safe and effective? Can the production process from lab prototype be scaled for mass manufacturing? Is the drug targeted enough with an acceptable therapeutic window? Would the clinical trial be reasonable to conduct in time and cost?

2. MARKET RISK The second major category is a market risk. Broadly, market risk equates to instances where your technology works as predicted, but no one will buy it. Market risk is something an innovator has considerably less control over. There is greater uncertainty, and this is where understanding the problem becomes so critical.

If an innovator misjudges a problem, then the chances their technology or solution will succeed in the marketplace drastically decreases. Conversely, a deep understanding of the problem helps enable the innovator to shape the product’s target profile to match the expectations of the patient and the provider, thrive in the competitive landscape, and mitigate regulatory and reimbursement challenges.

Stanford University’s bio-design process directs the innovator through the process of problem identification into a clear needs statement that is then solidified prior to any discussion around a solutions. Based on the tremendous breakthroughs in product innovation under the leadership of R. Rox Anderson M.D. at the Wellman Center for Photomedicine and Lilit Garibyan, M.D., Ph.D., Dr. Anderson created the Magic Wand Initiative at Massachusetts General Hospital. It is a program that centers on problem-driven innovation and research with clinician leadership. At the core of the Magic Wand approach is its relentless focus on a clinical problem that is worth solving, which clinicians oftentimes understand the best.

Each year, Advancing Innovation in Dermatology takes a small group of exceptionally talented, inquisitive and motivated residents and early-career dermatologists through a year of virtual lectures and experiential activities with the primary goal of leaving with a developed needs statement for a business solution.

At Northwestern University, it has been a privilege to work with medical students and trainees who are excited about clinical problems in dermatology. The first inclinations are usually to pursue a mobile app idea, device sketch or repurpose a mobile phone app idea, device sketch or repurpose...
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The role of cosmeceutical peptides

**by DR. ZOE DIANA DRAELOS**

Dr. Draelos is a consulting professor of dermatology, Duke University School of Medicine, Durham, N.C.

**Q. What are cosmeceutical peptides?**

Peptides are becoming a household name in prestige cosmeceutical facial moisturizers. Peptides sound very high tech, until you realize that hydrolyzed collagen, obtained from boiling cowhides, was one of the first peptide cosmetic ingredients. However, hydrolyzed bovine collagen is much different than the newer peptide ingredients.

The new peptides are engineered one amino acid at a time to mimic a functional human protein fragment. The intent is to induce a positive biologic change. Many peptides are available from supply houses for incorporation into cosmeceutical preparations, and they fall into three major categories: Carrier peptides, signal peptides, and neurotransmitter peptides.

**Q. What are carrier peptides?**

The first peptides were introduced into the pharmaceutical realm for enhanced wound healing. The idea was to engineer peptides to carry necessary wound healing cofactors to the active site efficiently and physiologically. For this reason, the first peptides were labeled carrier peptides. The first commercialized carrier peptide was designed to deliver copper, a trace element necessary for wound healing, into the wounded tissue. Metals are very difficult to deliver and are unstable in formulation, thus using the peptide carrier technique was novel and effective. The first carrier peptide labeled GHK was composed of glycine (G), histidyl (H), and lysine (K). It was isolated from human plasma and synthetically engineered. Linking GHK to copper, abbreviated GHK-Cu, was utilized in wound healing creams and subsequently adapted to a line of facial cosmeceuticals to minimize the appearance of fine lines and wrinkles. This technology, commercialized by Neutrogena, was based on *in vitro* observation of dermal keratinocyte proliferation in response to the copper linked peptide.

**Q. What are signal peptides?**

While carrier peptides are designed to carry unique ingredients, signal peptides are designed to create a biologic response. Currently marketed signal peptides have been designed and tested *in vitro* to increase collagen, elastin, fibronectin, proteoglycan, and glycosaminoglycan production. The first commercialized signal peptide was palmitoyl pentapeptide, abbreviated Pal-KTTKS. This engineered peptide is composed of lysine (K), threonine (T), threonine (T), lysine (K), and serine (S) linked to palmitic acid (Pal). It is a procollagen I fragment used in a low concentration of four parts per million to act as a signal. The signal observed from *in vitro* fibroblast cultures was increased product of collagen I, III, and IV. The procollagen fragments are thought to down-regulate the production of collagenase thereby increasing dermal collagen. Pal-KTTKS, known commercially as Matrixyl, is still the most widely used peptide in facial cosmeceuticals.

**Q. What are neurotransmitter peptides?**

A third category of commercialized peptides is neurotransmitter peptides. These peptides became popular when facial cosmeceuticals began comparing themselves to botulinum toxin injections, asking the question if a facial moisturizer could be “Better Than Botox.” These clever advertising campaigns did not say the moisturizer was better than Botox, only the question was asked. Neurotransmitter peptides, such as acetylhexapeptide-3, were developed to attempt to inhibit release of acetylcholine at the neuromuscular junction. The peptides are similar to botulinum toxin in that both selectively modulate synaptosomal-associated protein of 25,000 Daltons, abbreviated SNAP-25, however the mechanism is different. Botulinum toxin A proteolytically degrades SNAP-25 while acetylhexapeptide-3 mimics the N-terminal end of the SNAP-25 protein. This inhibits the SNARE (soluble N-ethyl-maleimide-sensitive factor attachment protein receptor) complex formation. Acetylhexapeptide-3 is the most widely commercialized neurotransmitter peptide and is purported *in vitro* to inhibit vesicle docking through prevention of the SNARE complex formation, which induces muscle relaxation.

The challenge here is to get the peptide to the neuromuscular junction in sufficient quantity for an adequate duration to induce chemodenervation. Injections are more efficient at bypassing the stratum corneum barrier and targeting a certain active site. Topical peptide penetration is challenged by the stratum corneum, which is uniquely designed to keep out proteins, and peptides are protein fragments. Nevertheless, these neurotransmitter peptides remain popular among consumers.
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José Raúl Montes, M.D., sings a metaphor for injectable synergy

JOHN JESITUS | Staff Correspondent

San Juan, Puerto Rico-based oculoplastic surgeon José Raúl Montes, M.D., credits his musical theater experience and his instinct for staying in the moment for his ability to connect with audiences worldwide.

Once a wallflower, Dr. Montes is now a sought-after speaker and trainer for injectable aesthetic treatments. He speaks regularly at conferences in the United States, Europe, Latin America and Asia. None of this, however, was planned.

He caught the music bug from his father, an amateur singer.

“I knew that I could sing, because, since I was a little boy, I was already secretly singing on my own,” he says.

HITTING THE RIGHT NOTES

Dr. Montes said that when he worked up the nerve to audition for a high-school musical, the director exclaimed that he was the only candidate who could hit all the notes. His talents were later displayed at the yearly talent show of the University of Puerto Rico School of Medicine.

Dr. Montes finished his medical school requirements as a junior at Cornell University.

“So during my last year, all I did was take Italian, Spanish literature and theater,” he says.

However, after his residency at University of Puerto Rico, the development of a vocal cord cyst halted his singing. After surgery, he could not even speak for a month.

Dr. Montes’ voice had healed by the time he finished his oculoplastic surgery fellowship at the University of Cincinnati. He now sings as a hobby and takes voice lessons to prevent future problems. Dr. Montes’ path somewhat parallels that of rheumatologist Ronan Kavanaugh, M.D., who plays piano and has a passion for treating musculoskeletal injuries in musicians. Dr. Kavanaugh was profiled on The Doctor Paradox podcast in 2016.

“Once in a while, when I have the opportu

Montes continues on page 78

Dr. Montes speaks at Cosmetic Bootcamp in 2016.

Photo courtesy of Dr. Montes.
FDA APPROVES TRETINOIN LOTION ACNE TREATMENT

THE U.S. FOOD AND DRUG ADMINISTRATION has approved Ortho Dermatologic’s new drug application for Altreno (tretinoin 0.05 percent) lotion for the treatment of acne vulgaris. Approved for use in patients ages nine and older, the formulation is the first of its kind in a lotion, according to a company news release. It is expected to be on the market by the fourth quarter of 2018.

Noting that retinoids often result in skin irritation, physicians stated that the new lotion provides an attractive option for many patients suffering from acne. “With the efficacy expected from a retinoid plus a proven tolerability profile, Altreno will be an ideal choice for many of my patients,” Joshua Zeichner, M.D., director of Cosmetic and Clinical Research in Dermatology at Mount Sinai Hospital, New York City, commented in the news release. Ortho Dermatologics states the lotion spreads easily and is quickly absorbed by the skin. In two multi-center, randomized, double-blind, vehicle-controlled phase three studies of 1,640 patients, Altreno demonstrated statistically significant reductions in inflammatory and non-inflammatory lesions compared to vehicle. At week 12, 16.5% and 19.8% of patients in trials one and two, respectively, demonstrated treatment success of at least a two-grade improvement in global severity by Evaluator Global Severity Scores, compared to 6.9% and 12.5% with vehicle. Skin dryness, swelling, irritation, peeling and pain was reported by fewer than 4% of patients.

“FDA approval of Altreno builds upon our strong acne portfolio, providing physicians and patients a trusted retinoid in a lotion formulation to enhance the user’s experience with the inclusion of moisturizing attributes of hyaluronic acid, glycerin and collagen,” stated Ortho Dermatologics President Bill Humphries.

BIOPHOTONIC SYSTEM EARN CE MARK

KLERESCA, A U.K.-BASED COMPANY offering biophotonic technology for various skin-care treatments, recently received CE mark approval, which will allow it to expand into the U.S., Canada, Australia and throughout Europe, according to a company news release.

The company’s technology uses a proprietary multi-LED lamp designed with pre-programmed wavelength settings and a photoreceptor gel to convert light waves from the lamp into dynamic, pulsing fluorescent energy to stimulate the skin’s repair mechanism. Kleresca is expanding the biophotonic technology into the U.S., Canada, Australia and Europe.

Kleresca’s system is used for addressing acne, rosacea and skin rejuvenation. The company operated under the CE mark of one of the brands that founded it, LEO Pharma, until June.

Kleresca also offers a pre-post biophotonic treatment that prepares the skin for invasive or high-energy laser procedures. It is designed to increase collagen buildup, activate the skin’s regenerative processes, and reduce inflammation and erythema.

CANFIELD ACQUIRES VISIONMED

In September, CANFIELD SCIENTIFIC, INC., announced its acquisition of German Dermoscopy company, Visionmed AG. The acquisition combines the two companies’ decades of experience in aesthetic documentation, 3D imaging, clinical photography and reflected light microscopy, the company says.

According to Doug Canfield, Canfield Scientfic president, the acquisition of Visionmed’s optical and digital dermatoscopes create a natural extension of Canfield’s imaging portfolio, which will provide more choices and services to Canfield’s customers.

“Canfield Scientific and Visionmed’s collaborative synergy allows us to not only grow our product portfolio and research efforts, but also continue expansion of our European footprint,” says Peter Klar, who will assume responsibility for commercial sales of Canfield’s imaging systems as chief Sales Officer (CSO) for Europe. “In this way, we can offer our customers a complete line of medical and aesthetic imaging solutions while still maintaining the highest level of quality.”

The merged product lines will be available from Canfield Scientific, Inc. in the United States and Canfield Scientific GmbH in Germany.
EPHINITY DERMATOLOGY PARTNERS WITH SUN CITY DERMATOLOGY

EPHINITY DERMATOLOGY, an Austin, Texas-based practice with offices throughout the South and West, has joined forces with Sun City Dermatology of El Paso, Texas, according to a company news release. The six-provider group at Sun City, was founded by Adri- an Guevara, M.D., in 2006. Dr. Guevara, who was joined by Brett Ozanich, M.D. in Sun City, opened the practice after earning his medical degree at University of Texas Health Sciences Center, San Antonio. Dr. Ozanich received his medical degree from Kansas City Uni- versity of Medicine, followed by residency at San Antonio Uniformed Services Health Education Consortium.

“I picked Epiphany because they have been committed to the El Paso and Las Cruces market for over two years, and with high patient satisfaction,” Dr. Guevara stated in the news release. “Another factor is that Epiphany is focused on maintaining high standards of care company-wide, so that the dermatological care is excellent at all of their locations.”

Epiphany offers clinical, cosmetic and other dermatologic services in 36 locations in seven states through partnerships with other physicians.

“Through our interactions with Dr. Guevara, we were pleased to learn that he is as com- mitted as we are to delivering excellence in his hometown of El Paso,” Epiphany CEO Gheorghe Pusta said in the news release. “Furthermore, we are delighted to see Dr. Guevara continue his leadership as Epiphany’s El Paso Market medical director.

The new collaboration will allow for greater access to administrative resources, marketing, IT, human resources and other support services for the practice.

NYC, PHILADELPHIA DERMATOLOGY FIRMS MERGE

SCHWEIGER DERMATOLOGY GROUP, a New York firm with more than 40 offices, has merged with Pennsylvania Centre for Dermatology. Founded in 2004 by Glen Crawford, M.D., the Pennsylvania Centre for Dermatology offers medical and aesthetic derma- tology services, while also con- ducting research on occupa- tional dermatology, laser medi- cine and skin allergies.

Dr. Crawford earned a med- ical degree from New York Uni- versity School of Medicine and completed his res- idency at the University of Pennsylvania. A fellow of the American Academy of Dermatology, Dr. Crawford serves as a clinical associate professor at the University of Pennsylvania.

“We are very excited that Dr. Glen Crawford and his distinguished team of providers are join- ing forces with Schweiger Dermatology Group,” Eric Schweiger, M.D., founder and CEO of Sch- weiger Dermatology group.

This merger represents Schweiger Dermatol- ogy Group’s first expansion to the Philadelphia area. The firm comprises more than 120 healthcare provid- ers to more than half a million patients, and promises short patient wait times with convenient provider access.

“The strategic partnership with SDG will improve our ability to provide evidence-based treatments, scientifically sound procedures, and compassionate delivery of care to our patients in Philadelphia and the Del- aware Valley,” Dr. Crawford said.

AIVITA BIOMEDICAL NAMES NEW CFO, VP OF BUSINESS DEVELOPMENT

AIVITA BIOMEDICAL, a biotech firm that focuses on regenerative medicines, such as stem cell applications, recently named two new mem- bers to its senior management team, according to a company news release.

New chief financial officer Scott Burrell joined from Com- biMatrix Corporation, where he also was CFO and helped manage that company’s sale.

Mr. Burrell

His background includes 25 years in corporate finance and compliance, working in health- care, high-tech and biotech fields.

Kevin Green was named AIVITA’s vice president of busi- ness development. For 10 years at Allergan, he was senior director of business development, overseeing transactions, including the $2.1 bil- lion Kythera acquisition.

“Mr. Burrell and Mr. Green bring decades of B2B, corporate finance and capital raising expe- rience to AIVITA. These appointments reflect our plans for further capitalization via investment and partnership,” AIVITA Chairman and CEO Hans S. Keirstead, Ph.D., said in a news release.

AIVITA, a privately-held company, also recently made hires to support its Root of Skin and Root of Skin MD skincare lines.
Sexual history can inform diagnostic and Tx decisions

Ken Katz, M.D., chief, Outpatient Pharmacy and Therapeutics, Kaiser Permanente, San Francisco

C

Sexual orientation might not correlate with sexual behaviour.

Gay men and other men who have sex with men are at higher risk for HIV and other sexually transmitted diseases.

They also have a higher risk of non-infectious diseases, including skin cancer.

Many doctors, including dermatologists, might not be comfortable taking a sexual history, especially for gay men, but practice makes perfect. And often it’s only the doctor who’s uncomfortable.”

Reference
The Only FDA Approved Clobetasol Propionate 0.025%

IMPOYZ™ (clobetasol propionate) Cream 0.025% is indicated for the treatment of moderate to severe plaque psoriasis in patients 18 years of age and older.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Topical corticosteroids, including IMPOYZ Cream can cause reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or after withdrawal of treatment. This may require that patients be evaluated periodically for evidence of HPA axis suppression. Factors that predispose to HPA axis suppression include, use of high-potency steroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure, and young age. If HPA axis suppression occurs, gradually withdraw the drug, reduce frequency of application, or substitute with a less potent corticosteroid. If signs and symptoms of withdrawal occur, systemic corticosteroids may be required. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids. Although rare, systemic effects of topical corticosteroids may manifest as Cushing’s syndrome, hyperglycemia, and glucosuria. Pediatric patients may be more susceptible to systemic toxicity because of their larger skin surface to body mass ratios. Local Adverse Reactions with Topical Corticosteroids - Local adverse reactions from topical corticosteroids may be more likely to occur with occlusion, prolonged use, or use of higher potency corticosteroids. Some local adverse reactions may be irreversible. Concomitant Skin Infections - Use an appropriate antimicrobial agent if a skin infection is present or develops. If appropriate, discontinue use of IMPOYZ Cream. Allergic Contact Dermatitis - Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. Adverse Events - The adverse reaction that occurred in at least 1% of subjects treated with IMPOYZ Cream and at a higher incidence than in subjects treated with vehicle cream was application site discoloration (2% versus 1%). Less common local adverse events occurring in < 1% of subjects treated with IMPOYZ Cream were application site atrophy, telangiectasia and rash.

Please see Brief Summary of Prescribing Information on the following page.
INDICATIONS AND USAGE
IMPOYZ Cream 0.025% is indicated for the treatment of moderate to severe plaque psoriasis in patients 18 years of age and older.

DOSAGE AND ADMINISTRATION
Apply a thin layer of IMPOYZ Cream to the affected skin areas twice daily and rub in gently and completely. Use IMPOYZ Cream for up to 2 consecutive weeks of treatment. Treatment beyond 2 consecutive weeks is not recommended, and the total dosage should not exceed 50 g/week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis [see Warnings and Precautions (5.1)]. Discontinue IMPOYZ Cream when control is achieved. Do not use if atopy is present at the treatment site. Do not bandage, cover, or wrap the treated skin area unless directed by a physician. Avoid use on the face, scalp, axilla, groin, or other intertriginous areas. IMPOYZ Cream is for topical use only. It is not for oral, ophthalmic, or intravaginal use. Wash hands after each application.

DOSAGE FORMS AND STRENGTHS
Cream, 0.025%: each gram contains 0.25 mg of clobetasol propionate in a white-to-off white cream base.

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
Effects on the Endocrine System: IMPOYZ Cream can cause reversibly hypoactive hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or after withdrawal of treatment. Because of the potential for systemic absorption, use of topical corticosteroids, including IMPOYZ Cream, may require that patients be evaluated periodically for evidence of HPA axis suppression.

Factors that predispose a patient to HPA axis suppression include the use of high-potency steroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure, and young age. Evaluation for HPA axis suppression should be done by determining a baseline morning plasma cortisol concentration before the initiation of treatment and periodically during treatment. If evidence of HPA axis suppression is noted, institution of systemic corticosteroid replacement therapy may be required.

Evaluation of adrenal reserve may be useful in clinical situations characterized by stress such as major surgery, trauma, extended periods of severe illness, and severe stress. A decision to use corticosteroids in such a situation should not be based on the results of the suppression test alone, but should also take into account clinical judgment. In some patients requiring prolonged full-dose corticosteroid treatment, occasional午后 dosing may be required to maintain HPA axis function.

Local adverse reactions from topical corticosteroids may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. These may be more likely to occur with occlusive use, prolonged use, or use of higher potency corticosteroids, including IMPOYZ Cream. Some local adverse reactions may be irreversible.

Concomitant Skin Infections: Use of an antimicrobial agent if a skin infection is present or is likely to occur. If a favorable response does not occur, discontinue use of IMPOYZ Cream until the infection has been adequately treated.

Allergic Contact Dermatitis: Allergic contact dermatitis with clobetasol propionate is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. Such an observation should be corroborated with expert dermatologic patch testing. If irritant dermatitis develops, discontinue the topical corticosteroid and institute appropriate therapy.

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

IMPOYZ Cream was evaluated in two randomized, multicenter, prospective, vehicle-controlled clinical trials in subjects with moderate to severe plaque psoriasis. Subjects applied IMPOYZ Cream or vehicle cream twice daily for 14 days. A total of 354 subjects applied IMPOYZ Cream and 178 subjects applied vehicle. The adverse reaction that occurred in at least 1% of subjects treated with IMPOYZ Cream and at a higher incidence than in subjects treated with vehicle cream was application site discoloration (2% versus 1%). Less common local adverse events occurring in <1% of subjects treated with IMPOYZ Cream were application site atrophy, telangiectasia, and rash.

Postmarketing Experience
The following adverse reactions have been identified during post-approval use of clobetasol propionate: striae, irritation, dryness, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, hypertrichosis, and milia. 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.

USE IN SPECIFIC POPULATIONS
Pediatric Use: Local adverse effects on the breastfed infant from IMPOYZ Cream or from the underlying maternal condition. Clinical Considerations: To minimize potential exposure to the breastfed infant via breast milk, use IMPOYZ Cream on the smallest area of skin and for the shortest duration possible (see Data). In animal reproduction studies, increased malformations, such as cleft palate and skeletal abnormalities, were observed after subcutaneous administration of clobetasol propionate to pregnant mice and rabbits. No comparisons of animal exposure with human exposure are provided due to minimal systemic exposure noted after topical administration of IMPOYZ Cream [see Clinical Pharmacology (12.3)].

Long-term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate. In a 13-week repeat dose toxicity study in rats, topical administration of clobetasol propionate cream 0.01%, 0.005% and 0.0025% at corresponding doses of 0.004, 0.02 and 0.1 mg/kg/day resulted in corticosteroid class-related systemic effects such as reductions in body weight gain, reductions in total leukocytes and individual white cells, decrease in weight maintenance of potent or very potent topical corticosteroid exceeded 300 g during the entire pregnancy, use was associated with an increase in low birth weight infants [adjusted RR, 7.74 (95% CI, 1.49–40.11)]. In addition, a small, additional cohort study, in which 28 sub-Saharan women using potent topical corticosteroids (27/28 used clobetasol propionate 0.05%) for skin lightening during pregnancy, noted a higher incidence of low birth weight infants in the exposed group. The majority of exposed subjects treated large areas of the skin (a mean quantity of 60 g/month (range, 12–170g) over long periods of time.

Data
Human Data
Multiple observational studies have no significant associations between maternal use of potent and/or potent topical corticosteroids during pregnancy and congenital malformations, preterm delivery, or fetal mortality. However, when the dispensed amount of potent or very potent topical corticosteroid exceeded 300 g during the entire pregnancy, use was associated with an increase in low birth weight infants [adjusted RR, 7.74 (95% CI, 1.49–40.11)]. In addition, a small, additional cohort study, in which 28 sub-Saharan women using potent topical corticosteroids (27/28 used clobetasol propionate 0.05%) for skin lightening during pregnancy, noted a higher incidence of low birth weight infants in the exposed group. The majority of exposed subjects treated large areas of the skin (a mean quantity of 60 g/month (range, 12–170g) over long periods of time.

Animal Data
In an embryo-fetal development study in mice, subcutaneous administration of clobetasol propionate resulted in fetotoxicity at the highest dose tested (1 mg/kg) and malformations at the lowest dose tested (0.03 mg/kg). Malformations included cleft palate and skeletal abnormalities. In an embryofetal development study in rabbits, subcutaneous administration of clobetasol propionate resulted in malformations at doses of 0.003 and 0.01 mg/kg. Malformations included cleft palate, craniofacial and other skeletal abnormalities.

Lactation: Risk Summary
There is no information regarding the presence of clobetasol propionate in breast milk or its effects on the breastfed infant or on milk production. 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 clobetasol propionate could result in sufficient systemic absorption to produce detectable quantities in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for IMPOYZ Cream and any potential adverse effects on the breastfed infant from IMPOYZ Cream or from the underlying maternal condition. Clinical Considerations: To minimize potential exposure to the breastfed infant via breast milk, use IMPOYZ Cream on the smallest area of skin and for the shortest duration possible while breastfeeding. Advise breastfeeding women not to apply IMPOYZ Cream directly to the nipple and areola to avoid direct infant exposure.

Pediatric Use: The safety and effectiveness of IMPOYZ Cream in patients younger than 18 years of age have not been established; therefore, use in children younger than 18 years 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 systemic toxicity, including HPA axis suppression, when treated with topical drugs [see Warnings and Precautions (5.1)]. Rare systemic toxicities such as Cushing’s syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in pediatric patients, especially those with prolonged exposure to large doses of high potency topical corticosteroids. Local adverse reactions involving skin and atrophy have also been reported with use of topical corticosteroids in pediatric patients. Avoid use of IMPOYZ Cream in the treatment of diaper dermatitis.

Geriatric Use: Clinical studies of IMPOYZ Cream did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience with topical corticosteroids has not identified differences in responses between the elderly and younger persons. Clinical pharmacology studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate cream. In a 13-week repeat dose toxicity study in rats, topical administration of clobetasol propionate cream 0.01%, 0.005% and 0.0025% at corresponding doses of 0.004, 0.02 and 0.1 mg/kg/day resulted in corticosteroid class-related systemic effects such as reductions in body weight gain, reductions in total leukocytes and individual white cells, decrease in weight maintenance of potent or very potent topical corticosteroid exceeds 300 g during the entire pregnancy, use was associated with an increase in low birth weight infants [adjusted RR, 7.74 (95% CI, 1.49–40.11)]. In addition, a small, additional cohort study, in which 28 sub-Saharan women using potent topical corticosteroids (27/28 used clobetasol propionate 0.05%) for skin lightening during pregnancy, noted a higher incidence of low birth weight infants in the exposed group. The majority of exposed subjects treated large areas of the skin (a mean quantity of 60 g/month (range, 12–170g) over long periods of time.

This Brief Summary does not include all the information needed to use IMPOYZ safely and correctly. See full Prescribing Information.

IMPOYZ (clobetasol propionate) Cream, 0.025%, for topical use

Manufactured by DPT Laboratories Ltd. San Antonio, TX 78213 For Encore Dermatology, Inc. Scottsdale, AZ 85254 © 2018 Encore Dermatology, Inc., Malvern, PA 19355 - IMPOYZ is a trademark of Encore Dermatology, Inc.

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There are no other specialties with this expertise. Even though this may not be day-to-day office dermatology, trained dermatologists have all the expertise needed to ... [help] these patients.”

Gayle Fischer, MBBS, University of Sydney, Australia

Vulvar diseases are skin diseases

INGRID TORJESSEN | Staff Correspondent

It might not be the first place dermatologists look, but diseases of the vulva are skin conditions. An itchy, sore vulva can be caused by a number of different skin conditions, which were described by Gayle Fischer, associate professor of the University of Sydney in Australia, who has an interest in pediatric and gynecological dermatology.

“Vulvar disease is skin disease. It is dermatology with a twist,” she said. The commonest non-erosive dermatoses of the vulva are dermatitis, psoriasis, chronic vulvovaginal candidiasis and lichen sclerosus, Fischer added. “All these conditions are itchy, and, if excoriated or fissured, they can be sore. They are also all erythematous, except for lichen sclerosus, which is white.”

A suspected diagnosis of lichen sclerosus can be confirmed with a skin biopsy; the histology is distinctive, so a biopsy will help to differentiate it from other skin diseases.

Lichen sclerosus can scar the vulva, and around 5% of women will develop cancer, but long-term preventive treatment with topical corticosteroids can reduce the risk of these complications, she said.  

Unfortunately, there are no diagnostic tests for erythematous non-erosive skin conditions, so diagnosis is reliant on the skills of the clinician, she emphasized, but there are some pointers, for example, dermatitis and psoriasis do not involve the vagina, whereas candidiasis does.

In terms of treatment, lichen sclerosus, dermatitis and psoriasis should be treated similarly to anywhere else on the skin, Fischer said. However, low-dose acitretin can be very effective for psoriasis, in post-menopausal women; although, it should of course be avoided in women of childbearing age because of the risk of birth defects.  

Chronic vulvovaginal candidiasis has a very large impact on quality of life because it is associated with pain and dyspareunia. In contrast to recurrent vulvovaginal candidiasis, where patients are asymptomatic between discrete attacks, in chronic vulvovaginal candidiasis patients present with chronic, continuous symptoms, which improve during menstruation and remit with antifungal therapy, often recurring when this therapy has ceased, particularly after short courses.

A diagnosis of chronic vulvovaginal candidiasis depends on accurate history taking, as vaginal swabs are not always positive for Candida, even in the presence of intense symptoms and obvious signs, Fischer pointed out. Long-term antifungal treatment can control chronic vulvovaginal candidiasis, which is an estrogen-dependent and, probably, genetic condition.

Other presenters discussed a number of rarer conditions that affect the vulva that fall under the umbrella of “erosive or ulcerative” diseases. They include dermatological conditions like mucosal lichen planus, fixed drug eruption and cicatricial pemphigoid.

Aphthous ulceration, infective conditions, such as genital herpes, as well as systemic diseases, such as Crohn’s disease, also involve the vulva.

“Unless dermatologists become involved in identifying and managing these conditions, it leaves these patients with no place to go,” Fischer told Dermatology Times. “There are no other specialties with this expertise. Even though this may not be day-to-day office dermatology, trained dermatologists have all the expertise needed to extend their skills to helping these patients.”

References
4 Fischer G. Chronic vulvovaginal candidiasis: what we know and what we have yet to learn. Australas J Dermatol 2012;53:247-54

Gender-based CONSIDERATIONS

Quick TAKES

A variety of skin conditions can affect the vulva.

Some conditions should be treated similarly to anywhere else on the skin.

Dermatologists have the expertise to help these patients.
Adverse reproductive outcomes rise with psoriasis

WHITNEY J. PALMER | Staff Correspondent

Psoriasis and psoriatic arthritis put pregnant women at an increased risk for adverse pregnancy and birth outcomes, according to recently published research. Findings from a study in *Advances in Dermatology and Venereology* revealed women of reproductive age who also have psoriasis or psoriatic arthritis are more likely to develop gestational diabetes, gestational hypertension, and pre-eclampsia. They also have elective or emergency caesarean deliveries more often, and they are at higher risk for preterm birth or low birth weight.

According to study authors, many of these correlations have never before been reported.

THE STUDY

The study, conducted in Sweden and Denmark, gathered data on single-child births between April 2007 and December 2012 that were recorded in national birth registries. Some women gave birth more than once, and each birth was counted independently. Researchers focused on assessing how maternal psoriasis and its severity affected pregnancy and birth outcomes.

During the time period analyzed, 741,973 women gave birth 952,907 times. Of those pregnancies, 8,097 (0.9%) occurred in 6,103 women with diagnosed psoriasis, and 312 (4%) of that group were categorized as having severe psoriasis. An additional 964 pregnancies (11%) occurred in 753 pregnant women who were identified as having psoriatic arthritis.

Based on demographic data, the women with psoriasis and psoriatic arthritis were older (above age 30) and had a high pre-pregnancy body mass index (above 25.0). Data revealed women with severe psoriasis and severe psoriatic arthritis were smokers, approximately 14% and 25%, respectively. They also had more frequent diagnoses of diabetes, hypertension, and depression than women without psoriasis.

Study analysis showed, when adjusted for maternal age, parity, and country, pregnant women with psoriasis had an increased risk for gestational diabetes (aOR 1.36, 95% CI 1.18-1.57), gestational hypertension (aOR 1.26, 95% CI 1.10-1.44), and pre-eclampsia (aOR 1.28, 95% CI 1.14-1.44). Their elective caesarean section risk was also elevated (aOR 1.17, 95% CI 1.08-1.26), as was their risk for emergency caesarean section (aOR 1.16, 95% CI 1.08-1.20).

When researchers further adjusted for smoking, body mass index, hypertension, diabetes, and depression in women with psoriasis, they, again, found an increased risk of gestational diabetes (aOR 1.20, 95% CI 1.02-1.40), gestational hypertension (aOR 1.17, 95% CI 1.02-1.35), and pre-eclampsia (aOR 1.15, 95% CI 1.01-1.30). Risk was also greater for elective caesarean section (aOR 1.11, 95% CI 1.02-1.20), as well as emergency caesarean section (aOR 1.09, 95% CI 1.01-1.18).

Women with severe psoriasis were also more likely to experience moderate preterm birth (aOR 1.64, 95% CI 1.03-2.61), as well as low birth weight (aOR 1.81, 95% CI 1.14-2.89).

While children born to women with psoriasis did have a higher Apgar score than those born to women without psoriasis, they did not face a higher risk of antepartum hemorrhage, venous thromboembolism, being small for gestational age, stillbirth, or major congenital malformations.

Among women with psoriatic arthritis, researchers identified an increased risk of gestational hypertension (aOR 1.60, 95% CI 1.13-2.29), pre-eclampsia (aOR 1.49, 95% CI 1.08-2.05), and elective caesarean section (aOR 1.49, 95% CI 1.18-1.81).

However, the authors acknowledge that some modifiable lifestyle factors could contribute to the increased risks of negative pregnancy and birth outcomes among these women. Obesity, diabetes, hypertension, and depression are commonly reported among women with severe psoriasis and psoriatic arthritis. Those conditions have also been previously, and independently, linked to adverse pregnancy and birth outcomes.

The study had both strengths and weaknesses, they added. The size and population-based design enabled researchers to examine multiple and rare outcomes and limit selection bias. However, because the data were not collected strictly for research purposes, it’s possible that some misclassification of participants could exist. Any impact, though, would be minor. Additionally, using drug treatment and psoriatic arthritis diagnosis as a proxy for identifying severe disease could have created the small change some women with severe psoriasis were incorrectly classified as non-severe.

Ultimately, the authors wrote, women with psoriasis and psoriatic arthritis should take steps to limit any outside factors that could augment their already elevated risk for pregnancy and birth complications.

“Modifiable lifestyle factors should be addressed in women with psoriasis who are of childbearing age,” they wrote. ▶

**Reference**

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hint that she knows of other women accessing oral contraceptives for this purpose where their physician codes their prescriptions as acne treatment.

The article, published in the July 2018 issue of the AMA Journal of Ethics, addresses what happens when a physician attempts to balance duty to patient, duty to institution and duty to the medical profession. 2

The Catholic Church does not prevent the use of medical therapies to cure diseases “even if a foreseeable impediment to procreation should result therefrom—provided such impediment is not directly intended for any motive whatsoever,” wrote the authors Jane Morris, M.D., an obstetrics and gynecology resident at the Case MetroHealth Medical Center program in Cleveland, and Kavita Shah Arora, M.D., MBE, assistant professor of reproductive biology and bioethics at Case Western Reserve University.

If the patient has a demonstrable diagnosis—such as abnormal uterine bleeding, dysmenorrhea or acne—in their medical history for which birth control is a medically accepted therapy, the clinician could prescribe contraception on the basis of the principle of “double effect.”

DOUBLE EFFECT

“It would be permissible to use birth control when the intent of the medication is for something other than pregnancy prevention if it is consistent with the principle of ‘double effect,’” the authors wrote, “whereby the effect of the action that is presumably ‘good’ (eg, treating a medical condition such as acne) is intended and has more weight in justifying that action than does a consequence of the action that is merely foreseen and possibly ‘bad’ (eg, pregnancy prevention).”

To meet the standard of double effect, the good effect must not only outweigh the bad effect but also come about as a direct consequence of the action, rather than as a secondary consequence of the bad effect. “In fact, the double effect is only possible if the bad effect cannot be avoided without failing to attain the good effect,” Drs. Morris and Arora wrote.

Therefore, if the patient makes it clear that the primary purpose of her request for contraception is not for the treatment of acne, the principle of double effect cannot be used with sincerity.

In this case, or if the clinician is unable to make an alternative relevant diagnosis allowing the prescription of contraception, the clinician should inform the patient that they are unable to provide contraception for the sole reason of preventing pregnancy and signpost her to someone whose employer does not restrict prescribing. “She could either do so explicitly, by formally transferring care to another clinician, or unofficially, by telling the patient about other healthcare organizations in the community that could provide more comprehensive care,” they wrote.

The American College of Obstetricians and Gynecologists states that referral is ethically necessary in cases of moral or religious objection, and the American Medical Association (AMA) states that a clinician “should offer impartial guidance to patients about how to inform themselves regarding access to desired services.” 

Deciding to prescribe a contraceptive and coding it as acne is not advisable as the clinician would be committing health care fraud which is considered a federal criminal offense that can result in a prison term and hefty fines. The legal ramifications would result not from the provision of contraception itself but from the reason given for prescribing it, Drs. Morris and Arora wrote. The U.S. Code defines health care fraud as “knowingly and willfully executing . . . a scheme or artifice to defraud any health care benefit program . . . in connection with the delivery of or payment for health care benefits, items, or services.” By submitting a falsified diagnosis of acne for coverage by an insurance plan, even when the treatment as a combined oral contraceptive pill would be covered under a different program . . . it is a violation of the law.

CASE EXAMPLE
The alternative, which includes prescribing the combined oral contraceptive pill as a contraceptive, would put a clinician’s job in jeopardy as most employment contracts with Catholic health care organizations will almost certainly include a clause preventing a clinician from doing so. Doctors who have ignored this clause and provided contraception have had their contracts terminated in the past.

For example, Gary and Christine Mar- cotte had a medical practice in Crete, Indiana, which they sold to St. Margarett Mercy Healthcare Centers in 1997, remaining on as contracted employees. In 2002, Christine was summoned by hospital administrators and told to resign or her contract would be terminated because they had learned that she was prescribing birth control pills. She resigned. Her husband was suspended for the same reason, and also later resigned.

“We signed a contract with them and the contract said we would follow the ethical and religious directives of the Catholic church,” Gary Marcotte said. “The bishops say you should not practice contraception. We prescribe birth control pills for many other problems. In modern practice, birth control pills for younger and even middle-aged women are certainly prescribed to prevent pregnancy. I’m not going to say we never prescribed them for that purpose, but it certainly wasn’t the sole purpose.”

References

The Catholic Church ‘does not consider at all illicit’ use of medical thera-pies to cure diseases.”

Jane Morris, M.D., Case MetroHealth Medical Center, Cleveland, Kavita Shah Arora, M.D., Case Western Reserve University, Cleveland.
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Synovial biopsies may hold clues to PsA treatment

JOHN JESITUS | Staff Correspondent

Quick Takes

Synovial tissue may lead to more personalized therapeutic decisions.

Newer studies indicate differences in molecular patterns of tissues among patients with different joint diseases.

Variation in expression of TNF-induced genes may be a severity marker.

In inflammatory arthritis, the molecular and genetic makeup of synovial tissues appears to hold clues that one day may guide clinical decision-making, says a physician who presented at the European Congress of Rheumatology/European League Against Rheumatism (EULAR) meeting in June.

“We live in a paradoxical period in which rheumatologists use 21st-century therapies – monoclonal antibodies blocking very specific targets, including tumor necrosis factor (TNF), interleukin (IL)-6 in rheumatoid arthritis (RA) and IL-17 in psoriatic arthritis (PsA). Yet the categories we use to classify patients are 20th- or even 19th-century categories,” said Bernard Lauwerys, M.D., Ph.D., of Université Catholique de Louvain, Belgium.

Rheumatologists spend considerable time determining whether patients have rheumatoid, psoriatic or other types of arthritis, he explained. But these labels say nothing about disease severity and prognosis, or how to treat patients.

“It’s time to move on. Many of us are looking at a new molecular taxonomy of rheumatic disorders. We believe that to design a molecular classification that makes sense, you should look in the joints rather than the blood, which is far away from where the disease occurs.”

It is sometimes a diagnostic challenge even using all the tools we now have; namely, blood tests, x-rays, ultrasound, MRI and more. The tools we are developing probably will help us make the distinction,” Dr. Lauwerys said.

To date, he said, treatment decisions for arthritis have rested largely on trial and error. “You start with a first-line drug. If that fails, you go to another first-line drug, and then second-line drugs according to the usual scheme. Can we do better? Can we personalize our therapeutic decisions? That’s where looking at synovial tissue really can make a difference.”

Histology has shown that in any arthritic joint, “You always see the same pattern of changes – hypervascularity, infiltration by inflammatory cells, diffuse aggregate and proliferation of fibroblasts.” Yet different patient groups bear different histologic signatures. “With rheumatoid arthritis, you have more of everything; in psoriatic arthritis, you have more hypervascularity.” When looking at individual patients’ tissue samples, however, Dr. Lauwerys said it remains difficult to tell one condition from another.

“But when we started to do high-throughput transcriptomic studies, what we found is that the molecular patterns in the tissues are very different. In rheumatoid arthritis, we had a lot of transcripts involved in T-cell and B-cell activation. In psoriatic arthritis, we had none of those. This tells us that although histology is very similar for whatever arthritis you see, molecular patterns are different.”

In PsA, he said, investigations into the clinical utility of these markers are lacking. However, “In rheumatoid arthritis, we see that those variations in molecular patterns tell you something about the patient’s status. In rheumatoid arthritis, those T-cell and B-cell activation genes correlate well with disease activity. We also found that variation in the expression of TNF-induced genes tells you something about disease severity.”

The more of these genes in a tissue sample, he explained, the less likely a patient is to respond to therapy.

“We are now trying to confirm these findings in multicentric prospective trials, to correlate the molecular patterns with clinically relevant information because this is what it’s all about – can we base clinical decisions on those data? Apparently, it is possible,” according to a study published by Lauwerys et al. in Arthritis Research & Therapy in January 2016.

Crucial to the process, said Dr. Lauwerys, is the quality of clinical data used to supplement molecular and genetic data.

“Everybody is running high-throughput genetic studies. But if you want that kind of experiment to succeed, you also need good quality clinical information. That’s where I believe we make a difference – we combine those techniques with very good clinical characterization of patients.”

For example, correlating a specific molecular pattern with poor response to therapy requires using validated tools to document clinically that the patient is indeed a poor responder. “That is the job of the clinician,” he said and it is an area where physicians can contribute, by tracking skin signs of psoriatic disease.

Ultimately, Dr. Lauwerys said, “I’m convinced that looking at the joints of patients with arthritis will tell us a lot about severity of the disease and the probability that a patient will respond to therapy.”

Disclosures: Dr. Lauwerys owns a patent licensed to DNAlytics, which sells a kit to help rheumatologists diagnose undifferentiated arthritis based on molecular patterns.

Reference

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MSL-163 Rev A
For adults with a moderate-to-severe case of atopic dermatitis (AD) that cannot be resolved with topical therapies, systemic immunosuppressants such as ciclosporin A are often the next step, but some patients cannot tolerate these agents and others have a poor response. For those patients who can tolerate ciclosporin A, which suppresses Th1, TH2 and TH17/22, long-term use beyond one year is not recommended due to side effects like increased hypertension, nephrotoxicity as well as headache, fatigue and tingling in fingers and toes. So, researchers led by Marjolein de Bruin-Weller, M.D., Ph.D., of the University Medical Center Utrecht, the Netherlands, conducted a 16-week trial of a dupilumab/topical corticosteroid treatment in adult patients with AD who have a history of inadequate response or intolerance to ciclosporin A. They found that weekly or biweekly administration significantly improved itch, mood and quality of life for patients with moderate-to-severe atopic dermatitis. The study included 325 patients who were treated with both topical corticosteroids and dupilumab for 16 weeks. The patients were divided into three groups: 110 received 300 mg dupilumab once-weekly, 107 received it every two weeks, and 108 received placebo once-weekly.

At baseline the Eczema Area and Severity Index (EASI) scores averaged 31 on a scale of 0–72. By week 16, 59–62% of patients treated with dupilumab experienced an improvement in their condition by at least 75% as compared to 29.6% of patients who received a placebo.

WHAT’S NEXT FOR DUPILUMAB?
When dupilumab injection (Dupixent, Sanofi/Regeneron) was approved by the U.S. Food and Drug Administration in March 2017 as the first biologic for adults with moderate-to-severe eczema (specifically, atopic dermatitis), it was one of the most studied treatments for this condition. Its approval was

**Quick Takes**
- **Qol studies may be warranted, expert says.**
- Electronic patient-reported symptom monitoring should be investigated.
- Dupilumab should be explored for efficacy in other indications.

**Combined AD Tx shows promise**

**Quick Takes**
- Many AD patients cannot tolerate ciclosporin A, this study may offer a viable alternative.
- Depression lessened in patients receiving dupilumab.
- Treatment with dupilumab was associated with conjunctivitis in some patients.

**BY THE NUMBERS**

75%

PATIENTS TREATED WITH DUPILUMAB WHO EXPERIENCED IMPROVEMENT BY WEEK 16
based on the results of three clinical trials that included 2,119 adult patients whose symptoms could not be controlled by topicals. By comparison, 1,659 patients were included in 34 clinical trials of other systemic treatments (ciclosporin, azathioprine, methotrexate, mycophenolate, and systemic glucocorticosteroids) for moderate-to-severe atopic eczema.

In an editorial that accompanied the study, Jochen Schmitt of the Center for Evidence-Based Healthcare in Dresden, Germany, asks what’s next for dupilumab. In addition to long-term studies, safety trials of large groups of patients and “real-world health economic investigations,” more quality of life studies may be warranted, he said.

“Electronic patient-reported symptom monitoring may also be an effective way to improve the medical care of patients with atopic eczema and other chronic skin diseases and should therefore be subject to future investigations,” Dr. Schmitt said.

Future studies should also explore the possibility of other indications for dupilumab, treatment duration and discontinuation of biological therapy, the need for new or conventional therapies, and the development of treatment decision aids for patients, he wrote.

With an abundance of research data available on dupilumab, now may be the time to delve into predictive modeling research, he said.

“Driven by more and more powerful information technology, predictive modeling and learning computer algorithms, individualized care and precision medicine no longer appear to be a vision, but rather a realistic scenario to be reached in the near future,” Dr. Schmitt wrote in his editorial.

References


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While some studies reported comparable water transepidermal water loss significantly fell below that of younger men. In both men and women beyond 70 years old significant differences in skin elasticity between the sexes.

The molecular mechanism that drives these differences remains to be defined, but knowing they exist and treating patients accordingly may improve treatment outcomes. In this article, we summarize key takeaways from the review.

### HYDRATION

A healthy skin barrier protects against UV damage and other assaults, plus, it holds in moisture. Without adequate hydration the skin’s physical and mechanical properties are impaired.

The review cites a 2013 German study by Luebberding et al. that shows young men tend to have “high levels of stratum corneum hydration,” but as the men aged beyond 40 years, the hydration decreased. Hydration on the forehead in both men and women beyond 70 years old significantly fell below that of younger men.

### TRANSEPIDERMAL WATER LOSS

While some studies reported comparable water barrier functions in both sexes, the 2013 study by Luebberding et al. showed that in men younger than 50 years old, transepidermal water loss was significantly lower in men, but on the forehead, cheeks and neck, it was higher than that of women.

### SEBUM PRODUCTION

Up until a 2012 study by Bailey et al., it was believed that sebum production between men and women was equal, but Bailey et al. described higher sebum levels in men on the face, except forehead. However, Luebberding et al. reported sebum content increased slightly on the forehead with age, but progressively decreased in women. In 2006, Roh et al. described a correlation between excessive sebum production and larger pores.

### SKIN THICKNESS

In 1975, Shuster et al. first documented the loss of skin collagen (which is associated with skin thinning) with age, particularly in women after 50 years. In men, however, it decreases equally over time.

But the most recent study on skin thickness Dr. Firooz and colleagues cited was in 2008 in which Mogensen et al. confirmed the results of a 2006 study by Gambichler et al. who found no differences in epidermal thickness among men and women. Their study was based on optical coherence tomography imaging.

### SKIN PH

Men tend to have lower acidic levels according to a 2012 study by Bailey et al., which differs from a 1987 finding Zlotogorski and a 1991 study by Wilhelm et al. that showed no sex differences.

### SKIN ELASTICITY

A 2012 study by Firooz et al. reported that females had slightly higher skin elasticity than men, but the findings were not statistically significant, which is in agreement with a 2012 report by Bailey et al. who found that women had higher skin elasticity, but only in the abdominal region. The 2014 Lueberding et al. study found that: “The mechanical properties changed differently in men and woman over their lifetime and that female skin is less distensible but has a higher ability to recover after stretching in comparison with male skin.”

### SKIN FRICTION

A 2011 study by Zhu et al. showed a “significant positive correlation between skin friction coefficient and stratum corneum hydration on the canthus and dorsal hand skin for women and on the forehead and dorsal hand skin for men.”

### WRINKLES

In 2013, Tsukahara et al. reported that among men and women between 65-75 years, women disproportionately had more wrinkles than men.

### References


### THE STUDY

The following findings are based on a literature search of PubMed and Google Scholar conducted in 2017 using these key words: skin, hydration, water loss, sebum, circulation, color, thickness, elasticity, pH, friction, wrinkle, sex, male and female. Initially, 1,070 studies were identified, but it was narrowed down to 57 of the highest quality and most relevant studies.
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What’s next for vaginal rejuvenation?

LISETTE HILTON | Staff Correspondent

Quick Takes

No energy-based devices are approved or cleared to treat symptoms related to vaginal rejuvenation.

Physicians must know that using devices for such indications is off-label use and subject to oversight from respective medical boards.

In late July, the U.S. Food and Drug Administration (FDA) released a safety communication warning against the use of energy-based devices to treat a host of vaginal conditions and symptoms that fall under vaginal rejuvenation. The purpose of the communication was to “Alert patients and healthcare providers that the use of energy-based devices to perform vaginal rejuvenation, cosmetic vaginal procedures, or non-surgical vaginal procedures to treat symptoms related to menopause, urinary incontinence, or sexual function may be associated with serious adverse events. The safety and effectiveness of energy-based devices for treatment of these conditions has not been established.”

The FDA’s focus is on nonsurgical procedures that providers perform to treat vaginal laxity; vaginal atrophy, dryness or itchiness; pain during sexual intercourse; pain during urination; decreased sexual sensation; and more. In fact, there are no energy-based devices cleared or approved by the FDA to treat these or any symptoms related to menopause, urinary incontinence, or sexual function. What’s worse, using energy-based therapies to treat these symptoms or conditions could lead to serious burns, scarring and pain, according to FDA.

While the government communication might seem scary, providers shouldn’t worry about the FDA raiding their practices. But they should take note of one thing, according to Jay D. Reyero, J.D., an attorney with ByrdAdatto, a firm in Dallas and Chicago that specializes in healthcare law.

“The FDA does not have any control over a physician’s ability to prescribe off-label, which in this case would be when physicians are using the energy-based devices to perform vaginal rejuvenation procedures,” Mr. Reyero writes says. “Although the particular devices are approved by the FDA, they are approved for a very specific use, which is not the performance of vaginal rejuvenation procedures. What is important for medspas and other healthcare professionals to understand is that such off-label use is subjected to the oversight of their medical boards.”

At this point, Mr. Reyero says, it’s important for medspas and providers that provide vaginal rejuvenation options or are thinking about adding these services to practice to review how they are or will be performing these procedures.

“Not only should the physicians or medical directors responsible for performance of the procedure be properly trained and qualified for it specifically, but they should also have a good understanding of any available scientific and clinical data relating to the procedure in order to, in their professional judgment, determine it safe for patients,” Mr. Reyero says. “In addition, they also need to confirm they are meeting the supervision required of those healthcare practitioners providing the medical services. Finally, they need to ensure patients are being fully informed and understand the risks about the procedure and that all information communicated satisfy state medical board rules and laws, including those relating to advertising.”

WHAT’S NEXT FOR VAGINAL REJUVENATION?

Jason Emer, M.D., a cosmetic dermatologist who offers vaginal rejuvenation services at his West Hollywood, Calif., practice isn’t planning to change practice but encourages more research, patients reporting of any harm from the procedures, and being upfront and honest with patients about the lack of research.

“The issue here is that everyone knows [radiofrequency] technologies and lasers help tighten skin, improve function/blood flow and overall quality. It makes sense it would help genital areas, and for years I have been doing this treatment despite claims. I don’t think it should change what we are already doing because patients are happy and getting amazing results,” Dr. Emer says.
Physicians should have a good understanding of any available scientific and clinical data relating to the procedure.”

Jay D. Reyero, J.D., ByrdAdatto, Dallas and Chicago

There are reasonable and unreasonable ways to promote off-label uses of devices, according to Michael Ingber, M.D., a urologic and female pelvic medicine and reconstructive surgeon practicing in Denville, NJ.

It’s important that providers tell patients when there is and isn’t data to support a specific indication.

“The MonaLisa Touch [Cynosure/Hologic] has over 40 published studies and most of them focus on atrophy symptoms, so things like vaginal dryness, itching, pain with intercourse. I think the challenge is when people start touting all vaginal rejuvenation devices for overactive bladder and sexual symptoms like arousal and improving orgasms,” Dr. Ingber says.

Dr. Ingber uses the MonaLisa off-label for treating lichen sclerosus. He says it works well in his experience and there are a couple studies that have shown treatment success for patients with lichen sclerosus.

“So, if the patient with lichen sclerosus has tried the creams, we can present them with the data and say it’s not officially approved for that condition but it may help them. I think that’s reasonable,” Dr. Ingber says. “It is reasonable to tell a patient that a device might help improve stress urinary incontinence (SUI). What would be unreasonable is to tell a patient that a device will help SUI, or that a device will improve things that have no data to support the claim.”

Yet, even Dr. Ingber says he has noticed that patients treated with the Votiva (Inmode) for vaginal laxity or mild prolapse after childbirth seem to also experience improved symptoms of mild stress incontinence. To give what he sees in practice some research clout, he has launched an investigator initiated trial funded by Inmode looking at patients with stress incontinence.

Rebecca Dunsmoor-Su, M.D., MSCE, owner and lead physician of RenuvaGyn, in Seattle, Wash., says she purchases and uses devices based on research. Dr. Dunsmoor-Su, an OB/GYN who promotes her practice as offering medical vaginal rejuvenation services, says she uses the MonaLisa Touch laser, but not for aesthetics. Rather, she uses it to treat the indications for which the device has been studied: menopausal symptoms and genitourinary syndrome of menopause.

Making claims that the MonaLisa or any other energy-based device will tighten vaginal tissue or increase sexual pleasure is selling patients a bill of goods and patient safety could be at risk, she says.

“I think part of the problem is that, now, all of these devices are not only sold to gynecologists or urologists. So people use them in practices when they’re not familiar with how to use something like this in the vagina. They may not be familiar with vaginal physiology. Each of these devices are different. I think most of them are probably harmless when done correctly. But especially when you’re dealing with a laser, you could go too deep if you don’t know how to use it correctly,” Dr. Dunsmoor-Su says.

There are those who say promoting the term vaginal rejuvenation is a sham. Gynecologist and female genital plastic and cosmetic surgeon Michael P. Goodman, M.D., in Davis, Calif., says that he’s not at all surprised by the FDA’s alert.

“There is virtually no evidence-based research on outcome and risk in any area other than usage for post-menopausal atrophy [vaginitis], where there does happen to be a modest amount of data,” Dr. Goodman writes. “There is also anecdotal data on short-term improvement for urinary incontinence. There is decent data on usage for lichen sclerosus. But for vaginal rejuvenation, zip, zilch!”

Dr. Goodman says he applauds the FDA for taking a closer look, but suggests FDA’s warning about dangers from these devices might be over-exaggerated.

“…basically these devices are safe, overall, but not necessarily effective,” according to Dr. Goodman. “Personally feel the term vaginal rejuvenation is so vague and non-directive as to warrant removal from the lexicon.”

RECOMMENDATIONS, WARNINGS

FDA has contacted Alma Lasers, BTL Industries, Cynosure, InMode, Sciton, Thermigen and Venus Concept about its concerns and requested the manufacturers address those concerns within 30 days.

Among the companies to acknowledge the FDA’s recent move, Cynosure issued a statement August 2 to its customers. Cynosure suggests the FDA’s letters to each company vary in content, depending on the agency’s specific concerns.

“The letter received by Hologic did not question the safety of the device but did question some of the claims located on our website and whether our existing 510(k) clearances adequately include those claims,” according to the letter. “We are evaluating the concerns raised in the letter and we intend to work collaboratively with the agency to respond to their questions.”

The FDA warns women and providers about what it calls serious concerns about deceptive marketing of unproven treatments. The agency makes it clear that it has not established that energy-based devices are safe for vaginal rejuvenation or cosmetic vaginal procedures, and consumers should understand this means the devices haven’t been cleared or approved for treatment of vaginal symptoms related to menopause, urinary incontinence or sexual function.

The FDA encourages people who have had complications after undergoing vaginal rejuvenation treatment to file reports through MedWatch, the FDA Safety Information and Adverse Event Reporting program.

The government agency recommends the same to providers, and advises those who offer such procedures to talk with patients about the benefits and risks of all available treatment options.

“As part of our Medical Device Safety Action Plan and our ongoing commitment to advancing women’s health, we’ve begun building out important device safety registries. We’ve also established the Women’s Health Technologies Strategically Coordinated Registry Network (CRN) to provide more complete evidence in clinical areas that are unique to women, such as uterine fibroids and pelvic floor disorders,” according to an FDA press release.

Disclosures: Dr. Ingber is a speaker for Hologic. Dr. Emer has ties with Cutera, BTL Aesthetics, Inmode, Bovie, Sotera/Val tent, Eclipse, Aerolase and Venus. Dr. Dunsmoor-Su: none.
The use of neurotoxins and dermal fillers in men has been on the rise for nearly two decades, but men don’t often achieve the same results as women. To provide the same degree of success, dermatologists should take into consideration the more masculine features, according to several studies published recently.

Since 1997, there has been a nearly 300% increase in the number of cosmetic procedures performed on male patients. Neurotoxins and dermal fillers have been among the most common. In fact, cosmetic injections have increased in men by 81% since 2010 and 254% since 2000. Despite the increased use, however, men still experience lower levels of efficacy. For example, based on a 2013 study published in *Dermatologic Surgery*, only 33% of men reported a significant response to abobotulinumtoxinA (Dysport, Ipsen) compared to 83% of women.

The reason, according to most investigators, is that men have more muscle mass. And, treating them correctly requires a more individualized approach.

“A lot of men come to me and say they were told that Botox wouldn’t work for them, they were resistant to it, or that it wasn’t an option,” says Derek Jones, M.D., a dermatologist with Skin Care & Laser Physicians of Beverly Hills. “That’s not true. For the vast majority, it’s because the proper dose hasn’t been used. You have to dose escalate with many male patients.”

For example, on average, he said, men can require a dose of approximately 40 U or more of onabotulinumtoxinA (Botox Cosmetic, Allergan). That high a dose is off-label and is approximately double the Food & Drug Administration (FDA)-approved 20-U dose most commonly used to reach the desired effect in women.

**HOW ARE MALE FEATURES UNIQUE?**

There are several gender-based characteristics that set men apart when considering neurotoxin treatments.

Not only are men’s skulls about 20% larger than women, but they have more facial muscle mass, subcutaneous tissue, and blood vessel density.

In particular, men have more prominent jawlines and chins, higher and wider foreheads, and their eyebrows have a flatter contour, sitting lower along the orbital rim. In contrast, women’s eyebrows have a more feminine, arched appearance. Additionally, men’s eyes, while larger than women’s, are proportionally smaller in relation to their skull size, and their noses tend to be wider and straighter than women’s.

According to a study published in 2015 in the *Journal of Drugs in Dermatology*, these anatomical differences also impact facial expressions. Men’s facial expressions are larger after adjusting for face size, and men tend to develop more severe, deep wrinkles in all facial areas. This is largely due to lower levels of subcutaneous adipose tissue compared with women, the investigators found. Male patients also have more skin collagen density and larger

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**Optimizing fillers for men**

Consider masculine features to achieve desired outcomes

**WHITNEY J. PALMER | Staff Correspondent**

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**Quick Takes**

Since 1997, there has been a large increase in number of procedures performed on male patients.

Differences in muscle mass and facial anatomy means injection doses may vary in male patients.

**Gender-based Considerations**

Since 1997, the increase in the number of cosmetic procedures performed on male patients.

Physicians of Beverly Hills. “That’s not true. For the vast majority, it’s because the proper dose hasn’t been used. You have to dose escalate with many male patients.”

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**INJECTIONS CONTINUES ON PAGE 42**
Ozenoxacin cream 1% for the topical treatment of impetigo in adults & children is effective & safe & offers advantages vs other antibiotics

By Lawrence Schachner, MD

Clinical implications of antibiotic and antiseptic resistance in skin infections

The World Health Organization (WHO) recognizes antimicrobial resistance (AR) as a “rapidly evolving health issue extending far beyond the human health sector.”1,2 Antimicrobial stewardship is critical to optimizing the use of antibiotics while preventing the development of resistance and improving patient outcomes.3 Antimicrobial stewardship has been defined as “the optimal selection, dosage, and duration of antimicrobial treatment that results in the best clinical outcome for the treatment or prevention of infection, with minimal toxicity to the patient and minimal impact on subsequent resistance.”4

Dermatologists are the most frequent prescribers of antibiotics. Resistance patterns in a wide range of pathogens against oral and topical antibiotics and antiseptics used for the treatment of dermatological conditions, such as atopic dermatitis, acne, and impetigo have been observed.5,6 AR such as in methicillin-resistant Staphylococcus aureus (MRSA) is threatening to compromise the effectiveness of crucial medical treatments.7 Mupirocin, frequently used for the treatment of impetigo, is an important component in MRSA prevention, however, reports of increasing mupirocin resistance are of serious concern.5,7 Topical agents that are effective in treating skin infections with resistant strains are developed which may help to avoid resistance and adverse effects from the use of antibiotics.

Impetigo presentation and treatment

Impetigo is a common bacterial skin infection or a result of secondarily infected lesions such as in atopic dermatitis.6 The non-bullous type which accounts for 70% of cases, is caused by S aureus or Streptococcus pyogenes and both or occurs frequently in children of two to five years of age but may also affect adults.8 Bullous impetigo (30% of cases) is frequent in intertriginous areas and is exclusively caused by S aureus.8

Both types of impetigo typically resolve within two to three weeks without scarring and complications.6 Treatment includes topical antibiotics such as mupirocin, retapamulin, and fusidic acid or oral antibiotic therapy (e.g., amoxicillin/clavulanate, dicloxacillin, cephalaxin, clindamycin, doxycycline, minocycline, trimethoprim/sulfamethoxazole, and macrolides).8,9

Ozenoxacin cream 1% is an effective and safe treatment for impetigo

Ozenoxacin (Xepi®, Cutanea Life Sciences) 1% cream is the only FDA approved non-fluorinated quinoline for the topical treatment of impetigo in adults and children 2 months or older.10 Ozenoxacin acts as a potent selective inhibitor of DNA replication, blocking the bacterial DNA gyrase and the topoisomerase IV enzymes which are critical enzymes for the transcription and replication processes of bacterial DNA.10,11 The 1% cream has been shown to have potent bactericidal activity against Gram-positive pathogens associated with skin infections.10,11 Ozenoxacin has been shown to be active against MRSA. Overall, the rate of selection of resistant mutants of ozenoxacin is lower than the observed with ciprofloxacin and similar or lower than observed with levofloxacin in MRSA organisms.4

Dermal application studies measuring ozenoxacin levels demonstrate negligible systemic absorption suggesting a safety advantage versus oral antibiotics.10 A multicenter, randomized, vehicle-controlled, parallel, double-blind study using ozenoxacin cream 1% on 412 patients 2 months and older with impetigo, demonstrated the clinical superiority of 1% cream compared to the vehicle after 5 days of treatment (Fig. 1).11 Moreover, after two days of treatment, the 1% cream showed better microbiological clearance compared to vehicle (Fig. 2).11 These results are consistent with a previously published study evaluating the clinical efficacy and safety of ozenoxacin 1% cream in adults and children with impetigo.7

Conclusions

• Antimicrobial resistance is of growing concern in dermatology.
• Ozenoxacin 1% cream is a novel prescription medicine, FDA-approved for topical treatment of impetigo in adults and children 2 months or older.
• The 1% cream offers potent bacterial activity as demonstrated in in-vitro, in-vivo and clinical studies.
• Ozenoxacin 1% cream offers low dosing frequency and short treatment regimen (twice daily for 5 days).
• Dermal application studies measuring ozenoxacin levels demonstrate negligible systemic absorption suggesting a safety advantage versus antibiotics.7

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FIGURE 1: Clinical response at day 6-7 (end)

FIGURE 2: Microbiological response at day 3-4 and at day 6-7 (end of therapy)
Injections in men require different considerations than when injecting women

Facial pores that produce sebum that waterproofs, lubricates, and maintains skin’s flexibility.

**CLINICAL IMPLICATIONS**

Currently, the three forms of Botox available — abobotulinumtoxinA, onabotulinumtoxinA, and incobotulinumtoxinA (Xeomin, Merz Aesthetics) — mainly target the muscles underlying the glabella. These muscles already require higher neu- rotoxin doses than other facial muscles, meaning the dose needed to impact greater muscle mass is even larger.

Although 20 U is the FDA-approved dose for onabotulinumtoxinA, a 2012 study published in the *Journal of Drugs in Dermatology* revealed higher doses are safe. When adjusted for small, medium, and large muscle mass, doses of 50 U, 60 U, and 70 U, respectively, were safe in women, and 60 U, 70 U, and 80 U, respectively were safe in men.

There is no published dose data that can direct dermatologists on the exact amount to give men based on their size and muscle mass, though. Much is left up to clinical judgment and incremental dose escalation, says Dr. Jones, who has published and presented research on incobotulinumtoxinA at the 2017 American Society of Dermatologic Surgery meeting.

Assess the patient’s muscle mass and proceed slowly to prevent paralyzing the facial muscles, over-widening the inter-brow space, or distorting the brow contour.

“There’s no magic formulation for identifying the right Botox dose for men. It largely boils down to experience,” he says. “One of the best ways to determine a male patient’s muscle mass is to put the corrugator muscle in the brow between the thumb and forefinger and have the patient contract the muscle so you can feel the thickness between your fingers.”

Aim the needle away from the eye to avoid injecting behind the septum into the orbiculare orculus, which can cause eye droop. Angling the needle parallel to the corrugator body can improve the chances of injecting directly into the muscle. With greater blood vessel presence, men are more vulnerable to bruising, so visible blood vessels should be avoided.

Dermatologists must also exercise care when determining dose for treating the male brow, Dr. Jones says.

“We want to avoid arching the brow in men because it has a feminizing effect,” he says. “We must make sure we’re injecting the elevator mus- cle of the lateral brow in a certain way to avoid overarch- ing.”

According to the 2015 *Journal of Drugs in Dermatology* study, dermatologists can effectively treat forehead rhytides in men, and side-step brow over- arching, by equally injecting the medial and later- al frontalis.

**CHALLENGES**

With the steady increase in knowledge among men of what Botox is and how it can work for them, Dr. Jones says, only one main challenge remains to augmenting use in this group — the cost. Achieving the desired effect with more toxin makes the procedure more expensive.

“I use the analogy of the hair cut with women. When women go to the hair dresser, they have more hair and often pay more to have it cut, colored, and styled,” he says. “It’s the same with men and Botox. Many practices charge by the amount used. So, when you escalate the dose, the price tag goes up.”

Consequently, men who have denser muscle mass in their faces can anticipate paying more for Botox treatments than their female counterparts.

Still, despite the growing number of men undergoing cosmetic treatments, greater educa- tion around Botox procedures in men is needed to optimize results, Dr. Jones says.

“It’s very important to continue to research how Botox affects and works in men. We’ll see new toxins coming to market within the next year, and they’ll likely act just like the other toxins have done,” he says. “The take-home point is that there will be a lot of variation. What’s good for one man might not be good for another, so we’ll have to pay attention to dose.”

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The value of online reviews

Insight into patient experiences can guide marketing, education

WHITNEY J. PALMER | Staff Correspondent

Online patient reviews on social media sites can be an effective tool to help dermatology practices market and educate patients about minimally invasive fat reduction procedures, a new study has found.

Body contouring is one of the fast growing areas of dermatology. According to the American Society of Dermatologic Surgery, body sculpting procedures are among the top four treatments patients request. Consequently, knowing what patients do and don’t like about them and how they rate their experiences can help clinicians influence patient choices, study authors say.

“Minimally invasive and non-invasive fat reduction procedures are rated extensively online,” says study author Sreya Talasila, M.D., a dermatologist with Northwestern University Feinberg School of Medicine. “Aesthetic providers should use this available information to guide decision-making around minimally invasive technique selection and price setting within their own practices.”

The study, published in Dermatologic Surgery, analyzed 11,871 patient reviews on fat-reduction procedures from the website RealSelf.com, a well-known aesthetic platform where patients share experiences. The website’s reviews, extracted by researchers in 2017, divided patient satisfaction ratings into “worth it” (positive), “not worth it” (negative), and “not sure” (neutral).

For more accurate comparisons, Dr. Talasila says, the team grouped reviews of 13 unique minimally invasive procedures into five body contouring modality categories: laser, cryolipolysis, injectables, radio frequency, and ultrasound. The ratings only included patient satisfaction feedback and did not offer information about patient demographics, including body mass index, age, or treatment goals.

Investigators also compared these reviews to patient responses about invasive body contouring (traditional liposuction).

The overall intent, Dr. Talasila says, was to determine which body contouring procedures are most popular and accepted among patients, especially newer ones that are used less-widely to date.

“With all the different procedures and the different number of treatments that need to be done, dermatologists should discuss treatment length and cost variability with patients up front,” she says. Being knowledgeable of online satisfaction assessments can help dermatologists manage patient expectations and set benchmarks for procedure length-of-treatment and outcomes, she says.

According to study results, researchers reviewed 7,170 patient reviews that encompassed all five minimally invasive procedure categories. The overall satisfaction rating was 58%. But, despite being more expensive and more invasive, liposuction, which had 4,645 patient reviews, still had a higher satisfaction rating of 66%. The average cost for minimally invasive procedures ranges from $1,350-$6,025. Liposuction’s price tag can be up to $7,000.

Conversations about cost can be important because minimally invasive procedures are typically out-of-pocket costs which vary by patient due to the number of needed treatment sessions.

In addition, researchers also analyzed and compared patient reviews of tumescent liposuction, an intermediate-invasive fat reduction technique. This procedure, which can be performed in one session, can address larger

\[1a, b, c\] Body contouring is one of the fast growing areas of dermatology. An analysis of online reviews showed that patients were most satisfied with ultrasound therapies (73%) and least satisfied with injectables (49%). These photos show before and after treatment with Zerona-Z6, a non-invasive laser used for fat loss. Photos courtesy of Erchonia.
Social media is one of the easiest ways for people to get reviews of other people’s experiences. Clinicians should want to see what information is out there and what their patients are gleaning from it.”

Sreya Talasila, M.D., Northwestern University Feinberg School of Medicine, Chicago

Reviews can inform physicians for managing patient expectations and setting practice benchmarks

FROM PAGE 44

volume patient cases than minimally invasive procedures, but it doesn’t require the operating room and anesthetist needed for traditional liposuction. In reviews, patients gave tumescent liposuction a 63% satisfaction rating.

Despite having a lower umbrella positive rating than more traditional, extensive techniques, the minimally invasive procedures still had a median global rating of 81% satisfaction. Laser procedures received 3,565 reviews and a 61% satisfaction score. Patients completed 2,707 cryolipolysis reviews, giving the technique a 55% satisfaction score. A total of 319 patients reviewed injectable treatments, resulting in a 49% satisfaction score. And, 314 patients reviewed radio frequency techniques, and 275 patients expressed opinions about ultrasound, giving these options satisfaction scores of 63% and 73%, respectively.

The researchers highlighted patient responses for some specific procedures, as well. Zerona, a laser procedure, received 43% satisfaction, and CoolSculpting, a cryolipolysis technique scored a 55% satisfaction rating. Kybella (injectable), Liposonix (radio frequency), and UltraShape Power (ultrasound) received satisfaction scores of 49%, 43%, and 91%, respectively.

The study did not delve into the reasons why patients gave positive or negative reviews, however, Dr. Talasila says, noting further research would be necessary to pinpoint their reasons, such as procedural pain or disappointment in effectiveness and results.

“Patient choices are different, and we didn’t parse out the demographic data to further stratify their differences,” she says. “This information could be most helpful for clinical cost setting because cost data is available on RealSelf. It may encourage aesthetic and cosmetic providers to be aware of the website for benchmarking and even modality selection. They need to know what patients are aware of.”

This information could also help clinicians understand how patients view the benefits and pitfalls of these minimally invasive procedures from a real-world perspective.

Based on data from other industries, Dr. Talasila says, online reviews have been shown to directly impact customer decisions, indicating popularity, consumer demand, and product awareness. Consequently, the more aesthetic providers can tell patients about how other individuals have responded to these body contouring techniques, the more informed the patient’s overall decision will be, she says.

Staying abreast of what patients say online about these medical procedures can also give clinicians the tools they need to correct any misperceptions or misinformation patients gather from searching about fat reduction techniques online. While patient reviews can include factual information about one individual’s experience, not all online resources provide accurate assessments of patient satisfaction or of a procedure’s efficacy and safety.

For example, in a recent study, published in JAMA Facial Plastic Surgery, researchers from Rutgers New Jersey Medical School found the majority of YouTube videos on facial plastic surgery procedures were misleading marketing campaigns. Out of 240 videos with 160 million combined views, only 72 videos included a board-certified physician qualified to accurately assess the procedure and offer information to patients.

Aesthetic providers should familiarize themselves with online reviews, so they will be prepared to help patients make the right decisions. “Social media is one of the easiest ways for people to get reviews of other people’s experiences,” she says. “Clinicians should want to see what information is out there and what their patients are gleaning from it.”

References:

Dermatologic Surgery: DOI:10.1097/DSS.0000000000001509

Gender-based CONSIDERATIONS

ONSIDERATIONS

Gender-based impacts skin cancer awareness

ELYA PETROU, M.D. | Staff Correspondent

A recent study shows that a significant number of patients scheduled for a regular screening of breast cancer showed interest and could easily be encouraged to further screen for melanoma via self-skin examination (SSE) when given the opportunity and instructions to do so in an outpatient mammography environment.

The introduction of such an intervention program could be an effective strategy to increase skin cancer awareness in a large proportion of at-risk women and presents a golden opportunity for the early detection of melanoma in those patients who are already invested in preventive health.

“The ongoing outreach effort with women having mammograms is intended to increase awareness of their risk of developing a melanoma. Self-skin examinations among this group of women is a natural add-on to their existing health promotion manifested by their having regular mammograms. The program encourages SSE as a means to become aware of concerning moles and provides information as to when to seek an appointment with a dermatologist,” said June Robinson, M.D., department of dermatology, Northwestern University Feinberg School of Medicine, Chicago.

PILOT STUDY

Dr. Robinson and fellow colleagues recently conducted a pilot and feasibility study designed to promote the early detection of melanoma among women who underwent a mammogram at the Lynn Sage Breast Center at the Northwestern Medicine/Prentice Women’s Hospital in Chicago. The first of the three-phase study consisted of the development of the materials such as an informational poster and brochure that included a list of risk factors that would enable the patient to assess whether she had an increased risk to develop a melanoma, the “ABCDE” rules with instructions on how to reach decisions on seeking further medical care for a suspicious lesion, as well as exemplary images of benign moles and melanoma.

The second phase consisted of the delivery of the educational SSE program with each of the changing rooms in the mammography center equipped with an informative poster, 10 brochures, a large mirror, a magnifying glass, and a ruler.

The third phase of the study encompassed the researchers’ assessment of the program effectiveness. Patients were also asked a small set of questions in a structured interview regarding their impressions of the SSE information and materials provided and their opinions of the intervention program on a whole. Responses were recorded and made available for further evaluation and analysis at the end of the study.

FINDINGS

Of the 650 patients who had scheduled a mammogram appointment during the study time period, 560 (86.2%) agreed to participate in the study. Among these women, 68% noticed the SSE information in the changing rooms, 78% thought the information provided applied to them, and 68% identified with at least one of the risk factors for melanoma. Data showed that 20% percent of patients performed the SSE in the changing room, 13% noticed a concerning mole, and 60% of those women who noticed a concerning lesion voiced their intention to see a dermatologist for further evaluation.

“The vast majority of people do not know they are at-risk to develop melanoma nor do they understand the potential benefit of SSE to assist with life-saving early detection of melanoma. As performing a full body SSE can be challenging, the person performing the SSE needs a skin check partner to observe those areas they cannot see alone such as the top the head, behind the ears, the back, as well as the soles of feet,” Dr. Robinson said.
The ongoing outreach effort with women having mammograms is intended to increase awareness of their risk of developing a melanoma. Self-skin examinations among this group of women is a natural add on to their existing health promotion manifested by their having regular mammograms.

Junc Robinson, M.D., Northwestern University Feinberg School of Medicine, Chicago

Performing SSE well requires time and patience, and those individuals willing to perform SSE require skills training and practice to be confident of their lesion evaluation accuracy. According to Dr. Robinson, melanoma patients and their skin check partners can achieve such confidence in about 8-12 months and appropriately make appointments for concerning moles. Clearly, a multidisciplinary approach is requisite for the optimal efficacy of such an interventional program. Those implementing a program would need to work closely with dermatologists to optimize care for those patients with suspicious lesions.

During a patient appointment with an at-risk patient, Dr. Robinson said that engaging the accompanying spouse or family member in assisting with SSE will be seen by the pair as an expression of the doctor’s concern for the patient’s well-being. It is best to limit SSE recommendations to those at-risk to develop melanoma, i.e., patients with a personal or family history of melanoma, people with a history of sunburn, and/or people with a history of 10 or more indoor tanning sessions.

“Building relationships with patients and their families by health promotion activities can be an important part of the care and can be performed by staff. The dermatologist needs to monitor staff performance and reward those staff members who do it well,” she said.

Reference

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Indoor tanners lax on sunscreen, skin checks

WAYNE KUZNAR | Staff Correspondent

People who use indoor tanners may be putting themselves at greater risk for skin cancer because they use low SPF sunscreen.

A study published in *JAMA Dermatology* compared the skin cancer prevalence and screening habits of people who tan indoors with those who don’t. Researchers found that indoor tanners are more likely to be screened for skin cancer, but only if they have the risk factors for skin cancer, such as family history or age.

The study was a survey of 30,352 adults from the 2015 National Health Interview Survey who were older, had a higher income, had a family history of skin cancer, used very high SPF sunscreens and used spray-on tans.

**THE FINDINGS**

- Use of very high SPF sunscreen and receipt of a spray-on tan at a salon in the past 12 months were significant protective correlates in indoor tanners and non-tanners.
- Cancer diagnosis, other skin cancer, always using sun protection, and use of self-applied sunless tanning products in the past 12 months were significant protective correlates in non-tanners.
- Compared with non-tanners, those who had tanned more than 12 months ago were more likely to have been screened for skin cancer, but indoor tanning in the past 12 months was not significantly associated with screening.
- Of individuals who had tanned indoors more than one year ago, 32.14% had been screened for skin cancer compared 23.07% who had tanned indoors in the past 12 months and 19.52% of non-tanners.

Researchers found that only 30.18% of indoor tanners and 19.52% of non-tanners reported receiving a full-body skin cancer examination by a physician.

While still under-used, indoor tanners are more likely than non-tanners to be screened for skin cancer and at an earlier age, researchers wrote.

The researchers called for interventions that target this population group, especially people under 40 years and who are in a high income bracket (over $100,000).

“The FDA recommends that individuals repeatedly exposed to UV radiation be screened regularly for skin cancer, but it is likely that [indoor tanners] and their general practitioners are unaware of this recommendation, which should be disseminated more widely,” the researchers stated. 

Reference

Carolyn J. Heckman, PhD; Elizabeth Handorf, PhD; Melissa V. Aeuboc, PhD. “Prevalence and correlates of skin cancer screening among indoor tanners and non-tanners.” *JAMA Dermatology* 2018;154(5):554-60.

Patients want genetic testing

WAYNE KUZNAR | Staff Correspondent

Nearly half of patients at an outpatient primary care clinic elected to learn about genomic testing to assess their risk of melanoma, and the vast majority went on to request *MC1R* testing and submit the test kit.

These were the main findings from a randomized clinical trial among patients at University of New Mexico General Internal Medicine clinics. The data appear in *JAMA Dermatology*.

In the study, 1,998 patients were approached with invitation flyers in both English and Spanish and National Cancer Institute skin cancer information for diverse skin types. Patients were randomized in a 5:1 ratio to an invitation to consider personalized genomic testing (via *MC1R*) for skin cancer screening/2680741?widget=personalizedcontent&previousarticle=0

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The final study sample included 499 patients randomized to the *MC1R* testing website. Of these, 44% were non-Hispanic white and 48% were Hispanic, 79% were female, and 23% had a high school diploma or less.

A total of 232 (46%) accepted the invitation and logged onto the study website (18 viewed it in paper form). Some 88% who logged onto the website requested the saliva test kit. The test kit request rate was higher in non-Hispanic whites, men, those with higher educational attainment, and those with internet access. A total of 167 of 204 (82%) who requested the test kit completed and returned the saliva kit.

Sunburn history emerged as an important predictor of patients seeking genetic testing. The investigators concluded that the study “has advanced the public health translation of skin cancer genetic testing in providing insight into how such information may be received in populations unscreened for risk status drawn from the general population.”

Reference

Jennifer L. Hoy, PhD; Kate Zielakowski, MS; Kirsten Meyer White, PhD, et al. “Interest and Uptake of *MC1R* Testing for Melanoma Risk in a Diverse Primary Care Population, A Randomized Clinical Trial,” *JAMA Dermatology* 2018;154:684-93. 
https://jamanetwork.com/journals/jamadermatology/article-abstract/2680741?widget=personalizedcontent&previousarticle=0
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- ~75% are men2,5
- Typically between 60-70 years of age, but all ages can be affected2,5

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Blastic plasmacytoid dendritic cell neoplasm (BPDCN) is an aggressive and deadly hematologic cancer with skin lesions that may be mistaken for other skin disorders.1,2 Plasmacytoid dendritic cells (pDCs) invade the dermis where they proliferate, resulting in skin lesions that take the form of1-3,6:

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- Bruise-like macules (12%)

For more information, visit BPDCNinfo.com.

When biopsyng skin lesions, ask your pathologist to test for α123. Refer patients early.

*BPDCN diagnosis can include other markers, such as α4, α56, TCL1, and α303 (BDCA2).7

Melanoma subtypes differ in children and teens

Quick TAKES
Melanoma in children may be a distinct biologic entity.

Pediatric melanoma is often misdiagnosed because it might not present with typical features.

Children in this study tended to have more advanced melanoma.

Spitzoid melanomas seem to be more common in children than in adolescents diagnosed with melanoma. And, adolescents diagnosed with melanoma tend to follow a more aggressive disease course than younger children, shows a small study.

Findings of the study, published March 23 in Pediatric Dermatology, support the thinking that pediatric melanoma in younger children might be a distinct biologic entity.

“These results suggest that children and adolescents present with different melanoma subtypes and that adolescents have a more aggressive disease course than children,” wrote researchers who were led by Elena B. Hawryluk, M.D., Ph.D., Massachusetts General Hospital, Boston.

Melanoma is rare in children, especially during the prepubescent years. Data from the Surveillance, Epidemiology and End Results cancer registry shows 1,185 pediatric melanoma patients (ages 0-19) between 2000 to 2010. Of these patients, 11% were diagnosed by 9 years old and 89% between 10 to 19 years old.

Pediatric melanoma is often misdiagnosed in children because it might not present with the typical ABCD features. Gaining a better understanding of pediatric melanoma is important, the authors wrote. Adult protocols that are used to treat pediatric melanoma might result in unnecessary morbidity in children whose disease follows a less aggressive course.

THE STUDY
This was a small retrospective study of 32 children diagnosed with melanoma between Jan. 1, 1995 and Dec. 21, 2016. The study included 12 children (11 years old and younger) and 20 adolescents (between 11-19 years old).

The spitzoid melanoma subtype occurred in half of the patients, making it the most common among younger patients, but with no mortalities. It occurred in only two of the 20 adolescents with four deaths.

There were no significant differences in the pediatric age groups in Fitzpatrick skin phototype, tumor site, sex or race. Few of all children studied presented with a first-degree family history of melanoma, a previous blistering sunburn, indoor tanning use, significant medical comorbidities or a predisposing skin lesion.

In addition to presenting most commonly with spitzoid melanoma, six children presented with in situ, nodular, superficial spreading and unclassified melanoma. The most common melanoma subtype among adolescents was superficial spreading, diagnosed in seven adolescents, followed by six patients with in situ, four with unclassified, two with spitzoid and one with nodular melanoma.

While not a significant difference, children in this study tended to have more advanced melanoma, histologically.

Prior studies have found children and adults with comparable disease stages of melanoma have similar mortality rates. But, like this study, others have found that very young children with melanoma seem to have more favorable outcomes than adolescents and adults with melanoma. In fact, few children who are younger than 11 when diagnosed with the skin cancer die, despite research suggesting that they’re often diagnosed later, more likely to present with thick tumors and have sentinel lymph node metastasis.

“During more than 20 years at this tertiary referral center, no one with melanoma younger than 11 died, with a follow-up ranging from 9 to 137 months and a median follow-up of 44 months,” the researchers write.

While these researchers didn’t find significant differences in survival when they looked at melanoma subtype, they write melanoma subtype might drive survival differences between children and adolescents. Another reason for the better outcomes in young children could be better parental surveillance than in the adolescent years.

Reference
A phase I trial found promising activity and good tolerability with the combination of pembrolizumab and a stimulant of Toll-like receptor 9 (TLR9) known as SD-101 in patients with unresectable or metastatic melanoma, particularly in those who had not received prior anti–programmed death 1 (PD-1)/programmed death ligand 1 (PD-L1) therapy.

PD-1/PD-L1 inhibition has improved outcomes in metastatic melanoma, and studies have indicated that combination therapy can increase immune responses further. “Despite the improvement in response rates with combination immunotherapy, a large unmet need remains,” wrote study authors led by Antoni Ribas, M.D., Ph.D., of the University of California, Los Angeles, Jonsson Comprehensive Cancer Center.

SD-101 is a synthetic oligonucleotide targeting TLR9 to stimulate plasmacytoid dendritic cells. Early research in mice showed that intratumoral injections of SD-101 enhanced the effect of pembrolizumab; promising results were also seen with this combination in a small study of patients with non-Hodgkin lymphoma.

In the new phase I dose-escalation study, 22 patients with unresectable or metastatic melanoma were included; 9 had not received prior anti–PD-1/PD-L1 therapy. Patients received intraslesional injections of SD-101 along with pembrolizumab; SD-101 dose levels included 1 mg, 2 mg, 4 mg, and 8 mg. The results of the study were published in *Cancer Discovery*.

Among the nine patients who were naive to anti–PD-1/PD-L1 therapy, seven had at least one evaluation of their tumors; of those, all seven had a confirmed objective response to the therapy, and tumor shrinkage was seen in all target lesions.

Responses were observed at all SD-101 dose levels, with complete responses at the 2-mg and 4-mg levels. The median progression-free survival (PFS), duration of response, and overall survival (OS) have not yet been reached, and the estimated 12-month PFS and OS rates were 88% and 89%, respectively. After a median 18 months of follow-up, 86% of the responses were ongoing.

For the 13 patients who had received prior anti–PD-1/PD-L1 therapy, 12 had at least one evaluation. In these patients, only 2 partial responses were observed, 1 in the 1-mg SD-101 cohort and 1 in the 8-mg cohort. Reduction in target lesions was observed in five patients. Ten patients developed progressive disease between 1.5 months and 8 months after enrollment in the study.

The combination was generally well tolerated, though all 22 patients experienced at least 1 treatment-emergent adverse event. Most adverse events were grade 1/2, and there was no relationship between adverse events and SD-101 dose level. The most common grade 3/4 adverse events related to SD-101 included chills, myalgia, and injection site pain, each occurring in 14% of patients. Three patients had new-onset immunerelated adverse events, including pneumonitis, polymyalgia rheumatica, and hypothyroidism.

“This early-stage, first-in-human trial of an intratumoral TLR9 agonist with an anti–PD-1 checkpoint inhibitor demonstrated the combination was well tolerated with a high response rate in a small number of patients who were naive to anti–PD-1 therapy at baseline,” the authors concluded. “The correlation of immune activity with response suggests that, independent of prior anti–PD-1/PD-L1 therapy, the addition of SD-101 may have the potential to reverse the resistance to anti–PD-1/PD-L1 monotherapy.”

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**TLR9 agonist may improve melanoma Tx response**

**Antoni Ribas, M.D., Ph.D., UCLA Medical Center, Santa Monica**

“Despite the improvement in response rates with combination immunotherapy, a large unmet need remains.”

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**Quick Takes**

*From the pages of* Cancer Network

A combination of pembrolizumab and a stimulant of Toll-like receptor 9 demonstrated promising results in a phase 1 trial.

The addition may have the potential to reverse resistance to anti–PD-1/PD-L1 monotherapy, authors noted.

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**DAVE LEVITAN | Staff Correspondent**
Attracting and retaining LGBTQ employees

KIRSTIN BYERS | Staff Correspondent

With more than 5 million working Americans identifying as lesbian, gay, bisexual or transgender questioning (LGBTQ), how can business owners tap into this large employment demographic and not only attract, but retain, this niche group of talent in the workplace?

In general, employers support workplace equality when they are hiring and retaining qualified applicants based on the knowledge, skills and abilities needed for the job they are applying for. They may not all realize that equal employment includes, and doesn’t limit LGBTQ individuals.

Regardless of state or local laws, Equal Employment Opportunity Commission (EEOC) enforces Title VII of the Civil Rights Act of 1964 prohibition of sex discrimination based on gender identity or sexual orientation, which is upheld by the Supreme Court. Society may be shifting towards greater acceptance of LGBTQ issues, but discrimination and bias are still reported.

An area where leaders have an opportunity to shift their workplace culture is in LGBTQ healthcare. Organizations like American Medical Association (AMA) include resources for LGBTQ inclusion through the AMA Journal of Ethics and adaptation of the GMLA’s Compendium of Health Profession Association LGBT Policy and Position Statements. Examples of such policies include enhancing diversity, promoting awareness and education of LGBTQ health issues, and equity in healthcare for domestic partnerships.

Here’s where medical practices can set themselves apart. Some employers have decided to discontinue offering domestic partner coverage now that same-sex couples can get married. However, employees may face a dilemma in limiting benefits to those who choose to stay unmarried and are denied benefits.

If organizations want to lead through inclusion, they need to consider the culture they want to employ before making changes to benefits packages. A way to do this is by creating all-encompassing and equitable benefits to all groups, no matter how family is defined. By setting a practice standard, this creates an opportunity to support a healthy and diverse workforce.

The Family Medical Leave Act (FMLA) requires employers by federal law to give eligible employees 12 consecutive weeks off for certain family and medical reasons. However, the U.S. Department of Labor has made it clear that FMLA doesn’t apply to LGBTQ workers because federal law does not recognize same-sex couples; therefore employers are not legally required to grant the same rights to LGBTQ employees. Thirty-seven states have no laws providing LGBTQ inclusion insurance protections. Thirteen states, in addition to Washington, D.C., have laws that prohibit health insurance discrimination based on sexual orientation and gender identity.

To combat this workplace challenge, employers can craft unique employee benefit packages that include maternity and paternity leave, same-sex partner healthcare coverage options, and PTO and job-protection policies for family and medical leave for same-sex couples. Competitive employer-provided benefit packages help attract and retain top talent. Providing LGBTQ benefits to employees and their families can be a low-cost, high-return investment.

Cardinal Health in Dublin, Ohio, supports 50,000 employees in 60 countries and is ranked among the top 25 on the Fortune 500, offering a competitive benefit package that includes career planning, leadership development, mentorship, and tuition reimbursement. The provider of medical products and pharmaceuticals has been named Best Places to Work for LGBTQ Equality by the Human Rights Campaign for 10 years and 100 Best Companies supporting female career advancement for the sixth time in 2017 by Working Mothers magazine. Offering better-than-aver-
Providing LGBTQ benefits to employees and their families can be a low-cost, high-return investment.”

Kristín Byers

age benefits to all practice employees encourages and promotes a positive work-life balance and opportunities to build successful careers.

Another opportunity for companies to think about when considering their recruitment and retention strategies is appealing to Millennials. They are the largest generation in the workforce, and according to a recent Gallup Poll, more than 8% of Millennials identify as LGBTQ. This makes them the largest LGBT generation in the workforce.

As Millennials drive the LGBTQ population growth both in and out of the workplace, business owners need to bridge the gap between these two key workplace demographics with modern culture tactics, such as restructuring the traditional 9-5 workday, offering work remote programs and incentives, provide life-value perks such as in-house dry cleaning and laundry services, implement transparent 360-degree operational standards, and provide leadership and professional growth workshops. These programs will foster an inclusive culture and drive overall employee satisfaction, retention and recruitment to positively impact the bottom line.

Shifting the culture in a workplace can help overcome challenges to workforce gaps. When the organizational design encourages empathy, perspective, and understanding, employees can build successful businesses. Workplaces who can inspire, motivate, and empower employees to encourage equality are the organizations that are going to lead this charge.

Disclosures: Kristín Byers has more than 10 years of experience in human resources specializing in company policy, planning, programming, management, training and development, budget evaluation, and financial management.

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Marketing aesthetics to the male patient

JEFFREY FRENTZEN | Staff Correspondent

As increasing numbers of males seek aesthetic treatments, techniques and technologies continually improve to provide better results with reduced discomfort and downtime. Marketing aesthetic services to men, though, can be a tricky proposition.

At the practice level, growing the male patient population has mostly relied on word-of-mouth and referrals from wives and significant others. At the industry level, manufacturers have started supporting this mega trend by rolling out male-centric marketing campaigns to capture this audience and expand the patient pool.

“A lot of manufacturers are doing direct-to-consumer marketing directed at men,” said Jason D. Bloom, M.D., a facial plastic and reconstructive surgeon in Ardmore, Penn. “The increasing availability of non-surgical procedures that are safe and have no downtime is an important factor, as well.”

In recent years, Dr. Bloom’s male patient base has grown from 10% of his practice to around 15%. “More men have been coming in the last few years because cosmetic treatments have become more acceptable, and it is not taboo for a man to get neurotoxin or dermal filler injections,” he said. “Among Baby Boomers, men want to stay competitive in an increasingly aggressive job environment and that is driving a lot of them.”

According to Sunee Chilukuri, M.D., F.A.A.D., F.A.C.M.S., a dermatologist and dermatologic surgeon in Houston, Texas, who has also experienced a large increase in male patients, gateway procedures that attract men are the ones to actively market both internally and externally. “Body shaping and skin tightening are big, along with neurotoxin and/or dermal filler injections, gynecomastia, hair regrowth or removal, tattoo removal and physician-dispensed skincare,” he said.

The appropriate place to start when creating a male-centric marketing plan is for practitioners to recognize that men have different priorities than women, said W. Grant Stevens, M.D, F.A.C.S., a plastic surgeon in Marina Del Rey, Calif., who developed Marina ManLand, a man cave built into his clinic.

Dr. Stevens in his man cave. He has recognized the importance of creating a space that is appealing to male patients.

The phenomenon of specialized man caves, as well as the use of separate clinic entrances and even treatment rooms, has developed into a fruitful marketing hook that caters to this growing market.
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For dermatologists who offer aesthetic services, the decision to offer non-invasive body contouring may seem like a smart move for growing your practice. But once you’ve invested in ultrasound technology, what steps can you take to ensure your investment is a sound one?

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Featured physician: Alix Charles, MD, FAAD

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We’ve done some events in the past and we are now planning a new one: The Cigar Bar. This is a Botox and bourbon concept that appeals to men.”

Jason D. Bloom, M.D., Ardmore, Penn.

Marketing to the male patient requires research FROM PAGE 68

growing patient population. “Our ManLand is a cross between a sports bar and a cigar lounge,” said Dr. Stevens. “My goal was to make it feel like the bar at The Lanesborough hotel in London.”

Dr. Stevens’ success was not a matter of chance. Targeting the male patient involved market research, he said. “When I started on the Marina ManLand project, I interviewed over 100 men and received over 200 questionnaires. I built my marketing around the responses received from this questionnaire.”

In the process, Dr. Stevens was able to confirm the treatments that he would market directly to men. “For instance, men want more hair on their heads and they want less hair on their backs. They want to have a V-shaped face, a smaller waist and bigger shoulders. Some of my male patients are starting to venture into IPL and other energy-based treatments. A lot of men have brown spots and they want to get rid of them,” he said.

Additionally, he sought the smallest details of patient preferences. “Our research found that men don’t like couches, they like leather chairs,” Dr. Stevens noted. “When I did olfactory tests with men, I found they don’t like the smell of flowers, but rather they prefer the smell of leather and a new car. They like watching sports programs on flat screens and using Wi-Fi.”

Other marketing approaches that work for men include consumer-facing events, which have also been used successfully over the years to capture female patients.

“We’ve done some events in the past and we are now planning a new one: The Cigar Bar,” according to Dr. Bloom. “This is a Botox-and-bourbon concept that appeals to men. At this male-centered event we’ll talk about neurotoxin and dermal filler treatments for men, neck rejuvenation, and microinvasive procedures. These are things that men are interested in.”

While CoolSculpting fat reduction procedures are considered the gateway treatment for Dr. Stevens’ male patients, “They actively seek other types of services as well,” he said. “I track my male patients and follow what they keep coming back for. This includes Botox and fillers, as well as procedures to tighten their necks and faces. Surprisingly, a lot are getting monthly or bi-monthly facials. When I first introduced this idea of facials to men, a lot of them scoffed. The attitude was what you would expect, ‘I don’t need no stinkin’ facial!’ I would counter with, ‘you don’t want a beautiful woman rubbing on your face for 30 minutes for free?’ That’s when they say, I’ll take it. Once they do, they say they want another and another.”

It is important to note that marketing to the gay male inhabits a uniquely diverse niche embracing various geographic regions, political stances, physical categories and professions. “Gay men are in some ways easier to market to than straight males,” said Dr. Chilukuri. “Their demographic profile encompasses all ages, races, professions and incomes,” he continued. “And as with women, the gay male openly talks to his friends about the work he’s had done, so word-of-mouth is a good method. The straight male, on the other hand, will get the work done but doesn’t necessarily want anyone to know about it.”

In addition to the gay male, practitioners must start reaching out to the Millennial generation of males, as well. “I’ve seen many young men come in looking for what I call preventive work,” Dr. Chilukuri noted. “They’re asking about skincare, neurotoxins and how those treatments can be used in preventive work.”

Millennials are attracted to non-invasive treatment modalities. “Today, we have solutions that don’t have severe side effects,” Dr. Chilukuri pointed out. “For instance, with the toxins and fillers we have today we are able to do far more preventive work. We can see people looking basically the same age for decades now.”

Want more on marketing to male clients?

01 70% OF MEN MISS SKIN CANCER WARNING SIGNS
Eight skin cancer warning signs men should know.

02 HOW TO EDUCATE MEN ON AESTHETIC TREATMENT
Men may not know how to express the aesthetic changes they want.

03 MEN: A GROWING AESTHETIC SEGMENT
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Ready or not, quality-based reimbursement is here.

JOSEPH SIEMIENCZUK, M.D. | Contributing Writer

Healthcare providers show strong interest in population health management but often struggle to assess the financial impact of the change from fee-for-service (FFS) to the value-based reimbursement (VBR) models that accompany it. The assumption that quality models could have negative financial impact on the enterprise is holding many back, even if they are committed to a quality-focused practice. The catalyst required to inspire widespread adoption is a realization that emerging payment models are fundamentally tied to quality.

This shift from volume to value is accelerating, whether provider organizations are ready or not. As is often the case, uncertainties about the future are delaying preparations, including planning for necessary changes to operations, workflow, and compensation design. Now that quality measures have been explicitly defined by payers and purchasers, the data points required to forecast income from managing to quality targets are readily available. And the impact quality improvement has on operating margins can be estimated with precision.

“For years I have searched and not found financial modeling tools to help healthcare providers evaluate the financial viability of the terms of at-risk contracts and understand the financial impact of the dual reimbursement models,” writes Cynthia Burghard, research director, Value-based Healthcare IT Transformation Strategies at IDC Health Insights. “Enli Health Intelligence has developed a methodology and modeling tool based on actual customer experience for that purpose … By calculating the revenue potential for closing gaps in care and the revenue from meeting quality metrics in upside risk contracts, healthcare organizations have a ‘de-facto budget’ that can be used to negotiate budget for and support at-risk contract investments in both technology and people.”

The pioneers of value-based healthcare delivery are gauging economic return under new reimbursement models by conducting two financial assessments. In the first, activities required but not billable in a risk contract are identified. The sum of reimbursement dollars that would have been due under a fee-for-service arrangement represents the total lost revenue.

The off-setting revenue gained by closing process and treatment gaps is then calculated. If the enterprise operates revenue centers such as labs, imaging, and endoscopy, those will be favorably impacted by activities related to quality improvement. The process of closing care gaps to achieve quality targets drives incremental fee-for-service revenue in these high-margin, often under-utilized areas.

Finally, the attainment of quality targets is typically a prerequisite for the incentive components present in most agreements. Assumptions are made about the enterprise’s ability to achieve these targets and the incentive components are added to the total.

The second assessment calls for a calculation of the incremental cost of attaining targets prescribed within the health system portfolio of risk-based contracts and defined by the spectrum of clinical quality measures (CQMs). The organization may need to add staff to fill gaps in expertise to address specific risks and conditions. It will certainly spend more time monitoring patient health and deploying health management programs and interventions across the population. These new workflows require that individuals work together in teams, coordinating care, using an intelligent care plan that brings clinical and financial insights to every member of the team, and decision-support to the point of care.

As our world shifts from relative to absolute value, quantified by CQMs, the early adopters of VBR are focusing on improving quality metrics and optimizing visit volume and time spent in the encounter room. This means the patients that providers see face-to-face must be those who need high-touch care when it has the greatest health and financial impact. This requires information technology that will continuously monitor and stratify patient cohorts according to risk, assign them to an evidence-based care plan, and support the communications and coordinated care essential to achieving better outcomes. Now that healthcare quality has been quantified in a standardized way for reimbursement, it is possible to measure and even predict return on investment in a value-based world. It is an exciting future, if one is ready for it.

Disclosures: Joseph Siemienczuk, MD, is chief medical officer for Enli Health Intelligence. Siemienczuk leads Enli’s efforts to translate the latest evidence-based guidelines into codified clinical algorithms used by the Enli platform to enable providers to practice at the height of their licensure and reduce unwarranted variation in care delivery. Previously, he served as CEO of Providence Medical Group where he oversaw the operational and financial accountability of the integrated healthcare delivery system, which spans over 700 physicians, 80 clinics, and eight hospitals. During his tenure at Providence, he received the President’s award for Excellence in recognition of best-in-nation outcomes in disease management using CareManager, the population health management software application offered by Enli.

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¹ In a clinical study at 12 weeks following the third treatment.

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In addition to federal efforts, states are marching forward with their own laws aimed at undermining restrictions on off-label promotion spurred by lobbying by advocacy groups.”

Michael Sinha, M.D., J.D., MPH, Brigham and Women’s Hospital, Boston

State of off-label drug laws

Proposed laws focus on expanded rules for communications

BOB KRONEMYER | Staff Correspondent

Prescribing drugs off-label can sometimes be the best option for patients. It’s an unavoidable part of medicine. Some of the most important discoveries have been accidental discoveries in which a patient has benefited from an off-label use of a drug.

Currently, federal law allows manufacturers to respond to unsolicited questions from physicians, share peer-reviewed articles and sponsor continuing medical education courses. Congress has proposed two bills that are designed to expand those rules.

Introduced in March 2017, the Medical Product Communications Act of 2017 (H.R. 1703) seeks to create a “scientific exchange” in which healthcare providers can receive scientific, non-promotional off-label information about drugs. The legislation would allow sharing of clinical data.

H.R. 2026

The Pharmaceutical Information Exchange Act introduced in April 2017

Drug manufacturers would be permitted to share information about unapproved uses to formulary or technology review committees.

H.R. 1703 was followed by H.R. 2026, the Pharmaceutical Information Exchange Act, in April 2017. It would allow drug manufacturers to share information about unapproved uses to formulary or technology review committees that the manufacturers believe might be sufficient to support future FDA approval of unapproved use, including preclinical data.

“The legislation would allow sharing of clinical data to healthcare providers who might otherwise be unable to provide patients with the best treatment,” Sinha said.

THE HISTORY OF OFF-LABEL PROMOTION LAW

“Off-label promotion is an important health policy because of the substantial amount of harm such promotion has caused patients in the past. And, while off-label marketing is currently illegal—apart from some safe harbors—there are advocacy groups pushing to change rules and make it more widespread,” Sinha added.

In both cases, manufacturers would have to make clear that these are off-label, not FDA-approved uses. However, similar disclaimers for nutritional supplements have proven ineffective, Drs. Sinha said.

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In both cases, manufacturers would have to make clear that these are off-label, not FDA-approved uses. However, similar disclaimers for nutritional supplements have proven ineffective, Drs. Sinha said.
“The ruling limits the degree to which the government can restrict off-label marketing. This creates a situation in which pharmaceutical manufacturers can freely promote their products for non-FDA-approved uses that might be dangerous for patients. Classic examples of such cases include widespread off-label promotion of antidepressants for elderly patients with dementia or antidepressants for children,” Dr. Sinha said.

The Caronia decision led to some changes in off-label promotion. The 21st Century Cures Act of 2016 allows manufacturers to provide “healthcare economic information” about off-label drug uses to formulary committees insurers rely on when considering whether to approve coverage for a specific drug.

STATES PUSH FOR NEW LAWS
Manufacturers would have to make clear that these are off-label, not FDA-approved uses. However, similar disclaimers for nutritional supplements have proven ineffective, Drs. Sinha said.

“In addition to these federal efforts, states are marching forward with their own laws aimed at undermining restrictions on off-label promotion spurred by lobbying by various advocacy groups. These state laws could place additional pressure on Congress to pass national legislation addressing the topic,” he said.

In March 2017, Arizona became the first state to broaden off-label marketing with its Free Speech in Medicine Act, which explicitly allows manufacturers to communicate with physicians and other prescribers about off-label uses.

“State laws change rapidly,” Dr. Sinha says. For example, after the publication of the editorial, Tennessee became the second state to pass similar legislation, with the same stipulation that information given to clinicians be truthful. That law went into effect July 1.

MORE EFFORTS BY THE FDA
The FDA itself continues to advocate additional safe harbors for off-label marketing, like in 2014 when the agency proposed two draft guidances that would have allowed manufacturers to distribute non-peer-reviewed clinical practice guidelines describing off-label uses. Peer-reviewed studies showing lower estimates of product risks than those deemed by the FDA would have also been sanctioned.

Knowing the distinctions between FDA indications and off-label uses are paramount for individual physicians because physicians neither have the time nor the expertise to evaluate the critical data as do highly trained FDA scientists, Drs. Sinha and Kesselheim wrote.

Patients could also be exposed to more high-cost drugs that lack efficacy and safety evidence, thus posing increased risk.

Marketing of off-label indications might also lead pharmaceutical firms to saturate the market with biased and/or incomplete information that could influence prescribing practices.

Drs. Sinha and Kesselheim write that over the past three decades, tens of billions of dollars in civil and criminal penalties have been paid by nearly all the major pharmaceutical manufacturers for engaging in illegal off-label promotion.

Disclosures: This research was supported by the Lauren and John Arnold Foundation. ASK is also funded by the Engelberg Foundation and the Harvard Program in Therapeutic Science.

Reference

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Telehealth law: How policy shapes the marketplace

JOHN D. FANBURG, J.D., AND JONATHAN J. WALZMAN, J.D. | Contributing Writers

In today’s age of advanced connectivity, technology is shaping the delivery of healthcare services. By engaging in telehealth, providers can utilize technologies such as mobile devices, video conferencing, and real-time data sharing to provide healthcare services remotely.

Despite the vast opportunities for healthcare delivery available through technology, legal policy poses a great barrier to telehealth. In the United States, 49 states have some form of legislation relating to telehealth, the Medicaid programs in 48 states and the District of Columbia provide coverage for some form of telehealth, and the Medicare program has its own set of telehealth coverage rules. These state and Medicare telehealth policies vary widely, although there have been attempts to establish more uniform rules.

While many different aspects of telehealth are regulated, telehealth policies tend to revolve around where the services take place, who provides the services, and the technology utilized. Typically, a telehealth encounter is considered to occur at the “originating site,” which is where the patient is physically located when receiving telehealth treatment. Medicare typically limits telehealth services to rural or underserved areas, and requires a patient to be at certain specified origination sites, such as a practitioner’s office, a hospital, a rural health clinic or a skilled nursing facility. Like Medicare, a few states also restrict telehealth services to rural and underserved areas. While certain states, such as New York, also restrict telehealth services to certain origination sites, more than half of the states, including New Jersey and California, allow patients to receive telehealth services at any location.

Who provides the services is another issue that must be carefully considered. Medicare and most states, including New Jersey, New York, and California, require a provider to be licensed in the state where the telehealth patient is located, thus requiring the practitioner to follow that state’s professional practice rules and recordkeeping requirements. Over 20 states have adopted the Interstate Licensure Compact that makes it easier for member-state physicians to obtain a license in another member state, and almost 30 states have adopted the Nurses Licensing Compact that allows member-state licensed nurses licensed to practice in another member state. Several states, including Ohio and Texas, even offer special telehealth certifications to out-of-state practitioners.

The technology used to provide the services also matters. Most states and Medicare require the use of live or interactive technology, such as video conferencing, that permits two-way communication, and limits the use of real-time data sharing to certain specified services. A few states, however, are more relaxed regarding the types of technologies that may be used, and an increasing number of states are permitting physicians to remotely monitor patients with chronic conditions through real-time data sharing technology.

Other aspects of telemedicine that are typically regulated under state laws include the types of services that may be provided through telehealth, whether private payers must cover telehealth services, and remote prescribing. For example, New Jersey and California allow physicians to prescribe medications to telehealth patients, except that certain classes of controlled substances may only be prescribed after an initial in-person physician-patient encounter. Contrast that with New York, which does not have any specific telehealth prescription rules.

Telehealth and other technology can be useful tools in providing broader access to healthcare services. Telehealth also creates opportunities for providers to expand their patient base and grow their medical businesses by reaching across borders that have historically been barriers. Despite the benefits of telehealth to consumers, laws designed to protect state health-care providers and patients often stand in the way. As with any other business, the business of telehealth requires providers to understand the rules where they intend to conduct business. Therefore, before a telehealth provider expands into a new state, it is imperative that the provider seeks the right information, asks the right questions, and engages the right advisors in order to ensure compliance with the law.

Disclosures: John D. Fanburg is chair of the Health Law Practice and the managing member at Brach Eichler LLC, a law firm based in Roseland, N.J. He can be reached at (973) 403-3107 or jfanburg@bracheichler.com. Jonathan J. Walzman is an associate in Brach Eichler’s Health Law Practice. He can be reached at (973) 403-3120 or jwalzman@bracheichler.com.
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Montes: Hurricanes Irma and Maria hit Puerto Rico interrupting clinical practice FROM PAGE 16

nity, I sing,” Dr. Montes says. For example, at the recent Cosmetic Bootcamp in Aspen, Colorado, he crooned a couple lines of the Sinatra standard “Love and Marriage” as a metaphor for the synergy of neuromodulators and fillers.

“When I speak, I look at people and try to connect with them. That’s why I never speak from the podium,” he says. Instead, he walks among the audience with a mobile microphone and earpiece monitor.

Dr. Montes chose oculoplastic surgery for fairly practical reasons. By the time he had finished his ophthalmology residency, the department director, who was also a renowned oculoplastic surgeon, had just retired, leaving no attending oculoplastic surgeons at the University. The incoming director offered to hire Dr. Montes if he chose oculoplastics.

“I knew I was coming back to a position at the department,” Dr. Montes recalls. 

He started performing mainly large-scale functional surgeries.

“I never thought I was going to end up having a completely cosmetic practice,” Dr. Montes notes. However, during his ophthalmology training and oculoplastic fellowship, Dr. Montes had gained experience and confidence injecting neuromodulators in the eyelid and perioral areas for medical indications, which led him to a successful practice.

He started injecting Botox (onabotulinum toxin A, Allergan) for cosmetic indications shortly after its approval in 2002.

“Suddenly, I had large clinics of people coming in just to get Botox,” he recalls. He reorganized his schedule to perform aesthetic procedures in the afternoons. Dr. Montes’ practice grew further with the addition of injectable fillers a few years later. After eight years with an ophthalmology practice group, he ventured into private practice. Despite the growth of Dr. Montes’ cosmetic practice, he is still committed to his responsibilities as a professor in the Department of Ophthalmology at the University of Puerto Rico School of Medicine. These duties include holding weekly clinics, overseeing residents and spearheading workshops, such as the Dr. Guillermo Picó Santiago Basic Ophthalmology course.

Over time, manufacturers of injectable treatments took notice that he was purchasing products in such large amounts that they approached him to be a trainer and speaker for their products. Many manufacturers have given him exclusive rights to introduce new treatments in Puerto Rico. These duties have allowed him to continue learning from and exchanging expertise with master innovators and injectors worldwide.

In his aesthetic practice, Dr. Montes will not rely on daylight, and a generator for their server. Dr. Montes is a speaker, medical education faculty member and medical board member for Allergan and Galderma. He is also a medical education faculty member for Merz. Aesthetics and a speaker/trainer for SkinCeuticals.

RIDING OUT THE STORM
When hurricanes Irma and Maria hit Puerto Rico in September 2017, the connections Dr. Montes has made through the years with peers have been critical. “I realized at that moment that my practice was resistant even to a natural disaster.” Dr. Montes and his employees relied on daylight, and a generator for their server. They were able to start working without electric power. Having many patients who live in New York, where he is also licensed, Dr. Montes took Diane S. Berson, M.D., up on the offer. The following week, manufacturers sent products to her office so he could treat patients.

After speaking at the American Society for Dermatologic Surgery meeting in Chicago, Dr. Montes could not immediately return to Puerto Rico due to lack of flights. He was fortunate, he said, that all of his close colleagues in New York reached out, assuring him that if he needed temporary office space, they would provide it. Having many patients who live in New York, where he is also licensed, Dr. Montes took on October 8. His office was intact with minor flood damage. “I called all my employees and said, ‘We’re going to start working without electricity. We’re going to make sure that we can connect somehow with our patients to let them know we’re here.’” Dr. Montes and his employees relied on daylight, and a generator for their server.

To Dr. Montes’ surprise, his was the only ophthalmology conference in 2016.

Disclosures: Dr. Montes is a speaker, medical education faculty member and medical board member for Allergan and Galderma. He is also a medical education faculty member for Merz. Aesthetics and a speaker/trainer for SkinCeuticals.
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genetic-based assessment, with the hope that molecular tools can “bypass the quagmire of race.”

But genotyping is expensive, may never be as cost-effective as clinical evaluation, and may not ultimately be more precise. The imperfect sensitivity and specificity of oncogenes like prostate specific antigen, melanoma markers and breast cancer has exposed many patients to repeated prostate biopsies, wide excisions and prophylactic mastectomy/oophorectomy. Even high-resolution genotyping has been unable to detect or confirm ultimate risk for many diseases. The promise of whole exome sequencing to identify a cause for a patient’s constellation of abnormalities has mostly yielded a disappointing array of polymorphisms of uncertain significance.

Siddhartha Murkerjee’s “The Gene: An Intimate History” eloquently summarized the complexities and shortcomings of molecular biology: “Genes influence form, function, and fate, but these influences typically do not occur in a one-to-one manner. Most human attributes are the consequence of more than one gene; many are the result of collaborations between genes, environments and chance.”

Because these factors are ultimately important, even precision medicine is likely to be imprecise. Just as clinical and molecular categorization gives us a framework for understanding human disease and developing a differential diagnosis, oversimplification can result in stereotyping, as well as medical mismanagement.

Clinicians should embrace the importance of the doctor-patient relationships in informing their medical decisions, just as racism, sexism, size-ism and homophobia can be conquered one relationship at a time.
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- Jessica Feig, MD

“This is my second year here and I’d have to say it’s become my favorite meeting because of the great combination of science, education, straight talk and a lot of fun.”
- Zakia Rahman, MD

“Great talks and great discussion where people can really say how they feel and give real opinions. Really good information and a really good experience.”
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“I will continue to come back every year because it is honest and very fresh - this is one of the most honest meetings that there is.”
- Jill Fitchel, MD

“The conference started on Thursday morning at 8 o’clock and by 8:30 my life had changed. The very first talk was incredibly informative!”
- Candace Spann, MD

Course Director: Joel Schlessinger, MD  *CME credits are subject to change
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TruVu is part of Altru Health System, a regional health center that has a referral system that includes over 200 multi-specialty physicians and a service area treating over 225,000 patients. We are affiliated with the University of North Dakota School of Medicine and Health Sciences, the state’s only medical school, providing teaching and faculty positions to support the medical and residency students.

We offer excellent school systems, four seasons, sporting events, fine arts and a vibrant community.
DERMATOLOGIST
Penn State Health Community Medical Group is seeking several BE/BC Dermatologists as we proudly expand Dermatology services in the scenic Lancaster and Berks County areas. This is an exciting opportunity to start your practice in an area with a pre-existing large, system-owned referral base. The two practices, once established, will consist of 2 Dermatologists, 1 Advanced Practice Provider and a Mohs Surgeon. Successful candidates will have the opportunity to interact with both patient care and in the area of continuing education with the faculty of Penn State Health Department of Dermatology, a high-quality program with a national reputation for teaching, research and state-of-the-art patient care.

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The Pennsylvania State University College of Medicine and the Penn State Health Milton S. Hershey Medical Center, Department of Dermatology, is seeking applicants for the following BE/BC Dermatologist positions. Successful candidates will have the opportunity to join a high quality program with a national reputation for teaching, research and state-of-the-art patient care.

Who We’re Looking For:
- Pediatric Dermatologist
- General Dermatologist
- TeleDerm/General Derm position

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Dual formula skincare system works around the clock

Allergan announced the launch of the LUMIVIVE™ System, which combines two distinct formulas: one to shield skin during the day from blue light and environmental pollutants that cause premature aging, and another to revitalize the skin at night, the company says.

The products combine a blend of antioxidants and coenzyme Q10 to reduce fine lines, discoloration, redness, as well as counteract free radical damage.

In clinical studies, LUMIVIVE™ improved the appearance of skin tone, evenness and restored stressed skin for a more luminous complexion, the company notes. Company reported findings showed 85% of patients agreed the system reduced the effects of environmental damage on their skin and kept their skin looking radiant throughout the day.

FOR MORE INFORMATION: www.skinmedica.com/products/correct/lumivive

Encore Dermatology launches high-potency topical corticosteroid

In May, Encore Dermatology, Inc., announced the availability of Impozy Cream for the treatment of moderate-to-severe plaque psoriasis in adult patients 18 years of age or older. It is the only FDA-approved high-potency topical corticosteroid with 0.025% clobetasol propionate. Clobetasol propionate had previously been available in only one strength.

“Now we are especially excited to launch IMPOYZ Cream, as it offers dermatology providers with their first new strength as an alternative to topical clobetasol – allowing providers to treat their patients with a lower concentration,” said Bob Moccia, president and CEO of Encore Dermatology.

The product meets the demand from psoriasis patients for new topical medication vehicles.


Scar cream uses growth factors to improve appearance

Skinuva has announced a new scar cream formulated with growth factors to soften and flatten the appearance of scars and reduce redness and discoloration.

In a randomized double-blinded, multicenter study recently published in Aesthetic Surgery Journal, 74% of scars treated with Skinuva Scar Cream showed overall improvement of 12 weeks versus 54% of scars treated with silicone, as rated by investigators.

Forty-five participants were enrolled, and 49 bilateral and 12 unilateral scars were treated. Participants rated 85% of scars treated with Skinuva as having moderate-to-severe improvement versus 51% of the silicone-treated scars. The authors concluded that Skinuva was well tolerated and effective for surgical scar management.

FOR MORE INFORMATION: skinuva.com

Collaboration provides physicians new-in-office skincare treatment offering

A collaboration between Hydrafacial and Colorscience provides physicians a new-in-office skincare treatment to offer patients. The companies are introducing Total Eye Serum delivered by Perk, which is designed to refresh and revitalize the eyes.

A patented roller-flex technology gently exfoliates while replenishing skin with the Total Eye™ system to help hydrate the eyes as well as improve the overall appearance of dark circles, puffiness, fine lines and wrinkles, according to Perk. Perk is non-invasive and works with all skin types.

FOR MORE INFORMATION: colorscience.com

Dermatologist-developed natural spray targets pruritis

Miami, Fla., board-certified dermatologist Betty Bellman, M.D., has developed a natural spray-on moisturizer that is patented for the use in patients with dry, itchy skin, as well as eczema/atopic dermatitis.

Capriclear is made from fractionated Coconut Oil, a method that removes the smell of coconut. The coconut oil provides intense moisture for the skin and a protective very soothing barrier. The product contains no emulsifiers, steroids, fragrances, or other additives or preservatives that can lead to irritation, and it has been awarded the seal of approval from the National Eczema Association since 2012.

FOR MORE INFORMATION: www.bettybellmanmd.com/Products.html
HOW MEN & WOMEN ARE different

In this table, we highlight the biophysical, chemical and physiological skin differences between men and women. These are differences that may determine which topical products are better suited for patients by gender. The following summary was compiled based on a review of articles that compared skin differences by sex. The review was published in the International Journal of Women’s Dermatology this year.

**MALE SKIN**
- Sebum content is higher and pores are larger (Pochi and Stuass, 1974).
- Men tend to have impaired barrier function more than women (Mizukoshi and Akamatsu, 2013).
- The skin is thicker in women (Shuster et al., 1975).
- Facial wrinkles are deeper.
- Male skin tends to be less hydrated.
- Facial sagging is more prominent in the lower eyelids.
- Transepidermal water loss may be significantly lower in men than in women (Luebberding et al., 2013).
- The supraorbital ridge (eyebrow) is more developed than in women (Inoue, 1990).
- Fine lines are more common in men (Li et al., 2014).

**FEMALE SKIN**
- Skin collagen decreases with age more frequently than men (Shuster et al., 1975).
- Skin pH may be higher in women (Kim et al., 2006; Luebberding et al., 2012; Bailey et al., 2012).
- Women tend to have less oily faces and neckline (Mizukoshi and Akamatsu, 2013).
- Skin disorders due to psychosomatic problems are more common.
- Skin pigmentation issues are more prevalent in women with one study showing the skin melanin index higher in men.
- Autoimmune-related skin conditions are more common.
- Skin-related allergic diseases are more common.
- Some skin malignancies (such as melanoma) may occur more often in women due to hormonal changes during pregnancy, for example.
- Stratum corneum dehydration regulates epidermal proliferation, differentiation and inflammation. In sun-damaged skin, this can negatively affect the forehead and dorsal hand, particularly in women.