Digital tools impact daily practice

WHITNEY J. PALMER | Staff Correspondent

Robot dermatologists aren’t yet seen in Thessaloniki in Greece, because they’re concerned about how the technology will change their status quo.

“Any human is resistant to any development...
Digital tools impact daily practice

WHITNEY J. PALMER | Staff Correspondent

Robot dermatologists aren’t yet seeing patients for routine care, but artificial intelligence (AI) and other technology tools are growing in popularity throughout the industry. And, as they become more prevalent, they’re greatly impacting daily business and practice management.

In many pockets, dermatologists have approached these tools gingerly, said Aimilos Lallas, M.D., a dermatologist-venereologist at Aristotle University in Thessaloniki in Greece, because they’re concerned about how the technology will change their status quo.

“Any human is resistant to any development that he or she considers threatening,” said Dr. Lallas, the lead author of a recent study looking at AI use with melanoma diagnosis. “However, I think, this concern for AI is false because humans cannot be replaced in medical care.”

Between 58% and 69% of overall physicians, including dermatologists, are interested in increasing digital tool use, according to results of the Deloitte 2018 Survey of U.S. Healthcare Consumers and Physicians. But, technology adoption and implementation does have financial, staff, and patient volume implications.

AAD updates cutaneous melanoma guidelines

INGRID TORJESEN | Staff Correspondent

Treatment options for metastatic melanoma have greatly improved, including in the adjuvant setting, and these advances are reflected in the recently updated American Academy of Dermatology clinical guidelines on the management of primary cutaneous melanoma.

The guidelines, last revised in 2011, also take into account the American Joint Committee on Cancer (AJCC) latest recommendations on staging and the use of information from biopsy, pathology, primary surgery, and sentinel lymph node biopsy (SNLB).

“It is only in the past year that effective systemic adjuvant therapies for surgically resected stage III melanoma have been FDA-approved,” says Susan Swetter, M.D., chair of the guidelines working group and director of the Pigmented Lesion and Melanoma Program at Stanford University Medical Center and Cancer Institute.

“Adjuvant anti-PD-1 monotherapy and combination BRAF/MEK inhibitors are now associated with improved disease-free and overall survival, making accurate staging of patients with cutaneous melanoma even more important. This currently involves pathological staging with sentinel lymph node biopsy in appropriate patients,” she said.

BIOPSY

Although various molecular and imaging techniques have been studied as adjuncts to histopathologic assessment, biopsy remains the first
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PROGRESS YOU CAN SEE
Improvement in psoriatic plaque on the knee over 28 days of treatment.

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Investigator’s Global Assessment of treatment success.

20.3% at day 15* versus vehicle, 5%; P < .001 (n=538)*

75% Nearly 75% of all plaques on elbows and knees were clear or almost clear of redness and scaling by day 29**

*Primary endpoint
**Secondary endpoint

IMPORTANT SAFETY INFORMATION
SERNIVO Spray can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. Systemic effects of topical corticosteroids may also manifest as Cushings syndrome, hyperglycemia or unworsk of latent diabetes mellitus, and glucosuria. These events are rare and generally occur after prolonged exposure to larger than recommended doses, particularly with high-potency topical corticosteroids. Do not use if a trophy is present at the treatment site. Do not use with occlusive dressings. Avoid use on the face, scalp, axilla, groin or other intertriginous areas. Use of SERNIVO Spray is not recommended in pediatric patients as they are more susceptible to systemic toxicity. Allergic contact dermatitis may occur.

The most common adverse reactions (≥15%) were application site pruritus, burning and/or stinging, pain, and atrophy. Local reactions and skin atrophy are more likely to occur with occlusive use, prolonged use, or use of higher potency corticosteroids. These are not all the possible side effects of SERNIVO Spray.

Please see Full Prescribing Information at SERNIVO.com and brief summary of prescribing information on adjacent page.

INDICATION AND USAGE
SERNIVO Spray is indicated for the treatment of mild-to-moderate plaque psoriasis in patients 18 years of age or older.

To report SUSPECTED SIDE EFFECTS, call Promius Pharma at 1-888-966-8766 or contact the FDA at 1-800-FDA-1088.

Minimize the unwanted risks from endocrine effects by mitigating the risk factors favoring increased systemic bioavailability and by using the product as recommended [see Dosage and Administration].

Pediatric patients may be more susceptible to systemic toxicity due to their larger skin surface to body mass ratios. Use of SERNIVO Spray is not recommended in pediatric patients [see Use in Specific Populations].

**Allergic Contact Dermatitis**

Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. Corroboration such an observation with appropriate diagnostic patch testing. If irritation 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 clinical practice. In two randomized, multicenter, prospective vehicle-controlled clinical trials, subjects with moderate plaque psoriasis of the body applied SERNIVO Spray or vehicle spray twice daily for 4 weeks. A total of 352 subjects applied SERNIVO Spray and 180 subjects applied vehicle spray.

Adverse reactions that occurred in at least 1% of subjects treated with SERNIVO Spray for up to 28 days are presented in Table 1.

<table>
<thead>
<tr>
<th></th>
<th>SERNIVO Spray b.i.d. (N=352)</th>
<th>Vehicle Spray b.i.d. (N=180)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application site pruritus</td>
<td>6.0%</td>
<td>9.4%</td>
</tr>
<tr>
<td>Application site burning and/or stinging</td>
<td>4.5%</td>
<td>10.0%</td>
</tr>
<tr>
<td>Application site pain</td>
<td>2.3%</td>
<td>3.9%</td>
</tr>
<tr>
<td>Application site atrophy</td>
<td>1.1%</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

Less common adverse reactions (with occurrence lower than 1% but higher than 0.1%) in subjects treated with SERNIVO Spray were application site reactions including telangiectasia, dermatitis, discoloration, folliculitis and skin rash, in addition to dysesthesia and hyperglycemia. These adverse reactions were not observed in subjects treated with vehicle.

**Postmarketing Experience**

Because adverse 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.

**WARNINGS AND PRECAUTIONS**

Hypothalamic-Pituitary-Adrenal (HPA) Axis Suppression and Other Unwanted Systemic Glucocorticoid Effects

SERNIVO Spray can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during or after withdrawal of treatment. Factors that predispose to HPA axis suppression include the use of high-potency corticosteroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure, and young age.

Evaluation for HPA axis suppression may be done by using the adrenocorticotropic hormone (ACTH) stimulation test.

In a study including 48 evaluable subjects 18 years of age or older with moderate to severe plaque psoriasis, abnormal ACTH stimulation test results suggestive of adrenal suppression were identified in 5 out of 24 (20.8%) subjects after treatment with SERNIVO Spray twice daily for 15 days. No subject (0 out of 24) had abnormal ACTH stimulation test results after treatment with SERNIVO Spray twice daily for 29 days [see Clinical Pharmacology].

If HPA axis suppression is documented, gradually withdraw the drug, reduce the frequency of application, or substitute with a less potent corticosteroid. If signs and symptoms of steroid withdrawal occur, supplemental systemic corticosteroids may be required.

Systemic effects of topical corticosteroids may also manifest as Cushing's syndrome, hyperglycemia, and glucosuria. These events are rare and generally occur after prolonged exposure to larger than recommended doses, particularly with high-potency topical corticosteroids.
Dermatology Times is guided by a core group of trusted physician experts who review meetings; suggest topics & sources; & conduct interviews.

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Our Mission: Provide practical analysis of recent studies, regulatory updates, techniques, devices and business solutions; and facilitate discussion to optimize practice and improve patient care.

content

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“Helping people with their dermatologic problems and seeing their response to my treatment HAS defined my life.”

What’s your definition of success?

by DR. RONALD G. WHEELAND, M.D.

Dr. Wheeland is in private practice in Tucson, Ariz. He is a past president of the American Academy of Dermatology, the American Society for Dermatologic Surgery and the American Society for Laser Medicine and Surgery. He is a member of the Dermatology Times editorial board and a co-medical editor.

Recently I got the ultimate measure of success from a former patient of mine. I received a letter from a patient born with a port wine stain that I had performed laser treatment on 35 years ago, when she was just seven years old. Along with the letter, she included a recent photograph of herself to show how she looks today. While there were still small vestiges of the port wine stain remaining, she reported that she felt good enough about her appearance to be comfortable going out in public without makeup. She also reported being married and the mother of three children (none of whom had any birthmarks, which she said was one of her biggest worries), and that she couldn’t thank me enough for making her life “whole.” Wow, talk about success, this letter did it for me!

MEASURES OF SUCCESS

Many professionals have decided for themselves how to define success. For a number of people, that definition might include a nice home, fancy car, corner office, exotic travel or simply the luxury of free time. It seems to me that, in many professional societies that have defined my life.

MY DEFINITION(S) OF SUCCESS

At different periods of my medical career, I’ve chosen to partially define success using different metrics. Early on, the number and quality of my publications served me as a sign of success. This definition slowly evolved for me to include the quality of research I was performing, interactions with my colleagues and the level of research support I received.

Further refinement of my definition of success later in my career included the types of invitations I received to speak at professional meetings, academic titles and elections to various professional society leadership positions.

However, one of the most consistent areas that helped define success for me over the years was watching my former students, residents, fellows and colleagues achieve success of their own. It’s very much like being a proud father witnessing former trainees attain success of their own climactically, academically, or politically and know that I played a small role in that process.

The second area that has consistently helped define success for me has been in the clinical setting. Nothing is more rewarding that obtaining a favorable outcome from some dermatologic treatment I’ve provided.

I feel success when I can see both the physical and psychological improvement in a teenage acne patient after only a few months of my treatment. The same can also be said about patients with psoriasis or atopic dermatitis or skin cancer. Those emotional rewards are certainly considerable but they are often seen relatively quickly after institution of treatment.

In my own experience, it hasn’t been money or things like achieving full professor status at multiple institutions, chairmanship of three departments and election to the presidency of professional societies that have defined my life.

Helping people with their dermatologic problems and seeing their response to my treatment HAS defined my life.

That is what has made me the physician I always wanted to be, and that is what makes me feel successful.

My only wish for everyone reading this column is that you are also successful in achieving your definition of success, whatever that may be — for only then will your life feel “whole.”
**Physicians are forbidden from even acknowledging that person was a patient.**

How social media leads to a HIPAA violation

*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.

Dr. Derm is beyond upset. He reaches out to his attorney to ask how something placed on the public domain by a patient, then used by him can be a violation of health care privacy?

When can a physician disclose protected health care information?

What is clear is that a covered entity, such as a physician’s practice or health system can disclose protected health information (PHI) in a couple of different scenarios:

1) The patient provides his/her formal written authorization, and/or
2) there is a statutory exception to requiring formal written authorization.

An appropriate compliant HIPAA authorization has a number of requisite details. The requirements include a description of who is authorized to make the disclosure and receive the PHI, a specific and meaningful description of the PHI, a description of the purpose of the disclosure, an expiration date or event, signature of the individual authorizing the use or disclosure of her/his own PHI and the date, information concerning the individual’s right to revoke the authorization, and information about the ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization.

Conversely, there are situations when a physician does not need a patient’s written authorization for every disclosure. These invariably are where there is a statutory basis for the exception.

For example, the broadest exceptions are known as Treatment and Payment Operations. Within those categories, a dermatologist does not need a patient’s authorization to disclose PHI to get paid or to send information to another treating doctor to take care of a patient. These exceptions are clearly spelled out in the HIPAA statute.

Thus, if a patient has described her healthcare journey with Dr. Derm on his or her Facebook page, can he say thanks? Or can Dr. Derm even “correct the record” if the posting is incorrect?

The reality is that unless Dr. Derm has the patient’s authorization, the answer is no.

In fact, physicians are forbidden from even acknowledging that person was a patient. It can be argued that it is absurd that a patient might publish every detail about his or her care and, yet, Dr. Derm must remain silent — even if the record is full of inaccuracies.

It’s doubly absurd because Dr. Derm may not be disclosing any more than the patient already disclosed on his or her own. But, the regulations on this are clear.

A recent Connecticut case highlights this issue:

In 2015 a patient contacted a local TV station stating a medical practice turned her away because she had a service animal. The reporter called the practice for its side of the story. The physician’s office, in defending themselves, disclosed PHI.

A subsequent Office of Civil Rights investigation found that the doctor’s discussion with the reporter demonstrated a reckless disregard for the patient’s privacy rights, and that the disclosure occurred after the doctor was instructed by the practice’s own privacy officer to either not respond to the media or to respond with no comment.

Additionally, the Office of Civil Rights’ investigation revealed that the medical practice failed to take any disciplinary action against the doctor or to take any corrective action following the impermissible disclosure to the media, the statement notes.

The medical practice was found liable and forced to pay $125,000 for this violation.

There are now documented million dollar fines to hospitals for similar violations.

What appeared to be a simple benign action by Dr. Derm may in fact be a HIPAA violation.
Cleanser mildness concepts

by DR. ZOE DIANA DRAELOS
Dr. Draelos is a consulting professor of dermatology, Duke University School of Medicine, Durham, N.C.

Q. What is cleanser mildness?
Mildness is a common advertising claim associated with liquid and bar cleansers. Cleansing requires a delicate balance between achieving excellent skin hygiene and maintaining the stratum corneum barrier.

During cleansing, micelles are created with external hydrophilic groups surrounding an internal lipophilic pocket. These micelles can surround oily substances, such as sebum, dispersing the oil in water for removal and rinsing. Unfortunately, the micelles can also surround the oily intercellular lipids, damaging the skin barrier.

The bipolar structure of skin soils is similar to the fatty acids, cholesterol, and ceramides comprising the lipid bilayers of the stratum corneum.

Mildness is important because cleanser-induced barrier damage increases transpidermal water loss (TEWL) and facilitates removal of natural moisturizing factor, which acts as a sponge to hold water in the skin.

This dehydration leads to alterations in stratum corneum function leading to desquamation failure with increased corneocyte retention. This is the mechanism by which cleansers induce the rough scaly skin.

Q. What are the chemical characteristics of mild cleansers?
The component of soap that induces barrier damage is the high charge density of the carboxyl head group, which promotes strong protein binding. This chemistry provides excellent cleansing, but damages stratum corneum proteins, denatures enzymes, and alters corneocyte water holding capacity.

It is possible to predict the barrier damaging characteristics of a cleanser by examining the balance between shorter soluble chains (C12, C14) and longer, less soluble chain lengths (C16, C18) of the soap fatty acids. Soaps with a higher soluble short chain component are less skin damaging. Shorter soluble chains are found in plant-derived ingredients, such as C12 coconut fatty acids. The longer soluble chains are from animal-derived ingredients, such as C18 rendered animal fat. Thus, the shorter chains are preferred due to reduced barrier damage.

Interestingly, these short plant-derived chains also exhibit increased lathering ability, which is considered desirable by consumers when cleansing, even though lathering ability has no relation to good hygiene or cleanser mildness.

Q. What is the test for cleanser mildness?
While mildness can be estimated by examining the chemistry of a cleanser, testing is still required to determine the final skin effects. The most important consideration in cosmeceutical cleansers is mildness. Usually, a new cleanser formulation is first tested in vitro followed by in vivo and use testing prior to marketing. The most commonly used in vitro screening tests to evaluate the irritant potential of cleansers are the collagen swelling test, pH rise test, and zein test.

The collagen swelling test employs a one square centimeter collagen sheet, which is incubated for 24 hours at 50 degrees C with a solution of the finished cleanser product at 1% of the dry extract at its own pH. The collagen is weighed before and after exposure to determine the amount of swelling. More swelling indicates potential increased cleanser irritation as the collagen is absorbing more water due to protein denaturation.

Another approach to assessing cleanser irritation is to examine pH increase. Alkalization of the skin is always associated with irritation. This test incubates equal volumes of a 2% solution of bovine serum albumin at a pH of 5.6 with a 2% solution of the cleanser at room temperature. The pH of the solution is measured in one hour. Greater pH rises indicate the potential for increased product irritation.

Finally, the zein test can be used to predict cleanser irritation. This is probably the most popular of the in vitro cleanser irritancy evaluations. The zein test utilizes a protein that is insoluble in aqueous solution until denatured by irritating cleansers. The protein and cleanser are mixed to determine how much of the protein is solubilized. The more protein solubilized, the more irritating the cleanser may be when used on human skin. Of course, these predictive in vitro tests can be used to refine formulations and predict cleanser suitability, but are not a replacement for actual human-use testing.

“Lathering ability is considered desirable, but it has no relation to hygiene or mildness.”
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*Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio. Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen.

IMPORTANT SAFETY INFORMATION
The most common adverse events with TRIANEX Ointment include burning, itching, irritation, dryness, and folliculitis. TRIANEX Ointment is contraindicated in patients who are hypersensitive to any of the ingredients of this product. As with all topical corticosteroids, systemic absorption can produce reversible HPA-axis suppression.

INDICATION
TRIANEX 0.05% (Triamcinolone Acetonide Ointment, USP) is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

To report SUSPECTED SIDE EFFECTS, call Promius Pharma at 1-888-966-8766 or contact the FDA at 1-800-FDA-1088.

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Alcohols NF. The white ointment is for topical use only.

Purified Water USP, White Petrolatum USP, Heavy Mineral Oil USP, Mineral Wax, and Lanolin

Triamcinolone Acetonide USP in a water-in-oil emulsion composed of Light Mineral Oil NF,
corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees.

DOSAGE AND ADMINISTRATION

Topical corticosteroids may be a valuable therapeutic adjunct for treatment of resistant dermatoses (see
substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive
disease processes in the skin increase percutaneous absorption. Occlusive dressings
Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other
including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.
Topically applied corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE

Triamex® 0.05% (Triamcinolone Acetonide Ointment, USP) is indicated for the relief of the
inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

CONTRAINDICATIONS

Triamex® 0.05% (Triamcinolone Acetonide Ointment, USP) is contraindicated in those patients
with a history of hypersensitivity to any of the components of the preparation.

PRECAUTIONS

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary- 
adrenal (HPA) axis suppression, manifestations of Cushing’s syndrome, hyperglycemia, and
Corticosteroids are generally teratogenic in laboratory animals when administered systemically
at relatively low dosage levels. The more potent corticosteroids have been shown to be
Corticosteroids are constitutive of primarily synthetic steroids used as anti-inflammatory and antipruritic
agents.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors
including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.
Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other
diseases processes in the skin increase percutaneous absorption. Occlusive dressings
substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive
dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses (see
DOSAGE AND ADMINISTRATION). Once absorbed through the skin, topical corticosteroids are
handled through pharmacokinetic pathways similar to systemically administered
corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys.
Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INFORMATION FOR THE PATIENT

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

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.

2. Patients should be advised not to use this medication for any disorder other than that for
which it was prescribed.

3. The treated skin area should not be bandaged or otherwise covered or wrapped so as to be
occlusive unless directed by the physician.

4. Patients should report any signs of local adverse reactions especially under occlusive
dressing.

5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute
occlusive dressings.

Laboratory Tests

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

Carcinogenesis, Mutagenesis and Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential or the
effect on fertility of topical corticosteroids.

Studies to determine mutagenicity with prednisolone and hydrocortisone showed negative results.

Pregnancy: Teratogenic Effects Category C

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

Nursing Mothers

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

PEDIATRIC USE

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid
induced HPA axis suppression and Cushing’s syndrome than mature patients because of
a larger skin surface area to body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing’s syndrome and intracranial
hypertension have been reported in children receiving topical corticosteroids. Manifestations of
adrenal suppression in children include linear growth retardation, delayed weight gain, low
plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of
intracranial hypertension include bulging fontanelle, headaches, and bilateral papilledema.
Administration of topical corticosteroids to children should be limited to the least amount
compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere
with the growth and development of children.

ADVERSE REACTIONS

The following local adverse reactions are reported infrequently with topical corticosteroids, but
may occur more frequently with the use of occlusive dressings. These reactions are listed in
an approximate decreasing order of occurrence:

Burning, itching, Irritation, Dryness, Folliculitis, Hypertrichosis, Acneiform eruptions,
Hypopigmentation, Perioral dermatitis, Allergic contact dermatitis, Maceration of the skin,
Secondary infection, Skin atrophy, Striae and Miliaria

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

Apply a thin film to the affected area two to four times a day.

Occlusive Dressing Technique

Occlusive dressings may be used for the management of poison ivy or other recalcitrant
conditions. Apply a thin film of ointment to the lesion, cover with a pliable nonporous film, and
seal the edges. If needed, additional moisture may be provided by covering the lesion with a
dampened clean cotton cloth before the nonporous film is applied or by briefly wetting the
affected area with water immediately prior to applying the medication.
The frequency of changing dressings is best determined on an individual basis. It may be
convenient to apply Triamcinolone Acetonide Ointment under an occlusive dressing in the
evening and to remove the dressing in the morning (i.e., 12-hour occlusion). When utilizing the
12-hour occlusion regimen, additional ointment should be applied, without occlusion, during
the day. Reaplication is essential at each dressing change.
If an infection develops, the use of occlusive dressings should be discontinued and appropriate
antimicrobial therapy instituted.

How Supplied

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007850 Revised 0317
“Through... digital health, dermatologists can direct implementation that best improves patient care.”

Digital health and dermatology

by STEVE XU, M.D., FAAD

Dr. Xu is a board-certified dermatologist and medical director of the Center for Bio-Integrated Electronics at the Simpson Querrey Institute for Bio.nanotechnology, Northwestern University. He is a co-founder of the Advancing Innovation in Dermatology Accelerator Fund.

What exactly is digital health? The scope and definition of digital health is broadening and now, it seems, digital health is essentially anything that isn’t a drug or traditional medical device.

It encompasses hardware (mobile phones, wearable sensors), software (AI, machine learning, mobile phone apps), and digital communication platforms (telemedicine, text, email) to improve health.

Over the past three years, digital health has seen tremendous growth with many firsts. The first artificial intelligence technology was approved by the FDA (IDx-DR) for the diagnosis of diabetic retinopathy based on retinal images in 2018. While there are many clinical decision software systems approved by the FDA, IDx-DR is the first that operates completely without the need for further physician interpretation.

The pivotal trial of the system included more than 11,000 images from 5000 patients showing specificity and sensitivity that exceeded 90%. There are now FDA-approved mobile apps that treat opioid addiction (2017) and contraception (2018). ABILITY MYCTE® approved by the FDA in 2017 as a drug-device combination, represents the first digital pill partnership.4

Dermatology has been an active area for digital health and a key beachhead. AI has already been shown to demonstrate equal — and even slightly better — performance to board-certified dermatologists in diagnosing skin cancer.5

Apps for melanoma detection have a checkered past — Mole Detective, for instance, was marketed to be able to diagnosis melanoma and faced fines from the Federal Trade Commission for doing so. SkinVision, available only in Europe currently, has a CE-mark and boasts more than one million users with nearly 3.5 million images. The company is focused on skin cancer with an initial assessment done via software with a high-risk assessment leading to a review by a dermatologist. For challenging rashes and inflammatory skin diseases, VisualDx released a consumer app in 2018 called AYSA that uses machine learning to identify inflammatory skin conditions and make preliminary recommendations for self-help and treatment. These innovations represent important examples of how digital health is impacting dermatology.

While there is no shortage of articles that predict the demise of physicians, digital health is so much more than simply replacing doctors with an algorithm. The demand for dermatological services far exceeds the supply of board-certified dermatologists — the practice of dermatology by non-dermatologists leads to significantly higher diagnostic error.7

Digital health presents an opportunity to close that gap by improving patient triage to dermatologists. Even if AI and mobile applications can detect suspicious lesions or recommend biopsy, a dermatologist is still needed to discuss the procedure, perform the procedure, and handle the aftermath with regard to the need for further testing or treatment options.

Non-diagnostic mobile phone applications have the opportunity to drive greater patient engagement by offering more education beyond what little time we have with our patients and even deliver behavioral health interventions to address the significant psychiatric comorbidities associated with dermatological diseases. Wearable sensors and the data they produce can drive far deeper insights on the impact of skin disease on daily life and track changes in a naturalistic setting.

Through engagement with digital health, dermatologists can direct implementation that best improves patient care.

References

2. FDA news release, “FDA clears mobile medical app to help those with opioid use disorder stay in recovery programs,” Dec. 10, 2018
6. “VisualDx launches Aysa, a consumer-facing dermatology app,” MobiHealth News
DERMATOLOGY INDUSTRY FORECAST

THE GLOBAL DERMATOLOGY DEVICES market will continue to grow through 2027, according to a recent report from Research And Markets.com. Contributing trends cited include a rise in aesthetic procedures, an increasing need for early diagnosis, recent technology developments, and additional growth and investment opportunities.

The global report—Global Dermatology Devices Market Analysis and Trends, Industry Forecast to 2027—is based on an assessment of markets in 23 countries, including the United States, Canada, Mexico, U.K., Germany, Spain, France, Italy, China, Brazil, Saudi Arabia, and South Africa.

The company’s Global Dermatological Drugs Market Report predicts that through 2022, the cost of dermatology drugs will continue to rise while the market will grow by 11.9%. According to the report, “one driver influencing this market is the emergence of improved diagnostic modalities. One challenge affecting this market is the presence of access barriers for novel biologics and biosimilars. The originators (biologics manufacturers) have extended their current monopoly profits by creating several legal and regulatory barriers to the entry of biosimilars as they restrict the adoption of biologics.”

FAST-TRACK DESIGNATION FOR AD DRUG

ON DEC. 10, ASANA BIOSCIENCES announced that the U.S. Food and Drug Administration granted fast-track designation for the investigational ASN002, an oral treatment for moderate-to-severe atopic dermatitis that is based on the inhibition of both a JAK and spleen tyrosine kinase (SYK) inhibitor.

“This designation recognizes the importance of accelerating the development of new medicines for the treatment of challenging dermatological/inflammatory diseases that have a major impact on patients’ daily quality of life,” said Sandeep Gupta, founder and CEO of Asana.

ASN002 is currently under study in a phase 2b trial, RADIANT (Relief from Atopic Dermatitis with JAK and SYK Inhibition—NCT03664755). And, in a phase 2 trial for patients with severe chronic hand eczema (NCT03728504).

Asana reports that ASN002 is the first oral drug to demonstrate improvement in atopic dermatitis.

A THIRD BIOSIMILAR FOR SANDOZ

On Oct. 31, SANDOZ, A DIVISION OF NOVARTIS, announced that the U.S. Food and Drug Administration approved its biosimilar, adalimumab-adazx (Hyrimoz, Novartis AG), for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis in patients four years of age and older, psoriatic arthritis, ankylosing spondylitis, adult Crohn’s disease, ulcerative colitis and plaque psoriasis.

In clinical trials, adalimumab-adazx was shown to match the safety, efficacy and quality of its reference biologic. Adalimumab-adazx met its primary endpoint in a randomized, double-blind, three-arm, parallel study confirming its pharmacokinetics, immunogenicity and safety. A follow-up study demonstrated therapeutic equivalence in patients with moderate to severe chronic plaque-type psoriasis.

Adalimumab-adazx is the third FDA-approved biosimilar for Sandoz in the United States.

THE FDA HAS REVERSED a long-standing guidance stating that sponsors of clinical trials for atopic dermatitis (AD) in pediatrics need not start the trial in adults first. The decision, which was announced in October, was influenced by recommendations from its Dermatologic and Ophthalmic Drug Advisory Committee.

There are some caveats:

- Upon approval, applicants should disclose how to use the drug safely and effectively in pediatric patients.
- AD trials should be initiated early in development once efficacy and safety data are available.
- Safety questions, such as the risk for long-latency or low-frequency adverse reactions, do not have to be resolved before initiation of studies in pediatric patients with AD.
- It is not necessary to have an extensive safety database in adults before starting pediatric atopic dermatitis clinical trials due to the extent of disease-related morbidity in children, the high risk of disease-related progression in this population, and the relatively risk-benefit calculus with off-label use of immunosuppressive therapies.
- All pediatric age groups should be studied, including children two years old and younger. However, it may be necessary to first have safety outcomes from trials conducted in older pediatric patients; resolve age-related technical issues; and, address any potential safety-related concerns.

Bringing Molluscum Contagiosum to Light

While as many as 1 out of every 5 healthy children contract molluscum contagiosum, this disease and the patients it affects receive very little attention.\(^1\) Quality of life can be negatively affected by a molluscum infection.\(^2\) Children with the disease may become stigmatized and experience teasing, embarrassment, and social isolation. Up to 82% of parents and caregivers express moderate to great concern about molluscum.\(^3\) Lesions may be mostly asymptomatic, but reports indicate that patients do complain about itching, burning, and tenderness.\(^3\)

Although lesions can resolve within 6 to 9 months, patients typically have the infection for 13 months, and some infections can persist for 2 years or more.\(^2,3\) Treatment at the time of diagnosis provides the best chance of decreasing the number of lesions and spread of the disease.\(^3\)

No current FDA-approved treatment option addresses the problem of successfully treating molluscum.

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References
FROM BENCH TO PHARMACY: $25 MILLION

THE COST OF CLINICAL TRIALS to get a dermatology drug to market may cost as much as $25 million — slightly above a median $19 million, researchers reported in JAMA Internal Medicine in September. The study, by researchers at the Institute for Safe Medication Practices and Johns Hopkins University, analyzed the cost of drug trials for 59 drugs developed between 2015 and 2016.

While dermatology drugs cost on average $25 million, cardiovascular drugs averaged more than $157 million. Other fields associated with expensive trials included oncology, $45 million; gastroenterology, $29 million; and neurology (central nervous system), $26 million.

The more patients required for the trials, the more expensive the trial. “Pivotal clinical trial costs increased if more patients were needed to document treatment benefit, if active drug comparators were used, or to measure clinical end points rather than a change in a surrogate outcome,” researchers wrote. “The highest-cost trials were those in which the new agent had to be proved to be noninferior with clinical benefit end points compared with an agent already available or those that required larger patient populations to achieve statistical power to document smaller treatment effects or accrue infrequently occurring end points.”


HOW MUCH DOES IT COST TO GET A DRUG TO MARKET?

- **$19m** - **AVERAGE**
- **$25m** - **DERMATOLOGY**
- **$26m** - **CENTRAL NERVOUS SYSTEM**
- **$29m** - **GASTROENTEROLOGY**
- **$45m** - **ONCOLOGY**
- **$157m** - **CARDIOVASCULAR**

AAD ANNUAL MEETING STARTS MARCH 1

EARLY BIRD REGISTRATION for the American Academy of Dermatology annual meeting closes January 23. Advance registration will run through February 20 for the meeting which runs March 1-5 in Washington, D.C.

For more information about the meeting, visit: https://www.aad.org/meetings/annual-meeting

LAUNDRY SOAP EArNS STAMP OF APPROVAL FOR SENSITIVE SKIN

THE NATIONAL PSORIASIS FOUNDATION (NPF) and the National Eczema Association have awarded Procter & Gamble’s Tide Free and Gentle Liquid Laundry Detergent and Tide PODS Free and Gentle Laundry Detergent a “Seal of Recognition” and “Seal of Acceptance” for people with eczema or sensitive skin.

The two products were reviewed by a panel of dermatologists and psoriasis patients. They were “recognized by the NPF as proven to be gentle for skin afflicted with psoriasis, psoriatic arthritis or any type of sensitive skin,” Procter & Gamble stated in a news release.

The designations highlight over-the-counter products that are recognized to help ease irritation associated with psoriasis, eczema or those with sensitive skin or limited mobility.
Warning signs of life-threatening purpura

INGRID TORJESEN | Staff Correspondent

There are warning signs that purpura can be potentially life threatening, says Roderick Hay, D.M., FRCP, a consultant dermatologist with a special interest in infectious disease.

Purpura occurs when blood escapes from the vascular system into the skin. It can manifest in various ways from very small petechiae to large bruises, but despite its presentation, “they are all manifestations of the same problem. Although, the more most severely affected you are, the greater the leak is likely to be,” said Dr. Hay, of King’s College Hospital in London.

There are three main causes of purpura: Disorders of platelets, disorders of coagulation and vasculitis. These are not mutually exclusive, he explains, because if platelets and the factors involved in coagulation have been destroyed or incapacitated, coagulation is disrupted.

During a session on life threatening diseases in dermatology held at the European Academy of Dermatology and Venerology Congress last September in Paris, Dr. Hay outlined some potentially life-threatening conditions in which purpura is involved and which are often related to infections.

LIFE THREATENING CONDITIONS

The first of these is purpura fulminans, a rare...
A preparatory webinar which approximates the image segment of the new Core Practical/Certifying Examination of the American Board of Dermatology. Open to all 1st, 2nd and 3rd year residents, as well as, those dermatologists preparing for the Maintenance of Certification (MOC).

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• Infections (Bacterial, Viral, Fungal) and Infestations
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Digital recruitment for clinical studies

BRUCE E KATZ, M.D.; ALEKSANDER EIKEN, M.D.; VALERIJA MISEV, M.D.; AND, JOHN ROBERT ZIBERT, M.SC., PH.D. | Staff Correspondent

Quick Takes

Recruitment time for phase three A trial was shortened by two weeks with the Studies & Me online platform.

For the New York site, study subjects were prequalified via teledermatology.

Seven patients with severe AD were randomized over three months.

Recruitment time for phase three A trial was shortened by two weeks with the Studies & Me online platform.

Randomized controlled trials (RCT) are the gold standard for studying the safety and efficacy of new treatments. The most important factor involved in these trials are the patients. Patients, however, are also one of the most unreliable factors creating significant struggles in terms of recruitment and dropout rates. Today, around 30% of the total clinical trial time used during development of a new drug can be attributed to patient recruitment (6). Only one-third of clinical trials manage to meet their target for patient recruitment within the predefined period for patient recruitment (6).

There is an urgent need to improve these statistics and get more people to sign up for clinical trials.

For patients, RCT often provide an opportunity to get access to free medical care involving either standard treatment for their condition or an investigational drug. In fact, emerging research suggests that patients participating in clinical trials have better treatment outcomes than patients who have not participated in a clinical trial (6).

However, despite an extensive need for patients willing to participate in trials, only a fraction of eligible patients are offered the chance to participate. This is largely due to limited awareness amongst patients (8), and the fact that traditional methods for study recruitment focus mainly on recruiting subjects from a site’s existing patient flow or population (8). As a result, the demographics of the recruited population most often reflect the site’s patient population, but not necessarily the patient population at large (8).

Trial site start-up and management is expensive for sponsors (7), so most try to limit the number of sites. This may explain why patients who live outside the catchment area or are being treated elsewhere (which, by far, is the majority of eligible patients), may not be offered participation in a trial. Meanwhile, as sites are often involved in several trials with similar eligibility criteria, situations may arise where one trial is competing against other trials for recruitment from the same patient pool (8).

For pharmaceutical sponsors, delays in novel drug development could cost millions of dollars in lost revenue (9). Forponsors (7), so most try to limit the number of sites. This may explain why patients who live outside the catchment area or are being treated elsewhere (which, by far, is the majority of eligible patients), may not be offered participation in a trial. Meanwhile, as sites are often involved in several trials with similar eligibility criteria, situations may arise where one trial is competing against other trials for recruitment from the same patient pool (8).

For pharmaceutical sponsors, delays in novel drug development could cost millions of dollars in lost revenue (9). For

Improving the reporting of social media recruitment for clinical trials

By KATJA REUTER, PH.D.

The popularity of social media has created a new opportunity for the research community to recruit study participants.

Recent data indicate that nearly 70% of U.S. adults use some social media (1). Coinciding with the surge of social media adoption, study teams increasingly report the use of social media to enhance recruitment in clinical research with promising but mixed results (2). Recruitment of study participants is a significant problem, particularly in clinical trials. It remains a critical roadblock to successful clinical and translational research (3).

In this issue of Dermatology Times, Katz and colleagues describe the results of a targeted advertising strategy on social media and search engines for 150 days. The goal was to recruit patients with moderate to severe atopic dermatitis in a randomized, double-blind, placebo-controlled, phase three trial and to evaluate the efficacy and safety of tralokinumab monotherapy.

While the authors cogently describe the need for new solutions to enhance clinical trial recruitment and the potential of social media, they overlooked the importance of methodology and data transparency. For example, to assess the recruitment success, it is essential to provide the exact measurements (rather than estimates “over 15,000 people being directed to the customized landing page through the advertisement”) and to include proportions such as enrollment rate (2) or the message click rate (2) to look at potential selection bias and generalizability issues. Equally important is to discern recruitment results by digital platform (they also mention search engine marketing via Google) and to include any data the authors used for comparisons. Katz and colleagues conclude that the social media approach resulted in “significant improvement compared to similar previous trial engagements.” Another critical aspect is the transparency about the number of social media engagements. Conti...
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patients, delays in market approval of new drugs due to prolonged patient recruitment could mean reduced life quality, suboptimal treatment outcomes and potentially avoidable deaths. For payers, new drugs increase the market competition, which often results in more cost-efficient care.

It’s in everyone’s interest to improve patient recruitment for clinical trials, but how do we solve this emerging problem?

ONLINE RECRUITMENT

Industries throughout the world are finding that the adoption of digitalization can optimize business operations making transactions convenient and efficient for customers. In 2017, 81% of people in developed countries—or, 48% of the world’s population—had internet access. In April 2018, 4.1 billion people used the internet, 3.2 billion of these people were active on social media where Facebook was the most predominantly used service by its 2.2 billion users. In other words, social media and digital platforms posit an effective opportunity for reaching more patients that reflect the demographic of the general patient population. There are several digital platforms designed to optimize patient recruitment (i.e. clinicaltrials.gov, trialx.com, antidote.me), building patient communities (i.e. claralhealth.com, patientslikeme.com, bethetablet.com) or through scanning electronic medical records (i.e. deep6.ai, epatientfinder.com).

However, to our knowledge only one company, Studies&Me of Denmark (www.studiesandme.com), has developed a solution that leverages qualified dermatologists to evaluate potential patients. After seeing an ad, patients are guided to a customized landing page where they are presented with general information about clinical trials before entering a pre-qualification process via store-and-forward teledermatology involving a team of remote dermatologists and artificial intelligence.

This process is designed to direct patients to the sought after clinical study at the closest possible site. The process is made possible by a team of healthcare providers, digital developers and data scientists. The entire process can be completed in less than 48 hours: From clicking on the advertisement to signing up, pre-screening, and transferring contact information to a trial site.

PILOT STUDY

The Studies&Me platform was recently piloted as an add-on recruitment strategy in a “randomized, double-blind, placebo-controlled, phase three trial to evaluate the efficacy and safety of tralokinumab monotherapy in subjects with moderate to severe atopic dermatitis who are candidates for systemic therapy (ClinicalTrials.gov Identifier: NCT03131648).” Four study sites for this trial leveraged the platform (one in New York, N.Y.).

Social media campaigns for patient recruitment were published over the course of 150 days with over 15,000 people being directed to the customized landing page. Of these, over 1,500 signed up to be pre-screened for study eligibility. Patients answered the pre-screening questionnaires, provided consent and submitted a self-taken picture of a representative skin lesion. Of the patients living in proximity of the site, 46 patients were considered eligible to participate in the study by a remote dermatologist. The patients had a maximum travel distance of 10 miles to the site. Contact information of these patients were via an encrypted portal transferred to the study site.

All patients were contacted by phone or e-mail by the New York investigator where 27 patients responded, and 20 were scheduled for a screening visit. Of this group, nine of the scheduled screenings took place (the remaining patients either withdrew consent or didn’t show up). Finally, seven patients had a positive screening and all seven were randomized to participate in the trial. Of the 1,500 patients who signed up, additional patients were transferred and randomized with the three other sites involved in the recruitment initiative.

This pilot recruitment initiative highlights that digital recruitment platforms can offer an effective alternative to the traditional approach, even for studies with complex eligibility criteria.
ALL ABOARD ONEXTON GEL

Efficacy and tolerability matter when it comes to treating acne. In the pivotal trial, ONEXTON GEL was shown to treat both inflammatory and noninflammatory acne, and no patients discontinued due to an adverse event.1,2

TOLERABILITY > EFFICACY

INDICATION
ONEXTON (clindamycin phosphate and benzoyl peroxide) Gel, 1.2%/3.75% is indicated for the topical treatment of acne vulgaris in patients 12 years of age or older.

IMPORTANT SAFETY INFORMATION
- ONEXTON Gel is contraindicated in patients with a known hypersensitivity to clindamycin, benzoyl peroxide, any component of the formulation, or tretinoin.
- ONEXTON Gel is contraindicated in patients with a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis.
- Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin. ONEXTON Gel should be discontinued if significant diarrhea occurs.
- Orally and parenterally administered clindamycin has been associated with severe colitis, which may result in death.
- Anaphylaxis, as well as other allergic reactions leading to hospitalizations, has been reported in postmarketing use of products containing clindamycin/benzoyl peroxide. If a patient develops symptoms of an allergic reaction such as swelling and shortness of breath, they should be instructed to discontinue use and contact a physician immediately.
- The most common local adverse reactions experienced by patients in clinical trials were mild and moderate erythema, scaling, itching, burning, and stinging.
- ONEXTON Gel should not be used in combination with erythromycin-containing products because of its clindamycin component.
- ONEXTON Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. A decision should be made whether to use ONEXTON Gel while nursing, taking into account the importance of the drug to the mother.
- Patients should be advised to avoid contact with the eyes or mucous membranes.
- Patients should minimize exposure to natural and avoid artificial sunlight (tanning beds or UVAs/Bs treatment) while using ONEXTON Gel. To minimize exposure to sunlight, protective clothing should be worn and a sunscreen with SPF 15 rating or higher should be used.

To report SUSPECTED ADVERSE REACTIONS, contact Ortho Dermatologics at 1-800-321-4576 or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

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


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BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

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

ONEXTON® (clindamycin phosphate and benzoyl peroxide) Gel, 1.2%/3.75%, for topical use

Initial U.S. Approval: 2000

CONTRAINDICATIONS

Hyper-sensitivity

ONEXTON Gel is contraindicated in those individuals who have shown hypersensitivity to clindamycin, benzoyl peroxide, any components of the formulation, or licorice extract. Anaphylaxis, as well as other allergic reactions leading to hospitalization, has been reported in postmarketing use with ONEXTON Gel [see Adverse Reactions].

Colitis/Enteritis

ONEXTON Gel is contraindicated in patients with a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis [see Warnings and Precautions].

WARNINGS AND PRECAUTIONS

Colitis

Systemic absorption of clindamycin has been demonstrated following topical use of clindamycin. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin. If significant diarrhea occurs, ONEXTON Gel should be discontinued.

Severe colitis has occurred following oral and parenteral administration of clindamycin with an onset of up to several weeks following cessation of therapy. Antiperistaltic agents such as opiates and diphenoxylate with atropine may prolong and/or worsen severe colitis. Severe colitis may result in death.

Studies indicate toxin(s) produced by Clostridium is one primary cause of antibiotic-associated colitis. The colitis is usually characterized by severe persistent diarrhea and severe abdominal cramps and may be associated with the passage of blood and mucus. Stool cultures for Clostridium difficile and stool assay for C difficile toxin may be helpful diagnostically.

Ultraviolet Light and Environmental Exposure

Minimize sun exposure (including use of tanning beds or sun lamps) following drug application [see Nonclinical Toxicology].

ADVERSE REACTIONS

The following adverse reaction is described in more detail in the Warnings and Precautions section of the label.

Colitis [see Warnings and Precautions].

Clinical Trials Experience

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

These adverse reactions occurred in less than 0.5% of subjects treated with ONEXTON Gel: burning sensation (0.4%); contact dermatitis (0.4%); pruritus (0.4%); and rash (0.4%). During the clinical trial, subjects were assessed for local cutaneous signs and symptoms of erythema, scaling, itching, burning and stinging. Most local skin reactions either were the same as baseline or increased and peaked around week 4 and were near or improved from baseline levels by week 12. The percentage of subjects that had symptoms present before treatment (at baseline), during treatment, and the percent with symptoms present at week 12 are shown in Table 1.

Table 1: Local Skin Reactions - Percent of Subjects with Symptoms Present. Results from the Phase 3 Trial of ONEXTON Gel 1.2%/3.75% (N = 243)

<table>
<thead>
<tr>
<th></th>
<th>Before Treatment</th>
<th>Maximum During Treatment</th>
<th>End of Treatment</th>
<th>Maximum During Treatment</th>
<th>Maximum During Treatment</th>
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<tbody>
<tr>
<td></td>
<td>Mild</td>
<td>Mod.*</td>
<td>Severe</td>
<td>Mild</td>
<td>Mod.*</td>
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<tr>
<td>Erythema</td>
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<td>6</td>
<td>0</td>
<td>28</td>
<td>5</td>
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<td></td>
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<td>14</td>
<td>3</td>
<td>&lt;1</td>
<td>15</td>
<td>3</td>
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<tr>
<td>Burning</td>
<td>5</td>
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<td>7</td>
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<td>Stinging</td>
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<td>&lt;1</td>
<td>0</td>
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</tbody>
</table>

*Mild = Moderate

Postmarketing Experience

Because postmarketing adverse 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.

Anaphylaxis, as well as allergic reactions leading to hospitalizations, has been reported in postmarketing use of products containing clindamycin phosphate/benzoyl peroxide.

DRUG INTERACTIONS

Erythromycin

Avoid using ONEXTON Gel in combination with topical or oral erythromycin-containing products due to clindamycin component. In vitro studies have shown antagonism between erythromycin and clindamycin. The clinical significance of this in vitro antagonism is not known.

Concomitant Topical Medications

Concomitant topical acne therapy should be used with caution since a possible cumulative irritant effect may occur, especially with the use of peeling, desquamating, or abrasive agents. If irritancy or dermatitis occurs, reduce frequency of application or temporarily interrupt treatment and resume once the irritation subsides. Treatment should be discontinued if the irritation persists.

Neuromuscular Blocking Agents

Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. ONEXTON Gel should be used with caution in patients receiving such agents.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C

There are no adequate and well-controlled studies in pregnant women treated with ONEXTON Gel. ONEXTON Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Animal reproductive/developmental toxicity studies have not been conducted with ONEXTON Gel or benzoyl peroxide. Developmental toxicity studies of clindamycin performed in rats and mice using oral doses of up to 600 mg/kg/day (240 and 120 times amount of clindamycin in the highest recommended adult human dose based on mg/m², respectively) or subcutaneous doses of up to 200 mg/kg/day (80 and 40 times the amount of clindamycin in the highest recommended adult human dose based on mg/m², respectively) revealed no evidence of teratogenicity.

Nursing Mothers

It is not known whether clindamycin is excreted in human milk after topical application of ONEXTON Gel. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to use ONEXTON Gel while nursing, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness of ONEXTON Gel in pediatric patients under the age of 12 have not been evaluated.

Geriatric Use

Clinical trials of ONEXTON Gel did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently from younger subjects.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity, mutagenicity and impairment of fertility testing of ONEXTON Gel have not been performed.

Benzoyl peroxide has been shown to be a tumor promoter and progression agent in a number of animal studies. Benzoyl peroxide in acetone at doses of 50 and 200 mg administered topically twice per week for 20 weeks induced skin tumors in transgenic Tg.AC mice. The clinical significance of this is unknown.

Carcinogenicity studies have been conducted with a gel formulation containing 1% clindamycin and 5% benzoyl peroxide. In a 2-year dermal carcinogenicity study in mice, treatment with the gel formulation at doses of 950, 2700, and 15000 mg/kg/day (1.2, 3.6, and 12 times amount of clindamycin and 1.6, 4.8, and 16 times amount of benzoyl peroxide in the highest recommended adult human dose of 2.5 g ONEXTON Gel based on mg/m², respectively) did not cause any increase in tumors. However, topical treatment with a different gel formulation containing 1% clindamycin and 5% benzoyl peroxide at doses of 100, 500, and 2000 mg/kg/day caused a dose-dependent increase in the incidence of keratoacanthomas at the treated skin site of male rats in a 2-year dermal carcinogenicity study in rats. In an oral (gavage) carcinogenicity study in rats, treatment with the gel formulation at doses of 300, 900, and 3000 mg/kg/day (1, 3, 6, and 12 times amount of clindamycin and 1, 2, 3, and 5 times amount of benzoyl peroxide, respectively) for up to 97 weeks did not cause any increase in tumors. In a 52-week dermal photocarcinogenicity study in hairless mice, (40 weeks of treatment followed by 12 weeks of observation), the median time to onset of skin tumor formation decreased and the number of tumors per mouse increased relative to controls following chronic concurrent topical administration of the higher concentration benzoyl peroxide formulation (5000 and 10000 mg/kg/day, 5 days/week) and exposure to ultraviolet radiation. Clindamycin phosphate was not genotoxic in the human lymphocyte chromosome aberration assay. Benzoyl peroxide has been found to cause DNA strand breaks in a variety of mammalian cell types, to be mutagenic in S. typhimurium tests by some but not all investigators, and to cause sister chromatid exchanges in Chinese hamster ovary cells.

Fertility studies have not been performed with ONEXTON Gel or benzoyl peroxide, but fertility and mating ability have been studied with clindamycin. Fertility studies in rats treated orally with up to 300 mg/kg/day of clindamycin (approximately 120 times the amount of clindamycin in the highest recommended adult human dose of 2.5 g ONEXTON Gel, based on mg/m²) revealed no effects on fertility or mating ability.

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Patient Information).

Manufactured for:

Valeant Pharmaceuticals North America LLC
Bridgewater, NJ 08807 USA

By:

Valeant Pharmaceuticals International, Inc.
Laval, Quebec H7L 4A8, Canada

U.S. Patent 8,288,434

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Rev 04/2018
randomized subject, the time used by the New York site was less than one-third (21.4 vs. 65.5 days).

CONCLUSION

Key advantages of digital patient recruitment include fast and efficient recruitment. Key challenges include selecting sites that are motivated and capable of receiving pre-qualified subjects. And, who prioritize to contact the subjects immediately in order to optimize the odds of the subjects still willing to participate.

In fact, 30 out of the 46 patients in this pilot either never responded once contacted (even though they stated that they were interested in participation), withdrew consent or were no shows for screening(13). This demonstrates the need for engaging patients fast in the recruitment process making sure that subjects who are transferred from the digital platform are contacted and scheduled instantly for a screening visit.

Overall, the recruitment time of this phase three A trial was shortened by two weeks as a direct result of the Studies & Me platform. For the site in New York, seven patients with severe atopic dermatitis were randomized during three months, which is a significant improvement compared to previous trial recruitment initiatives. This could be attributed to the pre-qualification via teledermatology that the platform offers. ■

Author Affiliations: Drs. Katz and Misev are with the JUVIA Skin & Laser Center, New York, NY. Drs. Eden and Zibert are with LEO Innovation Lab, Copenhagen, Denmark.

REFERENCES


Improving the reporting of social media recruitment for clinical trials

Sociael media can be used to promote and recruit participants for clinical trials. However, it is important to ensure that the data collected are accurate and that the methods used to recruit participants are transparent and consistent. This can be achieved by using social media platforms to advertise clinical trials and by tracking the success of these efforts. References:

7. The number of people who consented and enrolled divided by the number of people who clicked the link in the message to visit the study page. An impression is a viewable display of a social media post or ad, whether the post is interacted with (e.g., clicked, shared) or not.

Dr. Reuter

Purpuro 24  CLINICAL TRIAL RECRUITMENT  Skin hemorrhaging 32
Identifying why patients have skin hemorrhaging can be difficult. The reasons behind the condition are myriad. Consequently, pinpointing the right diagnosis can be critical to pursuing proper treatment.

According to Warren Piette, M.D., dermatology professor at Rush University Medical Center, clinicians are more likely to correctly identify the lesions' underlying cause with careful observation rather than with several lab tests. “There are lots of tests that can be done, but my feeling is we must have a focused approach to the patient based on the number and distribution of lesions, as well as the individual lesion morphology,” he said. “The problem with simply ordering several lab tests is they can be falsely positive or negative. They should generally only be ordered if we have particular evidence suggesting we should be worried about a certain condition.”

To give dermatologists guidance on how best to assess and diagnose lesions, Dr. Piette discussed the characteristics of various lesion types during a presentation at the 2018 European Academy of Dermatology & Venerology conference. He also provided guidance on when biopsying a lesion, if needed, would produce the best results.

“My goal is always to remind dermatologists they are physicians first, and they’re often the best eyes and minds in the room to analyze skin lesions,” he said. “We can be critical in helping sort through the many different possibilities for what’s causing bleeding in the skin.”

Ultimately, he said, he wants to help clinicians learn to use the pattern and number of lesions, as well as their distribution and individual shape and appearance, in patients with visible hemorrhaging of the skin or mucous membranes, to accurately categorize lesions into three groups:

- **Simple hemorrhage**: Lesions where mechanisms fail to keep vessels intact, allowing leakage.
- **Inflammatory hemorrhage**: Lesions where the body actively attacks the vessel, leading to a break in the vessel wall and hemorrhage.
- **Microvascular occlusion**: A situation where the skin’s small vessels, often many simultaneously, develop clots or an occlusion of some sort, including cold protein precipitation or other foreign material.

It’s also important to note, Dr. Piette said, that lesions have individual life cycles during which a biopsy can deliver a proper diagnosis — usually 24-48 hours. Conducting a biopsy at the right time is vital because performing one on older lesions can render a wrong diagnosis and treatment.

Classic vasculitis lesions appropriate for biopsy have some blanching or color loss. This is characteristic of lesions with both hemorrhage and inflammation. Clotting lesions present minimal blanching initially, he said, but after 4-7 days redness might appear at the margin due to burgeoning wound-healing responses. Lesions most suited for biopsy have, at least, partial blanching, and are partially palpable. Those with significant necrosis or no color change at all are inappropriate, he said.

“A dermatologist must know to look for lesions that fit the pattern of early lesions,” he said. “Patients can’t keep track. It’s our job to pay attention and know what’s early and what’s late.”

Overall, Dr. Piette stressed, biopsy is an effective tool in identifying vasculitis. However, when used incorrectly, it can lead to delayed treatment and unnecessary testing. Trained observations are an integral part of clinical care.

“It’s been very difficult to get people to realize doing blind biopsies doesn’t give you relevant results. You can’t expect it to give you a better answer,” he said. “It’s like trying to diagnose thyroid dysfunction by checking levels when a patient is taking thyroid hormones. No one does that, but they’ll biopsy any lesions and think it will tell us what happened. It doesn’t.”

**Reference**

2019 Dermatology Hall of Fame
1st Annual
February 28, 2019 - Washington, D.C.

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Purpura can surface due to underlying infection and may manifest in various ways from page 24.

The absolute key to saving patients is much more general things like supporting circulation, because very often they are in shock."

Roderick Hay, D.M., FRCP, King's College Hospital, London

Three main causes of purpura

- Disorders of platelets
- Disorders of coagulation
- Vasculitis

Three causes of life threatening purpura

- Platelet disorders
- Disorders of coagulation
- Vascular factors, such as purpura fulminans

and severe complication of meningococcal septicaemia which is caused by Neisseria meningitidis. Although far more common in tropical countries than in North America, when meningococcal septicaemia does occur, it carries a high mortality—largely because it is not recognized until it’s too late. The bacteria latch on to the endothelial lining of blood vessels and activate the immune system, causing huge inflammation and massive leakage of vascular contents.

The characteristic rash of meningococcal septicaemia is often the diagnostic prompt, but there are lots of things that can occur before and alongside it to suggest the condition may be a possibility, particularly in children, he adds. These include limb pain, cold hands and feet, pale or mottled skin. People affected are likely to also have non-specific symptoms such as fever, drowsiness, rapid or laboured breathing, sometimes diarrhoea, and possibly thirst in older children.

“There is now a very effective molecular screening test which if used at a stage is likely to be positive,” Dr. Hay says, “and immunization against it has now been rolled out in many European countries.”

Another condition associated with purpura which is much more widespread elsewhere in the world is dengue. Imported cases are seen in the United States in returning travellers. Patients often present early in the disease with a particular red rash. This can be maculopapular, like measles (islands of white in a sea of red petechiae) to extensive purpura.

The warning signs of the patient getting really ill are largely relate to shock. The rash often becomes widespread, so for example conjunctival

Haemolytic uraemic syndrome is generally triggered by E coli infection. E coli shiga toxin binds to ceramide trihexoside on endothelial cells leading to platelet and clotting activation and the condition presents as bleeding and bruising, bloody diarrhoea, vomiting and abdominal pain and renal failure.

The condition is most common in children, but there is an adult version that used to have a very dire prognosis, Dr. Hay said, but modern techniques of support, early diagnosis and treatment with anti-CD5 inhibitors can reverse it.

Thrombotic thrombocytopenic purpura has a very specific mechanism where an antibody to ADAMTS13 (A Disintegrin And Metalloprotease with a Thrombospondin type motif member 13) forms which cleaves a clotting factor (Von Willibrand) leading to uncontrolled clotting. Thrombotic thrombocytopenic purpura can be linked to a wide range of conditions, including HIV and systemic lupus erythematosus (SLE), and there is a very specific test for diagnosing it that assesses the levels of ADAMTS13 protein. Treatment include immunotherapy and plasmapheresis.

In all these different conditions the individual causes can be identified and in some such as meningococcal septicaemia and thrombotic thrombocytopenic purpura, there are specific molecular tests for diagnosis. But Dr. Hay emphasizes: “The absolute key to saving patients is much more general things like supporting circulation, because very often they are in shock, and finding ways of reversing the clotting abnormalities via plasma exchange and platelets. Plus, of course, if there is an underlying disease then treating that makes a difference and that is particularly true of the infections.”
Pigment-targeting laser advancements

JOHN JESITUS | Staff Correspondent

While picosecond lasers and other advances continue to boost tattoo clearance rates, there’s still a place for earlier-generation pigment-pummeling technologies, according to Paul M. Friedman, M.D., a dermatologist with offices in Houston and New York. He spoke at the recent Cosmetic Bootcamp.

Picosecond lasers improve physicians’ ability to break up ink particles more effectively, including tough-to-treat green and blue inks, he said.

“The 1,064 nm should be your primary wavelength for a tattoo-removal laser. It allows you to treat all skin types, which is important to me, practicing in Houston, Texas,” Dr. Friedman said.

He showed photos of a patient with type VI skin and a black tattoo, who achieved an excellent outcome after three treatment sessions with a 1,064 nm picosecond Nd:YAG laser — without the dyspigmentation that frequently occurs when treating darker skin types with shorter wavelengths.

More impressive, he said, was the laser’s performance in removing red ink with the 532 nm laser light.

“We’ve all seen hyper- or hypopigmentation when treating patients with skin of color because the melanin is a competing chromophore. The lower fluence required compared to Q-switched technology allows for safer treatment in skin of color.”

For accelerated tattoo removal, the R20 method allows one to perform multiple passes on the same day by waiting 20 minutes between passes. This approach was published in the February 2012 Journal of the American Academy of Dermatology. The R20 method achieved excellent results in the original Harvard study, said Dr. Friedman; however, it may not be efficient to have a patient in your office for that length of time, he noted.

To streamline tattoo treatments, he uses the perfluorodecalin (PFD) patch, because it provides a barrier, so that none of the tissue is splattering back, he said. He also likes PFD’s ability to serve as an optical clearing agent. Because heat is conducted from the epidermis into the patch instead of the skin, the patch provides an extra layer of safety for darker skin types, he explained.

“More importantly, it clears out those little microbubbles that occur between passes. So it allows us to do multiple passes on the same session without having to wait 20 minutes between passes,” Dr. Friedman said.

One published study showed that use of a PFD patch allowed investigators to perform 3.7 passes with a nanosecond Q-switched 755 nm alexandrite laser in five minutes with less erythema and edema.

Quick Takes

The 1,064 nm laser provides the ability to treat all skin types and break up ink particles more effectively, one expert says.

To streamline treatments, Dr. Friedman uses the PFD patch, which allows one to perform multiple passes on the same session without waiting in between.

Photos: Paul M. Friedman, M.D.
INDICATION
ALTRENO™ (tretinoin) lotion, 0.05% is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

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

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

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

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

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

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

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

Please see Brief Summary of Prescribing Information on following pages.

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

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

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

CONTRAINDICATIONS
None.

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

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

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

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

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

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

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>ALTRENO N=767</th>
<th>Vehicle N=783</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application site dryness</td>
<td>29 (4)</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Application site pain</td>
<td>25 (3)</td>
<td>3 (&lt;1)</td>
</tr>
<tr>
<td>Application site erythema</td>
<td>12 (2)</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Application site irritation</td>
<td>7 (1)</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Application site exfoliation</td>
<td>6 (1)</td>
<td>3 (&lt;1)</td>
</tr>
</tbody>
</table>

Application site pain defined as application site stinging, burning or pain.

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

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

<table>
<thead>
<tr>
<th></th>
<th>ALTRENO Mild/Mod/Severe</th>
<th>Vehicle Mild/Mod/Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythema</td>
<td>51%</td>
<td>44%</td>
</tr>
<tr>
<td>Scaling</td>
<td>49%</td>
<td>30%</td>
</tr>
<tr>
<td>Hypopigmentation</td>
<td>12%</td>
<td>10%</td>
</tr>
<tr>
<td>Hyperpigmentation</td>
<td>35%</td>
<td>35%</td>
</tr>
<tr>
<td>Itching</td>
<td>35%</td>
<td>28%</td>
</tr>
<tr>
<td>Burning</td>
<td>30%</td>
<td>14%</td>
</tr>
<tr>
<td>Stinging</td>
<td>21%</td>
<td>8%</td>
</tr>
</tbody>
</table>

USE IN SPECIFIC POPULATIONS

Pregnancy

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

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

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

Data

Human Data

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

Animal Data

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

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

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

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

Lactation

Risk Summary

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

Pediatric Use

Safety and effectiveness of ALTRENO for the topical treatment of acne vulgaris have been established in pediatric patients age 9 years to less than 17 years based on evidence from two multicenter, randomized, double-blind, parallel-group, vehicle-controlled, 12-week trials and an open-label pharmacokinetic study. A total of 318 pediatric subjects aged 9 to less than 17 years received ALTRENO in the clinical studies [see Clinical Pharmacology and Clinical Studies in full Prescribing Information]. The safety and effectiveness of ALTRENO in pediatric patients below the age of 9 years have not been established.

Geriatric Use

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

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

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

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

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

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

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).
Investigational injection improves cellulite appearance

LISETTE HILTON | Staff Correspondent

Quick Takes

Patients treated with collagenase clostridium histolyticum (CCH, Endo International) improved the appearance of cellulite in the buttocks in two phase 3 studies. Compared to subjects receiving placebo, those treated with CCH achieved at least a two-level composite improvement in cellulite severity in the treated buttocks 28 days after the last treatment, or at day 71, compared to subjects receiving placebo.

A total of 846 women, 18 years and older with moderate-to-severe buttock cellulite were enrolled.

54.3% of treated subjects in RELEASE-1 and 46.6% in RELEASE-2 reported being “satisfied” or “very satisfied” with treatment at day 71, compared to 25.8% and 13.6% of placebo subjects, respectively.

THE STUDIES

Endo International released results of the identical RELEASE-1 and RELEASE-2 multicenter studies in early November in a press release. The company studied a bacteria-derived collagenase (Clostridium histolyticum) in 846 women, 18 years and older with moderate-to-severe buttock cellulite 28 days after the last CCH treatment. Subjects received up to three CCH treatments of up to 12 injections each in the buttocks or placebo treatments, about 21 days apart.

Among those receiving CCH in RELEASE-1, 7.6% experienced significant improvement in the composite investigators’ and patients’ assessments of the appearance of cellulite, as measured by the Clinician Reported-Photonumeric Cellulite Severity Scale (CR-PCSS) and Patient Reported-Photonumeric Cellulite Severity Scale (PR-PCSS) at day 71, compared to 1.9% of placebo subjects. In RELEASE-2, the percentages were 5.6 in the CCH group versus 0.5 receiving placebo. Endo International helped to develop scales used in the study, according to the release.

The active treatment passed all but one of eight secondary endpoints in both studies. The secondary endpoints measured investigators’ and patients’ assessments of the appearance of cellulite, patient satisfaction and more.

For example, 54.3% of subjects in RELEASE-1 and 46.8% in RELEASE-2 who received CCH reported being “satisfied” or “very satisfied” with treatment at day 71, compared to 25.8% and 13.6% of placebo subjects, respectively. And while those receiving CCH in RELEASE-1 demonstrated a statistically significant improvement in the composite investigator and patient assessments of the appearance of cellulite, as measured by a two-level improvement in both the CR-PCSS and PR-PCSS scores, at day 71, the endpoint failed to show statistical significance in RELEASE-2.

Subjects tolerated CCH well, with most adverse events being mild to moderate, such as bruising, injection site pain, discoloration, nodules and pruritus, according to the release.

“Cellulite is tough,” says Alexander W. Sobel, D.O., president of the American Board of Cosmetic Surgery. He was not a part of this study and has no ties to the company. “What makes it tough is that you have these ligaments — these myofascial cutaneous ligaments — that are basically tethered from the underlying muscle structure to the skin. A variety of treatments over the years have been attempted to improve the appearance of cellulite, but they tend to fail in the long-term. So, whenever I evaluate a cellulite treatment, what I’m first and foremost interested in is whether it is really doing anything to those ligaments in the long-term to improve the appearance?”

Bacteria-derived collagenase clostridium histolyticum is used to treat Dupuytren’s contracture and Peyronie’s disease in adults. It breaks down collagen.

“This product is a novel way of approaching cellulite in terms of trying to dissolve those ligaments,” Dr. Sobel says.

In the past, doctors have used devices to sever the bands, including the Toledo V (Wells Johnson) liposuction cannula, more affectionately known as the “pickle fork,” according to Dr. Sobel. Still, the dimples of cellulite often returned, he says.

“Cynosure came out with a very extensive side-firing laser that was supposed to cut these ligaments, and, in the long-term, it didn’t work terribly effectively either. There are a number of technologies that heat up the skin on top and tend to improve basically the tightness of the quilt in between these little quilling tethers. They improve the appearance of cellulite for a time but don’t defeat the ligamentous structure,” he says. “If this works in the long-term, that’s something that is really exciting.”

But even if results don’t last years after treatment, patients often see benefit from temporary reduction of their cellulite, Dr. Sobel says.

“That’s especially if the treatment is minimally invasive, carries low risk and fits in the beauty budget. So, I think there are some aspects of this to be excited about even before the presentation of long-term data,” he says.

Among today’s treatments, Subcision, a registered trademark with the Cellfina (Ulthera), boasts the longest FDA clearance for a cellulite treatment at three years.
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At multidisciplinary conferences, attendees may be so focused on fillers, neuromodulators and more invasive procedures that they overlook the importance of improving the surface of the skin.”

Paul M. Friedman, M.D., dermatologist with offices in Houston and New York

Adjunctive treatments boost results for tattoo removal, PIH and skin resurfacing from PAGE 36

in between. Therefore, we achieve more effective clearing per treatment session.”

In a 30-patient study published in Lasers in Surgery and Medicine in March 2017, using a PFD patch with a nanosecond Q-switched 755 nm alexandrite laser allowed investigators to perform 3.7 passes in five minutes (versus 1.4 passes with the laser alone) with less erythema and edema.

Experts are now considering the role of acoustic shockwave technology (ASWT), which is traditionally used to remove kidney stones, in tattoo removal. “ASWT has been shown to increase vascular endothelial growth factor, which increases local blood circulation. The theory is that it may enhance tattoo clearance by increasing lymphatic drainage and metabolic activity in the treated area.”

He uses the 1,550 nm wavelength for deeper treatment of conditions such as acne scarring, as well as wrinkles.

“Although the 1,550 nm is a shorter wavelength, there is deeper penetration because there is less water absorption compared to the 1,927 nm thulium wavelength,” he said.

The real value of the fractionated non-ablative device, he added, is its ability to treat all skin types and off-face areas, such as the neck, chest and hands — areas he previously would not resurface due to the risk of scarring.

“Tattoo removal is a game-changer in the population of patients who do not want to have the significant downtime or risk associated with traditional resurfacing procedures,” he said.

When treating postinflammatory hyperpigmentation (PIH) associated with scars, he commonly chooses the 1,550 nm wavelength. For example, he used the 1,550 nm wavelength to treat a patient with type III skin who had burn scars and got excellent results after two sessions.

For a female patient with type IV skin with atrophic scarring and PIH following herpes zoster infection of the forehead, Dr. Friedman began with the 1,927 nm low-powered diode laser, which he uses for patients with PIH in all skin types.

Subsequently, he performed non-ablative fractional resurfacing with the 1,550 nm wavelength to improve the patient’s atrophic scarring.

Dr. Friedman frequently combines fractional and Q-switched lasers for same-day treatment. For a patient with minocycline hyperpigmentation, this approach achieved almost complete clearance after one session.

“Tattoo removal is a game-changer in the population of patients who do not want to have the significant downtime or risk associated with traditional resurfacing procedures,” he said.

To treat a woman with PIH, fine telangiectasias and hemosiderin deposition following lipotransfer under the eyelids, Dr. Friedman chose a combination of pulsed-dye laser, non-ablative fractional resurfacing (to stimulate collagen remodeling) and a Q-switched alexandrite laser (to break up the hemosiderin). The patient improved dramatically after two treatment sessions.

For melasma, Dr. Friedman recommends a multimodality approach that includes low-energy and low-density non-ablative fractional resurfacing or picosecond technology.

“It’s part of a combination approach along with a topical antioxidant, retinoid and skin brightener with tranexamic acid, and for some patients, oral tranexamic acid,” he said.

In more challenging cases such as nevus of Ota, he typically combines technologies to reduce the number of treatment sessions required.

“We often find that these patients plateau — in these cases I prefer combining non-ablative fractional resurfacing with Q-switched or picosecond laser technology on the same treatment session,” he said.
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Cost of care vs. value of life

BOB KRONEMYER | Staff Correspondent

What is a life worth? Does it come down to dollars and cents? Should it be measured by quality of life? Should economic burden be considered?

These are not easy questions, but in a November 21 analysis published in *JAMA Dermatology*, Ivo Abraham, Ph.D., of the University of Arizona shows that the cost of a treatment that could add one progression-free quality-adjusted life-year, one additional progression-free life-year, or to have one additional patient attain objective response for patients with advanced and unresectable melanoma could cost about $1.6 million — an amount most payers may be unwilling to pay.1

“As an absolute number, you could say the difference of 21% in objective response rate is really a lot. But in reality, this is not an impressive result because the ipilimumab-only objective response rate was low at 18% and the talimogene laherparepvec plus ipilimumab objective response rate was very modest at 39%,” he said.

**RE-EVALUATING THE COST OF TREATMENT**

The American Cancer Society estimated that in 2018, there were 91,270 new cases of melanoma and 9,320 deaths.3 And, according to a report in the *Journal of the National Cancer Institute*, the national cost of melanoma treatment is projected to reach $3.16 billion by 2020, which is up from $2.36 billion in 2010.4

“Melanoma is one of these diseases where for so long we had virtually no progress in treatment options, but now we have several options,” Dr. Abraham said.

For advanced and unresectable melanoma, these treatment options have shown promise. A study published in *JAMA Dermatology* showed that combining ipilimumab and talimogene laherparepvec resulted in a 38.8% (38 of 98 patients), respectively—objective response rate—compared to a 18% (18 of 100 patients) rate with ipilimumab alone.

Authors suggest re-evaluating the cost of care.

**BY THE NUMBERS: FIVE-YEAR SURVIVAL RATES FOR MELANOMA**

<table>
<thead>
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Dermatofibrosarcoma is a common, but unusual locally aggressive cutaneous tumor. Its characteristic tentacle can grow into surrounding fat, muscle and even bone. For dermatologists, this means that understanding treatment options is a priority, according Onofre Sanmartin, M.D., of the Instituto Valenciano de Oncologia in Spain. He presented an overview of the diagnosis and treatment for dermatofibrosarcoma during the European Academy of Dermatology and Venereology (EADV) Congress in Paris.

OVERVIEW
Dermatofibrosarcoma is most commonly found on the trunk, followed by proximal extremities, and the head and neck. In the protuberans form (DFSP), the clinical presentation is plaques with some nodules. The non-protuberans form is more commonly seen in children.

Pathologically, dermatofibrosarcoma is easy to diagnose. It infiltrates the epidermis and becomes subcutaneous. It has a typical fibroblast-like proliferation with little or no mitosis, and the main characteristic is the tendency to spread into subcutaneous tissue with tumor tentacle-like extensions. Tumors can even reach the fascia and muscle in one third of patients.

Despite the characteristic histology, there are more than 10 clinical subtypes of DFSP and many different clinical presentations. Variants include fibrosarcomatous dermatofibrosarcoma, which has a fascicle appearance with a herringbone pattern. Another variety is subcutaneous, which is mainly found on the head and neck and characterized by no connection with the dermis or epidermis.

Immunohistochemical diagnosis is possible with 90-95% of patients positive for CD34 and 10% negative for CD34. Cytogenetics is the main tool for diagnosis, but DFSP is characterized by the translocation T (17;22) (q22;q13), which results in the platelet-derived growth factor B (PDGFB)/COL1A1 fusion gene. This causes overproduction of PDGFB, leading to PDGF receptor activation.

RNA gene sequencing (e.g. RT-PCR) can be used for diagnosis, as can FISH.

“FISH is faster and sensitive enough, and should be recommended as a routine diagnostic tool,” Dr. Sanmartin said. Some patients (4%) with typical DFSP are negative for translocation in routine molecular screening, and 50% of cases defined as negative by FISH are positive with RT-PCR. While MRI is not useful for the lateral delineation of tumor or detection of a residual tumor, it can be suitable for large tumors and gauging the involvement of deep structures.

The main treatment for DFSP is surgery. The tumor must be completely removed.

“This can be a challenge given its infiltrative nature,” said Dr. Sanmartin. The tumor extensions can be more than 5 cm away from the clinical part of the tumor, which means that much normal skin must be eliminated.

DFSP also tends to recur in the same location. In one review, 2,069 patients showed a recurrence rate of around 17% after surgery. It is possible that this standard surgery is not the best approach, Dr. Sanmartin said.

Only 0.84% recurrence is reportedly seen after Mohs micrographic surgery. This option can spare 50% of the skin at 2 cm, and according to Dr. Sanmartin, should be used as the treatment of choice.

PDGF receptor inhibitors are an option for locally advanced and metastatic DFSP. Improved indication has been seen with imatinib mesylate, for example. However, Dr. Sanmartin considers 800 mg to be a very high dose of tyrosine kinase inhibitor (as has been used in previous studies) — he treats with 400 mg.

Pathologically, dermatofibrosarcoma is easy to diagnose.”
Quick Takes

CM guidelines were last updated in 2011.

The guidelines include new therapies for surgically resected stage III melanoma.

New treatments are associated with improved disease-free and overall survival.

Guidelines include new therapies for surgically resected stage III melanoma.

Pathology Report for Biopsies

1. The pathologist should be provided the patient’s age, sex and precise anatomic location of the biopsy site.
2. The clinician should provide their impression and differential diagnosis, lesion size, and intent of the biopsy (i.e., excisional vs. partial, and type of diagnostic biopsy performed: elliptical/fusiform, deep shave/saucerization, broad shave, or punch).
3. Macroscopic satellites around the clinical lesion should be pointed out. They can escalate cutaneous melanoma to stage III and can be associated with microscopic satellites in the primary tumor.
4. Clinical photographs of the site should be provided for review.
5. Include the level of suspicion for cutaneous melanoma, clinical description and history of the lesion beyond size (including whether there has been a change in the lesion or previous biopsy), and dermoscopic features (with or without an accompanying photograph).

Pathology

When a biopsy of a suspicious lesion is performed, the guideline says that the pathologist should be given essential information about the patient including their age, sex and precise anatomic location of the biopsy site.

It is strongly recommended that the clinician include their clinical impression and differential diagnosis, the size of the lesion, and intent of the biopsy (i.e., excisional vs. partial, and type of diagnostic biopsy performed: elliptical/fusiform, deep shave/saucerization, broad shave, or punch).

Macroscopic satellites around the clinical lesion should be pointed out, as they escalate cutaneous melanoma to stage III and can be associated with microscopic satellites in the primary tumor, and any clinical photographs of the site provided for review.

Other useful information that may be useful for the pathologist include the level of suspicion for cutaneous melanoma, clinical description and history of the lesion beyond size (including whether there has been a change in the lesion or previous biopsy), and dermoscopic features (with or without an accompanying photograph).

Surgical Management

Surgery remains the first line treatment for cutaneous melanoma of any thickness as well as melanoma in situ (melanoma cells in epidermis; stage 0), so following initial biopsy, wider and deeper excision is performed to ensure complete removal of the lesion, confirm histologically clear margins, and reduce the risk of local recurrence.

Surgical margins should be based on tumor thickness and greater for thicker tumors. For invasive cutaneous melanoma (CM) they should be >1 cm and <2 cm (1 cm is recommended for 1 mm tumours and 2 cm for 2 mm tumours) and measured clinically around the primary tumor, although they may be narrower to accommodate function and/or anatomic location. For melanoma in situ, wide excision with 0.5- to 1.0-cm margins is recommended.

The recommended depth of excision is to (but not including) the fascia.

Recommended surgical excision margins are measured from the edge of the lesion or prior biopsy at the time of surgery and are not histologic margins as measured by the pathologist.

Sentinel lymph node biopsy, when indicated, should be performed before wide excision of the primary tumor, and in the same operative setting, whenever possible.

Follow-Up Frequency

How often a patient follows up with a dermatologist should depend on:

- The agent(s) used.
- Age of patient.
- Underlying skin cancer risk factors, and/or
- Potential role of skin findings as a biomarker for response.
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The guidelines emphasize the advantages of multidisciplinary collaboration among dermatologists, surgeons, and medical oncologists, particularly for those patients at higher risk of disease recurrence.”

Susan Swetter, M.D., Pigmented Lesion and Melanoma Program, Stanford University Medical Center and Cancer Institute

Guidelines for melanoma treatment emphasize advantages of multidisciplinary collaboration.

MOHS, IMIQUIMOD & RADIATION THERAPY

There has been much progress in the use of Mohs micrographic surgery and other staged surgery techniques (utilizing permanent sections) for treatment of melanoma in situ on anatomically constrained sites (typically the lentigo maligna subtype).

However, Dr. Swetter says: “Current data are insufficient for the guidelines to recommend Mohs surgery for invasive cutaneous melanoma, in which the use of surgical margins less than 1 cm has not been adequately studied worldwide.

“Non-surgical approaches, including the off-label use of imiquimod and traditional forms of radiation therapy, may be considered if surgery is impractical or contraindicated, and only for melanoma in situ, lentigo maligna type, as cure rates are lower. These modalities all require further prospective investigation, which is in progress in the US and abroad.”

SURVEILLANCE

Although the optimal interval and duration of follow-up for CM are not well defined, the guideline working group recommends that patients with CM be monitored regularly following diagnosis, particularly for tumors at increased risk of recurrence (e.g., >2.0 mm in thickness and/or with ulceration, lymphovascular invasion, high mitotic rate).

Although most metastases occur in the first 1 to 3 years after treatment of the primary tumor, skin examinations for life are generally recommended.

For patients with melanoma in situ (stage 0), reviews are recommended at least every 6 to 12 months for 1 to 2 years and then annually. Review should involve a physical examination to check for local recurrence and a full skin check to spot any new primary cutaneous melanoma.

Patients with stage IA-IIA should also be reviewed every 6 to 12 months initially, but for 2-5 years, and then annually. These reviews should involve a comprehensive history and physical examination focused on the skin and regional lymph nodes. Patients with stage IIB and greater tumors should receive a similar review every 3-6 months for the first 2 years, then at least every 6 months for the next 3-5 years and then at least annually. Patients with stage IIB and greater tumors also likely to benefit from radiological testing for 3 to 5 years.

KEY QUESTIONS

The guidelines working group considered the key clinical questions that frequently arise in the management of cutaneous melanoma and three new topics emerged: Melanoma in pregnancy, genetic testing for hereditary melanoma, and dermatologic toxicities associated with newer melanoma drugs (e.g., targeted agents such as BRAF/MEK inhibitors and immune checkpoint inhibitors) which dermatologists will see more of given their broader use across the cancer spectrum.

The guidelines say that a diagnosis of cutaneous melanoma during pregnancy does not alter prognosis or outcome for the woman, however, work-up and treatment must take the safety of the fetus into consideration. The approach taken to melanocytic nevi in the pregnant woman should be identical to that in the nonpregnant patient. Any changing nevus during pregnancy should be evaluated and subjected to biopsy if clinically and/or dermoscopically concerning.

Dermatologists should collaborate with oncologists for management of cutaneous toxicity during BRAF/MEK kinase or immune checkpoint inhibitor therapy, the guidelines say, because appropriate recognition and control of skin side effects may improve the quality of life of patients with cutaneous melanoma and avoid unnecessary interruption of medication. The frequency of dermatologic assessment depends on the agent(s) being used, age of the patient, underlying skin cancer risk factors and/or potential role of skin findings as a biomarker for response.

Assessment is recommended every 2-4 weeks for the first 3 months of BRAF inhibitor monotherapy for patients with numerous squamoproliferative neoplasms, although combination BRAF/MEK inhibition is standard and associated with less skin toxicity. With immune checkpoint inhibitors, it should take place within the first month of therapy and continue as needed. Patients with atopic dermatitis, psoriasis, or other autoimmune dermatoses, should be seen by a dermatologist for pre-emptive counseling and treatment before initiation of therapy.

THE FUTURE

Novel molecular techniques are being studied for melanoma prognostication, to help determine which patients should be treated and followed more intensively.

“These techniques require ongoing prospective validation studies to determine their predictive value, how well they compare with and add to known histopathologic factors (and prognostic prediction models based on AJCC 8th edition staging), and how best to incorporate them into clinical practice. This is an exciting area that dermatologist can look forward to in the future,” Dr. Swetter says.

“As molecular techniques are further investigated, we anticipate improvement in our ability to determine which patients benefit most from surgery and/or systemic therapy. As such, the guidelines emphasize the advantages of multidisciplinary collaboration among dermatologists, surgeons, and medical oncologists, particularly for those patients at higher risk of disease recurrence,” she said.

References


“Our analysis is a way of … informing the debates about the value that we may or may not get out of these treatments.”

Ivo Abraham, Ph.D., University of Arizona

Balance: The mid-point between what is reasonable to charge and what is too much.

Options include BRAF inhibitors (vemurafenib, dabrafenib/mesylate and encorafenib), immune checkpoint inhibitors (ipilimumab, nivolumab and pembrolizumab), and oncolytic virus (talinogene laberparvec). Treatment can be as monotherapy, but research is beginning to indicate that combination therapy is more effective for some patients.

“The treatments we have now are much better than what we used to have. These drugs are very expensive to manufacture and their studies are very expensive to conduct. We have to come to grips with the fact that these drugs are going to cost more. The balance we now need to find is what is reasonable to charge and what is too much,” Dr. Abraham said.

Because patients with cancer tend to be more accepting of adverse events in return for positive outcomes, economic evaluations are evolving so that these inherent adverse events are not penalized, but rather are considered as part of a complete picture with clinical outcomes.

“For economic analysis of drug treatments, we are sort of being forced to still think in terms of the established or classical pharmacoeconomic methods that come out of an era of small molecules in which drugs are relatively simple to make, versus biologics or oncolytic virus treatments for melanoma,” Dr. Abraham says. He says he and his colleagues are struggling with the fact that these classic analyses have low cost thresholds.

“It is also important to have economic evaluations that are conducted independently from industry but also from payer organizations. Industry has an interest in coming up with results that portray favorably upon them. The same holds true for payers,” he said. “We do not consider pharmacoeconomics as a way to set policy, but to inform policy. Our analysis is a way of stimulating and informing the debates about the value that we may or may not get out of these treatments,” he said.

In 2018, the President’s Cancer Panel, an NIH group formed to examine out-of-pocket costs associated with cancer treatment, recommended (1) that cancer treatment pricing be replaced with value-based or outcome-based pricing, (2) the adoption of payment models that incentivize clinicians and healthcare organizations to use high-value drugs, and the group recommended that (3) patients be encouraged to choose treatments with high-value drugs.

But in this article, the authors state that we need to move beyond focusing on cost and instead, “adopt a workable definition of value to operationalize and quantify value. In 2010, Porter et al., writing in the New England Journal of Medicine, suggested that value be defined as the “health outcomes achieved per dollar spent,” which is a concept the authors of this new study described as one that should be explored further. The American Society of Clinical Oncology, the European Society for Medical Oncology and the National Comprehensive Cancer Network measure value by clinical benefit, toxicity, and quality of life. The American Society of Clinical Oncology includes actual costs.

THE FINDINGS

The economic model used in this evaluation consisted of the cost of treatment, medication administration, monitoring, management of grade three and four adverse events for each of the two treatment arms, utilities and disutilities.

The analysis concluded that for combination therapy, the cost to gain just one additional progression-free quality-adjusted life year (QALY) was roughly $2.2 million, compared to about $2.1 million for one additional progression-free life-year or $1.6 million for an additional single patient to attain an objective response.

“These numbers are very high and are well outside the willingness of payers to pay. In the end, it seems to all consistently converge around $1.6 million per unit of improvement,” he said.

To reconcile the imbalance of cost and outcome, the investigators say that the price of the combination therapy must be drastically reduced or demonstrate another clinical benefit like increased overall survival.

Pricing of therapy that more closely matches the demonstrated effect should also be encouraged, so that price points align with their therapeutic benefit.

The economic construct of the cost per quality-adjusted life-year (QALY) may also vary by disease, treatment options and prognosis because the construct assumes that patient preferences, clinician treatment patterns and a payer’s willingness to pay are consistent.

Dr. Abraham says the standards of $50,000 to $150,000 for one additional QALY are unrealistic.

LIMITATIONS

This study was based on a phase two randomized, open-label trial, but it did not include survival data. There were other limitations of note as well, such as whether safety and tolerability measures were fair in this case.

“Several of the above clinically oriented frameworks, together with the QALY-based approach, consider safety and tolerability a negative that requires a downward adjustment of the benefits of a treatment. This overlooks the reality that most cancer treatments have more (and more severe) safety and tolerability issues compared with general medicine treatments. Therefore, applying similar utilities and disutilities for cancer as for general medicine ignores the fact that patients with cancer tend to be more willing to accept adverse events in return for effective treatment,” the authors wrote.

Reference


Access to care varies by demographic

Differences worthy of exploration since they impact outcomes

WHITNEY J. PALMER | Staff Correspondent

Quick Takes

Researchers conducted a retrospective analysis of dermatologic services data from the Medical Expenditure Panel Survey (MEPS) between 2007 to 2015.

- Hispanic and African-American patients were less likely than non-Hispanic white patients to receive outpatient care for dermatologic conditions.
- Males were less likely than females to visit an outpatient dermatologist.
- High-income patients received the greatest level of care.

Outpatient dermatology services can be available to any patient. However, according to recent research, that doesn’t mean all patients access or take advantage of this clinical care in the same way.

A new study published in *JAMA Dermatology* highlights the factors that affect how patients use outpatient services, including gender, age, race/ethnicity, educational level, income, insurance status, geographic region, self-reported condition, and self-reported health status.

“We’ve known for a while dermatologic conditions can cause a lot of other medical issues, and we know visits to a dermatologist reduce adverse events and improve mortality,” said Raghav Tripathi, M.D., a Case Western Reserve University School of Medicine student and first author. “But, we also know various differences exist in outcomes of conditions among different demographic groups.”

It’s important to understand the differences in how racial and ethnic groups access care, according to the study, because minorities are predicted to comprise the majority of the U.S. population by 2044. Exploring these differences can also shed light on reasons why patients from minority groups could have different dermatology experiences. For example, existing data shows minority groups have a lower level of awareness around skin conditions and understand a dermatologist’s patient-care role less.

To better understand these disparities and identify where improvements are possible, Dr. Tripathi and his team conducted a retrospective analysis of nationally representative data from 2007 to 2015. The information came from the Medical Expenditure Panel Survey (MEPS) and was provided by the Agency for Healthcare Research and Quality. The team concentrated on data detailing services used for dermatologic conditions, including skin cancers, infections, dermatologic inflammatory conditions/ulcers, and other issues.

Of the 183,054 respondents, 19,561 self-reported a dermatologic condition. Most patients, 74,547, were non-Hispanic whites. There were 54,943 Hispanic, 36,146 African-American, and 17,418 patients from other races and ethnicities. Fifty-two percent were female.

All total, 9,654 patients accounted for 11,761 outpatient dermatology visits. Among the patients, 405 had a melanoma diagnosis, 2,045 had nonepithelial skin cancer, and 3,152 were diagnosed with skin or subcutaneous tissue infections. An additional 3,152 had other inflammatory conditions of the skin, and 870 received diagnoses of chronic skin ulcers.

The patients also received varying degrees of past dermatology care. For those with diagnosed dermatological conditions, 36.5% attended at least one outpatient dermatology visit between 2007 and 2015. The visit rate varied by diagnosis — 70.9% for melanoma, 74% for nonepithelial skin cancer, 13.2% for...
skin and subcutaneous tissue infection, 44.1% for other inflammatory skin conditions, and 10.6% for patients with chronic skin ulcers. Based on this data, more than twice as many non-Hispanic white patients had at least one outpatient visit compared to Hispanic or African-American patients.

According to data, Hispanic patients were less likely to receive outpatient care for dermatologic conditions relative to non-Hispanic white patients (aOR 0.55, 95% CI, 0.49-0.61). The same was true for African-American patients (aOR 0.42, 95% CI, 0.38-0.46). Additionally, males were less likely than females to undergo outpatient care (aOR 0.66, 95% CI, 0.62-0.70).

Location and insurance coverage also affected the level of dermatological care patients received, Dr. Tripathi’s team discovered. Midwestern patients received less dermatological care than patients in the Northeast (aOR 0.80, 95% CI, 0.70-0.91). Patients with private insurance were more likely to receive care. Medicare and Medicaid recipients received less care (aOR 0.75, 95% CI, 0.68-0.83), as did uninsured patients (aOR 0.39, 95% CI, 0.33-0.47).

The researchers also found higher educational levels were associated with increased odds of receiving outpatient dermatologic services. Patients with some college education (aOR 0.69, 95% CI, 0.64-0.75), a high school diploma or equivalency (aOR 0.49, 95% CI, 0.45-0.54), or no degree (aOR 0.52, 95% CI, 0.46-0.59) were less likely to undergo outpatient treatment for conditions than patients with a bachelor’s degree or higher.

Income also helped determine treatment likelihood, the study analysis revealed. High-income patients received the greatest level of care. Individuals with income levels classified as poor (aOR 0.48, 95% CI, 0.43-0.54), near poor (aOR 0.46, 95% CI, 0.40-0.53), low income (aOR 0.48, 95% CI, 0.41-0.56), or middle income (aOR 0.68, 95% CI, 0.63-0.73) had lower odds of seeing a dermatologist.

The study also highlighted healthcare expenditure differences between groups. Non-Hispanic white patients spent approximately three times as much as Hispanic and African-American patients — $209.50, $73.09, and $62.70 per capita, respectively. Per visit costs were also greater for non-Hispanic white patients than for Hispanic or African-American ones — $244.88, $191.14, and $170.94, respectively.

Investigators acknowledge possible reasons behind these disparities. Cost variances could result from different conditions affecting each group. Some healthcare institutions might not offer dermatological care, making referrals difficult. Language barriers could prevent some patients from taking advantage of services, and many patients could live in areas with low dermatologist density.

Ultimately, Dr. Tripathi said, while additional research is necessary to fully understand the disparities, he hopes these findings will encourage dermatologists to tailor their approaches to outpatient care based upon the demographic and socioeconomic characteristics of the individual patient. Dermatologists can augment outreach by making translators available, offering financial counseling, and tailoring marketing to address minority patient needs.

Dr. Tripathi also said he hopes these findings will encourage dermatologists to engage policy leaders and medical associations, encouraging them to reach out to underserved communities to improve their level of care.

“We need to be more aware of how to bring different groups back into the office so we can continue to provide the services they need,” he said.

Reference
Technology and telemedicine should be used to enhance our healthcare system, not overturn it.”

Aaron George, D.O., Chambersburg, Penn.

The need to expand telemedicine capabilities

AARON GEORGE, D.O. | Contributing Author

With office visits jammed with complex patients and underserved communities aching from lack of access, physicians need to think outside of the box. Or at least outside of the 10 x 10 exam room.

Expansion of telemedicine capabilities is one solution. Telemedicine often imparts thoughts of a futuristic technology, yet teleconsultation is ingrained in our American medical identity. Some of the first telephone lines were strung to connect rural physicians with patients and to bypass the late-night horseback ride to the bedside.

Apocryphally, the very first telephone call placed in 1876 was a telemedicine consult, as Alexander Graham Bell spoke the infamous words, “Dr. Watson—come here—I want to see you” shortly after spilling battery acid on his trousers. Physicians have been teleconsulting with patients for generations.

We must expand our current expectations for telemedicine and meaningfully embed this tool into our daily practice.

State-of-the-art virtual care software platforms can be used to harness online and asynchronous patient interviews to transform the way in which patients can access their physician. Based upon condition and symptoms, patients are guided through a branching algorithm of detailed questions. For example, a young and healthy female with dysuria may answer a chain of questions about the duration of symptoms, history, allergies, and acknowledgment of any red flags. Following this structured framework of questioning (which mirrors that performed during an in-person interview) a templated document is generated and forwarded to their physician for review.

For dermatologic concerns, pictures can be uploaded as well. The physician can then review documents and choose to treat or to refer for the appropriate level of evaluation. If treatment is provided, a few clicks generate sufficient documentation to meet billing requirements in the 38 states that allow for telemedicine reimbursement, or patients may pay directly. Such platforms streamline evaluation and offer efficient treatment for simple, acute conditions. As digital monitoring capabilities continue to improve and artificial intelligence progresses, these capabilities will only become more valuable.

It is essential that telemedicine complement and expand our current healthcare delivery—not hinder our day-to-day activity. I personally provide patient portal messaging answers to over 100 medical inquiries a day in my practice without reimbursement. A balance must be struck between the futuristic technology and billing models expanded on above, and the reality of the in-the-trench physician.

Continuity of care still matters. Virtual care interactions are best performed in the context of an established patient-physician relationship. One recent study from Rock Health, a full-service seed fund that supports startups working in digital health, showed that only 53% of patients were satisfied with their experience in an isolated video consult with a provider they had never met before, whereas 92% reported satisfaction if they had already had a prior in-person visit. The key is that technology and telemedicine should be used to enhance our healthcare system, not overturn it.

Our patients are eager for new ways to connect with their physicians and to better understand their own health. There are currently over 165,000 health-related smartphone apps available, and these were downloaded over 1.7 billion times in 2017. Over 87% of patients report they have used at least one digital health tool this year.

Other industries are taking notice, with over $5 billion in venture capital funding for telehealth in just 2017 alone. I truly believe that telehealth has the potential to transform delivery, improve access, and decrease costs. Our patients are increasingly eager for such transformation and want us to guide them. As physicians we just have be willing to answer the call.

Disclosures: Aaron George, D.O., is a family physician practicing in his hometown of Chambersburg, Penn. He was an Audlinger fellow in health policy with the Center for Public Health in Vienna, Austria, and has been awarded both the Bristol-Myers Squibb award for excellence in graduate medical education, as well as recently named one of the 40 under 40 physicians by the Pennsylvania Medical Society.
Equipment financing for a modern practice

JUSTIN TABONE | Contributing Author

Technology in the healthcare industry is constantly evolving, and with these changes comes a higher standard for quality of care. To deliver the best patient outcomes in today's environment, your practice needs to stay competitive and keep ahead of new developments. However, for many physicians, the financial strain of a new equipment purchase may stand in the way.

Financing can help relieve the stress by making payments more manageable and within your budget. Rather than expending all your capital upfront to buy the equipment, financing allows you to spread payments over time and free up capital for other business expenses. Many physicians find the added flexibility makes financing a valuable alternative. Depending on the lender, financing can include the full equipment purchase price and add-ons like maintenance and consumables, which can offset the slightly higher overall cost of a cash purchase. Your equipment supplier may be able to recommend a lender for your needs or, while doing your research, consider looking for a lender that offers financing structures that meet your needs.

FINANCING STRUCTURES

As with any major purchase, it's critical to determine whether the benefits will be worth the investment. Fortunately, a practice can often find a lender that offers flexible financing terms for an initial period, with no or reduced payments before making full payments. This gives the practice sufficient time to learn how to use the equipment and have it generate income prior to taking on the bulk of the expense.

Though these arrangements may be structured differently depending on the practice's objective regarding ownership or lease, there are a number of options available to help your practice acquire new technology.

Deferred payment structure. This option requires no payment for the first three to six months, followed by standard payments for the remaining term.

"Token-payment" program. This plan allows a practice to pay a nominal monthly payment for a short period (around 6 to 12 months) before standard payments begin.

"Step-up" structure. This plan generally includes a deferral period, followed by minimum payments for up to a year (often 1 percent of the equipment cost), before standard payments begin.

USEFUL LIFE OF THE EQUIPMENT

Today, medical equipment financing terms tend to last between three to seven years, and innovations in technology may cause obsolescence before the end of the payment term. Since it's not always possible to match your financing term with the useful life of the equipment, make sure to discuss the risk with your lender beforehand. Both finance agreements and leases can include buy-out and upgrade clauses that can hedge against obsolescence and afford additional flexibility down the line.

WHAT TO DO IF YOU'RE LOCKED INTO A CONTRACT

Alternatively, if you're interested in new equipment but have an existing contract, there may be options available. It might be possible to trade-in the old equipment and carry over the remaining balance into a new contract and extend the term to maintain, or even lower your prior payment, and potentially receive a more attractive interest rate. Often a new lender can buy you out of an existing contract; however, it's generally more efficient to establish a long-term relationship with a lender to seamlessly negotiate upgrades.

Above all, it's critical to seek out a financing program that meets your practice's needs over the long-term. In addition to speaking with your supplier, you may want to consult a financial advisor, tax attorney, accountant, or other trusted professional to help you make the best choice for your practice.

Disclosures: Justin Tabone is the originations leader for healthcare vendor equipment finance at TIAA Bank in Parsippany, New Jersey.

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Quick TAKES

Equipment financing allows you to spread payments over time and free up capital for other business expenses.

There are several finance structure options available to help your practice acquire new technology.

Options also exist if you're interested in new equipment but have an existing contract.

"Since it’s not always possible to match your financing term with the useful life of the equipment, make sure to discuss the risk with your lender beforehand."

Justin Tabone, TIAA Bank, Parsippany, New Jersey
The costs of doing business

DAVID J. NORRIS, M.D. | Contributing Author

Quick TAKES
Distinguishing among business costs allows you to make sound decisions about your practice.

Fixed costs do not change with practice activity.

Variable costs change with practice activity level.

I have discovered physicians, regardless of their years of experience, share a common misunderstanding about the costs of doing business.

There are two broad types of costs: fixed or variable. Learning how to distinguish those costs—and monitor them individually—will help you better control them.

FIXED COSTS
Fixed costs are those costs that do not change with the activity of your practice. These costs occur just because you are in business. Whether you see one or 1,000 patients in a month, these costs do not vary.

Fixed costs also usually do not change during a specified time period. For example, your rental rate is determined by a square-foot price. Your rent is fixed from month to month for the term of your lease.

Other examples of fixed costs include medical malpractice insurance and health insurance. Depending upon your contract, your electronic health record (EHR) system might also be a fixed cost.

VARIABLE COSTS
Variable costs are costs that change with the activity level of your clinic. These costs rise as the activity of the clinic rise and decline as the activity of the clinic decline.

An example of a variable cost would be the hourly cost of nurses in your clinic. If they work more hours during the busy time of the year, your costs will be higher because the nurses

WHAT YOU NEED TO KNOW BEFORE SEEKING A LOAN

By AVERY HURT | Contributing Author

If you’re planning to expand your practice, you’ll be happy to know that banks generally consider physicians and medical practices great credit risks.

“Bankers are usually very willing to loan money to physicians for expenses related to their practice,” says Katherine Watts, partner in charge of healthcare services at Home, LLP.

However, the array of options can be overwhelming when it comes to getting a loan for your new location or expansion of your current one. Like medicine, banking has terminology and practices that can be confusing to non-experts. Fortunately, the basics are pretty simple.

There are several types of loans you may qualify for. An SBA loan can be a great option. These are funded through a bank or other lender but are partially guaranteed by the U.S. Small Business Administration. SBA loans usually have the lowest interest rates and longest repayment terms around. However, SBA loans are highly competitive, so your finances will need to be in excellent shape to qualify. Also, it can take some time to get through the approval process.

If you decide to go a more traditional route, you can still get some very good deals. Many banks have loan officers who have experience working with medical practices.

Loans for business real estate typically have shorter amortization than home loans. Your real estate loan will probably be amortized over 10 to 20 years. The rate will depend on several factors, including your credit history, annual revenue, and the age of your practice. Unlike home loans, you aren’t likely to get a fixed rate for the entire term of the loan. "It
are working more. During the slow season, your costs will decline following the activity level of your clinic. Other variable costs include utilities, transcription services, and medical supplies.

**DETERMINING YOUR COSTS**

There are many ways to determine your costs. The first is a reliable and accurate accounting system. You, your office manager, and your accountant can work together to install a comprehensive accounting system. It might be expensive up front, but it should make tracking costs easier for you.

The second, more budget-friendly option is to use a program such as Excel or other spreadsheet programs. You will need copies of your cost or expense reports and the productivity reports for the same time periods.

Collect a few months and then plot your costs as a function of activity. Next, create a scatter plot and then add a line to the graph. This will give you an equation that will estimate your costs as a function of activity in the form of $y = mx + b$. In this formula,

- $y$ represents your total costs,
- $x$ represents the level of activity,
- $m$ represents your variable costs, and
- $b$ represents your fixed costs.

In the example above, we see our fixed costs are $7,168.30. This means it costs us $7,100 each month just to stay in business. Our variable costs are $53.44 per patient. When we see more patients, our total costs will rise.

It's not an exact representation of your costs, but it's an excellent place to start. The critical thing to realize is that fixed costs do not change with the activity of your practice, so always account for these known costs.

Variable costs will rise and fall in line with the productivity level of your practice. If you know the average revenue per patient encounter at your clinic, you can use the fixed and variable costs to project your net income and know if you will need to plan to use a line of credit or not.

Budgeting and forecasting cash flow issues is not the only reason to identify the fixed and variable costs in your practice. You need to know this information if you want to expand your practice with either a new service line, extended hours of operation, or even a new location.

This cost information can also guide the decision for whether you can afford physicians to go part time. A common problem with having part-time practitioners in your practice is how to assign the costs fairly. The method above is a reasonable method in determining how to divide the costs of the practice between full- and part-time physicians. It is more accurate than if you were to spread the costs evenly between full- and part-time physicians.

In a following article, we will examine how to use this costing information with revenue data to determine our break-even point.

**Disclosures:** David J. Norris, MD, MBA, is a practicing anesthesiologist in Wichita, Kan. He is the author of The Financially Intelligent Physician: What They Didn’t Teach You in Medical School and a frequent speaker on physician finances. Read more about David at www.davidnorrismdmba.com.
AI. FRIEND OR FOE OF DERMATOLOGY?

By Whitney J. Palmer

Artificial intelligence (AI) tools are steadily growing in popularity throughout medicine, particularly in dermatology. And, as they become more prevalent, they are beginning to change how providers offer care on a day-to-day basis.

With the individual patient appointment, these technologies can augment a dermatologist’s ability to identify problems and render effective diagnoses, said industry leaders. And, that’s valuable, said Maryam Sadeghi, chief executive officer of DermEngine, a dermatology software and workflow improvement company, because the specialty includes more than 2,000 individual diagnoses.

“AI can play an important role in dermatology because there’s a good chance a dermatologist hasn’t seen a patient with all the possible skin conditions,” she said. “AI can search for patients with symptoms and lesion types to provide reference cases and treatments.”

To date, dermatology lags behind in digitization compared to other specialties, such as radiology, she said. AI adoption has also been low due to low reimbursement, high cost concerns, and worries over reliability and privacy, according to the Deloitte 2018 Survey of U.S. Healthcare Consumers and Physicians. But, that is slowly beginning to change as providers realize there are several ways AI tools can augment clinical practice.

WHAT IT CAN DO

The potential exists for AI to meet several unmet needs in dermatology, said Aimilios Lallas, M.D., a dermatologist-venerologist at Aristotle University in Thessaloniki in Greece.

Doctors could use AI, he said, to quickly identify new lesions in patients who have multiple moles. Or, dermatologists who have fewer years of clinical experience or less training, he said, could implement AI as a virtual consultant, giving them a higher degree of confidence in their diagnoses and possible treatment plans.

THE COST OF TECHNOLOGY

According to the Deloitte survey, the cost of technological tools, including AI, electronic health records, or practice management systems, greatly impacts the bottom line for many practices. On average, such systems hover around approximately $60,000.

Although price tags can be an initial adoption and implementation barrier, once in place, these systems can save practices money, research revealed. A recent study published in *JAMA Dermatology*, evaluated the per-participant cost for individuals involved in teledermatology and conventional referral groups. Overall, investigators found teledermatology cost $82 less.

REIMBURSEMENT

Getting paid for providing virtual care can still be complicated. More private insurance companies are beginning to cover these services, but the Centers for Medicare and Medicaid Services (CMS) has different requirements based on whether a patient submits photos and symptom descriptions for a later dermatologist analysis, or if the patient and dermatologist have a real-time conversation. Correct visit coding can ensure payment.

DERMATOLOGIST & STAFF IMPACT

While providers and staff need training to gain proficiency with new technology, practices must guard against technology fatigue, said Suzanne Steinbaum, M.D., director of women’s cardiovascular prevention, health, and wellness at Mt. Sinai Hospital. Providers can experience burn out from too many system launches and optimizations. Practices that both get provider pre-implementation buy-in and ensure their systems are well integrated will have the most success.

Investing in convenience tools, such as online scheduling systems where patients secure appointments themselves, can also increase staff efficiency. They’re freed to tackle other responsibilities, such as helping patients who need more assistance scheduling appointments, transferring prescriptions, or answering more in-office questions.

PATIENT VOLUME

According to the Deloitte survey, 23% of patients have already experienced a virtual visit, and 57% of those who haven’t are willing. Consequently, offering technologies that augment dermatology accessibility is likely to both retain existing and attract new patients.

Additionally, said Maryam Sadeghi, chief executive officer for DermEngine, a dermatology software and workflow improvement company, these tools can also bolster your patient satisfaction scores.

“By using AI tools, dermatologists can change conversations from not knowing exactly what’s going on with the patient,” she said. “Instead, they can tell patients they’ve found multiple patients cases with the same symptoms and successful treatments. This gets a much better response.”

Ultimately, even with business side impacts, industry leaders contend the long-term effects will be beneficial and opting out could have negative results.

“Our view is that, with a changing landscape that favors value-based payment models, growing consumer demand, and advances in digital technologies, virtual care is no longer just a nice-to-have but a must-have for physicians,” the survey authors wrote. “And the time for health systems to consider developing virtual care strategies is now.”

In that vein, Ms. Sadeghi said, some AI software, which can be up to 95% accurate, can search clinical data to compare a patient’s symptoms to other treatment cases. The tool scours high-quality clinical data to retrieve instances where similar patients were treated. The dermatologist can use this information to outline a specific treatment plan.

One potential use also offers wider, population-based health benefits. Dr. Lallas said dermatologists could eventually employ AI tools to conduct large-scale, periodic screenings to detect suspicious lesions. These screening could be implemented in all patient groups, he said, not just high-risk populations.

SHOULD DERMATOLOGISTS WORRY

In many pockets of dermatology, resistance exists to implementing AI solutions, citing concerns that machines will slowly eliminate the need for the doctors. However, he said, that likelihood is minute.

In fact, he said, the industry should pivot away from discussing whether AI will one day replace doctors. Feeding those fears could actually inhibit the development of AI tools that could help dermatologists streamline and facilitate the delivery of higher-quality clinical care.

Ms. Sadeghi agreed, saying a machine can never know a patient as well as their personal dermatologist can. Using an AI tool does not mean a provider abdicates their diagnostic responsibility to a machine.

“Our patients trust us,” she said. “We can be a better version of ourselves if we have better tools to serve them.”

The tool can provide details about how other patients with similar conditions have been treated, but the dermatologist and patient ultimately decide what therapy plan to pursue.

“AI is a consultation tool. Dermatologists should use it to make sure they’re making effective, evidence-based decisions,” she said. “But, the dermatologist will be in charge of determining what will be best for the patient and what treatment to pursue.”

Technology in practice is becoming a must-have from Page 1
Dr. Brian Biesman and Dr. Michael Gold invite you to the 2019 Music City SCALE Meeting. The meeting is for all physicians and clinicians interested in enhancing their practice and learning more about the latest procedures in aesthetic medicine. In addition to the educational sessions, there are live patient workshops and an exhibit hall with the leading members of the industry.

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<td>NEWSURG,INC</td>
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Forever Flawless diamond powder-infused products

Forever Flawless’ AGE-DEFYING COLLECTION features products with extra-fine natural diamond powder, which the company says restores skin, stimulates cell renewal and enriches skin with a blend of botanicals and vitamins.

Diamond Infused Age-Defying Serum: This serum is made up of a peptide formula with extra-fine diamond powder. Forever Flawless says that this serum combats the aging process with cell-reconstructing agents. The product also features essential oils, vitamins, minerals, and natural botanicals that moisturize and gently exfoliate the top layer of the skin.

Diamond Infused Age-Defying Cream: This face cream brings includes vitamins C and E, soybean oil, beeswax, glycerin, the advanced MDI complex and natural diamond.

For more information: foreverflawless.com.

CeraVe new products meet unique skincare need

CeraVe announced its DIABETICS’ DRY SKIN RELIEF line, which was developed with dermatologists and includes products that seek to address the unique skincare needs of people with diabetes. Each product contains ceramides 1, 3, 6-11 as well as bilberry and urea to moisturize the skin and restore the skin’s natural protective barrier.

Cleansing Wash: Containing bilberry and urea, this wash gently cleanses and helps soothe dry skin to provide long-lasting moisturizing.

Hand & Foot Cream: Free of drying alcohols and made from a non-greasy formula, this cream soothes dry and cracked skin to provide 48 hours of moisturization.

Moisturizing Cream: This non-greasy cream is formulated to provide 48 hours of moisturization and leave skin feeling soft and smooth.

For more information: cerave.com.

Exuviance introduces hyaluronic acid micro-filler regimen

Exuviance recently introduced EXUVIANC HA100 MICRO-FILLER REGIMEN, which is a two-step product that targets lines and wrinkles overnight. It features micro-cone patches that deliver hyaluronic acid and a serum with patented Aminofil, patentedNeoGlucosamin and Vitamin C. The micro-cone patches address lines by providing surface hydration while the serum addresses dark spots, loose skin and uneven skin texture, according to Exuviance.

Mikio Fujitsuka, Head of Exuviance Sales and Marketing, says, “With our new HA100 Micro-Filler, inspired by med spa treatments, we are introducing a regimen that delivers visible results while you sleep in a non-invasive regimen.”

Of the 34 women that participated in a consumer perception survey, 97% claimed their skin was smoother, more hydrated and more plump-looking. Women also reported a decrease in fine lines and wrinkles, as well as firmer skin.

For more information: exuviance.com.

Skin to You launches three affordable skincare collections

Skin to You has launched their CLEANSE, TREAT and MOISTURIZE COLLECTIONS, which are holistic and affordable skincare lines that seek to protect skin from pollution, sun damage, allergens and chemicals. The Cleanse collection can be used at morning and at night to rid skin of dirt, oil and makeup, while the Treat collection targets hyperpigmentation, fine lines and wrinkles, and the Moisturize collection provides 24-hour hydration for smoother skin.

I Mist You: This product is included in the Cleanse collection. The mist hydrates and soothes and can be used on bare skin or over makeup to keep skin moist throughout the day.

Rated X-foliate: This product is also part of the Cleanse collection and is formulated to gently exfoliate skin as a scrub or a mask.

Ready for This Jelly: A part of the Treat collection, this cleanser gently cleans skin to remove stubborn residue without stripping skin moisture.

I Scream for Eye Cream: This cream is part of the Treat collection and contains green tea and primrose to brighten, hydrate and smooth under-eye skin.

Vitamin C O: This product is included in the Treat collection and provides a brightening and moisturizing boost to skin.

Sun Sealed Delivered: A part of the Moisturize collection, this broad-spectrum facial moisturizer is gentle and can be used daily.

Vitamin C Cream: This cream is also part of the Moisturize collection. It contains jojoba and aloe, which hydrate skin.

The products are not tested on animals and are made in the United States.

For more information: skinyourbrand.com.
Medicare Physician Fee Schedule Changes

The Centers for Medicare & Medicaid Services (CMS) is in the process of finalizing changes to the Medicare Physician Fee Schedule (PFS) changes for office visits, surgical procedures, diagnostic tests, therapy services, and preventive services. These changes apply to healthcare practitioners, diagnostic testing facilities and treatment centers. In this table, we highlight some of the forthcoming changes for our readers.

**LESSEN ADMINISTRATIVE BURDEN**
- For established patients at check-in, nurses no longer need to re-record the patient’s record in detail if this was done in a previous visit. Instead, a review and update of the records with the patient will suffice.
- For new and established outpatient visits, physicians need not re-record the patient’s chief complaint and history that has already been entered into the record. A review will suffice.
- The practitioner may remove duplicative notations by residents or other members of the medical team.

**PAYMENTS FOR TELEMEDICINE SERVICES**
- Practitioners could be paid separately for virtual check-in services (HCPCS code G2012) done by telephone or other telecommunication devices.
- Practitioners could be separately paid for reviewing patient-transmitted photos or videos submitted by an established patient (HCPCS code G2010) to assess whether a visit is needed.
- CMS is also finalizing policies to pay separately for new coding describing chronic care remote physiologic monitoring (CPT codes 99453, 99454, and 99457) and interprofessional internet consultation (CPT codes 99451, 99452, 99446, 99447, 99448, and 99449).

**OTHER NEW REQUIREMENTS**
- In 2019 all practices must use Certified EHR Technology (CEHRT) that was certified using the 2015 Edition requirements to receive a score in the Promoting Interoperability performance category.

**MIPS 2019 PERFORMANCE YEAR CATEGORY WEIGHTINGS * **

- **Improvement Activities**
  - 15%

- **Quality**
  - 45%

- **Cost**
  - 15%
  (up from 10% in 2018)

- **Promoting Interoperability**
  - 25%
