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A SUPPLEMENT TO

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Current Approach to Acne Management: A COMMUNITY-BASED ANALYSIS

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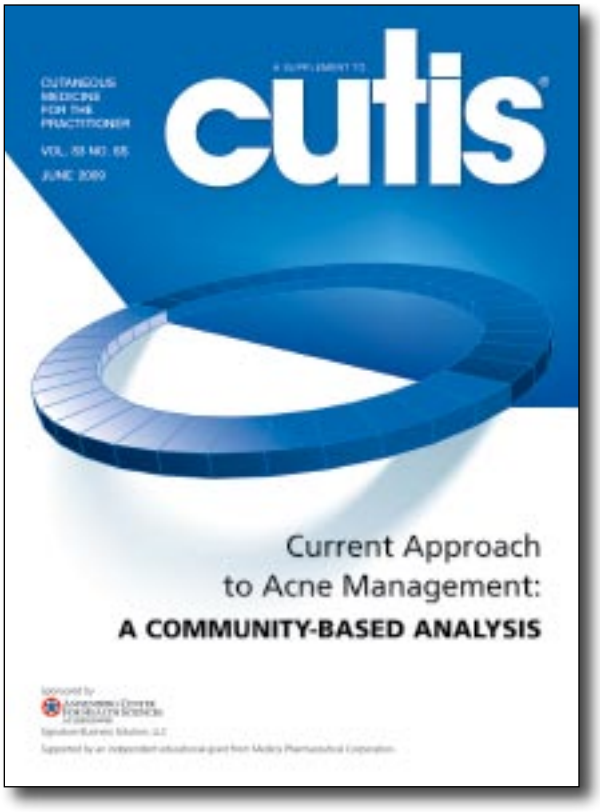

Current Approach to Acne Management:

A Community-Based Analysis

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Faculty and Disclosure Information
Current Approach to Acne Management: A Community-Based Analysis

INTENDED AUDIENCE
This activity was developed for dermatologists whose practice involves the treatment of patients with acne vulgaris.

STATEMENT OF NEED
The purpose of this activity was to bring forth perspectives in the management of acne vulgaris "from the ground up"—from clinicians working in the "trenches" who regularly treat acne vulgaris—and determine if these approaches align with expert opinion.

LEARNING OBJECTIVES
Upon completion of this activity, participants should be able to:
- State the importance of the patient-clinician relationship, patient education, and follow-up in the successful management of acne vulgaris.
- Develop a treatment strategy for topical treatments including antibiotics, benzoyl peroxide, and retinoids.
- List the most commonly prescribed oral antibiotics for the treatment of acne vulgaris and the evidence supporting their use.
- State the safety considerations in the use of oral isotretinoin for acne vulgaris.
- List hormonal suppression treatment options, the patients with acne vulgaris who are most likely to benefit from hormonal therapy, and factors that increase the risk for adverse reactions.

FACULTY
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AGENDA
- Patient 1: A Strategic Approach to Therapy Following an Initial Outbreak of Acne Vulgaris
- Patient 2: Systemic Antibiotic Treatment in Moderate Inflammatory Facial Acne Vulgaris
- Patient 3: Oral Isotretinoin for Moderately Severe Acne Vulgaris
- Patient 4: Hormonal Suppression in the Treatment of Severe Acne Vulgaris

This activity will address professional practice gaps in knowledge and competence.

ACCREDITATION AND CERTIFICATION
This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the Annenberg Center for Health Sciences at Eisenhower and Signature Business Solution, LLC. The Annenberg Center is accredited by the ACCME to provide continuing medical education for physicians.

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Dr. Baldwin is a consultant for Allergan, Inc, and is on the speakers bureau for Allergan, Inc; Galderma Laboratories, LP; Medicis Pharmaceutical Corporation; OrthoNeutrogena; Ranbaxy Laboratories Ltd; sanofi-aventis US LLC; and Stiefel Laboratories, Inc.

Dr. Keri is on the advisory board and is a speaker for Medicis Pharmaceutical Corporation.

Dr. Mancini is a consultant for Medicis Pharmaceutical Corporation; Sciele Pharma, Inc; and SkinMedica, Inc; and is on the speakers bureau for Galderma Laboratories, LP, and Graceway Pharmaceuticals, LLC.

Dr. Stein Gold is a consultant for Galderma Laboratories, LP; Medicis Pharmaceutical Corporation; and Warner Chilcott. She also is a researcher for Galderma Laboratories, LP; Stiefel Laboratories, Inc; and Warner Chilcott; and is a speaker for Galderma Laboratories, LP, and Warner Chilcott.

Dr. Webster is a consultant for Allergan, Inc; Coria Laboratories, Ltd; Dermik Laboratories; Galderma Laboratories, LP; Medicis Pharmaceutical Corporation; Ortho Dermatologics, a division of Ortho-McNeil-Janssen Pharmaceuticals, Inc; and Stiefel Laboratories, Inc.

Additional Content Planners

Karen Bickford; Toni Nouri, RPh; Robert Rullo; John Russo Jr, PharmD; and Christina Wright have nothing to disclose.

All staff at the Annenberg Center for Health Sciences at Eisenhower have nothing to disclose.

The faculty for this activity has disclosed that there will be discussion of the use of products for non–US Food and Drug Administration approved indications.

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This activity is supported by an independent educational grant from Medicis Pharmaceutical Corporation.

This activity is an enduring material and consists of a print piece. Successful completion is achieved by reading the material, reflecting on its implications in your practice, and completing the assessment component.

The estimated time to complete the activity is 1 hour.

This activity was originally released in June 2009 and is eligible for credit through June 2010.

Current Approach to Acne Management: A Community-Based Analysis

James Q. Del Rosso, DO; Hilary Baldwin, MD; Jonette Keri, MD, PhD; Anthony Mancini, MD; Linda Stein Gold, MD; Guy F. Webster, MD, PhD

During fall 2008, 10 roundtable discussions involving 70 practicing dermatologists and a physician assistant were conducted across the United States to address patient considerations and treatment strategies for acne vulgaris. A case study format was used to initiate discussion. This supplement is based on the issues raised during the roundtable discussions and at a final working session among the authors where suggestions, trends, and the consensus from each of the 10 roundtable discussions were reviewed regarding published, evidence-based recommendations for treating acne vulgaris. Effective treatment of acne vulgaris can prevent adverse emotional sequelae and physical scarring. We hope that the information presented herein will help guide our colleagues in improving the care of patients with acne vulgaris.

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During fall 2008, 10 roundtable discussions addressing patient considerations and treatment strategies for acne vulgaris were conducted across the United States. The goal of this project was to bring forth perspectives in the management of acne vulgaris "from the ground up"—from clinicians working in the "trenches" who regularly treat acne vulgaris—and determine if these approaches align with expert opinion. At each meeting, a case study format was used to initiate discussion. Roundtable participants, including 70 practicing dermatologists and a physician assistant, served as a needs assessment group.

To many teenaged individuals, the onset of acne marks the end of a previously idyllic existence with their physical being and self-image. For the first time, they confront the fact that their bodies are vulnerable and imperfect. In adults, acne may have a negative effect on their careers and social lives. Effective treatment of acne

vulgaris can prevent adverse emotional sequelae and physical scarring. We hope that the information presented herein will help guide our colleagues in improving the care of these patients based both on real-world perspectives from practicing dermatologists and on supporting evidence gleaned from the literature.

PATIENT 1: A STRATEGIC APPROACH TO THERAPY FOLLOWING AN INITIAL OUTBREAK OF ACNE VULGARIS

Case Report

A 13-year-old adolescent girl presented to the dermatology office with her mother. She complained about her first breakout of pimples and dryness, which presented approximately 3 months prior. Physical examination revealed 10 to 20 comedones on her forehead and a few small superficial inflammatory papules on her forehead and cheeks. Her neck, chest, and back were clear. Her friends recommended applying a baking soda and witch hazel mixture for 15 minutes daily and toothpaste to dry out the pimples. Neither remedy worked and both contributed to dryness of her skin. A brief course of an over-the-counter benzoyl peroxide product had some success, but the patient reported that the pimples "kept coming back." The mother stated that her daughter insisted they come to the dermatologist for help (see Roundtable Perspectives on Patient 1).

Roundtable Perspectives on Patient 1

The panelists in the roundtable discussions agreed that establishing rapport with the patient during the first office visit is essential. In addition, the office staff should be prepared to provide patient education and follow-up. According to the panelists, their office staff often plays a role in educating patients about acne and medication use, though the strategies to achieve these objectives vary. Explaining how medication should be used and emphasizing reasonable expectations of treatment response were considered to be important components of the educational process for patients and guardians (when applicable).

Approximately 80% of the panelists (53/67) listed social stigma or satisfaction with care as the main reasons for patient adherence to long-term treatment. Simplicity of the treatment regimen and skin tolerability were factors with the greatest impact on adherence to maintenance therapy, according to 68% of panelists (44/65).

In addition to establishing rapport, goals for the first office visit include setting reasonable response expectations and gaining a commitment from the patient for long-term treatment. The treatment regimen must be easy to follow. In addition, initial recommendations include counseling about skin care to clarify both its value and its limits in managing acne.

The panelists agreed that this patient is a candidate for topical therapy with an antibiotic, benzoyl peroxide, and a retinoid. Careful selection of the regimen is critical to achieving a successful outcome. Most panelists said they would schedule a follow-up visit every 6 to 8 weeks. Others preferred to see patients at least monthly for the first 3 to 4 visits to evaluate response, adjust therapy if side effects occur, and encourage compliance.

Establishing Rapport and a Commitment to Treatment

It is well-known that adherence to prescribed treatment regimens is poor among patients with acne and often is the predominant cause of treatment failure. Dermatologists gain trust by showing empathy and genuine concern. Several of the panelists noted the importance of neutralizing the potentially negative influence from a well-intended guardian. Accordingly, the adolescent's hand is shaken first and then the guardian's. All conversation is directed to the teenaged patient who is given an opportunity to lead the initial conversation. Situating the teenaged patient, guardian, and clinician in a triangle is inclusive yet offers the option to reposition to marginalize input from an intrusive guardian.[1]

After weighing the patient's expectations and the guardian's concerns, treatment recommendations can be presented and reinforced through patient education about the medications being prescribed and the value of proper skin care. Some panelists noted that they use photographs of individuals with acne scars to emphasize the seriousness of the condition and the importance of getting results through adherence to the prescribed treatment regimen.

Skin Care

Adolescents often lack basic information about proper skin care.[2] Routine daily skin care removes unwanted surface debris, allowing for a better interface between applied medications and the skin surface, which facilitates percutaneous absorption of topically applied medications.[3] Gentle washing twice daily is better than once daily,[4] and the patient should select products with mild synthetic surfactants and/or emollients that cause minimal barrier perturbation rather than strong deodorant soaps that can damage the epidermal barrier. Abrasive sponges or cloths as well as astringents with alcohol increase skin dryness and may worsen irritation.[2] Skin discoloration, if present, tends to be more persistent in the absence of photoprotection. Therefore, a sunscreen that is effective against both UVA and UVB should be used each morning and early afternoon.[5,6]

Treatment Options for Patient 1

Topical Retinoids—Most panelists recommended the use of topical retinoids early in the course of this patient's therapy. These agents normalize desquamation of the follicular epithelium and reduce formation of the microcomedone (acne precursor lesion). Through a variety of mechanisms, topical retinoids reduce both inflammatory and noninflammatory acne lesions and may be combined with other topical and systemic agents.[6]

Several formulations of topical retinoids in a range of strengths and vehicle types are available, including adapalene, tazarotene, and tretinoin.[7] Because localized irritation can limit treatment success, attention to factors that influence irritant reactions (ie, skin sensitivity, the retinoid and concentration used, vehicle formulation) can reduce irritation. For example, tretinoin microsphere, tretinoin containing polyolprepolymer-2, and crystalline tretinoin are vehicle modifications designed to release tretinoin in a slow controlled manner, thus minimizing the potential for irritation associated with standard tretinoin formulations.[8,9]

Benzoyl Peroxide—Use of a topical retinoid-containing product combined with a benzoyl peroxide formulation was a common treatment approach suggested by panelists. Topical benzoyl peroxide is a potent antimicrobial agent with marked activity against *Propionibacterium acnes* and also exhibits comedolytic properties.[10] It is not associated with *P acnes* resistance.[11,12] Furthermore, adding benzoyl peroxide to antibiotic treatment reduces emergence of antibiotic-resistant *P acnes* strains, as evidenced by studies with both leave-on benzoyl peroxide formulations and a branded benzoyl peroxide 6% cleanser formulation.[13-15] It also has been reported that a combination of benzoyl peroxide cleanser 6% and tretinoin microsphere gel 0.1% is well-tolerated and superior to tretinoin monotherapy as measured by a reduction in inflammatory lesion counts over 12 weeks of treatment (Figure 1).[16] For these reasons, benzoyl peroxide most often is combined with other medications that have a different mode of action.[10] Interestingly, based on data from 2003-2006, approximately 50% of benzoyl peroxide formulations prescribed by dermatologists are cleansers,[14] which was consistent with the experiences reported by the panelists.

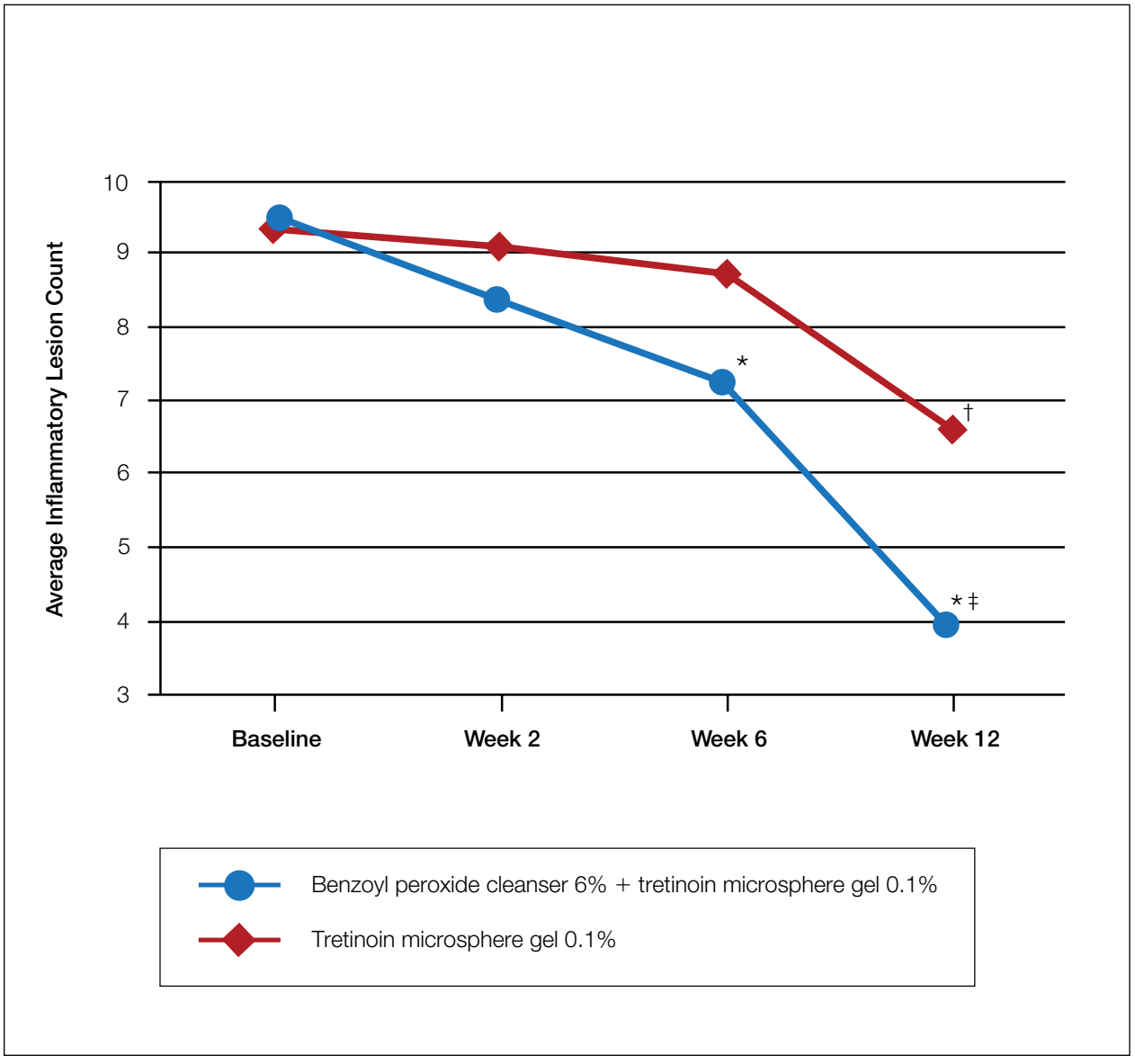

Figure 1. Average inflammatory lesion counts over 12 weeks of treatment with a combination of benzoyl peroxide cleanser 6% and tretinoin microsphere gel 0.1% vs tretinoin monotherapy. Asterisk indicates $P<.01$ vs combination group baseline value; dagger, $P<.001$ vs monotherapy group baseline value; double dagger, $P<.01$ combination group vs monotherapy at week 12. Reprinted with permission from *Cutis.* 2003;72:167-172. ©2003, Quadrant HealthCom Inc.[16]

The most common side effect of benzoyl peroxide is cutaneous irritation, which may be reduced through micronizing benzoyl peroxide or making it softer and less abrasive.[10] Accordingly, manufacturers have responded by producing several benzoyl peroxide vehicle formulations. The contribution of the formulation to benzoyl peroxide efficacy and tolerability makes it problematic to assume equivalence among generic benzoyl peroxide–containing products.

Bleaching of fabric (ie, clothing, towels, bed linens) by benzoyl peroxide occurs primarily with leave-on formulations. In addition, skin discoloration can occur in individuals of color and

when benzoyl peroxide is used with sunscreens containing *p*-aminobenzoic acid, which was a substantial concern to panelists treating patients with darker skin.

Topical Antibiotics—Approximately 95% of panelists (62/65) favored the use of topical clindamycin versus erythromycin to treat this patient's acne vulgaris, and 67% (43/64) associated topical clindamycin with a lesser concern for antibiotic resistance despite potential for in vitro cross-resistance. A review of studies evaluating topical antibiotics for acne vulgaris revealed that the efficacy of erythromycin but not clindamycin decreased over time.[17] Several additional monotherapy trials or study arms have confirmed the continued efficacy of topical clindamycin in markedly reducing acne lesions, including a 45% to 49% reduction in inflammatory lesions and a 30% to 41% reduction in comedones.[18-21]

The panelists essentially were evenly split in favoring topical clindamycin combined with either benzoyl peroxide or tretinoin to expedite clinical response in this patient, especially reduction in inflammatory lesions. Other advantages of combining topical clindamycin with benzoyl peroxide or tretinoin include complementary modes of action and a simplified treatment regimen for the patient.

Treatment Recommendations for Patient 1

The challenge clinicians face when presented with a case similar to this patient is the likelihood that the patient had an unsatisfactory history with over-the-counter benzoyl peroxide and other remedies. Frustrated, the patient expects the clinician's prescription to provide instant results, yet acne therapy requires a long-term commitment with a timeline to initial success of approximately 2 to 4 months. Setting realistic expectations and educating the patient about the earliest signs of success may encourage adherence. For example, papules and pustules heal sooner than residual discoloration and are preceded by tactile improvement. As inflammatory lesions resolve, they flatten. Using a mirror to point out differences between active lesions (raised lesions such as papules) and resolved lesions with only residual erythema (postinflammatory erythema) or brown hyperpigmentation (postinflammatory hyperpigmentation) is helpful.

Other factors that positively impact commitment to treatment are the patient's perception of the clinician, including his/her listening ability; time spent with the patient during the visit; thoroughness of the visit; and quality of the explanations given about the skin problem and its therapy. Convenient office hours, pleasant atmosphere, and helpfulness of the staff also are important.[22]

The treatment for this patient recommended by most panelists included topical clindamycin, benzoyl peroxide, and a retinoid. Two options were most popular: clindamycin phosphate 1.2%–tretinoin 0.025% gel plus a benzoyl peroxide cleanser, or clindamycin 1%–benzoyl peroxide 5% gel with separate application of a topical retinoid. Regarding simplicity and tolerability, several panelists noted that a benzoyl peroxide cleanser is convenient because it can be part of the evening shower, thereby simplifying the bedtime treatment routine by eliminating the need for another leave-on product. Additionally, a cleanser is more applicable for truncal use.

PATIENT 2: SYSTEMIC ANTIBIOTIC TREATMENT IN MODERATE INFLAMMATORY FACIAL ACNE VULGARIS

Case Report

A 17-year-old physically active Asian adolescent boy complained of sustained acne with repeated flares. A senior in high school, he was concerned that the acne and the "brown spots" on his cheeks were having a negative effect on his social life. He had approximately 40 comedones and 30 superficial inflammatory papules and pustules on his forehead, cheeks, and nose, with postinflammatory hyperpigmentation. There was no scarring or truncal involvement. Current treatment included a topically applied antibiotic, benzoyl peroxide, and retinoid. He was otherwise healthy, claimed to adhere to treatment, and had no allergies (see Roundtable Perspectives on Patient 2).

Systemic Antibiotic Treatment

Among the panelists, 73% (47/64) estimated that more than half of their patients with acne vulgaris are treated with oral antibiotics. Although many of these agents are available, the use of doxycycline

Roundtable Perspectives on Patient 2

Because prior treatment failure and sustained acne with repeated flares had a negative effect on this patient's peer interactions, the panelists recommended adding treatment that would result in a rapid response. They agreed he also would benefit from strong encouragement and it was worthwhile to review proper hygiene and skin care as well as to confirm his understanding of the correct use of acne treatments.

Hyperpigmentation was a concern among the panelists, and the potential role of azelaic acid or a topical retinoid to speed resolution was discussed. However, because of few clinical studies[23,24] and mixed success in personal experience with topical therapy alone, it was decided to add an oral antibiotic to a topical regimen to optimize efficacy and the reduction of inflammation.

Several panelists recognized that bacterial resistance is a potentially important public health problem but not all were convinced of its clinical significance in acne treatment. Most agreed that an oral antibiotic was justified because of the severity of the patient's acne and his frustration with his poor response to prior therapy. Panelists treating a large population of Asian patients noted that the guardians of these patients tend to be aware of issues related to development of resistant bacteria and sometimes oppose the use of antibiotics. It is important to consider that although antibiotic-resistant *Propionibacterium acnes* is a problem with some antibiotics, there are no data connecting their use in acne with emergence of community-associated methicillin-resistant *Staphylococcus aureus* infections. The goal of therapy with oral antibiotics in this patient was to control the acne; treatment then would be discontinued when feasible while continuing topical therapy.

and minocycline predominate,[25] accounting for 41% and 39% of prescriptions, respectively, with minocycline hydrochloride extended-release tablets accounting for 19%.[26] The panelists had experience with a broad range of anti-infective agents; however, the most common practice patterns paralleled these findings.

Although not approved by the US Food and Drug Administration (FDA) for this indication, doxycycline and immediate-release minocycline at dosages up to 200 mg daily are widely used to treat acne vulgaris based on decades of clinical experience and clinical studies.[17] The efficacy of tetracycline agents in treating acne vulgaris depends on their ability to reach the lipid-rich environment of the pilosebaceous follicles where *P acnes* proliferates.[27] This concept supports the use of doxycycline and minocycline for the treatment of acne vulgaris, with the latter exhibiting greater lipophilicity than other tetracycline derivatives.[28]

The more recent development and FDA approval of minocycline hydrochloride extended-release tablets to treat inflammatory lesions of nonnodular moderate to severe acne vulgaris with 1 mg/kg once daily provide a larger body of data than previously available with oral antibiotics used to treat acne vulgaris. Minocycline hydrochloride extended-release tablets were studied in two 12-week, multicenter, randomized, double-blind, placebo-controlled trials of moderate to severe facial acne vulgaris using weight-based dosing (N=924).[29] In both studies, the mean percentage improvement in inflammatory lesions was greater with minocycline hydrochloride extended-release tablets. In addition, the

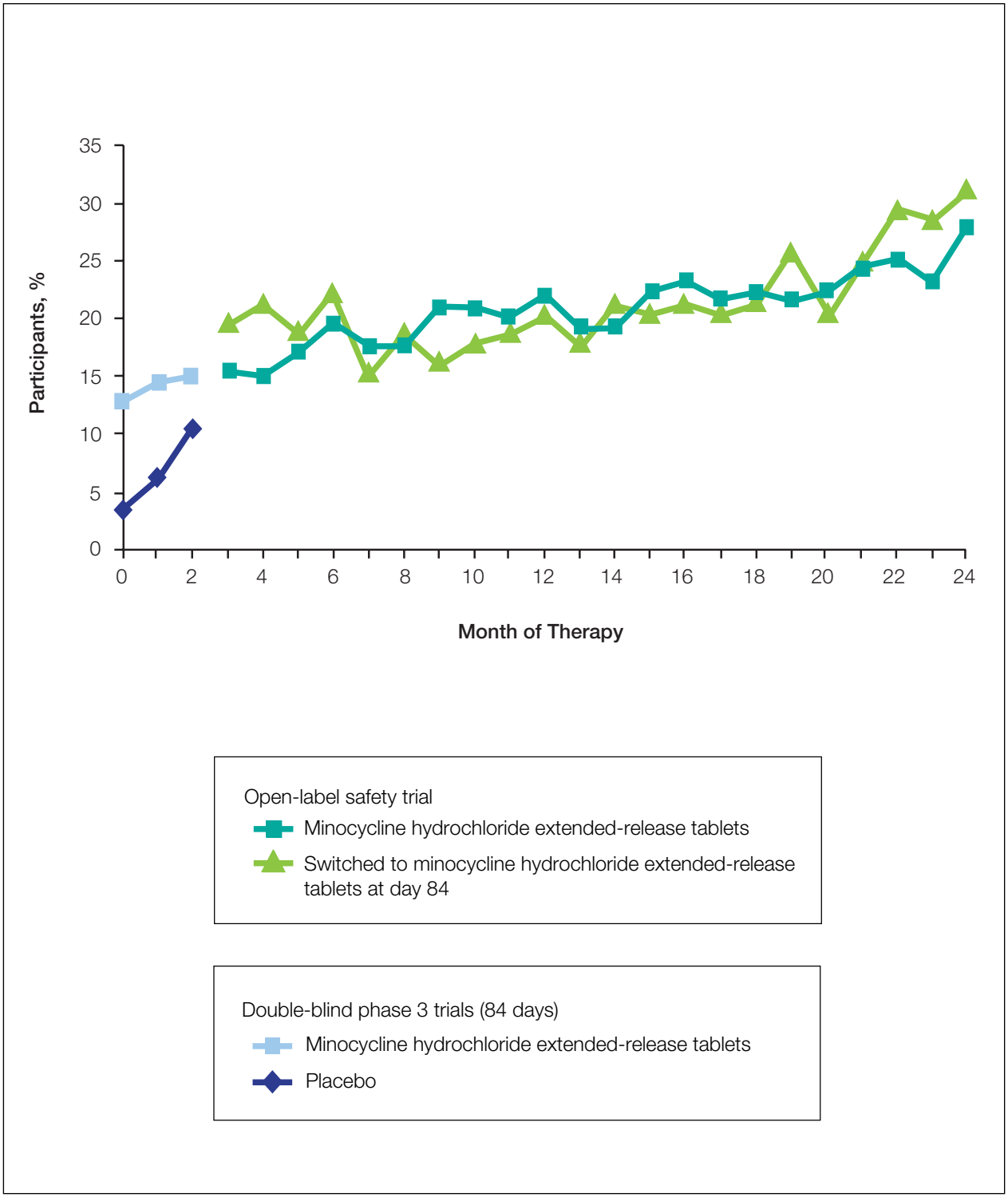

Figure 2. Percentage of participants rated as clear or almost clear during a 2-year open-label extension of 2 trials of minocycline hydrochloride extended-release tablets vs placebo (N=345). Participants received weight-based dosing of minocycline hydrochloride extended-release tablets (1.0±0.5 mg/kg) once daily. Data points reflect the response based on the evaluator's global severity scale.[31]

percentage of participants considered clear or almost clear was higher with the minocycline hydrochloride extended-release formulation.[29] Results of another study confirmed that minocycline hydrochloride extended-release tablets with a dosage of 1 mg/kg daily was equivalent in efficacy to 2 and 3 mg/kg daily.[30] Importantly, the incidence of acute vestibular adverse events was the same in the study groups treated with minocycline hydrochloride extended-release tablets 1 mg/kg daily or placebo, and markedly lower than the groups receiving 2 or 3 mg/kg daily.[29]

Continued and progressive long-term (2 years) improvement with weight-based minocycline hydrochloride extended-release tablets was reported in an open-label extension of the pivotal phase 3 trials described above (N=345)(Figure 2). In this study, other concomitant topical acne medications were used as needed in approximately two-thirds of the cases.[31]

All tetracycline agents are contraindicated in pregnancy because of teratogenic effects and they should not be used in children younger than 8 years because of their effects on dentition. A rare side effect with tetracycline agents is pseudotumor cerebri.[32] The major adverse reactions reported with doxycycline include gastrointestinal tract side effects and dose-related photosensitivity.[14,32,33] Doxycycline, especially formulations that are not enteric coated, is best administered with food and a large glass of water to reduce gastrointestinal tract distress and esophagitis.

Hyperpigmentation of skin and mucosa during minocycline therapy has been reported.[6] Although hyperpigmentation appears to be correlated with cumulative exposure to minocycline, the time to onset and resolution is variable.[32] No cases of hyperpigmentation were observed in the 2-year safety study with minocycline hydrochloride extended-release tablets. During this time, minocycline hydrochloride extended-release tablets were well-tolerated, with adverse events comparable with placebo, including acute vestibular adverse events (eg, nausea, dizziness, vomiting, tinnitus).[31]

Minocycline has been associated with rare reports of a lupuslike syndrome.[18] During the 2-year safety study, only 1 participant treated with minocycline hydrochloride extended-release tablets developed arthralgia and a "flulike syndrome," which resolved. In this participant, antinuclear antibody (ANA) positivity was reported once and subsequent test results were negative. No cases of drug hypersensitivity syndrome or drug-induced symptomatic hepatitis were reported.[34]

Antinuclear antibody positivity alone is not diagnostic of lupus erythematosus, including drug-associated cases.[35] In healthy individuals, the prevalence of a positive ANA test result is 5.0% at 1:160 serum titer and increases substantially with titers of 1:80 and 1:40. Clinical correlation is needed before making the diagnosis. Based on epidemiologic data, among 100 ANA-positive patients, 10% or less will have systemic lupus erythematosus, 2% will have drug-induced systemic lupus erythematosus, and 90% or more will have a false-positive ANA test result.[35]

Sporadically observed, single ANA-positive test results that revert to negative on repeat testing are not uncommon because of the high prevalence of false-positive ANA test results in the general population, especially with lower ANA titers. As anticipated, this phenomenon was observed in the 2-year safety study, with no reports of drug-associated lupuslike syndrome noted. Quarterly testing reported the prevalence of ANA positivity to be 3.8% using the last ANA test result taken from each study participant. This rate was less than the 5% ANA positivity expected in the general population. Thus, the likelihood of ANA positivity at the last testing was slightly lower than what would be expected in the general population.

Antibiotic Resistance

Despite the reported progressive increase in prevalence of antibiotic-resistant *P acnes* worldwide, oral doxycycline and minocycline continue to demonstrate efficacy in acne vulgaris.[29,36] Only 9% of panelists (6/65) identified lower risk for antibiotic resistance as the best reason to prescribe a combination antibiotic-containing product for this patient. More important reasons included addressing multiple aspects of acne pathology (56% [36/65]) and simplified treatment (35% [23/65]). However, during long-term (>8 weeks) treatment with oral or topical antibiotics, 86% of panelists (56/65) reported adding benzoyl peroxide to the regimen.

General guidelines for prudent use of oral antibiotics for acne vulgaris recommend continued treatment for at least 6 to 8 weeks, with a total duration of 12 weeks to 6 months.[6] Once reasonable

control of acne is observed, oral antibiotic therapy may be discontinued and topical therapy alone is attempted to maintain control of acne. However, in some cases, oral antibiotic therapy may need to be reinstated in combination with a topical regimen to control emergence of new acne lesions if topical therapy alone does not suffice.[33] If repeated treatment with an oral antibiotic is necessary, it is recommended to restart the same oral antibiotic that was previously effective.[6,33]

The importance of benzoyl peroxide to decrease the emergence of less antibiotic-sensitive *P acnes* organisms was well-accepted by most panelists.[10,28] Additionally, the role of topical retinoid therapy as a component of both the initial and long-term maintenance regimen is well-established and most panelists stated they incorporate this approach.[21,33,37]

Treatment Recommendations for Patient 2

Oral antibiotics are an important component of acne treatment, especially in patients with moderate to severe disease affecting the face and/or trunk. Considering that this patient's response to topical treatment alone was unsatisfactory and his self-esteem was adversely affected, it was recommended that an oral antibiotic treatment be added to the ongoing topical regimen.

In this case, the patient's lifestyle included a substantial amount of time outdoors. Most panelists recommended treatment with minocycline because of a lower risk for photosensitivity. Among the minocycline formulations, most panelists preferred the minocycline hydrochloride extended-release tablets 1 mg/kg daily. They agreed that clinical monitoring of therapeutic response and adverse reactions is sufficient when treating acne with oral tetracycline agents. Baseline and/or follow-up laboratory testing was not recommended and was not suggested in the medical literature with the use of oral tetracycline agents.[32,33]

PATIENT 3: ORAL ISOTRETINOIN FOR MODERATELY SEVERE ACNE VULGARIS

Case Report

An 18-year-old white man presented to the clinic after a poor response to over-the-counter and prescription acne treatments. A freshman in college, he was "bummed out" because of the acne. He avoided socializing, especially outdoor activities (eg, swimming, beach), and missed days at school because of his appearance. Prior treatments included several topical medications and a course of oral antibiotics. He used them for short periods, with temporary improvement until his skin became too dry and irritated. He frequently scrubbed and popped the pimples on his face.

Physical examination revealed widespread distribution of comedones and papules/pustules around the mouth and on the cheeks, forehead, and nose. Deeper inflammatory acne lesions were scattered on his cheeks, with some areas of pitted acne scarring. Acne also was present on his upper back and chest to a lesser degree. He was otherwise healthy, used no other medications, and had no drug allergies (see Roundtable Perspectives on Patient 3).

Oral Isotretinoin

Oral isotretinoin is effective against all 4 pathogenic factors responsible for acne vulgaris and is recommended for patients who do not respond to conventional therapy.[37] Its use, however, must be weighed against issues related to safety, including the risk for depression and the need for effective contraception in females to avoid birth defects.

The typical dosage of oral isotretinoin is 0.5 to 1 mg/kg daily in 2 divided doses, with a standard cumulative maximum dose of 120 to 150 mg/kg per treatment course.[40] Isotretinoin has been compared with placebo or other traditional therapies (dapsone, etretinate, minocycline, tetracycline) in 5 randomized controlled trials. In all cases, isotretinoin was more effective than its comparators.[41-45]

Results of an open-label study of low-dose isotretinoin suggest that lower doses also may be effective.[46] Patients with moderate acne were treated with isotretinoin 20 mg daily (≈0.3–0.4 mg/kg daily) for 6 months with follow-up up to 4 years (N=638). More than 90% of patients in each group (n=495 for first group [aged 12–20 years]; n=122 for second group [aged 21–35 years]) experienced improvement or complete remission. Relapse after 4 years was less than 6% in both groups.[46]

Higher relapse rates have been reported. In a retrospective study of 405 patients with acne

Roundtable Perspectives on Patient 3

The panelists agreed that college students represent a treatment challenge. During their freshman year, these patients are busy adjusting to new surroundings, money to spend on prescriptions is limited, and follow-up is difficult. Treatment at this time should include counseling and encouragement. Patient education regarding proper skin care and avoidance of self-manipulation of acne lesions is vital.

The failure of this patient to mention the presence of truncal acne, despite the fact that he avoids outdoor activities such as swimming and the beach, is not uncommon. However, it highlights the importance of an initial thorough skin examination to ensure comprehensive treatment. Approximately 50% of patients with acne vulgaris demonstrate involvement on the chest and/or back, but approximately 1 of 4 patients fail to mention it voluntarily, despite the presence of facial acne.[38]

Because of the widespread distribution of acne, the panelists recommended a benzoyl peroxide cleanser for the face and trunk. In addition, some recommended a topical retinoid or clindamycin-tretinoin combination gel for the face to be applied at bedtime, which allows for only 1 topical application step in addition to therapeutic cleansing with benzoyl peroxide. Others recommended facial application of a clindamycin–benzoyl peroxide combination gel in the morning and a topical retinoid at bedtime.

Regarding selection of oral antibiotic therapy, the panelists suggested either doxycycline or minocycline. A few suggested trimethoprim-sulfamethoxazole; however, concerns regarding rare but potentially serious adverse reactions with this agent were discussed, such as Stevens-Johnson syndrome, toxic epidermal necrolysis, and serious hematologic reactions (ie, agranulocytosis).[39]

Most panelists agreed that treatment with oral isotretinoin was indicated because of the severity of acne, scarring, and the marked negative impact of acne on the patient's quality of life and self-esteem. The most appropriate time to start treatment was debated, however, with some preferring to start isotretinoin immediately while others recommended waiting to evaluate response to a regimen selected and observed under their own care.

treated with a course of at least 150 mg/kg of isotretinoin, 23.2% experienced relapses severe enough to request further medical management.[47] Of these, 80.9% relapsed within the first 2 years following completion of a course of isotretinoin. Relapse was more common among patients who were in their early teens when first treated with oral isotretinoin.[47]

Isotretinoin is teratogenic and contraindicated in pregnancy, during lactation, and in patients with severe hepatic or renal dysfunction.[48,49] According to prescribing guidelines, most females with severe nodular acne who are of childbearing potential need a concomitant oral contraceptive (OC) or other highly effective birth control therapy before starting oral isotretinoin.[37]

To reduce fetal exposure to isotretinoin, the FDA-approved iPLEDGE™ program was developed. Females taking oral isotretinoin for any indication must report using 2 forms of effective contraception simultaneously for 1 month before, during, and for 1 month after isotretinoin therapy, and the negative results of a monthly pregnancy test must be documented.[50] There is no evidence that isotretinoin therapy in males can cause teratogenic effects in fetuses if their partner becomes pregnant.

Despite more than 20 years of use and much study, there is no clear proof of an association between mental illness and oral isotretinoin,[51,52] and 12 clinical studies published between 1984 and 2006 are not consistently conclusive on the association of suicide and depression during isotretinoin therapy.[40,53-62] However, panelists agreed that isotretinoin dramatically improves the quality of life of most patients, usually converting a patient who does not make eye contact into a confident individual who smiles and is more openly and voluntarily communicative.

Treatment Recommendations for Patient 3

Panelists recommended initiating oral isotretinoin therapy but differed in the timing of this treatment. Some panelists preferred to see this patient's response to a topical regimen (clindamycin, benzoyl peroxide, retinoid) combined with an oral antibiotic under their direction for 2 to 3 months before considering oral isotretinoin therapy. Others favored starting oral isotretinoin at the initial clinic visit. When prescribing isotretinoin, approximately 82% of panelists (52/63) reported that they monitor lipid levels and liver enzymes.

PATIENT 4: HORMONAL SUPPRESSION IN THE TREATMENT OF SEVERE ACNE VULGARIS

Case Report

A 25-year-old woman with severe acne vulgaris requested more effective treatment, as her current regimen was unsatisfactory. She was healthy and in a stable relationship with no plans to have children in the next 5 years. Current treatment included clindamycin phosphate 1.2%–tretinoin 0.025% gel applied at bedtime and a benzoyl peroxide cleanser. She did not want treatment with oral isotretinoin. Physical examination revealed multiple deep inflammatory lesions combined with smaller pustules and comedones as well as associated scarring on the face and neck (see Roundtable Perspectives on Patient 4).

Oral Contraceptives

Three FDA-approved OC products are available for the treatment of acne vulgaris in the

Roundtable Perspectives on Patient 4

Most panelists (62% [38/62]) agreed that hormonal therapy was indicated in this patient. An oral contraceptive (OC) was the first choice of 29% of panelists (18/62). Spironolactone was the first choice among 15% of panelists (9/62), with 18% (11/62) stating they would consider combined hormonal therapy.

Most panelists stated that they would refer the patient to her gynecologist for the OC prescription. Others reported that they would initiate OC therapy to cover the first 3 to 4 months of treatment but require her to follow up with her primary care physician or gynecologist. Experience with oral spironolactone in women with acne generally was positive in the absence of underlying risk factors for hyperkalemia.

United States: norgestimate–ethinyl estradiol (Ortho Tri-Cyclen®), drospirenone and ethinyl estradiol (Yaz®), and norethindrone acetate and ethinyl estradiol (Estrostep® Fe). They reduce acne lesion counts, severity grades, and self-assessed acne compared with placebo, and activity extends to inflammatory and noninflammatory facial lesions.[63-70] Three to 6 cycles often are needed to visibly appreciate improvement.[71] Differences in effectiveness among OCs based on progestin types and dosages are less clear.[53]

Common side effects associated with OCs include weight change, breast tenderness, mood changes, and breakthrough bleeding. Uncommon reactions include thromboembolism, myocardial infarction, and stroke.[72] The risk for thromboembolism is greatest during the first year of use and is higher in the presence of obesity, diabetes mellitus, and hypertension.[73] However, the risk for thromboembolism from OCs is lower than the risk for pregnancy-related thromboembolism.[74] A history of smoking places patients at higher risk for myocardial infarction and ischemic stroke, and women who smoke and are older than 35 years should not take OCs. Women with uncontrolled hypertension or migraine headaches with neurologic signs are not eligible for OC use.[75]

Long-term use of OCs is associated with an increased risk for cervical cancer in women who test positive for human papillomavirus but not in women who test negative.[76] Current or former OC use does not appear to be definitively associated with increased risk for breast cancer, regardless of treatment duration, age at treatment initiation, ethnicity, or family history of breast cancer.[77] Guidelines for patient evaluation prior to prescribing OCs for the treatment of acne have been published.[74]

Spironolactone

Spironolactone is an effective therapy for acne vulgaris in women.[78] As a single-drug therapy or an adjunct to standard therapies (antibiotics, OCs, antibiotics plus OCs), a retrospective review of spironolactone 50 to 100 mg daily for up to 24 months revealed complete clearing or marked improvement in 66% (48/73) of women who completed treatment.[79] These findings are supported by a recent study of spironolactone 100 mg and ethinyl estradiol 30 µg plus drospirenone 3 mg added to existing topical antiacne treatment in 27 women with severe papular or nodulocystic facial acne who failed to respond to at least 1 former standard acne treatment.[80] After 6 months, 23 patients (85%) were clear or had excellent improvement (≥75% clearance). Thus, augmentation of the antiandrogenic effect of drospirenone by spironolactone and the reduction of unwanted effects (eg, spotting, menstrual irregularities, weight gain, mood changes, pregnancy) make this combination attractive for moderate to severe acne vulgaris in females.[80]

In dosages of 50 to 100 mg twice daily, spironolactone has been shown to reduce sebum production and improve acne.[6] As with other hormonal therapies, an initial visible response in acne may take up to 3 months. Recommended maintenance dosages range from 25 to 200 mg daily of spironolactone.[81]

Menstrual irregularities, central nervous system symptoms (eg, lethargy, fatigue, dizziness, headache), and hyperkalemia (4.8–5.3 mEq/L [reference range, 3.5–5.0 mEq/L]) have been reported in 17.5% (14/80), 16.3% (13/80), and 13.7% (10/73) of women treated with spironolactone 50 to 100 mg daily for up to 24 months.[79] Less common (<5%) were increased urinary frequency (2/80), postural lightheadedness (2/80), melasma (2/80; reported in women who also received OCs), nausea (1/80), decreased libido (1/80), and xerosis (1/80). Mean systolic/diastolic reductions in blood pressure were −5/−2.6 mm Hg.[79]

During an 8-year follow-up study (mean treatment duration, 28.5 months [range, 0.5–122 months])(N=210), side effects were present in 59% of women and resulted in cessation of spironolactone in 15%. Diuretic effect and menstrual irregularities were the most common adverse effects, but there were no cases of serious adverse effects attributable to spironolactone.[78]

Caution is required when spironolactone is administered with potassium supplements, angiotensin-converting enzyme inhibitors, other potassium-sparing diuretics, corticosteroids, and nonsteroidal anti-inflammatory agents. Spironolactone can increase serum digoxin levels, requiring adjustment of the digoxin dosage. Elevation of serum lithium levels may occur if spironolactone is coadministered. Acne is not an FDA-approved indication for spironolactone. The FDA advises

that spironolactone has been shown to be a tumorigen in long-term toxicity studies in rats, and categorization of spironolactone as a pregnancy category C medication (contraindicated in females who are or may become pregnant) warrants, at minimum, patient counseling and consideration of concomitant use of an OC if clinically feasible.[82]

Treatment Recommendations for Patient 4

This patient's history does not suggest the presence of polycystic ovary syndrome. Therefore, in this patient with acne that is unresponsive to topical therapy, most panelists agreed that more aggressive treatment including an OC, with or without spironolactone, plus topical therapy and an oral antibiotic were indicated.

CONCLUSION

The roundtable discussions revealed that successful treatment of acne vulgaris depends on personalized treatment and strong patient-clinician relationships. Ongoing counseling and follow-up are critical, and each addition to the acne treatment regimen must be convenient, accessible to the patient, and tailored to address the specific needs of the patient who may be young and naive about the essentials of personal hygiene and skin care as well as impatient for rapid results.

For dermatologists, a knowledge of available treatment options that extends beyond pharmacology to product formulation is essential. For example, fine-tuning the use of different formulations of benzoyl peroxide and topical retinoid-containing products can make the difference between an effective, well-tolerated treatment and one that causes irritation and results in frustration for both the patient and clinician. Equally important is antibiotic dosing that focuses on achieving therapeutic levels in the pilosebaceous follicles, which may be independent of serum levels, as best exemplified by minocycline hydrochloride extended-release weight-based dosing for which efficacy and tolerability has been documented in long-term clinical trials.

The availability of multiple treatment options increases the probability of effective therapy, as the needs of individual patients may be addressed by the differentiating characteristic of specific treatment choices. Establishing rapport, dedicatedly educating patients, simplifying the treatment regimen, and using effective topical products that exhibit favorable skin tolerability profiles were considered by all panelists to be the most important factors influencing adherence to treatment.

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cutis® CME Test

INSTRUCTIONS: Based on the material you have read, select the most appropriate answer to each question. To obtain credit, please see page 23.

TEST VALID THROUGH JUNE 2010.

1. **Choose the incorrect statement regarding skin care.**
   - ☐ a. gentle washing once daily is better than twice daily
   - ☐ b. patients should select products with mild synthetic surfactants and/or emollients
   - ☐ c. routine proper daily skin care assists acne therapy by reducing the potential for skin irritation
   - ☐ d. strong deodorant soaps may damage the epidermal barrier

2. **Identify the factor(s) that lead to localized irritation and limit treatment success with topical retinoids.**
   - ☐ a. retinoid and concentration used
   - ☐ b. skin sensitivity
   - ☐ c. vehicle formulation
   - ☐ d. all of the above are correct

3. **Topical benzoyl peroxide is a potent antimicrobial agent with marked activity against *Propionibacterium acnes* and also exhibits comedolytic properties.**
   - ☐ a. true
   - ☐ b. false

4. **Which of the following is *not* true regarding benzoyl peroxide use in the treatment of acne?**
   - ☐ a. cleansers have not been shown to reduce *P acnes* strains
   - ☐ b. has been shown to reduce both inflammatory and noninflammatory acne lesions
   - ☐ c. leave-on formulations reduce the emergence of antibiotic-resistant *P acnes* strains
   - ☐ d. may be used in combination with a topical antibiotic or topical retinoid

5. **Select the correct statement regarding topical antibiotics in acne treatment.**
   - ☐ a. efficacy of clindamycin has decreased over time
   - ☐ b. efficacy of erythromycin and clindamycin is unchanged
   - ☐ c. efficacy of erythromycin has decreased over time
   - ☐ d. efficacy of erythromycin remained constant

6. **What is the US Food and Drug Administration–approved daily dosage of minocycline hydrochloride extended-release tablets to treat acne?**
   - ☐ a. 0.5 mg/kg
   - ☐ b. 1 mg/kg
   - ☐ c. 2 mg/kg
   - ☐ d. 4 mg/kg

7. **Select the correct statement pertaining to weight-based dosing with minocycline hydrochloride extended-release tablets.**
   - ☐ a. acute vestibular adverse events were comparable with immediate-release minocycline
   - ☐ b. acute vestibular adverse events were comparable with placebo
   - ☐ c. acute vestibular adverse events were significantly greater than placebo
   - ☐ d. answers b and c are correct

8. **Select the incorrect statement regarding oral antibiotics for acne vulgaris.**
   - ☐ a. low-dose antibiotic therapy should be indefinitely continued
   - ☐ b. treat for at least 6 to 8 weeks, with a total duration of 12 weeks to 6 months when clinically feasible
   - ☐ c. when necessary, restart the same oral antibiotic that was previously effective
   - ☐ d. answers b and c are incorrect

9. **Females taking oral isotretinoin must report using 2 forms of contraception simultaneously to their clinician and negative results of a monthly pregnancy test must be documented.**
   - ☐ a. true
   - ☐ b. false

10. **Select the correct statement regarding oral contraceptive treatment of acne vulgaris.**
    - ☐ a. acne severity but not acne lesion count is reduced
    - ☐ b. activity is limited to noninflammatory facial acne lesions
    - ☐ c. visible improvement consistently occurs within 1 to 2 cycles
    - ☐ d. all of the above are incorrect

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CME Test

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TODAY'S DATE

NAME
(Print Clearly) *First* *MI* *Last* *Degree*

AFFILIATION

ADDRESS (☐ HOME ☐ WORK)

CITY STATE ZIP

DAYTIME TELEPHONE E-MAIL

DATE OF BIRTH *(used for record-keeping purposes only)*

WHAT IS YOUR PROFESSIONAL DEGREE? ☐ MD ☐ DO ☐ OTHER

WHAT IS YOUR SPECIALTY?

☐ Dermatology ☐ Family practice ☐ Infectious disease ☐ Internal medicine ☐ Pediatrics ☐ Plastic surgery ☐ Other_____

MY PRACTICE IS PRIMARILY BASED IN *(Please check 1)*:

☐ Academics ☐ Private practice (solo/small group) ☐ Other_____
☐ Hospital ☐ Private practice (large group)
☐ Managed care ☐ Research

MUST BE COMPLETED: I HEREBY CERTIFY THAT I HAVE SPENT 1 HOUR ON THIS EDUCATIONAL ACTIVITY.

SIGNATURE DATE

ACTIVITY EVALUATION

PLEASE FILL IN THE APPROPRIATE SQUARE ON EACH LINE.	HIGH		AVG		LOW
HOW DID THIS COMPARE WITH OTHER EDUCATIONAL EVENTS IN WHICH YOU HAVE PARTICIPATED?	☐	☐	☐	☐	☐
PLEASE EVALUATE THE EDUCATIONAL LEVEL OF THIS CE ACTIVITY.	☐	☐	☐	☐	☐
PLEASE EVALUATE THE EDUCATIONAL FORMAT FOR THIS SUBJECT.	☐	☐	☐	☐	☐
UPON COMPLETION OF THIS ACTIVITY, THE DEGREE TO WHICH I CAN BETTER:					
• State the importance of the patient-clinician relationship, patient education, and follow-up in the successful management of acne vulgaris.	☐	☐	☐	☐	☐
• Develop a treatment strategy for topical treatments including antibiotics, benzoyl peroxide, and retinoids.	☐	☐	☐	☐	☐
• List the most commonly prescribed oral antibiotics for the treatment of acne vulgaris and the evidence supporting their use.	☐	☐	☐	☐	☐
• State the safety considerations in the use of oral isotretinoin for acne vulgaris.	☐	☐	☐	☐	☐
• List hormonal suppression treatment options, the patients with acne vulgaris who are most likely to benefit from hormonal therapy, and factors that increase the risk for adverse reactions.	☐	☐	☐	☐	☐
BASED ON CONTENT, HOW EFFECTIVE WAS THE ACTIVITY IN MEETING YOUR EXPECTATIONS AND OBJECTIVES?	☐	☐	☐	☐	☐

	HIGH		AVG		LOW
EVALUATE HOW RELEVANT THIS INFORMATION IS TO YOUR PRACTICE.	☐	☐	☐	☐	☐
THE LIKELIHOOD YOU WILL MAKE EVEN SMALL CHANGES IN YOUR PRACTICE BASED ON THE INFORMATION PRESENTED IN THIS ACTIVITY IS:	☐	☐	☐	☐	☐
PLEASE RATE THE DEGREE TO WHICH THE FOLLOWING ENHANCED YOUR LEARNING EXPERIENCE:					
• Patient 1: A Strategic Approach to Therapy Following an Initial Outbreak of Acne Vulgaris	☐	☐	☐	☐	☐
• Patient 2: Systemic Antibiotic Treatment in Moderate Inflammatory Facial Acne Vulgaris	☐	☐	☐	☐	☐
• Patient 3: Oral Isotretinoin for Moderately Severe Acne Vulgaris	☐	☐	☐	☐	☐
• Patient 4: Hormonal Suppression in the Treatment of Severe Acne Vulgaris	☐	☐	☐	☐	☐
TO WHAT DEGREE DO YOU BELIEVE THAT THE SUBJECT MATTER WAS PRESENTED OBJECTIVELY AND WITH FAIR BALANCE?	☐	☐	☐	☐	☐

PRACTICAL IMPLICATIONS

PLEASE RESPOND TO THE FOLLOWING STATEMENTS:

1. ESTABLISH A STRONG PATIENT-CLINICIAN RELATIONSHIP.

☐ ALREADY DO THIS ☐ WILL DO THIS ☐ WILL CONSIDER ☐ UNCERTAIN/NEED MORE DATA ☐ WILL NOT CONSIDER

2. INCLUDE PATIENT EDUCATION AND FOLLOW-UP AS PART OF THE TREATMENT STRATEGY FOR PATIENTS WITH ACNE VULGARIS.

☐ ALREADY DO THIS ☐ WILL DO THIS ☐ WILL CONSIDER ☐ UNCERTAIN/NEED MORE DATA ☐ WILL NOT CONSIDER

3. CONSIDER SIMPLICITY OF THE TREATMENT REGIMEN AND PRESCRIBE DRUG PRODUCTS THAT RESULT IN THE FEWEST APPLICATION STEPS.

☐ ALREADY DO THIS ☐ WILL DO THIS ☐ WILL CONSIDER ☐ UNCERTAIN/NEED MORE DATA ☐ WILL NOT CONSIDER

PLEASE LIST ANY BARRIERS TO OVERCOME BEFORE INITIATING ANY CHANGES:

ADDITIONAL COMMENTS: