ON THE FRONT LINES IN FLINT

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We are in the thick of the “dog days of summer” here in Norfolk.

With summer still in full throttle, vacation is on everyone’s mind. Hopefully you’ve either had some time to recharge or are planning for some in the coming days. Did you know that the expression the “dog days of summer” has nothing to do with summer heat? It comes from the ancient Greek and Roman astronomers and was used to describe the time of the year when the star Sirius appeared to rise before the sun. I guess most of us just pictured a panting hot dog in our mind’s eye. As a result of the slight wobble of the Earth, this star pattern actually occurs at a slightly different date with each passing year. Eventually this star pattern will occur in the dead of winter. Might not be a problem though if you believe in global warming.

Lots of things are not quite the way they seem. Take progress notes in EHRs. Notes have become much more extensive since we started using computers. Between note cloning, importing information, and templated notes, it has become relatively easy to document many a visit in a way that could support a level 5 complexity. Note cloning can be a perilous path that is best avoided when it doesn’t fit the relevant history and physical exam. It can also make reviewing the prior visit’s notes more unwieldy. No longer do we simply see the action taken for the patient, it can be embedded in a long, complicated mess of words. So while note cloning can be highly convenient when used appropriately, it is not all for the good. Read our piece to remind you about the potential pitfalls.

Sweating in the summer is just part of the territory as the thermometer heads north for each of us. When you have hyperhidrosis, however, things are different than expected. Patients sweat profusely no matter the environment — no need for heat or stress. For the patient, it can be quite overwhelming. Sometimes, though, things are just as they seem. The brown, smelly water in Flint turned out to be just what the community knew… it was polluted. Talk about some bad decisions by the government! I’m sure that most of you have read or heard about what happened. What about its impact on the skin? Read about our four colleagues in Flint who opened their doors to their communities and worked with the CDC to learn more about the possible impact. We applaud them and their desire to serve their communities. I hope that you enjoy reading about our unsung heroes in Michigan.

I’m looking out on the Chesapeake as I write to you this month. Boats are cruising by and the waves are gently rippling. Nothing like a view of the water to help one recharge. The peace that this type of moment brings is just as it seems… a little slice of heaven.

Enjoy your reading.

ABBY S. VAN VOORHEES, MD, PHYSICIAN EDITOR
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In just a few minutes, Nada Elbuluk, MD, catches you up on the hottest research in the field.

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What’s hot?

In this new monthly column, members of the Dermatology World Editorial Advisory Workgroup identify exciting news from across the specialty.

Rosalie Elenitsas, MD

Have you ever seen biopsy results of lentigo and melanoma in situ from the same lesion? In my experience this is not a rare phenomenon. I recently read with interest a publication from our Australian colleagues titled “Unstable solar lentigo: A defined separate entity” ([Australas J Dermatol. 2016 Feb 2. doi: 10.1111/ajd.12447. [Epub ahead of print]]). This paper describes the "unstable solar lentigo" as an isolated irregularly pigmented macule in actinically damaged skin. They may stand out as being solitary lesions that are markedly different than the patient’s other pigmented lesions. Histologically there is melanocytic hyperplasia and possibly mild cytological atypia, but the lesions lack other criteria for melanoma in situ. The authors hypothesize that this is a precursor lesion to melanoma in situ. While this is not a scientifically rigorous manuscript, the concept is appealing since we see numerous solar lentigines on a daily basis relative to the number of melanoma in situ. It is clear that further investigation is needed in this area before drawing final conclusions. In the interim, if the pathologist says that the lentigo shows atypia, perhaps complete removal or close follow-up of that site would be prudent.

Michel McDonald, MD

Older age at time of surgery, thicker tumor depth, and head and neck location may increase the likelihood of positive margins at the time of wide local excision of cutaneous melanoma ([Dermatol Surg 2016;42:646-652]).

A retrospective review of 543 patients with melanoma treated from 1997 to 2011 at one institution utilizing NCCN guidelines for margins revealed 6 percent with positive margins after wide local excision. Patients with positive margins were older (72.4 vs 60.7 years of age). Head and neck melanomas accounted for 56 percent of those with positive margins. Tumors greater than 2cm accounted for 38 percent of those with positive margins. Sex, ulceration, mitotic rate, and melanoma subtype were not predictive of margin status at the time of excision. While the five-year regional and systemic recurrence rates did not differ based on margin status at the time of initial excision, the local recurrence rate was significantly different for those with positive margins versus negative margins (16 percent vs 6.9 percent). While this study does not have sufficient evidence to vary from NCCN guidelines, it may be of value in deciding whether to consider delayed closure if a flap or a graft is needed for repair of the surgical defect.

Lakshi Aldredge, MSN, ANP-BC

Oregon Health & Science University (OHSU) has begun recruiting potential volunteers for the first human tests of its promising and novel HIV vaccine. The vaccine is based on a weakened but “live” version of cytomegalovirus (CMV) that’s been engineered to look like HIV to the immune system. By stitching HIV-like bits onto CMV, the immune system is trained to attack HIV. The vaccine attacks HIV after cells become infected, rather than relying on antibodies to kill pathogens before they take hold. In animal trials, the vaccine has cured 50 to 60 percent of infected monkeys. The lead scientist, Dr. Louis Picker, suspects the lower cure rate in monkey models has to do with the virulence of the Simian immunodeficiency virus, which is much more powerful than HIV.

In March of this year, scientists at the Oregon National Primate Research Center revealed that infant rhesus macaques treated with antibodies within 24 hours of being exposed to SHIV, a chimeric simian virus that bears the HIV envelope protein, were completely cleared of the virus. The study shows that antibodies given after a baby macaque has already been exposed to SHIV can clear the virus completely ([Nature Medicine, 2016; DOI: 10.1038/nm.4063]).

Healthy volunteers can sign up for the screening program at www.ohsu.edu/vaccineresearch. The first, three-year safety trial, due to start next year, will involve four groups, with the vaccine dose increasing in potency 10 times with each subsequent group. Each participant will be seen 10 times over 48 weeks.
Electronic devices have infiltrated everyday life both at home and at work. We use cell/smartphones, iPads, computers, laptops, gaming devices and consoles, etc. Increasingly we are seeing cutaneous reactions from these devices. A recent article in *Dermatitis* provides a review and a reminder of the reactions contact with electronic devices can cause (27[3]:82-89). Patients have been diagnosed with allergic contact dermatitis due to cell phones and video game controllers that contain nickel. Mouse pads have also been seen to cause reactions due to rubber allergens. Erythema ab igne is another identified reaction seen with the use of laptops. As electronic devices continue to permeate our work and recreation environments it is likely that we will see more skin reactions resulting from exposure to these devices. Clinicians should stay on the lookout.

When we diagnose a patient with an intermediate or thick melanoma we often refer them to surgical oncology for consideration of a sentinel lymph node biopsy (SLNB). In their article in the *British Medical Journal* (2015 Mar;172[3]:566-71), Sladden, et al help interpret the complex data from the Multicenter Sentinel Lymphadenectomy Trial (MSLT-1) and point out analytical errors made by the original investigators. In MSLT-1 patients were randomized to either wide local excision (WLE) with SLNB and immediate completion lymphadenectomy if the sentinel node was positive, or to WLE plus observation. Using the same data from MSLT-1, but correcting for design and analytical errors, the authors found that there is no difference in disease-free or overall survival in patients undergoing SLNB for intermediate thickness (1.2 – 3.5 mm Breslow depth) melanomas. The complication rates of SLNB and completion lymphadenectomy were reported by MSLT-1 to be 10.1 and 37.1 percent, respectively. With these high complication rates, and lack of clear benefit, this article provides a strong argument against recommending this procedure for intermediate thickness melanomas.

Recently in the *New England Journal of Medicine*, there was an article that addressed the need to view chronic disease as an issue that affects an entire family, not just the patient (2016;374:1804-6). It is easy to forget the impact that disease has on a family. We frequently focus treatment recommendations to treat a patient’s disease, but fail to be sensitive to the impact on the family. Particularly in dermatology, the majority of what we deal with are chronic conditions. This pertains not just to the typical chronic inflammatory dermatitis such as atopic dermatitis and psoriasis, it also applies to the common keratinocyte-derived skin cancers such as basal cell carcinoma and squamous cell carcinoma that are now being viewed as chronic diseases as well. This article highlighted the need to be more sensitive to the impact of chronic disease on the patient and their family members, particularly when the family members hold the role as the primary caregivers to the patient. Of course, there is a limit to what we can do, but this awareness is crucial to being effective in caring for our patients.
Cloning: it’s not just for sheep. Just as viruses have infiltrated the electronic data transmitting world, cloning has permeated medical record keeping, being particularly spurred on by the digital age. Cloning is basically defined as copy and pasting of identical information from a patient’s encounter to a subsequent encounter. Computerization of medical records facilitates both purposeful as well as inadvertent copying and pasting. Electronic health records (EHR) may facilitate listing factors in the history, past medical history, review of systems, and physical examination that are either unchanged from visit to visit and/or irrelevant to the presenting problem. This raises two issues of concern to payers, including the Centers for Medicare and Medicaid Services (CMS): first, repeating verbatim text from a previous visit is discouraged, as it may call into question whether any new information had been extracted during the patient visit. Second, extensive cloning of previous data may facilitate upcoding by way of increasing the billed level of evaluation and management (E/M) service. It is easy to collect data about a patient and watch an electronic health records program suggest up-ticks in E/M billing levels. However, one must keep in mind that any services provided, as reflected in the E/M documentation, must be both reasonable and necessary. Just because it is documented does not make it necessary for the problem being treated.

Examples of cloning that may facilitate E/M upcoding are verbatim repetition of past medical history, family history, social history, extensive review of systems, and physical examination findings from visit to visit. Particularly if each visit represents continuation management for an ongoing problem such as acne, for example, repetition of detailed history and/or examination data would call into question whether it was actually gathered at the time of the visit, and whether that information was reasonable and necessary for the treatment of the patient’s problem. CMS specifies that, for calculations of levels of service as well as to justify coverage, the collected patient data must prove medical necessity for treatment and must be reasonably needed for the patient’s treatment. Gobs of data alone do not justify levels of E/M billing. Overdocumentation may be a simple consequence of an EHR program automatically populating data from visit to visit. It may also be consequent to one’s checking off suggested data selections in a program that then generates identical verbiage from visit to visit. Lastly, inattentive copying and pasting of patient data may perpetuate errors if such were included in the original record that is copied, or if patient details had changed in the interim but were not discovered due to reflexive copying and pasting.
The Office of the Inspector General issued a May 2012 report, *Coding Trends of Medicare Evaluation and Management Services*, which determined that between 2001 and 2010 Part B Medicare payments for E/M services increased by 48 percent. It also found a shift to higher levels of E/M code billing, with a 17 percent increase in billings for 99214 and 99215 established patient CPT codes. Such findings lead to greater payer scrutiny of medical provider’s billing trends. Upon review, the medical record will be scrutinized for cloning and for medical necessity of the documented information that was used to determine a level of E/M service.

How should a medical professional react to payer concerns about cloning and upcoding? Simply, one should review each patient’s medical record to ensure accuracy, appropriateness, and individualization of information before signing the note, whether by hand or electronically.

Is all cloning of notes inappropriate? Well, not really. There are instances in dermatology where identical verbiage from service to service precisely describes what was done or found. For example, a surgical procedure may be preceded by identical preparation of the patient and infiltration of anesthesia every time that procedure is done. Indeed, select characteristics of a surgical procedure may be identical from patient to patient, and identical verbiage would be appropriate in such instances. In histopathology, certain descriptions of common tumors, such as of a nodular basal cell carcinoma, will be essentially identical from tumor to tumor. Although select descriptions in the record would be virtually identical from encounter to similar encounter, the essence is that a distinct service was provided, documented, and was both reasonable and necessary. It is also essential, however, to include individual details that vary from a “standard” description, when such are present.

What may happen if your Medicare patients’ records are audited and found to have insufficient, overdocumented, or cloned information that resulted in unjustified upcoding of E/M visits? At the least, your charges would be adjusted to a lower level of service and a refund would be sought for the upcoded charges. At worst, if a systematic and egregious purposeful upcoding of charges were discovered, you could be found to be in violation of the federal False Claims Act for knowingly submitting fraudulent claims. Bad news there, as the latter violation carries the threat of civil monetary and other punitive penalties.
Example 1

A patient with inflammatory facial and neck acne comes in for initial and subsequent office visits. For each visit the patient record documents a past medical, social, and review of systems history. Your record also lists palpation of the lymph nodal basins and the thyroid for each visit. Your EHR program suggests a level of E/M service commensurate with the data collected.

Answer: Big data, but no big charge. Just because data was collected and was then repeated verbatim for each subsequent visit does not make it relevant to the problem being treated. Overpopulation of data sets, particularly with cloned information, does not justify a higher level of service billing. One should be careful to review EHR-presented data to ensure that it is relevant to the visit and current.

Example 2

Your EHR carefully documents each step of gathering and processing tissue for each stage of Mohs surgery and words it identically for each patient treated with Mohs surgery.

Answer: Correct. If the procedure is identical in each case, then identical language cannot be construed as inappropriate. However, any details specific to each patient’s case, such as tumor involvement, tumor characteristics, location, and depth should be individually specified for each distinct surgical case.

Example 3

For each case of complex or adjacent tissue rearrangement repair your chart record lists exactly the same rationale from patient to patient. Such rationale may include: to diminish tension across a wound, to maximize cosmesis, to preserve functionality, to optimize scarring, to redistribute tension vectors, to minimize deformity, etc. You use the rationale as a basis for justifying your reconstruction technique of choice and then proceed to describe the reconstruction procedure in identical fashion for every complex repair or adjacent tissue rearrangement that is done.

Answer: Incorrect. Although in your mind the choice of reconstruction may be both reasonable and necessary, to an auditor rationale that is identically worded for every patient, in every chart, indicates cloning and lack of data individualization. Additionally, descriptions of reconstructions that are identical from chart to chart represent cloning and may lead to claim rejection upon audit. It is best to include some distinguishing procedural data from patient to patient, as not all rationales for repairs are identical, and not all repairs are exactly the same. dw
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State boards of pharmacy are adopting onerous compounding regulations in response to several actions and guidelines issued by the U.S. Food and Drug Administration (FDA), the United States Pharmacopeia (USP), and the Federation of State Medical Boards (FSMB).

In 2013, Congress passed the Drug Quality & Security Act (DQSA), which was intended to allow the FDA to regulate outsourcing facilities while still allowing state control over traditional compounders. The FDA has indicated that its interpretation of the DQSA gives the FDA the authority to restrict anticipatory compounding in a physician’s office as well as in-office use without a prescription.

Additionally, the USP has proposed amendments to its compounding guidelines (Chapter 797, Sterile Preparations) that will likely impact dermatology. The proposed changes do not consider compounding as the reconstituting or diluting of a conventionally manufactured sterile product such as botulinum toxin type A for administration to an individual patient, as long as there are no intervening steps in accordance with the manufacturer’s labeling. However, the amendments also state that any other reconstitution or dilution of a conventionally manufactured sterile product must be performed in accordance with the USP’s updated guidelines, which hold individual dermatologists to the same standards as compounding pharmacies. As such, the revised guidelines do not allow for the buffering of lidocaine with sodium bicarbonate or dilution of triamcinolone with lidocaine.

Finally, the FSMB issued a draft position statement on sterile compounding in physicians’ offices — encouraging physicians who compound medications to limit the compounding activity to non-sterile preparations because of safety concerns. The draft position statement also encouraged physicians to familiarize themselves with the USP’s new guidelines. Although the position statement would not have the force of law, it could serve as an influential guide for boards of pharmacy. The FSMB referred the position statement back to its board of directors after hearing concerns from the physician community, including the American Academy of Dermatology Association (AADA).

As a result of the FDA, USP, and FSMB’s actions, state boards of pharmacy are adopting new compounding regulations that will likely affect dermatology. The AADA is working within the states to show pharmacy boards and state lawmakers that the compounding activities that dermatologists engage in involve very low-risk sterile practices — such as compounding or administering compounded diluted solutions for intralesional injections to treat dermatologic conditions including acne cysts, keloids, alopecia areata, hypertrophic scars, and psoriasis — with the determination of the appropriate dilution often made during the patient visit.

The North Dakota pharmacy board has proposed to amend its compounding rules so that prescribers would be required to comply with the USP guidelines. The AADA submitted a letter in opposition to the changes in May.

The Ohio Dermatological Association (ODA) and the AADA met with the Ohio Board of Pharmacy in May to discuss concerns with regulations on the use of compounded drugs by physicians.
in their offices. In addition to comments submitted by the ODA, the AADA submitted a joint letter with the American Society for Dermatologic Surgery Association, the American Society of Mohs Surgery, and the American College of Mohs Surgery to the Ohio State Board of Pharmacy opposing regulations that, among other provisions, require facilities — where a prescriber is compounding drugs — to be licensed as a terminal distributor of dangerous drugs (TDDD license). Further, for low-risk sterile compounded drugs that may be used 12 hours or more after preparation (beyond use date), allergen extracts, and medium- and high-risk sterile compounded drugs, the prescriber must comply with the USP guidelines. As a result of feedback from the medical community, the pharmacy board revised its requirements concerning the TDDD license, advising previously exempt providers to refrain from applying for a TDDD license. The AADA will continue to work with the Ohio Board of Pharmacy to ensure dermatologists can continue their standard practices that have been performed in physician offices for years.

Legislation in New Jersey titled the “Hazardous Drug Safe Handling Act” addresses the concerns expressed by the National Institute for Occupational Safety and Health (NIOSH) regarding the occupational dangers of exposure to antineoplastic drugs in health care settings. The bill would require the state to regulate antineoplastics and other hazardous drugs in accordance with the NIOSH-recommended precautions. The bill would create a stakeholder group — consisting of practicing physicians from affected specialties, the Medical Society of New Jersey, nurse practitioners, health personnel labor unions, and personnel from the veterinary field — that would draft and disseminate new regulations, which could create an undue burden on the ability of dermatologists who store and compound drugs. The legislation passed the Assembly in May and heads to the Senate. 

**KEY**

- Pending regulations/legislation
Connections found between rosacea and dementia, glioma, and Parkinson’s

BY ABBY S. VAN VOORHEES, MD

In this month’s Acta Eruditorum column, Physician Editor Abby S. Van Voorhees, MD, talks with Alexander Egeberg, MD, PhD, about his recent Annals of Neurology, JAMA Dermatology, and JAMA Neurology articles, “Patients with Rosacea have Increased Risk of Dementia,” “Association of Rosacea With Risk for Glioma in a Danish Nationwide Cohort Study,” and “Exploring the association between rosacea and Parkinson disease: a Danish nationwide cohort study.”

Q Dr. Van Voorhees: We are going to cover three of your recent papers on the associations of gliomas, Parkinson’s disease, and dementia with rosacea. Let’s start with the JAMA Dermatology paper on gliomas. Was there a reason that you thought about studying the possible risk with this malignant tumor? Why might matrix metalloproteinases (MMPs) be associated with both?

Dr. Egeberg: Our interest and reasons for investigating the association between rosacea and glioma came since we, in a relatively short period of time, experienced two such cases at our department. I mentioned these findings to one of my colleagues, and he was stunned, since his spouse had a personal history of rosacea as well as a first-degree relative with glioma.

Based on these clinical observations, we searched the available literature, and noticed that there was virtually no data available on this association. Nevertheless, studies had linked MMP with both conditions, suggesting a potential, albeit hypothetical, link. MMPs are enzymes that are involved in tissue remodeling, organ development, and regulation of inflammatory processes, and these have increased activity in rosacea-affected skin regions, as well as contribute to glioma invasion, dissemination, and angiogenesis.

Q Dr. Van Voorhees: What about the link between rosacea and Parkinson disease?

Dr. Egeberg: Already back in 2001, one small study reported that in 70 patients with Parkinson’s disease, rosacea was present in 18.6 percent of patients, and one third of all patients had symptoms compatible with rosacea. We therefore performed comprehensive investigations to examine this potential connection in our population, and strikingly found that the risk of Parkinson’s disease was 71 percent higher among patients with rosacea.

Q Dr. Van Voorhees: Tell us about your study design. What did you find?

Dr. Egeberg: Since we have a free and tax-supported health care system, Danish citizens have equal and universal access to medical care, and our nationwide administrative registers capture complete and accurate information on all citizens. We therefore used a population-based epidemiological approach, and compared the risk of glioma, Parkinson disease, and dementia, respectively, between patients with rosacea and the general population. The designs were similar between all three studies; that is, we examined the risk in patients with rosacea compared with the general population while controlling for potential confounding factors. The glioma paper was the first of the three studies, and it really sparked our interest in the link between rosacea and the brain. Our primary finding was a 36 percent increased relative risk of glioma in patients with rosacea.
Our main finding was a small but appreciable increased relative risk of dementia (7 percent). The highest risk appeared to be associated with development of Alzheimer’s disease (25 percent increased risk).

Dr. van Voorhees: Were you surprised to find an association with Alzheimer’s? Were any particular groups at higher risk? Did you find a difference between men and women?

Dr. Egeberg: Prior to commencing the dementia study we had noticed that, compared with other dermatological patients, e.g. those with psoriasis or acne, a family history of Alzheimer’s disease was more frequent among our patients with rosacea. When we examined the risk in our population-based study, the risk was highest especially in patients aged ≥60 years (20 percent increased risk) and higher in women than in men (28 percent vs. 16 percent).

Dr. van Voorhees: Does the severity of the patient’s rosacea make a difference?

Dr. Egeberg: It is noticeable that for all three diseases, the risk was approximately two-fold increased when rosacea had been diagnosed by a hospital dermatologist, which may reflect a higher risk in patients with more severe disease. However, when we looked at patients treated with tetracycline-class agents (including doxycycline) as a proxy for disease severity, we did not find a higher risk among these patients compared with patients only treated with topical therapies.

Dr. van Voorhees: What are the practical implications for us as dermatologists? Should we be alerting primary doctors to be screening our rosacea patients for both gliomas and Alzheimer’s? Given this greater understanding of rosacea is it surprising that tetracycline family antibiotics are helpful in this disease?

Dr. Egeberg: First of all, these findings highlight the need for more high-quality research in rosacea. There are more than 20,000 and 40,000 PubMed-indexed articles related to atopic dermatitis and psoriasis, respectively, yet there are only about 3,000 papers on rosacea, suggesting that this disease is understudied. For clinicians, these findings may help to identify neurological disorders at an early stage, thus ensuring timely referral and adequate treatment in these patients.

Tetracyclines have been used in the treatment of rosacea for decades presumably due to their ability inhibit MMP expression, although their precise primary target is not clear. While our study protocols for the glioma and dementia studies did not include this research question, we did examine the effects of tetracyclines on the risk of Parkinson’s disease. Tetracyclines have previously been investigated in clinical trials as a potential treatment option for Parkinson’s disease. Notably, in our study the use of tetracycline-class antibiotics was associated with a slightly (2 percent) decreased risk of Parkinson’s disease. Whether this is due to neuroprotective effects of tetracyclines, or if this means that treating rosacea will reduce the risk of neurological comorbidity, is still unclear. dw
MACRA and MIPS are coming

What Medicare’s proposed new fee-for-service system means for you

BY CLIFFORD WARREN LOBER, MD, JD

Every month, Dermatology World covers legal issues in “Legally Speaking.” Clifford Warren Lober, MD, JD, presents legal dilemmas in dermatology every other month. He is a dermatologist in practice in Florida and a partner in the law firm Lober, Brown, and Lober.

Cathy: I just heard that Medicare is changing the way it is paying for physician services in 2019. Is this true?

Bryan: Absolutely. On April 27, CMS issued a 962-page proposed rule that describes how the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) will be implemented. Effective Jan. 1, 2019, every physician who is not a “qualified provider” in a CMS-approved advanced alternative payment model (APM) will be considered a fee-for-service provider (by default) and, as such, will be subject to the merit-based incentive payment system (MIPS). PQRS, value-based modifiers, and meaningful use will no longer exist as such but will be incorporated in MIPS. Under MIPS, you will receive a bonus, penalty, or neither depending upon your composite performance score.

Cathy: If this takes effect in 2019, why should I worry about it now?

Bryan: While MIPS payment adjustments take effect in 2019, the performance period those adjustments will be based on will be in 2017, just as the current PQRS, value-based modifier, and meaningful use penalties and bonuses are assessed based on performance two years prior. It may seem like we have years to grapple with this rule, but its impact will actually arrive in just a few months.

Cathy: Will all physicians receiving fee-for-service be affected?

Bryan: No. Exceptions will be made for those in their first year of practice, physicians billing Medicare no more than $10,000 and seeing no more than 100 Medicare beneficiaries annually, as well as for those who are “qualified providers” in approved advanced APMs.

Cathy: What is a composite performance score?

Bryan: Cathy, your composite performance score has four components: (1) PQRS and the quality component of value-based modifiers will be rolled into a category called “quality,” (2) meaningful use will be incorporated into a component called “advancing care information,” (3) the cost component of value-based modifiers will be reflected in a category called “resource use,” and (4) a new category called “clinical practice improvement activity” will be evaluated.

Cathy: How will “quality” be determined?

Bryan: Cathy, your composite performance score has four components: (1) PQRS and the quality component of value-based modifiers will be rolled into a category called “quality,” (2) meaningful use will be incorporated into a component called “advancing care information,” (3) the cost component of value-based modifiers will be reflected in a category called “resource use,” and (4) a new category called “clinical practice improvement activity” will be evaluated.

Suggested Topics

If you have any suggestions for topics to be discussed in this column, please email them to loberc@gmail.com.

See the February 2013 issue of Dermatology World for disclaimers.
Additionally, CMS is proposing a measure called “biopsy reporting time” which should be useful to dermatopathologists. In 2019, “quality” will count for 50 percent of your composite performance score.

Cathy: What is “advancing care information”?

Bryan: This component focuses on the electronic transmission of health information. The goal will be to get 100 points of 131 possible points that will be available in this category. Fifty (50) points will be determined by your base score, which reflects protection of patient health information, e-prescribing, registry reporting, patient access measures, coordination of care, and health information exchange. There will also be performance criteria worth up to 80 points and one bonus point available for registry reporting. In 2019, “advancing care information” will account for 25 percent of your composite performance score.

Cathy: What is “clinical practice improvement activity”?

Bryan: These are activities that enhance the availability and scope of your practice. The goal will be to get 60 points by performing activities worth 10 or 20 points each. Therefore, you only need to fulfill three to...

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1. Effective Jan. 1, 2019, with a performance period scheduled to begin Jan. 1, 2017, PQRS, meaningful use, and value-based modifiers will be incorporated into and replaced by the merit-based incentive payment system (MIPS) for physicians receiving fee-for-service.

2. You may receive a bonus, penalty, or neither depending upon your composite performance score which will be determined by “quality” (50 percent in 2019), “advancing care information” which focuses on the electronic transmission of health information (25 percent in 2019), “clinical practice improvement activity” (15 percent in 2019), and “resource use” (10 percent in 2019).

3. In 2019, you may receive a bonus or penalty up to 4 percent depending upon how your composite performance score compares to other providers. This bonus/penalty amount will increase every year until it reaches 9 percent in 2022.

4. Those with the highest scores will receive an additional bonus for “exceptional performance” which can be up to 10 percent of their Medicare payments during each of the first six years of the program.

5. Physicians in their first year of practice, providers receiving no more than $10,000 and seeing no more than 100 Medicare beneficiaries, as well as those in qualified advanced APMs will not be subject to MIPS.

6. The information presented is current as of publication. The final implementation rules will be published by CMS in coming months and changes may occur.
six activities to get full credit for this component of the CPS. There will be over 90 activities to choose from in the following areas: participation in an alternative payment system, expanded practice access, population management, care coordination, beneficiary engagement, patient safety and practice assessment, achieving health equity, emergency response and preparedness, and integrated behavioral and mental health. Although there are certainly activities that are typically less relevant to dermatology, such as those dealing with mental health, others should be easier to fulfill. In 2019, clinical improvement activities will account for 15 percent of your composite performance score.

Of significance to dermatologists, there is an exception that allows practices of 15 or fewer physicians to report only two of the criteria in order to receive full credit for this category.

Cathy: What is “resource use”? How will it be determined?

Bryan: Resource use will be determined by CMS on the basis of claims you have submitted. In addition to reflecting the cost component of value-based modifiers, over 40 specific episodes of care will be considered, such as mastectomy, acute MI, or hip replacement. No specific episodes for dermatology were mentioned in the proposed rule. Pharmaceutical expenses will be taken into account where “feasible and applicable.” If enough cost data is not available, CMS will redistribute the 10 percent of your composite performance score that reflects the “resource use” component (in 2019) to the other three components of your score.

Cathy: How will my composite performance score affect my Medicare payments?

Bryan: In 2019, you may receive a bonus or penalty up to 4 percent depending upon how your composite performance score compares to that of other providers. This bonus/penalty amount will increase every year until it reaches 9 percent in 2022. Additionally, those with the highest composite performance scores will receive an additional bonus for “exceptional performance” which can be up to 10 percent of their Medicare payments during each of the first six years of the program. Beginning in 2026, providers paid on a fee-for-service basis will also receive 0.25 percent annual increases.

Cathy: You mentioned that those in qualified advanced APM will not be subject to MIPS. How will it be determined who qualifies?

Bryan: In 2019 and 2020, you will have to get either 25 percent of your Medicare income or 20 percent of your patients through a qualified advanced APM to be eligible for the MACRA benefits available to advanced APM participants. However, in 2019 and 2020, you will be considered a “partially qualified” participant and may choose whether or not to be subject to the MIPS payment adjustment if you get either 20 percent of your Medicare income or 10 percent of your patients through a qualified advanced APM. Obviously, CMS is encouraging you to participate in advanced APMs.

To be continued next month...
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Each month Dermatology World tackles issues “in practice” for dermatologists. This month Rachna Chaudhari, the Academy’s practice management manager, offers tips on an area she commonly receives questions about from members.

Best practices for patient collections

BY RACHNA CHAUDHARI, MANAGER, PRACTICE MANAGEMENT

Patients are becoming more responsible for their own health care bills as health insurers continue increasing patient co-pays and deductibles. Your dermatology practice, in turn, needs to become more efficient at collecting payments directly from the patient. The following tips will help your practice fine-tune these collections and increase your reimbursement rate.

Data, data, data
Your practice can never have enough financial data at its disposal. Obtaining the right data and analyzing these metrics is key to managing your performance with patient collections. Review your patient receivables, point of service collections, time to collect, and accuracy of patient registration on a monthly basis and benchmark these figures against national averages. Your practice management system (PMS) should have features that allow you to easily export these reports and view them over a specific time period.

Patient receivables = payment collected by practice / payment owed by patient

This percentage should increase as you implement better collection strategies. Aim for a rate of 95 percent, and try to stay above 85 percent.

Point of service collections = point of service payments / total cash collected from patients

This percentage gives you a snapshot of how effective your staff is at collecting payments directly from patients. This percentage should also increase as you implement better collection strategies and can help you determine whether you need to provide additional training to your staff about the practice’s financial policies.

Time to collect = Average number of days to collect full patient payment

This figure should go down as you become more efficient at collecting payments from patients. The Medical Group Management Association’s (MGMA) Practice Perspectives on Patient Payment study found that it takes an average of 3.3 billing statements before a patient pays their full balance. Strategize with your office manager to lower this time period, so you can receive your payments in time to meet your financial obligations.

Accuracy of patient registration = Number of patient registrations without errors / Number of patient registrations

You PMS or patient management software should provide this figure and verify any errors. Your staff should be trained to fix these errors, so your accuracy rate should be close to 100 percent. The more accurate your patient’s registration information is on the first try, the more likely you are to collect the correct amount from the patient at the time of their visit.

Patient-friendly bills

**Train your staff**

Your front desk staff is your first line of defense in collecting payments from patients. They must be trained in how to effectively discuss payments owed and have patients sign the practice's financial policy form. The Academy’s Office Policy and Procedure manual, available at [www.aad.org/store/product/default.aspx?id=9969](http://www.aad.org/store/product/default.aspx?id=9969), provides model policies and procedures as well as standard collection scripts for staff to use when collecting patient payments. Ensure they are asking patients for co-pays upfront and requesting past-due payments before the patient leaves the office. Review your financial statements to patients and simplify them for maximum impact. Put one staff person in charge of this project to ensure consistency. (Learn more about creating a patient-friendly bill at [www.aad.org/dw/monthly/2015/august/creating-a-patient-friendly-bill](http://www.aad.org/dw/monthly/2015/august/creating-a-patient-friendly-bill).)

**Use technology to your advantage**

Real-time claims adjudication is key to maximizing your patient collections. Verify if your patients’ insurers offer this service or look to partner with a software vendor to obtain this information, so your staff can determine the appropriate patient charge even before they are seen by a physician. This will help you collect a more accurate deductible or co-insurance.

Collecting patient payments is no longer a strictly in-person or by-mail affair. Your practice should evolve with technology and offer online payments as well as payment via phone. You can contract with a financial portal for your patients, so they can log in and pay via credit card, or determine if your EHR or PMS offers this service. Your practice website should have an easy-to-find link on its homepage to process patient payments. You can also automate bill payment reminders to patients and include email and text messaging rather than conventional U.S. mail and link these back to your practice website for payment.

**Be flexible**

Always offer patients flexibility with payments. Be open to setting up an installment plan or simply ask the patient what they can afford at that time. Patients will be more amenable to paying small amounts for an extended period of time if they are asked for their buy-in. Additionally, have separate policies for your self-pay and cosmetic patients. Make sure they pre-pay or pay in installments up front rather than after the procedure and encourage this through discounts or promotions. Always be wary of sending past-due amounts to collections and determine how much is really worth the hassle. The MGMA study found that most practices only collect $15.77 for every $100 owed by a patient in collections. Be open to writing off these bad debts and instead focus on what your practice can realistically collect.
Breaking the Barrier of Increased Self-Pay Costs in Today’s Dermatology Practice

Strategies to help your patients overcome cost concerns

By CareCredit

Many patients are feeling the pain of higher out-of-pocket fees due to rising insurance deductibles and co-pays. These increasing costs can cause patients to delay, scale back, or decline dermatologic care, even against your treatment recommendations. It’s frustrating, right? The facts are clear: this situation may continue to get worse, not better.

- In a recent survey, 98% of dermatologists said they experience some cost objections from patients.1
- Enrollment in high-deductible, consumer-directed health insurance plans jumped from 18% to 23% of all covered employees in 2014.2
- The average 2015 deductible for all covered workers is $1,077, up 67% from 2010 and 255% from 2006.3
- Combined employee contributions and out-of-pocket costs increased by 8% in 2015, more than in prior years (6% in 2014 and 6.5% in 2013).4

Patients are looking for a way to fit your recommended skin treatments and potentially life-saving cancer surgeries comfortably into their budget. Promotional financing options* like those available with the CareCredit health and wellness credit card can help patients overcome underlying cost concerns.

Practices are also feeling the impact of high self-pay costs.

Facing lower treatment acceptance and slower payment? Are patients ignoring the statements you send, month after month? Resigned to lending money for free while your accountant stresses over your cash flow and bottom line, especially in Q1 of every year? When patients use their CareCredit card in your practice, you’ll see immediate cash flow with payment in just two business days, regardless of patient delay or default.**

CareCredit can help give patients a way to pay.

Discussing promotional financing options can help make the cost conversation easier for both your team and your patients. When you accept the CareCredit credit card, you help give patients a way to fit the care they want or need into their financial situation. Patients can use CareCredit to pay for medical dermatology procedures, as well as elective procedures such as fillers, injectables and skincare products, all with popular No Interest if Paid in Full Within Promotional Period special financing options.*

“**This is covered, right?”**

Your team knows all too well the difference between “covered” and “free.” However, many patients do not, and may turn to you for clarification. The cost conversation can be uncomfortable with patients who experience high self-pay costs, due to their new high-deductible plan, out-of-network reimbursement schedules, and non-covered ICD codes.

49% of CareCredit cardholders said they would have postponed or not moved forward with the complete recommendation if CareCredit had not been available.5 Many dermatologists want to help, and may even discount or delay treatment to provide some relief, leading to less-than-optimal treatment and lower-than-expected practice revenue.

Get the tools that can make the cost conversation easier.

In the busy day-to-day hustle of your practice, discussing details of promotional financing can be a low priority and a distraction. The solution? Give patients the information they need to apply with CareCredit Direct. This free tool is easy to download onto a patient-dedicated tablet or computer in your practice. It helps facilitate the application process while patients are still in your office, freeing you up to focus on their care. Patients are able to apply on their own and get an instant credit decision. For details, visit carecredit.com/direct.

To make payment with CareCredit even more convenient, CareCredit is launching Pay My Provider in late 2016, which will give patients a way to pay their post-care bills via an online portal. Pay My Provider will also help accelerate post-care payment to the practice and improve cash flow. To learn more, visit carecredit.com/pmp.

Rates and resources custom-made for AAD Members.

Because CareCredit is an AAD Preferred Provider, AAD Members receive a special 2.9% provider processing rate on the 6 Month No Interest if Paid in Full Promotional Financing Option. And, you can choose which options to offer in your practice, as long as they are consistently communicated. CareCredit also provides free patient education materials to let patients know you accept CareCredit, such as brochures, displays, posters, welcome kits, clipboards and a comprehensive aesthetic patient special event kit.

For almost 30 years, CareCredit has helped solve the problem of rising out-of-pocket fees for nearly 190,000 healthcare practices by providing promotional financing options that can help patients overcome cost barriers.

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1. Dermatology Provider Study, September 2014, conducted for CareCredit by Chadwick Martin Bailey.
4. 2015 Milliman Medical Index Study Report.
5. Cardholder Engagement Study, Q2 2015, conducted for CareCredit by Chadwick Martin Bailey.

*Subject to credit approval. Minimum monthly payments required. See carecredit.com for details. Minimum purchase of $200.
**Subject to the representations and warranties in the CareCredit Agreement with Participating Providers, including but not limited to only charging for services that have been completed or that will be completed within 30 days of the initial charge, always obtaining the patient’s signature on in-office applications and the cardholder’s signature on the printed receipt.
HOT TOPICS IN DERMATOLOGY

69% of providers saw an increase in patient self-pay amount.¹

CareCredit promotional financing options* help give patients a convenient way to pay for:

- Co-pays, deductibles and out-of-pocket costs not covered by insurance
- Acne treatment, skin care products, wart removal and prescriptions
- Skin cancer procedures,* including Mohs surgery
- Many other medical dermatology treatments

The CareCredit health and wellness credit card can help patients overcome rising out-of-pocket costs.

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¹ Dermatology Provider Study, September 2014, conducted for CareCredit by Chadwick Martin Bailey.
*Subject to credit approval. Minimum monthly payment required. See carecredit.com for details.
**FDA-approved skin cancer treatments only.
An eye for detail in stitching and skin

BY EMILY MARGOSIAN, CONTENT SPECIALIST

Each month, Dermatology World addresses issues “in practice” for dermatologists. This month, Dermatology World talked to Elizabeth Spiers, MD, about her quilting techniques.

“We have to be very precise and careful as physicians. You also have to be pretty precise when you’re making a quilt.”

- Elizabeth Spiers, MD

Elizabeth Spiers, MD, a dermatologist in Doylestown, Pennsylvania, has always had an eye for detail. A lifelong sewer, she took her first class at eight years old, but didn’t dive into the more complex world of quilting until 2000. Since then, she’s assembled a variety of quilts using contemporary and traditional techniques and patterns.

Traditional patternmaking
Dr. Spiers prefers to construct most of her quilts via sewing machine as opposed to by hand, using a traditional piecing technique. “That’s when you have many small pieces of fabric, and put them together to form classic designs,” she explains. Although Dr. Spiers enjoys using contemporary fabrics, she mostly favors patterns that utilize classic quilting motifs. “For example, there’s one called the ‘log cabin’ which is a little center square with interlocking fabric squares placed all the way around it. There are star patterns. There’s something called a friendship star, a saw tooth star, and an Ohio star. (pictured right) Those are patterns that have been made for probably several hundred years,” she explains.

In addition to traditional techniques, Dr. Spiers also uses appliqué methods to create more pictorial quilts, including her favorite creation. “My first appliqué quilt had a pieced background with a big sunflower and pumpkins in a garden, and that’s probably my favorite.” (pictured right)

Focus on fabric
Dr. Spiers enjoys using a mix of fabrics in her quilts, ranging from large-scale florals, to small checks, to polka dots. “Quilting is about putting a lot of different fabrics together and finding complements that play up interesting elements in the other fabric,” she says. Most visually cohesive quilts feature a “focus fabric” with prominent colors or patterns to draw the eye, with more subdued choices to complement it. Dr. Spiers estimates that most quilts have a minimum of five to six fabrics, with the potential for many more depending on the complexity of the design.

Some quilters pursue unique sources for their quilting materials beyond the local fabric store. Dr. Spiers sources some of her quilting fabric from nearby Amish country, in addition to less traditional finds. “With the rise of the internet, sometimes interesting fabrics will come in my email inbox. I also inherited my mother’s fabric, so I will put some of her fabric into quilts, especially if I’m making them for family members,” she says. “I’ve also recycled old t-shirts into a t-shirt quilt, although I’ve not really done much with other clothing recycling.”

To view the archives of Balance in Practice, visit the DW website at www.aad.org/dw
**Physician precision**

While all successful quilts need an iron-clad pattern base to start, a good quilter is able to adjust and improvise to suit their own goals without compromising the finished product. “You may decide, well I really like this design but it needs to be bigger, so you can add extra borders. Say you want to make a bed quilt for a king-sized bed and the pattern is smaller, so you might add extra blocks. You might add designs from another pattern that you’ve seen,” says Dr. Spiers.

This necessary balance between precision and adaptability is something that Dr. Spiers relates to her work as a dermatologist. “It’s like making sure that you’re not prescribing a medicine that someone is allergic to by looking at the whole person. We have to be very precise and careful as physicians,” she says. “You also have to be pretty precise when you’re making a quilt. If you aren’t, you might have points that are blunted, blocks that don’t fit together, or corners that don’t match, and that does not make a pretty quilt. So it’s not all creative artistry, there is some precision involved to make sure everything comes together.”

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**Elizabeth Spiers, MD,** is a dermatologist in Doylestown, Pennsylvania.
ON THE FRONT LINES IN FLINT

Local dermatologists partner with state and federal agencies to investigate rash reports
“From anybody’s standpoint it was a public health catastrophe. In 2016, in the United States of America, it’s pretty hard to believe that this actually happened,” said Robert Soderstrom, MD, a dermatologist in Flint, Michigan.

“But unfortunately it did. It’s an incredible story, and for the state to basically be complicit in this, still arguing over whether they should provide any money to the city of Flint to cover damages, is an ongoing farce in my opinion.” The Flint water crisis, a string of events resulting in elevated lead levels in municipal drinking water, has beleaguered the city since 2014 and has drawn scrutiny from all levels of government.

While the situation in Flint is extraordinary, it joins a growing list of public health outbreaks that have required the attention of dermatologists. The skin is often the body’s first line of defense against disease, and in many cases the first place where signs of illness manifest. With a global population facing increased health threats from ecological disaster and bioterrorism, dermatologists have begun expanding on their historic role as the first watchmen for these tell-tale skin symptoms. After widespread reports of rashes began to occur in Flint following the contamination of the city’s water, local dermatologists, working with the Michigan Department of Health and Human Services (MDHHS), initiated a joint investigation with the Centers for Disease Control and Prevention (CDC) and the Environmental Protection Agency (EPA) to establish a systematic approach for diagnosing the incoming reports. >>
The symptoms
“After all the government agencies came to town in mid-January when this thing blew sky-high, one of the things they were hearing from a lot of people was that they were having rashes they were concerned with,” explains Dr. Soderstrom. Widespread media coverage of brown water and conflicting statements from public officials over the course of nearly a year (see timeline) had steadily fanned flames of public outrage over the potential long-term impact of exposure to water on citizens’ health. “It’s on the news here every day. It never stops. That’s distressing for people,” explains Walter Barkey, MD, a Flint dermatologist. “People couldn’t taste the lead or see the effects, but they could see that their water looked and smelled awful. There was a big concern that maybe this was causing an increase in rashes. You couldn’t go 15 minutes without an attorney trying to collect people for a class-action suit. There was so much mistrust in the air.”

As the reports continued to roll in, the MDHHS began sending notices to all practicing physicians in the area asking them to diagnose rashes and report their findings. The same afternoon he received his notice, Dr. Barkey was struck with the thought that this was a job for dermatology. “This is a situation where we have a unique role. We are the ones who can accurately diagnose skin rashes. You have to start with an accurate diagnosis or you can’t treat anybody,” explained Dr. Barkey. “With primary care people being asked to make these diagnoses, I could see no one was really going to figure out the rash angle without dermatologists getting involved.”

The response from the MDHHS, the CDC, and the other local dermatologists to Dr. Barkey’s suggestion was immediate. After making a handful of phone calls that afternoon, Dr. Barkey soon had the support of his peers and state and national public health agencies to conduct screenings. “I think the CDC was very happy to have us involved in terms of getting reasonably definitive diagnoses on what these patients’ skin problems were,” said Dr. Soderstrom. “Because initially they were talking in terms of getting reasonably definitive diagnoses on what these patients’ skin problems were,” said Dr. Soderstrom. “Because initially they were talking about having primary care physicians do this. When we stepped in, it made the whole thing much more definitive.”

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**Flint water crisis timeline**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug. 2014</td>
<td>Flint switches its water source from treated Lake Huron water from Detroit to Flint River water in an attempt to save approximately $5 million over two years.</td>
</tr>
<tr>
<td>Sept. 2014</td>
<td>The Flint Public Library declares city water undrinkable and begins contracting out water coolers for public and staff use.</td>
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<tr>
<td>Jan. 2015</td>
<td>Flint city council votes to return to purchasing water from the Detroit water system. The state of Michigan subsequently blocks Flint from returning to Lake Huron water from Detroit.</td>
</tr>
<tr>
<td>March 2015</td>
<td>The EPA becomes aware of major health concerns with Flint’s drinking water.</td>
</tr>
<tr>
<td>April 25, 2014</td>
<td>Residents hold a public meeting complaining about water quality. The Detroit water system offers to reconnect Flint free of charge, which is declined by the city’s emergency manager. Michigan state officials begin trucking in bottled water to employees stationed in Flint.</td>
</tr>
<tr>
<td>June 2015</td>
<td>The state of Michigan grants Flint an emergency loan of $7 million.</td>
</tr>
<tr>
<td>July 2015</td>
<td>Michigan Governor Rick Snyder is made aware of the water crisis.</td>
</tr>
</tbody>
</table>
The investigation
Over the 11-week period that the skin screenings took place, Flint dermatologists collectively screened 122 people, beginning March 3, and formally concluding May 13. Participants in the screenings were pre-evaluated using a questionnaire developed by Dr. Barkey and the CDC. Patients who fit the right timeline of water exposure and criteria of symptoms were scheduled to meet with one of four local dermatologists, who each set aside spare mornings or afternoons to see patients. “We’d have anywhere from eight to nine patients scheduled in an afternoon, but not all would show up. We were aiming to screen about 60 patients each,” said Bishr Al Dabagh, MD, a dermatologist in Flint.

“I’m not sure how many I saw myself, but I would guess it was somewhere in the range of 30, maybe a little more,” estimates Dr. Soderstrom. Genesee County, Michigan, which includes Flint, is home to a population of 400,000 that is served by seven area dermatologists. “We tried to correct that disparity by seeing everybody we could. We publicized things. We got a hotline they could call. There were over 400 patients who tried to get into the system but they didn’t all meet the case definition or they didn’t want to complete the interview process or they didn’t decide to make or keep the appointment for the free screening exam,” Dr. Barkey said.

During each screening the dermatologists followed a protocol that included a basic history and physical of each patient with an attempt to make a diagnosis. All aspects of the screenings, including cultures and biopsies, were provided by the dermatologists free of charge. “The dermatologists would send out a copy of the encounter form with a letter to each participant’s primary care physician recommending specific interventions and medication. We have access to $4 topical steroids through several participating pharmacies, so all of this was going to be at minimal or no expense,” Dr. Barkey said. As part of their collaborative effort with the dermatologists, the EPA also collected water samples from the residences of each screened participant to aid in establishing any potential future correlation between chemical levels found in their present water and the diagnoses they had.
received for their skin conditions. These tandem sampling efforts measured much more than the usual lead and copper levels that all Flint residents were having performed. “As part of the rash investigation the EPA measured levels of 20 metals, various organic compounds, chlorine, byproducts of chlorine (some of which are potential carcinogens), particulate matter, pH, hardness, and alkalinity,” Dr. Barkey said.

**Cutaneous cover-up?**
The ability of the dermatologists to definitively connect Flint residents’ rashes to the water system was complicated by the fact that the EPA did not collect water samples in Flint while the city was still using river water. “The whole thing is really very difficult because they switched back to Great Lakes water,” Dr. Soderstrom explains. “I think the gross negligence, frankly, is that when Flint was having all that trouble with water out of the river, no one was testing it at all [for the presence of metals like lead]. What we have are water tests now that they’re back on the Great Lakes water system.”

In an April 2016 *New York Times* article, Jevon McFadden, MD, an epidemiologist for the CDC, confirmed that the agency’s joint investigation with local dermatologists is indeed only focused on rashes that developed since the city switched back to the Detroit water system, stating that scientists “can only test the water that’s there now.”

**Correlation?**
Overall, although most of the public focus surrounding Flint related to the possibility of lead poisoning, a key takeaway of the skin screenings was that patients shouldn’t have major skin concerns relating to the metal. “There’s no way to absorb inorganic lead through our skin, so that shouldn’t be a worry,” Dr. Barkey said. Definitive conclusions linking the water and the reports of rashes were more elusive. “I think it’s hard to correlate a disease process with an exposure from a limited amount of patients. Some of them weren’t so sure, and some would swear up and down that it was the water. Like I told them, I can only make an observation,” Dr. Al Dabagh said. “I won’t minimize their symptoms or deny that there could be some sort of link. This is the focus of the CDC’s study.” Although nearly all of the Flint dermatologists reported seeing primarily

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**Past, present, and future: dermatology’s role in biological warfare and disease outbreak**

“'I think one way to improve the perception of dermatology within the house of medicine is to realize that our specialty provides the sentinels; we are the first physicians to witness, investigate, and explain a lot of different conditions,” explains Scott Norton, MD, MPH. Historically, most of the pathogens that the CDC and World Health Organization (WHO) have identified as bioweapons (because they are easily weaponized and have the highest potential for fatalities) are likely to present with some form of cutaneous finding. As a result, “dermatology was recognized as a necessary partner in the national surveillance for any sort of biological warfare,” said Dr. Norton, who has collaborated with the CDC in the past regarding how to approach potential cases of anthrax and smallpox.

**Smallpox**

After attacks on Sept. 11, 2001, growing public unease and rumors regarding missing stores of smallpox virus prompted the Department of Defense (DoD), Department of Health and Human Services, and the Department of Homeland Security (DHS) to focus on the possibility of a smallpox outbreak in the United States. “Certainly, the biological weapon that would cause the most terror and the greatest disruption to society would be the reappearance of smallpox. Its reappearance would be a catastrophic medical, public health, political, and criminal event,” Dr. Norton said.

Due to the certainty that smallpox, if it were to reappear, would present with skin findings and that most modern physicians are unfamiliar with the disease, dermatologists were quickly identified as having the greatest ability to recognize and diagnose a true case of the disease. The increased public concern over smallpox led to dozens of suspected cases across the country. Each suspected case threatened to disrupt health care delivery in its particular community so dermatologists were called upon to diagnose these alleged cases correctly. “We had to get the word out what to expect in an index case of smallpox. In the first
eczematous rashes such as atopic dermatitis, they also saw alopecia, urticaria, and itching without visible rash. They were hesitant to directly fault water exposure as their cause — but were also hesitant to fully rule it out. “A lot of the diseases I saw have other etiologies to explain them. But does that mean that they weren’t exacerbated or caused by the water? I can’t tell you that,” Dr. Al Dabagh said.

The time of year that the majority of rashes hit also compromised any quick answers that could have been deduced from the screenings. Several of the local dermatologists noted that the colder climate in Michigan during the late fall to early winter had consistently filled their practices with eczema patients in prior years. “There is a higher incidence of eczema in the winter in Michigan in general, so I see a higher frequency of it in my practice just because of the environment and the weather. If I hadn’t known they were a Flint water case, I could probably have attributed it to another cause,” Dr. Al Dabagh explained.

Dr. Soderstrom agreed that the timing of the crisis complicated any immediate conclusions about whether the frequency of the rashes was abnormal. “In Michigan in the winter time, few months after 9/11, there were about 10 hospitals that shut down their emergency rooms because they feared they had a patient who actually had smallpox in their clinic,” Dr. Norton said. “Fortunately, no one had a true case of smallpox. Most of the suspected cases were a variant of chickenpox, disseminated zoster, or disseminated herpes in patients who had other underlying medical concerns that made the viral illness much more dramatic than it would ordinarily be.”

In response, Dr. Norton and other AAD members collaborated with the CDC to develop appropriate smallpox surveillance protocols, in addition to guidelines regarding smallpox vaccines. “Although we call it the smallpox vaccine, it’s a different virus,” Dr. Norton explains. “It’s a live vaccinia virus that’s related to smallpox and confers full immunity. It’s amazingly effective, but the problem is that in people who are pregnant, have atopic dermatitis, or are immunosuppressed, there is a risk that the vaccinia virus will replicate in an uncontrolled — and potentially lethal — way.”

Despite the potential complications of a smallpox vaccination program, the national push to resume vaccinating Americans against smallpox was strong. Dermatologists were again called on for their expertise to help decide if and when vulnerable individuals should be vaccinated. “It was difficult to prepare recommendations for people with atopic dermatitis, because even when the disease is quiescent, atopics are still at risk for virulent replication of the vaccinia virus across the skin. So dermatologists were necessary to help the public health authorities decide who would be eligible for smallpox vaccination.” Ultimately it was determined that people with atopic dermatitis should be vaccinated only if an actual outbreak of smallpox was underway in their community, knowing that the devastating consequences of contracting smallpox far outweighed the potential risks of the vaccine.
Anthrax

Approximately one week after 9/11, an already inflamed national climate was further stoked by anthrax attacks that infected 22 people, killing five. Immediately, concerns were raised that anthrax spores had the potential to be aerosolized for more widespread use as a biological weapon. Due to the visible effects of cutaneous anthrax, Dr. Norton and other AAD members worked with the CDC to provide the public with accurate information for identifying cases of cutaneous anthrax. “To our surprise, half of the 22 people who got anthrax in those terrorist attack had cutaneous disease. That was unexpected, but the CDC immediately recognized that dermatologists needed to be on board,” Dr. Norton said. “The AAD’s taskforce got together to create an algorithm for the clinical diagnosis of cutaneous anthrax, which the CDC then adopted. Fear of anthrax was a huge concern at the time and I remember the British journal The Lancet listed the AAD’s recommendations as the top website of the week.”

Because it was important to reduce possible public hysteria, the AAD report also emphasized that anthrax is not contagious between people. “Anthrax is a scary disease, and we felt that disseminating this information would help counter its terrifying aspects by letting people know that it can be managed in very simple ways,” Dr. Norton said.

Continued from p. 37

A community in need

Although the future of Flint still remains uncertain nearly two years since the crisis began, there have been some positives gained from the situation. “I didn’t know my fellow dermatologists well before. Boy have I gotten to know them well after this,” Dr. Barkey says. “We practice as solo people, and had a lot of respect for each other, but never spent this much time before talking about things. So there have been good things to have come out of this from a community perspective.”

Dr. Soderstrom agrees that their participation during the crisis marked a turning point for the dermatologists in the area. “I do think this is an
A major event in the history of American public health — the clinical observation of HIV in the United States — was in part based on cutaneous findings observed by dermatologists. “There were general dermatologists in New York City, San Francisco, and Los Angeles who noticed that they were starting to see two or three cases a month of a disease they were told in residency that they might never see: Kaposi’s sarcoma. If you start regularly seeing a disease that you’ve been told to expect once in a lifetime, that’s very striking,” recounts Dr. Norton. “The dermatology community and the CDC recognized that there was something unusual going on, and when the CDC went to investigate with the help of these dermatologists, they essentially discovered HIV.”

Dr. Norton argues that the dermatologic response in Flint should set a precedent for the specialty. Future environmental and geopolitical threats to human health are likely to appear as skin diseases. “Dermatologists aren’t always trained to look at the world that way. We’re trained to devote our intellectual energies and our diagnostic skills on the individual patient whom we’re seeing right at that moment. But many times the condition that we’re seeing isn’t occurring in just that particular patient. There could be other people — perhaps family members or coworkers — who have the same condition. I would argue that we need to remember this as we practice clinical dermatology. For me, it adds an element of excitement to know I’m always on the lookout for something worth calling my state public authorities about: are we seeing something new? Does this involve more than just my patient? Are we going to nip this in the bud? Have we detected it in time?”

For now, dermatologists in Flint hope to provide their community with some much-deserved answers about the state of their health and safety. “Our goal is to establish whether the water that we have right now coming out of your tap is safe to bathe or shower in,” Dr. Barkey said. Time will tell if the people of Flint still have cause for concern. dw
Experts discuss current and new treatments for hyperhidrosis
It’s a cool day and you’re relaxing in the shade. All of a sudden you find yourself drenched. It’s not raining, you’re not nervous, angry, or anxious, and you haven’t moved from the comfort of that shady spot. You’re simply sweating excessively. According to the International Hyperhidrosis Society (IHHS), this phenomenon occurs in more than 3 percent of the world’s population — roughly 220 million people. These people suffer from hyperhidrosis — a condition characterized by excessive sweating that isn’t caused by heat, exercise, or emotions. Rather, patients with primary focal hyperhidrosis often find their armpits, palms, soles of the feet, and/or face and head drenched in sweat even when they are in a comfortable temperature or at rest.

Unfortunately, this condition not only leads to discomfort; it also has significant quality-of-life effects. “When you look at DLQI [Dermatology Life Quality Index] scores of people with various and serious dermatologic diseases like psoriasis and atopic dermatitis, hyperhidrosis is right up there with them in terms of the negative effects on people’s quality of life,” said David Pariser, MD, secretary and founding member of the IHHS. “For many patients this is an embarrassing situation. They don’t talk to their family, friends, or even physicians about it.” Fortunately, physicians, researchers, and pharmaceutical companies are taking more notice of this devastating condition and are working to perfect current treatments and develop new ones. Dermatology World takes a look at some of the tried-and-true treatments and new options for patients with hyperhidrosis, including:

- OnabotulinumtoxinA
- Topical onabotulinumtoxinA
- Ultrasound
- Microwave thermolysis
- Lasers
- Conventional treatments
- Systemics
OnabotulinumtoxinA

When Dr. Pariser mentions OnabotulinumtoxinA (Botox®) to his hyperhidrosis patients as a possible treatment, he often gets a puzzled look. “They will say, ‘Botox? Isn’t that the stuff that people get injected for wrinkles? How could that possibly stop sweating?’ The answer is that it blocks a substance called acetylcholine which is released through the sympathetic nerves which stimulate the sweat glands to sweat,” Dr. Pariser said.

Botox has been a tried-and-true treatment for this condition for more than a decade — approved by the U.S. Food and Drug Administration (FDA) for treatment of hyperhidrosis in 2004. “It was approved for axillary sweating but it’s commonly used for other areas of the body.” Indeed, according to the IHHS, the injections can reduce sweating by 62 to 87 percent in axillary hyperhidrosis, and 80 to 90 percent in palmar hyperhidrosis. Additionally, “the injection doesn’t take very long to do — 10 to 15 minutes or so. The patients can basically get up and go about their business.”

According to Dr. Pariser, the treatment is often covered by insurance, making patient access a little easier to come by. And in terms of pain, for axillary treatments historically, there’s a very simple procedure of using ice and pressure which provides excellent anesthesia.

However, Botox does not offer permanent relief. “That’s the problem,” Dr. Pariser said. “I tell patients it’s going to last six to nine months. In some people, it’s three months, and in some people it’s a year. There’s not as much controlled data on palmar and plantar injections. A lot of people really undertreat that so palmar and plantar treatments generally do not last as long.” Additionally, Botox is considered off-label for treating patients under the age of 18. Yet, despite these drawbacks, Dr. Pariser’s patients are generally content. “People love the treatment. They love not having sweat rings under their arms every day or dripping palms.”

Topical onabotulinumtoxinA

For patients who are a bit squeamish about getting repeated injections, researchers are testing topical Botox for hyperhidrosis. According to Richard Glogau, MD, clinical professor of dermatology at the University of California San Francisco, the method of action for the topical gel is identical to the injections in that, at the nerve endings, the toxin blocks the release of acetylcholine, the chemical messenger which directly stimulates the sweat glands. “The only difference is the delivery system,” Dr. Glogau said. “Instead of being injected, you’re using a proprietary peptide attached to the toxin to actively transport it through the skin.”

In 2007, Dr. Glogau tested the gel on 10 patients with axillary hyperhidrosis, applying it for one minute and leaving it on for an hour, and found a 40 percent average reduction in sweating (Dermatol Surg. 2007;33:S76–S80). Since then, there have been only a handful of phase 2 trials testing the topical gel, and Dr. Glogau says there are still many unanswered questions. “We don’t know yet how often patients will have to be treated or how long it will last because the phase 2 studies were done with four-week follow-up intervals. They’re still basically looking to confirm the appropriate dose and duration beyond the month that’s been studied.”

When it comes to treating palmar and plantar hyperhidrosis, “We’re not there yet. Also, it’s going to require a doctor’s visit and the contact time is probably a minimum of half an hour so there’s some time sitting around the doctor’s office with the gel in place.” Yet, Dr. Glogau thinks that the treatment holds promise. “To use the injectable, particularly in the hand, is pretty cumbersome and painful. Obviously the topical can wipe all that away. I’m sure there’s going to be a lot of interest in looking at this down the road.”

Ultrasound

While Botox is proving to be effective in blocking the mechanism that causes sweat, other therapies seek to completely destroy the sweat glands. “Destroying the glands was probably the first thing that was ever done to treat this condition,” said Mark Nestor, MD, PhD, associate professor of dermatology at the University of Miami Miller School of Medicine. “Surgically, people just cut out that area, put in skin grafts, and, boom, the glands were gone. It’s not a very pleasant treatment to go through.” However, according to Dr. Nestor, the destruction theory has evolved over the years with the introduction of the use of ultrasound. By using the images produced by the ultrasound, dermatologists can locate the sweat gland and focus a beam of ultrasound energy on that gland. “The idea is that by using micro-focused ultrasound we theoretically can target the energy and heat the ducts or glands and destroy them.”

“We started looking at this for hyperhidrosis several years ago,” Dr. Nestor said. “I don’t think we’re at the point yet for FDA approval. But micro-focused ultrasound is approved in general, so people can use it. It certainly works.” Indeed, in 2014, Dr. Nestor
conducted two studies testing high-intensity micro-focused ultrasound plus visualization to treat patients with axillary hyperhidrosis. The first study found that more than half of the patients saw a greater than 50 percent reduction in baseline sweat production. The second study looked at the patients' Hyperhidrosis Disease Severity Scale (HDSS) scores, and found a positive HDSS response rate of 67 percent (J Clin Aesthet Dermatol. 2014 Apr; 7(4):14-21.) However, Dr. Nestor says more research will be needed to determine the most effective energy levels for different depths of the skin when using this treatment. “This is an evolving science.”

So far, however, Dr. Nestor argues that this technology is proving to be promising. “It’s not invasive. That’s one of the biggest advantages. Also, it’s very specific. With this you can really target the level extremely accurately.” However, there are some disadvantages. “It is somewhat painful but that’s easily remedied by injecting a little anesthesia. Also, for palms and soles this is not a good treatment option as it’s much more difficult to treat those glands because they are deeper in the skin.” Finally, like many emerging treatments, ultrasound is not covered by insurance, making access hard to come by.

Regardless, Dr. Nestor says there is still more to learn about this particular treatment option. “We need to better understand the energies and the combinations of depths. One of the things about micro-focused ultrasound that is so good is that these different attachment heads have different aspects of depths and we want to optimize that to get the least amount of any possible side effects, while being effective. This treatment is continuing to evolve from that perspective.”

**Microwave thermolysis**

While several options only offer temporary hyperhidrosis treatments, the use of electromagnetic energy offers more lasting relief. “Microwave thermolysis or the miraDry® device is a permanent treatment for underarm sweating,” Dr. Pariser said. This device was cleared by the FDA in 2011 to treat hyperhidrosis — although the technology has been used for cosmetic purposes and other medical procedures for several years. Unlike the ultrasound therapy, microwave thermolysis sends electromagnetic energy to the sweat glands two to five millimeters below the skin.
surface where they are heated and destroyed. According to the IHHS, most patients require two treatments — each of which takes about an hour.

The use of this procedure has shown encouraging results. In 2012, researchers at the University of British Columbia treated 31 adults with axillary hyperhidrosis with one to three sessions over a six-month period. At the one-year follow-up, 90.3 percent of the patients had HDSS scores of 1 or 2 and at least a 50 percent reduction in sweating. About 85 percent of the patients indicated a reduction of at least five points on the DLQI (Dermatol Surg. 2012 May;38(5):728-35).

However, while this particular modality is proving its worth, there are some disadvantages. “The microwave thermolysis is never covered by insurance,” Dr. Pariser said. In fact, according to Miramar Labs — developers of the miraDry technology — treatments can cost $2,000. “It’s also considered off-label for the treatment of patients under age 18, and it’s only approved for the underarms.” Additionally, as is the case with other treatments, microwave thermolysis does not come without side effects. “There is a good degree of swelling and pain afterwards,” Dr. Pariser said. “I usually tell people that they need to plan on staying at home the next day, taking high doses of ibuprofen, and applying a lot of ice to keep the pain down. However, for some people it’s worth it in order to get a permanent response.”

Lasers
Laser therapy is often a go-to treatment for hair and tattoo removal and the treatment of vascular and pigmented lesions. However, researchers are starting to look beyond traditional uses of the technology for conditions like hyperhidrosis. “It is a relatively new treatment for hyperhidrosis. What we do is we use the laser energy to destroy a good enough number of the sweat glands to reduce the sweating to normal,” said Bruce Katz, MD, clinical professor of dermatology at Mount Sinai Hospital. According to Dr. Katz, the concept stemmed from the use of lasers with side-firing fibers to treat cellulite. “We were doing laser liposuction where we would insert a laser fiber under the skin under local anesthesia to melt the fat. We realized that if we can aim it under the dermis and shoot it up at the undersurface of the skin, we can target sweat glands at the same time and reduce excessive perspiration.”

Although still a concept in its infancy, using lasers for hyperhidrosis is showing potential. In 2014, Dr. Katz tested the theory, treating 20 patients with scores of 3 or 4 on the HDSS with a single treatment using a 1,440-nm Nd:YAG laser with 800 mcm side-firing fiber. “We found that it was effective in about 80 percent of patients, but it was also long lasting.” In terms of benefits of the treatment, Dr. Katz says that the laser

### Hyperhidrosis: Treatment breakdown

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Indications</th>
<th>Length of procedure</th>
<th>Longevity</th>
<th>Side effects</th>
<th>Insurance coverage</th>
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<tbody>
<tr>
<td><strong>OnabotulinumtoxinA</strong></td>
<td>Axillary, palmar, plantar, face/head</td>
<td>10-15 minutes</td>
<td>Temporary@ 3-12 months</td>
<td>Pain (palmar and plantar)</td>
<td>Varies by insurance plan</td>
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<td><strong>Topical OnabotulinumtoxinA</strong></td>
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<td>30-60 minutes</td>
<td>TBD – more research required</td>
<td>TBD – more research required</td>
<td>No</td>
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<tr>
<td><strong>Ultrasound</strong></td>
<td>Axillary</td>
<td>2+ treatments @ 20 minutes each; 2-4 weeks apart</td>
<td>Considered permanent – more research required</td>
<td>Pain</td>
<td>No</td>
</tr>
<tr>
<td><strong>Microwave thermolysis</strong></td>
<td>Axillary</td>
<td>2-3 treatments @ 1 hour each; 3 months apart</td>
<td>Considered permanent – more research required</td>
<td>Pain, swelling</td>
<td>No</td>
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has the capability to directly target the glands. “We are aiming the laser beam right at the sweat glands. We don’t affect other aspects of the skin. It doesn’t damage other blood vessels or nerves.” Additionally, Dr. Katz indicates that with local anesthesia, the procedure has relatively few side effects. “Patients really have minimal downtime. After the treatment they may have a little bit of swelling and tenderness, but most people return to work the next day.”

Like many of the treatments for hyperhidrosis, however, the use of lasers is not covered by insurance. Additionally, the therapy is currently only applicable to axillary hyperhidrosis. “You really can’t circulate the fiber under the skin of the hands and feet because of the thickness of the skin. There’s really no space to insert the laser fiber.” Regardless, Dr. Katz is looking forward to other studies testing this treatment option. “I would say that it’s possible that we will eventually have lasers that don’t have to go under the skin and can go right through the surface of the skin to treat hyperhidrosis. We wouldn’t have to use local anesthesia. That’s my prediction, but we’ll have to see.”

**Conventional treatments**

Before there were Botox injections, sounds, waves, and lasers, there were more conventional modalities available for hyperhidrosis patients — many of which are still viable options today. Aluminum chloride has been used in antiperspirants since the early 1900s to curtail excessive sweating, with minimal side effects — itching and stinging — reported. “Aluminum chloride preparations and the newer clinical strength antiperspirants — which rely on more complex aluminum zirconium salts — do have some degree of effectiveness,” Dr. Pariser said. “We always try topical treatments in everyone just to see. Oftentimes, it’s required by insurance.”

According to the IHHS, the salts block the sweat gland ducts. “People who have very mild excessive sweating may see some improvement,” Dr. Pariser said. “But if you have rip-roaring, sweat-through-your-clothes, dripping-hands hyperhidrosis, those topical agents are just not going to work.” Similarly, these clinical strength antiperspirants have little effect on palmar and plantar cases.

Another conventional treatment for hyperhidrosis is iontophoresis — a therapy that has been used since the 1940s. Patients put their hands and feet in a pan of water for 20 to 40 minutes about three or four times a week. The device shoots mild electrical currents through the water; the water passes through the skin’s surface which causes sweating to stop. The theory behind this treatment option, however, is a bit fuzzy. “Nobody knows 100 percent for sure how this works,” said Dee

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<th>Insurance coverage</th>
</tr>
</thead>
<tbody>
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<td><strong>Lasers</strong></td>
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<td>Considered permanent – more research required</td>
<td>Swelling, tenderness</td>
<td>No</td>
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<td>Varies</td>
<td>Temporary</td>
<td>Itching, stinging</td>
<td>Varies by insurance plan</td>
</tr>
<tr>
<td><strong>Iontophoresis</strong></td>
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<td>20-40 minutes; 3-4x/week</td>
<td>Temporary</td>
<td>None reported</td>
<td>No</td>
</tr>
<tr>
<td><strong>Systemics</strong> (anticholinergics)</td>
<td>Axillary, palmar, plantar, face/head</td>
<td>Varies</td>
<td>Temporary</td>
<td>Vary – overheating, dry mouth/eyes, constipation</td>
<td>Varies by insurance plan</td>
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Anna Glaser, MD, president and founding member of the IHHS. “We think the electrolytes that are in tap water get electrically stimulated and form a little plug inside the sweat ducts that prevent the sweat from coming out. We know that if you use distilled water — that has all the electrolytes taken out — it doesn’t work. We also know that if you take a piece of Scotch tape and you repeatedly Scotch tape off the top layers of skin, the sweating starts to come back.”

Regardless, iontophoresis is particularly helpful in treating patients with plantar and palmar hyperhidrosis. Conversely, this treatment is not ideal for axillary, face, and groin cases given the way treatment is delivered. “It’s hard to submerge your underarm or face in water,” Dr. Glaser said. Patients have reported no significant side effects and some have seen long-term benefits by using the device just once a week. According to the IHHS, iontophoresis reduced sweating in 91 percent of patients with plantar and palmar hyperhidrosis. While treatment is not covered by insurance, patients can purchase the R.A. Fischer or the Hidrex models that are registered with and cleared by the FDA for $675 to $975, depending on the model.

Systemics

While many of the treatments for hyperhidrosis are specific to one or two areas of sweating, systemic treatments offer patients who have sweating in multiple areas some relief. “We used to think that hyperhidrosis was just in the underarms or hands,” Dr. Glaser said. “But what we’ve found is that patients may have a little under the breast, in the groin, maybe in the back of their neck. The problem is that they might have one area that’s worse but they have lots of areas that are bad, and you want to try to manage the whole disease spectrum.”

According to Dr. Glaser, for patients who sweat excessively as a result of anxiety and stress, beta blockers (propranolol) that slow down the heart rate and lower blood pressure may offer some relief. Similarly, alpha adrenergic agonists (clonidine) can work for patients with menopausal-related sweating, or those who sweat as a result of anti-anxiety or anti-depressant medications. For the general hyperhidrosis patient — where anxiety, menopause, and/or medications are not the primary drivers behind the sweating — anticholinergics (glycopyrrolate, oxybutynin, benztropine, and propantheline) may provide some relief. While off-label and not FDA-approved for hyperhidrosis, “The anticholinergics make the most sense from a mechanism-of-action perspective [for patients with multiple affected sites] because they block the release of acetylcholine from the nerve ending.” Dr. Glaser said.

However, this treatment is not without its challenges. “Really what we’re trying to do is capture one of the multiple side effects of the anticholinergics,” Dr. Glaser said. “Most of them are used for something like overactive bladder and when you’re looking at the side-effect profile you’ll see a whole list like dry eyes and decreased sweating. So what we’re trying to do is get that specific side effect but without all the other side effects. That’s a challenge because it’s dose dependent — the higher the dose that we’re using, you start to see more side effects including the one that we’re looking for which is reduced sweating.”

According to Dr. Glaser, another problem with anticholinergics is that the medication significantly reduces sweating from all over the body. “We know that sweating is the way that the body cools itself down when it’s hot. So you have to be careful to reduce the sweating where you want to, but not so much where they have the inability to sweat when they need it — especially people who do a lot of athletic activities or work outdoors. Also, oftentimes we’re battling dry eye, dry mouth, constipation, and some other side effects that can go along with that.”

Overall, Dr. Glaser thinks anticholinergics can be a viable option for hyperhidrosis patients, but more trials will be needed to determine specific dosages. “There really are no prospective, well-done, clinical trials.” For now, Dr. Glaser doesn’t recommend utilizing anticholinergics as a monotherapy. “When I’m prescribing these, I’m using them in combination with other focal treatments. So maybe I’m using it with a topical prescription antiperspirant or maybe we’re using Botox for their underarms to get that area under control and then I’m using some lower-dose anticholinergics to help control their sweating in other areas.” Regardless of these challenges, Dr. Glaser is looking forward to more research on systemic treatments, and how the medications can be adapted to specifically suit hyperhidrosis patients. “The next wave is hopefully going to be topical anticholinergics so we can minimize those side effects associated with systemic anticholinergics.”

Going forward Dr. Glaser thinks that research on hyperhidrosis treatments will start to focus more on non-axillary hyperhidrosis. “We need more studies with new and novel drugs in new and novel areas because patients often have multiple areas that are affected. That’s what we’re lacking.” Overall, current treatments for hyperhidrosis are just the tip of the iceberg. “Hyperhidrosis is definitely getting more attention, which is exciting and good for patients and physicians. It’s nice that people are really starting to understand the impact of the condition on our patients — the quality-of-life issues and how impactful treatment can be for them.”

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Upcoming CME Activities

Basal Cell and Squamous Cell Cancer Dermatopathology and Fundamentals of Mohs Surgery

DoubleTree Hotel San Diego, Mission Valley – San Diego, CA

November 1-2, 2016 – Basal Cell and Squamous Cell Cancer Dermatopathology
- Introductory (Day 1) and Advanced (Day 2) discussions
- Pure pathology approach to understanding BCC and SCC characteristics
- Examination of reactive changes commonly visualized at biopsy sites
- Identification of non-BCC and non-SCC structures in Mohs-excised tissue

November 3-6, 2016 – Fundamentals of Mohs Surgery
- Basic Mohs surgical, histopathologic, and laboratory skills for physicians and technicians
- Practice efficiencies including office/laboratory design, management of patient flow and tissue specimen transfer
- Appropriate indications for Mohs, based on histologic subtype and anatomic location
- Critical mapping considerations for proper orientation, correlation of histologic findings to surgical wound
- Multiple microscope laboratory sessions featuring small group and independent Mohs case reviews

Closure Course and Dermatologic Surgery: Focus on Skin Cancer

Sandestin Golf and Beach Resort – Destin, FL

May 24-25, 2017 – Closure Course
- Enhanced skill and confidence levels in approaching new and complex repairs
- Specific closure techniques appropriate for various anatomic locations
- Application of modified reconstruction decisions based on unique characteristics of defects
- Incorporation of valuable surgical pearls and new techniques in hand-on laboratory session

May 25-28, 2017 – Dermatologic Surgery: Focus on Skin Cancer
- Current topics for dermatologic surgeons and cutaneous oncologists at all levels of training and experience
- Expert panel discussions: complex closure approaches, melanoma treatment options and management of other challenging tumors
- Review of dermoscopy advances in melanoma diagnosis
- Comprehensive literature reviews
- Small-group histopathology discussions; Mohs and non-Mohs cases available for review

For additional information regarding ASMS educational activities, membership opportunities, and patient resources, please contact:

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ON TARGET

New approaches to skin cancer treatment and prevention
Soon-to-be published new AAD guidelines on the diagnosis and management of nonmelanoma skin cancer will likely hold few surprises, but that speaks to the soundness of current practice rather than to a lack of progress, said Murad Alam, MD, professor and vice chair of dermatology at Northwestern University’s Feinberg School of Medicine. “If there’s a well-established approach, there’s always the risk we become complacent and we continue to treat in a certain way, despite the fact that there’s new evidence indicating that a different method might be preferable,” said Dr. Alam, a co-chair of the nonmelanoma skin cancer clinical guidelines workgroup. “But we did a very thorough review of the evidence in a systematic, unbiased manner according to the best guideline process currently available. And we’ve come to the conclusion that many of those treatment modalities that we currently consider first line remain first line.”

The guidelines cover only basal cell carcinoma and squamous cell carcinoma, not the rarer nonmelanoma cancers that account for a much smaller proportion of such tumors. Dr. Alam noted that some dermatologists now prefer the more descriptive term “keratinocyte carcinoma” to refer to BCC and SCC, rather than “nonmelanoma,” but no position will be taken in the guidelines.

Surgical removal “remains at the top of the heap in terms of how skin cancers are treated,” Dr. Alam noted, adding that the appropriate use criteria for Mohs surgery published in the *Journal of the American Academy of Dermatology* (2012;67(4):531-550) were included in the group’s discussions and will be reflected in the final guidelines. He urged dermatologists to take a moment to read the guidelines when they appear in an upcoming issue of *JAAD*. “We’re keeping them pretty darn short, so they can each be read in 10 to 20 minutes,” he remarked. “These are important to all dermatologists, and since it is impractical for most of us to read the entire world literature on an ongoing basis, this will give a quick review of where we are right now.”

Four other dermatologists who are experts in nonmelanoma skin cancer, including two who served on the guidelines group with Dr. Alam, provided insight into current research and potential future directions relating to the management of BCC and SCC, including:

- **Agents for chemoprevention**
- **New hedgehog inhibitors**
- **Managing pediatric organ transplant recipients >>**
**Agents for chemoprevention**

An essential human nutrient is gaining attention for its role in preventing new BCC and SCC tumors. Nicotinamide, a form of vitamin B3, was studied in a phase 3 randomized trial recently published in the *New England Journal of Medicine* (2015;373:1618-1626). The authors randomly assigned 386 participants who had had at least two nonmelanoma skin cancers in the previous five years to receive either 500 mg of nicotinamide twice daily or a placebo for 12 months. The results showed a 23 percent lower rate of new nonmelanoma skin cancers overall among the nicotinamide group, which had 20 percent fewer new BCCs and 30 percent fewer SCCs. The number of actinic keratoses was 13 percent lower at 12 months among the patients receiving nicotinamide. The authors noted that “unlike nicotinic acid (niacin), nicotinamide does not cause vasodilatory side effects such as flushing, itching, hypotension and headaches.”

Commenting on the *NEJM* study, Thomas Stasko, MD, professor and chairman of the department of dermatology at the University of Oklahoma College of Medicine, said it “really showed some remarkable results for an agent that’s fairly innocuous, has a very low side effect profile, and is relatively inexpensive as well. A lot of people are putting their high-risk patients on nicotinamide. It needs more studies that are rigorously done to really tell us how good it is, but it’s a useful adjunct at this point.”

Chrysalyn D. Schmults, MD, associate professor of dermatology at Harvard Medical School, said her practice has recently begun recommending nicotinamide for patients with extensive sun damage. “Nicotinamide has a better side-effect profile, we think, than oral retinoids,” she said. “We have a lower threshold for putting people on nicotinamide; basically, anyone with extensive sun damage and a history of squamous cell formation, we think it’s appropriate to put on nicotinamide.”

Dr. Schmults said she has reduced the threshold for using the oral retinoid acitretin based on a study within her group. “We published a paper last year showing that people who have multiple squamous cell cancers have a higher chance of ultimately forming an aggressive one and therefore having poor outcomes,” she remarked (*JAMA Dermatol.* 2015 Nov;151(11):1220-5). “Based on that, we changed our thinking. We used to wait for people to have a high-stage tumor before prescribing acitretin. As for other agents that have come under discussion as possibly having chemopreventive properties, “we don’t use selenium or beta-carotene. I don’t think there’s much data on them; nothing as convincing as there is for nicotinamide.” Dr. Alam said a discussion of agents tested for chemoprevention will be included in the guidelines. “In general, the evidence is that some of them may be helpful; a lot of them, such as selenium, don’t appear to be very helpful,” he said. “It would be nice to have more data so that in the next iteration of these guidelines, we might be able to give even more guidance.”

**New hedgehog inhibitors**

The most significant development in the management of advanced BCC in recent years has been the introduction of drugs that inhibit the hedgehog pathway, said Christopher Bichakjian, MD, professor of dermatology and associate chief of the division of cutaneous surgery and oncology at the University of Michigan and a co-chair of the nonmelanoma skin cancer clinical guidelines workgroup. “In the guidelines, we’re still very much in the process of trying to define the appropriate use of these drugs,” he noted. “I think most dermatologists, and rightly so, feel that the vast majority of basal cell carcinomas can and should be managed surgically. However, while any tumor is theoretically resectable, for some patients surgery may be associated with unacceptable morbidity, in which case systemic therapy would be a more realistic option. The challenge is that the morbidity of surgery depends on the clinical and histological features of the particular tumor, the experience of the surgeon, and, last but not least, the desires and expectations of the patient. It is nearly impossible to capture all these variables into a straightforward treatment recommendation. The only exception is metastatic disease, which is exceedingly rare, for which hedgehog inhibitors are essentially the only treatment option.”

The first hedgehog inhibitor, vismodegib, was approved by the U.S. Food and Drug Administration in 2012. A second agent, sonidegib, received FDA approval last year. A phase 2, multicenter study of sonidegib in patients with advanced BCC, published online in *JAAD* (http://dx.doi.org/10.1016/j.jaad.2016.02.1226), demonstrated objective response rates of 57.6 percent and 43.8 percent for patients with locally advanced BCC receiving 200 mg and 800 mg daily of sonidegib, respectively. In patients with metastatic BCC, the response rate was 7.7 percent in the 200 mg group and 17.4 percent in the 800 mg group. The authors noted that while most adverse events were grade 1 or 2, consistent with the safety profile of other hedgehog pathway inhibitors, “some patients discontinue treatment because of low-grade adverse events that cause significant discomfort.”

Itraconazole, a third hedgehog inhibitor, is an antifungal drug that Dr. Stasko characterized as “something interesting on the horizon.” In a study published online Feb. 3, 2014, in the *Journal of Clinical Oncology*, itraconazole was shown to reduce BCC tumor.
size after one month of treatment, though the authors concluded it is less potent than vismodegib. However, as Dr. Stasko pointed out, “its side-effect profile is much less severe than that of other hedgehog pathway agents.” A handful of clinical trials of itraconazole are now recruiting or underway, including two that are testing the drug in a topical formulation and one that is testing it in basal cell nevus syndrome.

“We don’t know what the long-term results will be” for hedgehog inhibitors, said Dr. Bichakjian. “These drugs are able to shrink most tumors, but will the patient be able to tolerate treatment and if not, when and in what capacity will the tumors recur?”

Managing pediatric organ transplant recipients

Pediatric organ transplant recipients constitute a small but growing segment of nonmelanoma skin cancer patients. While the number of pediatric organ transplants has remained relatively steady over the past five years, improved post-transplant survival has led to an increase in malignancies among these immunosuppressed patients. Nonmelanoma skin cancer is the second most common malignancy in this population.

Joyce M. Teng, MD, associate professor of dermatology and pediatrics and director of pediatric dermatology at Stanford University, said that each year she diagnoses a few children with melanoma and nonmelanoma skin cancer. Especially vulnerable are those who require high levels of immunosuppression, such as leukemia patients and children receiving a stem cell or heart transplant. “Those patients, if they’re not educated before the transplant in terms of sun protection, can develop skin cancer very, very early,” she said. “After transplant, they are particularly prone to fungal infections. One particular antifungal medication, voriconazole, actually causes photosensitivity and increases the risk of skin cancer, so we see some nasty nonmelanoma skin cancer in very young children, 10 to 12 years old.”

Working closely with the infectious disease and organ transplant teams, Dr. Teng and her colleagues address the levels of immunosuppression, the combination of drugs for the immunosuppression regimen, and the choice of prophylactic therapies, including antifungal agents other than voriconazole. In an article accepted for publication by Pediatric Dermatology, Dr. Teng and her co-authors discuss the classes of immunosuppressive agents that contribute to the development of skin cancer and suggest that in selected cases, the inclusion of mTOR inhibitors “may be considered for inclusion in combination immunotherapy to reduce skin cancer risk.”

Revisiting ED&C

As more dermatologists acquire the skills to perform complex excisional procedures and Mohs surgery, is electrodesication and curettage (ED&C) — a decades-old procedure to treat basal cell and squamous cell carcinoma — falling by the wayside? It is, according to a Florida dermatologist who has practiced for 47 years and treats thousands of skin cancers each year. “I’ve been doing ED&C my whole career, and I think it’s been denigrated over the last 15 to 25 years,” said Douglas N. Robins, MD, adjunct assistant professor of dermatology at the University of Florida College of Medicine.

ED&C deserves a place in the treatment arsenal, Dr. Robins maintained, because it’s relatively easy to learn and perform and has a comparable cure rate to other forms of surgery as long as appropriate lesions are treated. (ED&C is one of the treatment modalities that will be evaluated in the forthcoming guideline.) A key advantage, he noted, is that ED&C can be performed at less than half the cost of traditional excisional surgery. “Based on the Medicare billing allowances in Northeast Florida, the biopsy and ED&C (normally done at the same time) for a squamous cell carcinoma on the torso would incur charges of $251, including pathology charges, vs. $620 for an initial biopsy with a scheduled follow-up excision done after the pathology diagnosis is determined. That’s important, because we have people coming in these days who have insurance policies with very high deductibles, $5,000 to $10,000, and are paying out of their pocket.” Dr. Robins added that while a surgical excision would require three visits (assuming a follow-up visit for suture removal), “I see patients with three or four superficial basal cells on their back that can easily be treated with ED&C in one visit.”

While ED&C is a fairly simple procedure, proper technique and patient selection are essential, Dr. Robins said. “I will do ED&Cs for many small, superficial lesions on the torso, arms, and legs,” he noted. “If I remove a lesion using ED&C and get back a pathology report that says it’s a more aggressive basal cell than what I thought, I always have the option of going back and re-excising the tissue to get clear margins.” In terms of tumor depth, “if you do an ED&C you get a pretty good idea of how deep it is. Once in a while if I misjudged a lesion clinically, and I see that the lesion is deeper than I thought it was, I’ll stop and schedule the patient for re-excision.” Because the cosmetic results of ED&C are generally not as favorable as with other surgical methods, Dr. Robins does not often perform ED&C on the face. “But, for example, if I have an elderly patient with poor health and mobility issues, I’ll go ahead and do the ED&C on a low-risk facial lesion. These are judgment calls that you make on a daily basis.”

Dr. Robins noted that he excises certain lesions after obtaining a biopsy report and refers 15 to 20 cases for Mohs surgery each month. But he believes many dermatologists “are just routinely exciting things that I think don’t need to be excised. If you have this feeling that ED&C is an old, out-of-date, anachronistic procedure that shouldn’t be done anymore, you’re not going to do it. I think it’s appropriate in many cases, and definitely has a role in controlling cost.”
As a specialty, we are very fortunate to have the American Academy of Dermatology Association (AADA) advocating on our behalf every day in Washington, D.C. The AADA is on the front lines of the constant battles that are being waged on the regulatory and legislative fronts. Our staff are tirelessly marching the halls of Congress, meeting with key officials at the FDA, and advocating with CMS to ensure that our specialty and patients are a priority when shaping policy and regulations.

While we have accumulated many notches on our collective belt of advocacy wins, we are undeniably facing a multitude of serious issues that need to be addressed. With the passage and implementation of the Medicare Access and CHIP Reauthorization Act (MACRA) legislation, dermatology — along with the entire house of medicine — is staring down some massive changes that will affect the way we run our practices and the methods by which we are reimbursed for the services we provide. Additionally, our patients continue to struggle to gain access to life-changing medications and services because of step-therapy policies instituted by insurance companies. Funding for essential medical research is stretched thin. To top it off, now we are facing the threat of compounding regulations that can severely limit the care we can provide for our patients. These are just a few of the many issues we’re facing, and we must be at the forefront of the discussions to make sure that the needs of our specialty and patients are met.

However, our D.C. staff can only do so much to affect policymakers and their decisions. The other half of the advocacy equation falls on us: the dermatologists. We know, firsthand, how these challenges affect our offices, our staff, and our patients. Fortunately, the Academy offers a host of opportunities for members to get involved in grassroots advocacy. First, the AADA Legislative Conference — held every year in Washington, D.C. — offers dermatologists from around the country the unique opportunity to receive advocacy training taught by health policy experts and to spend a day meeting with their members of Congress and their staff on Capitol Hill to talk about the most pressing issues facing our specialty and our patients. These face-to-face meetings on the Hill go a long way in ensuring that our message is heard and I cannot emphasize the value of our participation enough. Read more about the Legislative Conference at www.aad.org/meetings/legislative-conference.

However, if you can’t get away to Washington in the fall, the AADA has established the Dermatology Advocacy Network (DAN) — an online portal where you can send a quick email to your state or national representatives about the issues that are important to you. The AADA often sends us alerts asking us to act on some of these critical issues through DAN. I encourage you to open these alerts and take action when prompted. Log on to DAN and start advocating at www.aad-dan.com. Lastly, if you can’t join us in person or participate in other advocacy activities, I encourage you to log on to www.SkinPAC.org to learn more about SkinPAC, the American Academy of Dermatology Association’s political action committee.

Our AADA advocacy staff in Washington, D.C. does a great job telling our members of Congress about the issues that we’re facing. However, we are the ones who can show them firsthand how these issues affect every day patients. We must be present, active, and engaged in these policymaking efforts. I look forward to working with more Academy members as we roll up our sleeves and tell our story.
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 lincomycin.
• 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 UVA/B 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.

*This offer is only valid for patients with commercial insurance. Eligible uninsured patients will pay more. This offer is not valid for any person eligible for reimbursement of prescriptions, in whole or in part, by any federal, state, or other governmental programs, including, but not limited to, Medicare (including Medicare Advantage and Part A, B, and D plans), Medicaid, TRICARE, Veterans Administration or Department of Defense health coverage, CHAMPUS, the Puerto Rico Government Health Insurance Plan, or any other federal or state health care programs. This offer is good only in the U.S. at retail pharmacies owned and operated by Walgreen Co. (or its affiliates) or other participating independent retail pharmacies. This offer is not valid in Massachusetts or Minnesota or where otherwise prohibited, taxed or otherwise restricted. Visit www.Onexton.com for full terms and conditions.

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

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

WARNINGS AND PRECAUTIONS

Colitis/Enteritis
Systemic absorption of clindamycin has been demonstrated following topical use of clindamycin. Systemic or 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. Anaphylaxis, as well as severe opiates and clindamycin with atropine may prolong and/or worsen severe colitis. Severe colitis may result in death. Studies indicate toxin(s) produced by Clostridia is one primary cause of antibiotic-associated colitis. The colitis is usually characterized by severe persistent diarrhea and severe abdominal cramping 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 were mild and were not associated with symptoms or signs of toxicity. However, in some cases, local reactions were severe and were associated with systemic symptoms and signs of toxicity.

Postmarketing Experience

Anaphylaxis, as well as allergic reactions leading to hospitalization, has been reported in postmarketing use of ONEXTON Gel containing clindamycin phosphate/benzoyl peroxide. In postmarketing use with ONEXTON Gel [see Adverse Reactions]

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>Symptom</th>
<th>Before Treatment (Baseline)</th>
<th>Maximum During Treatment</th>
<th>End of Treatment (Week 12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythema</td>
<td>Mild * 4.0 28.5 &lt;1</td>
<td>15 2 0</td>
<td></td>
</tr>
<tr>
<td>Scaling</td>
<td>10 1 19 3 10 10 &lt;1</td>
<td>15 2 0</td>
<td></td>
</tr>
<tr>
<td>Itching</td>
<td>14 3 &lt;1 15 3 0</td>
<td>7 2 0</td>
<td></td>
</tr>
<tr>
<td>Burning</td>
<td>5 &lt;1 1 &lt;1 7 1 &lt;1 3 1 0</td>
<td>7 2 0</td>
<td></td>
</tr>
<tr>
<td>Stinging</td>
<td>5 &lt;1 0 7 0 &lt;1 3 0 0</td>
<td>7 2 0</td>
<td></td>
</tr>
</tbody>
</table>

* - Mild

Nonmuscular 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 5 and 10 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 900, 2700, and 15000 mg/kg/day (1.8, 5.4, and 30 times amount of clindamycin and 2.4, 7.2, and 40 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, 300, and 2000 mg/kg/day caused a dose-dependent increase in the incidence of keratoacanthoma at the tested 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 (1.2, 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) for up to 67 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).

DM/ONX/14/0031(1)
Envisioning the Future of Dermatology Through Medical Informatics
October 13, 2016
MSK COURSE DIRECTORS: Allan C. Halpern, MD
Steven Q. Wang, MD

www.mskcc.org/futurederm

12th Annual Dermoscopy Intermediate Course
October 14-15, 2016
MSK COURSE DIRECTOR: Ashfaq A. Marghoob, MD

www.mskcc.org/dermoscopy2016

5th Annual Dermatologic Care in Oncology
Friday, October 21, 2016
MSK COURSE DIRECTOR: Mario E. Lacouture, MD

www.mskcc.org/dermcare

Contemporary Management of Complex Skin Cancers
November 4-5, 2016
MSK COURSE DIRECTORS: Kishwer S. Nehal, MD
Bhuvanesh Singh, MD, PhD, FACS

www.mskcc.org/skincancercourse

For information regarding all upcoming MSK CME programs, please visit:
www.mskcc.org/cme
Applicants sought for research excellence award for young dermatology investigators

Each year the Academy recognizes outstanding basic, clinical, and translational research by young dermatology investigators through the AAD Awards for Young Investigators in Dermatology. The purpose of the award is to acknowledge significant research advances in the science and practice of dermatology by those beginning their research careers.

Two young investigators will be selected as the recipients of the 2017 awards. Each recipient will receive a $6,000 prize to be shared equally with the dermatology department supporting his or her research efforts. The award selection panel will evaluate submissions for originality of the research concept, soundness of the research design, quality and clarity of the submitted research report, and perceived value of the research to dermatology. Clinical and translational researchers are strongly encouraged to apply.

Applications for the 2017 awards are being accepted until Sept. 30, 2016. Eligibility criteria and online submission information are available at www.aad.org/members/awards/young-investigator-awards. For more information, contact Allen McMillen at amcmillen@aad.org.

These awards are made possible in part by contributions from Helen Gruber in memory of her husband, Murray Gruber.

PICMED grant applications requested

The American Academy of Dermatology (AAD) is requesting grant applications for its Program for Innovative Continuing Medical Education in Dermatology (PICMED). PICMED was established to facilitate dermatologists’ continuing education through support and development of innovative continuing medical education programs. The AAD offers this program through a generous contribution by the Elsevier Foundation and the Skin Disease Education Foundation.

The ideal educational proposal identifies or narrows gaps in competency and/or practice through the following:

- Innovative uses of technology that engage the learner;
- Unique approaches to specific subject matter;
- Novel presentation techniques; and/or
- Utilization of existing educational paradigms in new environments.

Sample proposals may include, and are not limited to, the following:

- Performance Improvement CME
- Internet-Point of Care CME
- Live educational activities with innovative means of learner engagement
- Web or digitally based instructional tools and enduring materials

Requests for grants for 2016 are due Sept. 1. Successful applicants will be notified in December.

To learn more and apply for a grant, visit www.aad.org/members/awards/picmed-grant.

- MEREDITH RUND
Apply today for Academy leadership programs

In order to encourage dermatologists to take leadership roles in their specialty going forward, the Academy is seeking applicants for three leadership programs in 2017.

Leadership Forum
The 2017 Leadership Forum will bring together aspiring leaders in dermatology with experienced mentors to enhance their communication and leadership skills. The event will take place March 31 through April 2 in Itasca, Illinois at the Eaglewood Resort. Aspiring leaders will engage in an interactive program with colleagues and Academy leadership, and will learn critical competencies for physician leaders, including self-assessment and leveraging innate skills. It is open to dermatologists in both private-sector practice and academic settings. The Academy will provide travel and lodging expenses, as well as on-site meals for the Leadership Forum. Applications will be open from July 1 through Sept. 1. For more information on the 2017 Leadership Forum, visit www.aad.org/LeadershipForum.

Academic Dermatology Leadership Program
The Academic Dermatology Leadership Program is administered by the Academy to provide physicians in academic settings the resources to meet the unique challenges of life in academe. A total of 15 Academy members will be chosen to participate in this highly selective program, which includes informative sessions at both the annual and summer AAD meetings, participation in the 2017 Leadership Forum, and opportunities to connect with an experienced mentor. This program requires a yearlong commitment of between five and eight hours per month in addition to the on-site sessions. Applications will be open from July 1 through Sept. 1. For more information on the Academic Dermatology Leadership Program, visit www.aad.org/ADLP.

Advanced Leadership Forum
The Academy also offers an Advanced Leadership Forum designed for mid-career level dermatologists. The event will take place March 31 through April 2 in Itasca, Illinois at the Eaglewood Resort in conjunction with the Leadership Forum. Applications are open to all dermatologists, especially those with a particular interest in developing leadership skills that are transferrable to both practice and advocacy settings. Eligibility requirements include the member being 10 years out of residency training or six years past Leadership Forum attendance. Applications will be open from July 1 through Sept. 1. For more information on the Advanced Leadership Forum visit www.aad.org/AdvancedLF.

– KATHY FRALE

Leadership Institute programs are made possible in part thanks to the generous philanthropic support of Academy members and other individuals. You can help train tomorrow’s leaders in dermatology by supporting the Leadership Institute. Visit donate.aad.org/leadership-institute to make your donation online, or call (847) 240-1409.
Academy seeks nominations for 2017 AAD election

The American Academy of Dermatology’s Nominating Committee seeks nominees for the offices of president-elect, vice president-elect, Board of Directors, and Nominating Committee member representatives (NCMR) in the Eastern Region. The current Administrative Regulation on Nomination and Election Procedures require that nominees submit all the required materials to the Nominating Committee no later than Oct. 1, for the election that will take place in spring 2017.

Successful officer and director candidates will take office in March 2018, at the close of the 76th Annual Meeting in San Diego and the successful NCMR will take office immediately. Nominees for the offices of president-elect and vice president-elect must have served on the Academy Board of Directors for at least one year prior to assuming office. President-elect nominees incur a four-year commitment — a one-year commitment prior to president-elect, one as president-elect, one as president, and one as immediate past president. Vice president-elect nominees assume a three-year commitment — a one-year commitment prior to vice president-elect, one as vice president-elect, and one as vice president.

The Nominating Committee screens and evaluates all nominees and selects a definitive slate of candidates based on professional, scholarly, and administrative skills, and geographic representation. To ensure that nominees have time to complete and submit all the required materials by the Oct. 1 deadline, make your nomination(s) early.

2017 Nominating Committee:
Ronald L. Moy, MD, chair
Thomas E. Rohrer, MD
Adnan Nasir, MD, PhD
Daniel M. Siegel, MD
Clay J. Cockerell, MD
Clifford W. Lober, MD, JD
Phoebe Rich, MD

Submit nominations through www.aad.org/aadnominations or by mail at:
American Academy of Dermatology
Attn: Call for Nominations
930 E. Woodfield Road
Schaumburg, IL 60173-4729

For more information, contact the AAD Executive Office at callfornominations@aad.org, or (847) 240-1046.

– JOAN TENUT

UNAUTHORIZED MEMBER ACTIVITIES

No member of the American Academy of Dermatology shall directly contact any member of the Nominating Committee regarding nominees under consideration. All letters of support and/or nominations should be addressed to the Nominating Committee chair at the Academy’s Schaumburg headquarters. Any lobbying of committee members may eliminate the nominee from consideration by the Nominating Committee.

PRESIDENT-ELECT CANDIDATES MUST AGREE TO ABIDE BY THE FOLLOWING EXCERPT FROM THE ADMINISTRATIVE REGULATION ON CODE FOR INTERACTIONS WITH COMPANIES

1.4. No Key Society Leader, defined for purposes of this Code as the Presidential-level of a Society’s membership organization (e.g., the President, President-Elect, and Immediate Past President as applicable)... may have Direct Financial Relationships with Companies during his or her term of service.

Direct Financial Relationship8: A Direct Financial Relationship is a relationship held by an individual that results in wages, consulting fees, honoraria, or other compensation (in cash, in stock options, or in kind), whether paid to the individual or to another entity at the direction of the individual, for the individual’s services or expertise. As used in this Code, the term Direct Financial Relationship does not mean stock ownership or intellectual property licensing arrangements.

8 Definition: A Direct Financial Relationship is a compensated relationship held by an individual that should generate an IRS Form W-2, 1099 or equivalent income report. Key Society Leaders [including the President, President-Elect, Immediate Past President, the Secretary-Treasurer, Assistant Secretary-Treasurer, the chief executive officer of a Society’s membership organization, and the Editor(s)-in-Chief of Society Journal(s)] may provide uncompensated service to for-profit health care products companies [“Companies”] and accept reasonable travel reimbursement in connection with those services. Key Society Leaders may accept research support as long as grant money is paid to the institution (e.g., academic medical center) or practice where the research is conducted, not to the individual. Exception may be made in certain circumstances for provision of consultant or investigator expertise related to protocol development and/or safety monitoring as long as the activities are not related to marketing or promotional efforts. In this event, the Secretary-Treasurer must be provided with background information and approval must be provided in advance for an exception to the policy. In these circumstances, compensation to the individual may not exceed $10,000/company/year. Verifying 1099 forms must be submitted to the Secretary-Treasurer when received. This exception may not be applied to the President, who shall remain free from any and all direct financial relationships during his/her term of office.
PROFESSIONAL OPPORTUNITIES

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WILMINGTON, DELAWARE

SAN DIEGO, CALIFORNIA
BC bilingual(Spanish) dermatologist per diem. Contact: grullan@drrullan.com or (619) 995-7630.

SOUTHBURY, CONNECTICUT

MIAMI, FLORIDA

LONE TREE, COLORADO

ORLANDO, FLORIDA

WATERBURY, CONNECTICUT

PONCHATOULA, LOUISIANA

CALUMET CITY, IL/DYER, IN

CLINTON, CONNECTICUT

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For more information, visit stjoeshealth.org/gme.
PROFESSIONAL OPPORTUNITIES

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WORCESTER, MASSACHUSETTS

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Physician peers weigh in on dermatology

BY EMILY MARGOSIAN, CONTENT SPECIALIST

Despite what some dermatologists may think, other physicians have high opinions of the specialty and its value to their own patients. A survey conducted in late 2015 by the AAD Specialty Positioning Workgroup evaluated 49 physicians (19 non-dermatologist physicians, 16 Academy members, and 14 Academy Board members), asking each group to identify their perceptions of dermatology, dermatologists, and dermatology’s present and future role in medicine. Although the sample of dermatologists identified negative terms such as “overpaid,” “good-lifestyle,” and “lazy,” as the top three phrases that they believed other physicians would use to describe them, conversely non-dermatologist physicians had a positive view of the specialty, choosing “smart,” “challenging,” and “patient-friendly” as their top three descriptors.

Other key takeaways included that although other physicians need and respect dermatologists’ expertise, they find them often inaccessible. See the graphics below and to the right for a breakdown of how other physicians rank the importance of dermatologic care for their patients, and how available they feel that care is.

1 in 3 physicians (32%) have trouble referring patients to a dermatologist

21 out of 25 physicians (84%) think it’s important that their patients have access to a dermatologist

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