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PATIENT CARE SUMMARY

BLANCHARD, Floyd

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INFLUENZA VACCINATION
YES

CHRONIC HEART FAILURE
- ACEI — YES
- Ejection Fraction — 45%
- BNA Screening — YES
- Warfarin Anticoagulant — YES

CORONARY ARTERY DISEASE
- Aspirin — YES
- Beta Blocker — YES
- Statin — YES

DIABETES
- Foot Exam
- Hemoglobin A1C — 7.3
- Low-density Lipoprotein Cholesterol — 128
- Microalbumin — YES

ASTHMA
- Spirometry — YES
- Peak Flow — YES
- SABA — YES

ADULT AND ADOLESCENT IMMUNIZATIONS
- Tetanus, Diphtheria, Pertussis Vaccine (Td/Tdap) — YES
- Varicella (Zoster) Virus (VZV) — YES

COLORECTAL CANCER SCREENING
- Colonoscopy — YES

BLOOD PRESSURE
160/105

BMI
39

HEIGHT
5' 10"

WEIGHT
250 lbs

eGFR
64 mL/min/1.73m²

SERUM CREATININE
YES

FASTING BLOOD GLUCOSE
142 mg/dL

TOTAL CHOLESTEROL
200 mg/dL

LDL 130 HDL 61

TRIGLYCERIDES
148 mg/dL

CLINICAL NOTES

Symphony

MEASURE

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- Cervical Cancer Screening
- Colorectal Cancer Screening
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- Obesity (Child & Adolescent)
- Preventive Services (Child & Adolescent)
- Tobacco Usage & Exposure
- Vital Signs

Chronic Care Suites

- Asthma
- Chronic Heart Failure
- Chronic Kidney Disease
- COPD
- Diabetes (Adult)
- Diabetes (Child & Adolescent)
- Hypertension (Child & Adolescent)
- Hypertension (Adult)
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American Osteopathic Board of Family Physicans Exam Schedule

EXAM	DATES AND EXAM LOCATION	POSTMARK APPLICATION DEADLINE
Sleep Medicine CAQ Certification Cognitive Exam	**Lombard, IL** August 22, 2015	CLOSED
Sleep Medicine CAQ Recertification Cognitive Exam	**Lombard, IL** August 22, 2015	CLOSED
Family Medicine/OMT Certification - Cognitive Exam	**Electronic Testing; Regional Sites** September 26, 2015	CLOSED
Family Medicine/OMT OCC/ Recertification - Cognitive Exam	**Electronic Testing; Regional Sites** September 26, 2015	CLOSED
Family Medicine/OMT Certfication Performance Evaluation ONLY	**AOA OMED Conference** October 17-21, 2015; Orlando, FL October 16-17, 2015	CLOSED
Family Medicine/OMT OCC/Recertfication Exam Performance Evaluation ONLY	**AOA OMED Conference** October 17-21, 2015; Orlando, FL October 17-18, 2015	CLOSED
Hospice & Palliative Medicine Conjoint CAQ Certification	**Orlando, FL** October 18, 2015	**June 1, 2015** filing with late fee July 1, 2015
Family Medicine/OMT Certification - Cognitive Exam	**Electronic Testing; Regional Sites** March 19, 2016	**October 1, 2015** filing with late fee thru December 1, 2015
Family Medicine/OMT Certfication Performance Evaluation ONLY	**ACOFP Conference** April 6-9, 2016; Puerto Rico April 4-8, 2016	**November 1, 2015** filing with late fee thru December 1, 2015
Family Medicine/OMT OCC/Recertfication Exam Performance Evaluation ONLY	**ACOFP Conference** April 6-9, 2016; Puerto Rico April 4-8, 2016	**November 1, 2015** filing with late fee thru December 1, 2015
Family Medicine/OMT Certfication Performance Evaluation ONLY	**ACOFP OMED Conference** September 16-20, 2016; Anaheim, CA September 16-18, 2016	**April 1, 2016** filing with late fee thru June 1, 2016
Family Medicine/OMT OCC/Recertfication Exam Performance Evaluation ONLY	**ACOFP OMED Conference** September 16-20, 2016; Anaheim, CA September 16-18, 2016	**April 1, 2016** filing with late fee thru June 1, 2016
Family Medicine/OMT Certfication - Cognitive Exam	**Electronic Testing; Regional Sites** September 24, 2016	**April 1, 2016** filing with late fee thru June 1, 2016
Family Medicine/OMT OCC/Recertfication - Cognitive Exam	**Electronic Testing; Regional Sites** September 24, 2016	**April 1, 2016** filing with late fee thru June 1, 2016

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Editor's Message

Summer Musings

Amy J. Keenum, DO, PharmD, Editor, Osteopathic Family Physician

Sunny weather is here and we have an article on sunscreens. As I sit here with the worst sunburn in years, it is clear to me that knowing and doing are two different things. Reapplication is very important and physical barriers are mentioned that include shade, clothing, hats and sunglasses. Use fresh sunscreen especially if the old ones have been stored in extreme temperatures in places like cars, boats and sport bags.

We are beginning a column that we hope to continue, with some visual dermatology. It is accompanied by information about the diagnosis and treatment of the condition of the month.

Dextrose prolotherapy is the topic of another article in this edition. It summarizes patient responses to treatment by one osteopathic physician. A small sample size and one operator limit this article but could be an example of a preliminary study mentioned in the funding article.

The use of osteopathic manipulative therapy in the treatment of concussion is explored in another preliminary study. This writing also has a small sample size and is retrospective so should be considered preliminary.

This edition of Osteopathic Family Physician has a long article on the topic of research funding. It may be of interest to those of us beginning an academic career or moving up a year in residency.

It is time for academic osteopathic family physicians to develop active research agendas. We need primary care research efforts in osteopathic family medicine. Our departments are focused on clinical teaching. We need to be exploring how we can work better and more efficiently. For example, many of my elder patients have hearing loss and cannot afford hearing aides. I know they cannot hear what I am saying. Multi-morbidity is a domain of primary care. What question do you have every day?

1877-5773X/$ - see front matter.

Physician Payment After SGR – What's Next?

FROM THE PRESIDENT'S DESK

Kevin de Regnier, DO, FACOFP dist.
2015 ACOFP President

President Obama signed HR-2, The Medicare Access and CHIP Reauthorization Act of 2015 into law on April 16, 2015, repealing the deeply flawed Medicare Sustainable Growth Rate (SGR) formula.

So now what? How will Medicare physician payment updates be calculated? Have we gone from the proverbial frying pan into the fire?

The good news is that the bill provides physicians with positive updates in each of the next five years. Granted, those updates are a paltry 0.5 percent, but we will not face the repeated uncertainty of threatened payment cuts and last minute reprieves. More importantly, HR-2 sets the stage for a shift in physician payment from volume based to performance based payments.

The bill directs Medicare to create a merit-based incentive payment system for physician payment to begin in 2019. "Merit" will be assessed in four performance categories: quality, resource use, clinical practice improvement activities, and meaningful use of a certified electronic health record. The specific measures will be developed later and may change annually. The Secretary of Health and Human Services is required to consult with physician organizations such as the ACOFP in the development of these measures.

Medicare participating physicians are scored in each category and a composite score is calculated. Composite scores range from zero to 100 and the various categories are weighted as follows: quality – 50 percent (first two years of the program) /30 percent (subsequent years), resource use – 10/30 percent, clinical practice improvement – 15 percent, meaningful use of EHR – 25 percent.

To calculate physician payment updates, the Secretary determines the mean/median performance of all providers for the year. Providers with a score at or above the mean/median receive an update of zero up to the maximum annual update that gradually increase from four percent in 2019 to nine percent in 2022. Providers at or below mean/median receive update of zero to the maximum negative update. Additional bonuses are available to physicians scoring in the top quartile and additional penalties may apply to those scoring in the bottom quartile.

In addition to affecting physician payments, your composite score and individual category scores will be published on the Medicare Physician Compare website.

One bit of good news is that if your practice is recognized as a patient centered medical home, you will automatically receive the maximum possible score in the clinical practice improvement category. Also, the Secretary is directed to give special consideration to practices of 15 or fewer providers, rural practices, and practices in a Health Professional Shortage Area, although what that special consideration looks like is not specified.

This new payment system has significant implications for physicians. The legislation requires that the merit-based incentive payment system be budget neutral, which means if somebody is getting paid more, somebody else is getting paid less. Physicians also need to ask themselves some hard questions such as:

- How will I determine if CMS has scored me properly?
- What am I doing now to track and improve the quality of care I provide?
- How will I know who is lifting my group up and who is pulling it down?
- How will this affect individual physician compensation?

Physicians need to begin preparing now for this new payment system by focusing on the quality of the care they provide, using existing EHR tools to develop and use disease registries, and implementing new quality tracking and measurement tools like ACOFP's Quality Markers Program.

Waiting until 2019 to start your practice transformation could have a serious negative impact on your Medicare payments. If you need help, check out www.acofp.org. We have a wealth of resources to help!

REFERENCE

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ORIGINAL RESEARCH

Effective Use of Dextrose-Prolotherapy within the Scope of Osteopathic Family Medicine

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Park Nicollet - Chanhassen Clinic - Family Medicine

KEYWORDS:

Prolotherapy

Hyperosmolar Dextrose

Injection Therapy

Tendinopathy

Chronic Musculoskeletal Pain

Background: Chronic pain is prevalent and often managed by family medicine-OMT (FM-OMT) physicians. By triggering the body's own healing mechanisms, prolotherapy embraces Osteopathy's second tenet, "The body is capable of self-regulation, self-healing, and health maintenance." Little has been reported to describe its utilization in FM-OMT or to formally designate its suitability to the scope of practice. **Hypothesis:** When prolotherapy is introduced within an existing FM-OMT practice, it can be delivered safely, pain scores will improve compared to baseline, and patient-preference toward prolotherapy will develop. **Methods:** 43 unique, adult patients (57 treatment areas) were treated with prolotherapy within the scope of practice of a FM-OMT physician over 15 months. The primary outcome measure was change in the 11- point numerical pain rating scale (NPRS). **Results:** 60.5% of participants reported pain improvement. 52.6% of treatment areas improved. 30.2% of participants requested treatment of an additional pain location. When adjusted for attrition, 73.2% of treatment areas improved from a total average NPRS score of 8 (standard error (SE) = 1.41) to 6.5 (SE = 2.83) (p-value <0.001), representing an 18.8% improvement. No significant complications were reported for the 170 treatments. **Conclusion**: Prolotherapy can be safely utilized within the scope of practice of FM-OMT physicians with improvement in patient-reported pain scores compared to baseline. Spontaneous development of patient-preference toward prolotherapy as a treatment for pain occurs. Additional research with a control group is warranted to further explore these outcomes.

INTRODUCTION

As of 2011, the prevalence of chronic pain in the general population of the United States has been estimated to be as high as 116 million adults.[1] If chronic pain is managed medically, it is typically done in the primary care setting. A modality that is underutilized in this setting, which has the potential to improve the care for those with chronic pain, is prolotherapy. Prolotherapy is a complementary injection-based therapy for chronic musculoskeletal pain that requires specialized training[2] and is used by providers of various allopathic and osteopathic specialties to treat pain conditions resulting from ligament and joint laxity,[3] low back pain, osteoarthritis, and tendinopathy.[2] Injections are often guided by palpation. Favorable outcomes have been reported in the treatment of lateral epicondylosis,[4, 5] Achilles tendinosis,[6, 7] groin pain,[8] plantar fasciitis,[9] and knee osteoarthritis.[10] While the exact mechanism of action has not been clearly established, various prolotherapy solutions ("proliferants") exist, and each may have a different mechanism of action. Proposed mechanisms include cellular irritation, chemotaxis of inflammatory mediators, sclerosis of pathologic neovascularity, and release of growth factors.[2, 11] Traditionally, the injection of proliferant has been hypothesized to stimulate localized irritation and inflammation that ultimately promotes healing of tissue and reduction of pain.[2, 3, 5, 7]

Prolotherapy is potentially a useful addition to the scope of practice of FM-OMT physicians. The skill of palpation used by osteopathic physicians utilizing osteopathic manipulative treatment (OMT) in clinical practice is likely to lend itself well to the recognition of ligament-laxity on physical examination, and also to effectively implement prolotherapy. Despite the utility of integrating prolotherapy within the FM-OMT scope of practice, little has been reported in the literature to describe the outcomes of doing so, the safety of implementation, and patient response to the offering. This study serves to describe observations after one year of implementation of dextrose-prolotherapy into an established osteopathic family physician's practice.

METHODS

Dextrose-prolotherapy (15% dextrose in 1% lidocaine) was utilized in an established osteopathic family practice for one year. Participants were enrolled over the course of 12 months as part of the routine family practice. Treatment sessions were completed within the year of the study. Outcomes were recorded for the year of implementation plus an additional three months for the purpose of surveillance of those whose treatment sessions occurred in the latter portion of the year-long study interval. Treatment was offered by

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an osteopathic family physician with specialized training in prolotherapy,[2] † who was a member of a larger family medicine group.

Adults aged 25 to 86 years from the primary care practice were enrolled (Table 1). Inclusion criteria included: the existence of pain conditions secondary to ligament-laxity; tendinopathy; or other indications as noted previously.[2-9] Diagnoses were made clinically by evidence of ligament-laxity on physical examination, tissue-texture abnormality and tenderness at entheses, or by demonstration of tendinosis on imaging. Participants did not have typical absolute contraindications for the implementation of prolotherapy (active local infection, such as cellulitis or abscess) or relative contraindications (acute gouty arthritis or acute fracture).[2] Prolotherapy was offered for all typical treatment locations other than the axial cervical spine.

The primary outcome measure was the amount of change in the 11-point numerical pain rating scale (NPRS) (0 = no pain; 10 = worst pain). This was assessed via paper visual questionnaire or verbal interview. The scale was assessed prior to each treatment session. If the final NPRS for a participant was unknown at the end of the study, the participant was contacted by telephone and asked for a final NPRS value verbally. If a participant reported improvement in the NPRS after prolotherapy, but later required a more definitive procedure, such as surgery, the treatment area was not included in the results section as improved.

Prolotherapy injections were implemented by palpation-guidance; no external modalities were used to assist in needle placement. Treatments were done no more frequently than at intervals of two weeks. Participation was voluntary and data were acquired observationally, not at prescribed intervals. Participants were billed a nominal fee for prolotherapy. No commitment was required to participate in follow-up treatments or evaluations. No incentive was offered for participation. The provider was not incented to perform prolotherapy. All follow-up treatments were initiated at the discretion of the participant and were not directed or requested by the provider. Treatment with prolotherapy did not exclude the continuation of additional concurrent treatment modalities, such as physical therapy or OMT. Avoidance of non-steroidal anti-inflammatory drug (NSAID) use was recommended in the days immediately following prolotherapy sessions.

TABLE 1

Baseline Participant Characteristics
(participants = 43, treatment areas = 57)

Female, n (%); Male, n (%)	27 (62.8%); 16 (37.2%)
Age, years, mean (SD)	52 (4.9)
Female treatment areas, n (%); Male treatment areas, n (%)	35 (61.4%); 22 (38.6%)

RESULTS

Over the course of one year, 43 unique participants aged 25 to 86 years, who had pain that persisted in duration from one week to 35 years, were enrolled into treatment with prolotherapy. 27 participants were female; sixteen were male. Locations of treatment included low-back/pelvis/sacroiliac region, shoulder, knee, hip, elbow, wrist, ankle, hand, and

TABLE 2

Locations of Pain, Number of Areas by Location, Number of Areas by Location with Improvement Compared to Baseline, and Chronic Pain Improvement by Location Compared to Baseline

Location of Pain	Total Number of Pain Areas (by location)	Total Number of Improved Pain Areas (by location) and (n) that were chronic
Low Back/Pelvis/ Sacro-Iliac	20	8 (8)
Shoulder	11	7 (6)
Knee	8	2 (1)
Hip	7	7 (7)
Elbow	6	3 (2)
Wrist	2	1 (0)
Ankle	1	1 (1)
Hand	1	0 (0)
Ribs	1	1 (1)
Total	57	30 (26)

ribs/thoracic spine (Table 2). Pain in each identified body region was individually assessed using the NPRS. The average number of treatments per area was three, and the range of treatments was one to 16. Using 11-point NPRS, 60.5% of participants reported improvement in pain (26 of 43 patients). If a participant requested more than one location be treated, the 11-point NPRS scores for each location were analyzed individually, and the participant accounted for more than one area of treatment. This resulted in a total of 57 unique treatment areas. Thirty-five treatment areas pertained to female participants; twenty-two treatments areas pertained to male participants.

In total, 43 unique participants contributed 57 unique treatment areas to the analysis. Improvement in pain was reported for 30 of the 57 unique treatment areas (52.6%). Acknowledging that a clinically important pain improvement is made when a two-point or greater improvement in the 11-point NPRS11 is achieved, 18 of 57 treatment areas (31.6%) met this criterion. Of the treatment areas that improved, 18 of 30 (60%) were clinically important. Forty-nine of the 57 total treatment areas were areas of chronic pain (86.0%), with chronic pain defined as pain persisting for more than three months. Improvement in pain was reported for 26 of the 49 chronic pain locations (53.1%), while four of eight non-chronic pain areas showed improvement in pain (50.0%) (Table 3). The cumulative number of treatments for the study was 170.

Of the 27 total treatment areas that did not demonstrate improvement compared with baseline, three treatment areas were lost to follow-up (5.3% of total treatment areas), eight treatment areas ultimately had a secondary procedure (14.0%), and four treatment areas were still receiving prolotherapy at the end of the recording period (7.0%). The total number of treatment areas lost to follow-up, receiving secondary treatment, or continuing to receive prolotherapy was 15 (26.3% of total treatment areas) (Figure 1).

When data are adjusted for participants lost to surgery (8), lost to follow up (3), lost to re-injury (2), and those who could not accurately describe initial pain (3), there were 32 unique patients with 41 unique treatment areas. Thirty treatment areas (73.2%) showed improvement (Table 4).

FIGURE 1

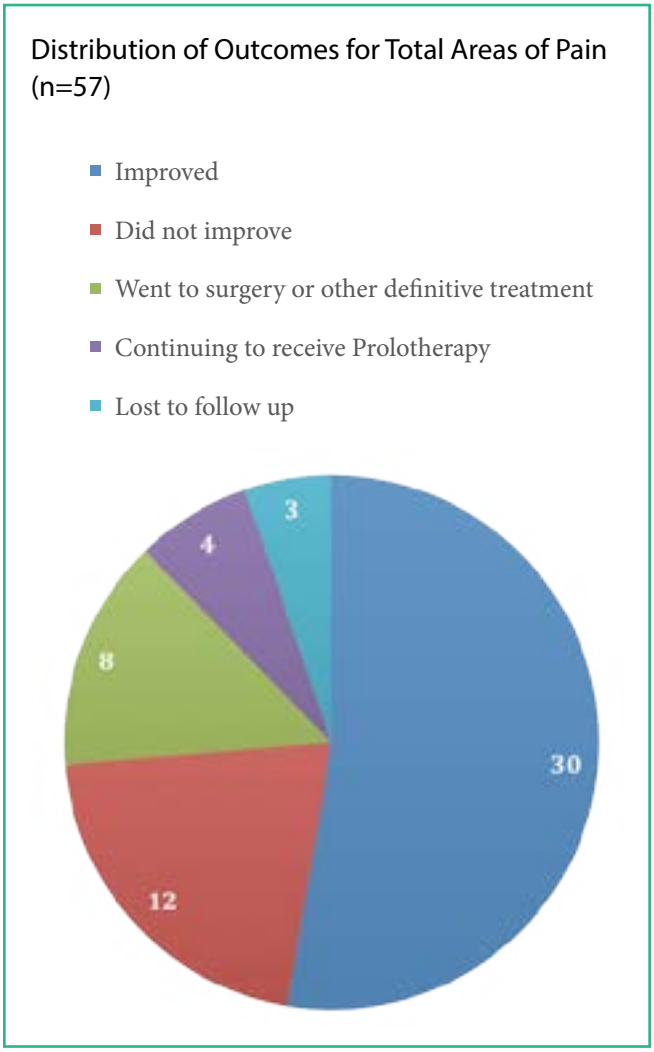

TABLE 3

Number of Treatment Areas of Chronic Pain and Non-Chronic Pain with Reported Improvement Compared to Baseline

	Number of Treatment Areas	Number of Areas with Improvement	Percent of Areas with Improvement
Areas of Chronic Pain	49	26	53.1%
Areas of Non-chronic Pain	8	4	50.0%
Total Areas	57	30	52.6%

TABLE 4

Change in 11-point NPRS Compared to Baseline (after data adjustment)

	Baseline Score	Change in Score Compare to Baseline	p-value
Total Average 11-point NPRS Score and Change in Score, (SE)Areas of Non-chronic Pain	8 (1.41)	-1.5 (2.83)	< 0.001
% total of 11-point NPRS Score Improvement	N/A	18.8%	N/A

During the 15 months the study was observed, there were no significant complications, such as allergic reaction, pneumothorax, nerve injury, infection, or hematoma. Two treatments (1.2% of total treatments) resulted in brief, amplified, post-procedural pain. In both cases, prednisone was prescribed and pain resolved.

Over the course of the study, 13 of the 43 unique participants (30.2%) spontaneously requested treatment with prolotherapy for an additional area of pain other than the treatment area for which he or she was originally enrolled.

DISCUSSION

This uncontrolled, observational study is a report of successful implementation of dextrose-prolotherapy as a general offering for multiple body locations within the scope of the FM-OMT practice setting, and demonstrates a positive effect in this clinical context for treatment of multiple locations of chronic pain on an 11-point NPRS compared with baseline status.

Previous studies suggest that prolotherapy is beneficial when compared with baseline status for several specific pain conditions, and randomized controlled trials continue to emerge.[4, 6-10, 12-15] While most studies are location-specific and utilize various scales for surveillance of treatment outcome, this study serves to suggest a utility of prolotherapy within the context of a typical family practice in which numerous pain conditions present, and highlights the patient-centered simplicity of the NPRS for treatment surveillance, which is common to the routine clinical setting.

Prolotherapy can be safely added to the scope of a FM-OMT practice when the provider has had additional specialized training. The osteopathic skill of palpation that is utilized in OMT lends itself well, logically, uniquely, and safely to diagnose ligament or tendon laxity/injury and to implement prolotherapy. For the duration of the 15 months in which the study took place, only two brief, self-limited complications were noted.

Participants experienced improvement in chronic pain; 86% of the areas treated in this study were areas of chronic pain. At least 53.1% of the total treatment areas had improvement in pain reported; 73.2% showed improvement after data correction. The participants largely enrolled from non-referral sources, and most had not found benefit with standard treatment modalities. Within the context of the FM-OMT setting, there was meaningful improvement of chronic pain compared with baseline that was unlikely to be realized otherwise.

Prolotherapy can become a treatment of choice for those who receive it. Most participants who entered the study had no prior knowledge of prolotherapy–only one participant had received prolotherapy prior to the study. Nearly one-third (30.2%) of participants spontaneously requested treatment with prolotherapy for an additional area of pain other than the treatment area for which they were originally enrolled. These data suggest that those who receive prolotherapy develop confidence in its use as an effective treatment independently of the potential bias of the provider.

DISCUSSION

Dextrose-prolotherapy can be safely utilized within the scope of practice of FM-OMT physicians with improvement in patient-reported pain scores compared with baseline. Patient preference of prolotherapy as a treatment for pain spontaneously occurs. Additional research with a control group is warranted to further explore these outcomes.

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REVIEW ARTICLE

Sunscreen in the Spotlight: A Comprehensive Review of Over-the-Counter SPF Drug Products for Sun Protection

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In 2012, the Food and Drug Administration revised their guidelines on sunscreen in an attempt to cease the misleading and unsubstantiated claims commonly published on sunscreen product labels. Skin cancer is the most frequently diagnosed form of cancer in the United States with cases of skin cancer increasing worldwide. Despite these statistics, misconceptions among both consumer patients and health care practitioners, regarding sun protection factor, ultraviolet radiation, sunscreen efficacy, and application remain prevalent. For these reasons, it is imperative that practitioners have a fundamental understanding of sunscreen formularies in order to provide evidence based skin cancer prevention recommendations to their patients. This article aims at providing practitioners with a simplified yet comprehensive review of over-the-counter sunscreen drug products and the most recent FDA sunscreen monograph.

INTRODUCTION

Skin cancer is the most frequently diagnosed form of cancer in the United States. According to the most recent Center for Disease Control (CDC) statistics, in 2011, there were nearly 71,000 people diagnosed with melanoma and over 12,000 melanoma related deaths in the US alone.[1] This is a steep rise from one year earlier when the CDC reported 61,000 new diagnoses and 9,000 deaths.[1] As if a 33% rise in melanoma deaths over a one year period wasn't concerning enough, studies have found that children born today have a one in 33 risk of developing melanoma, a drastic upsurge from the one in 1,500 risk calculated in 1935.[2] Despite these alarming statistics, medical students receive minimal education in over-the-counter SPF drug products and physicians report that that skin cancer prevention counseling is not a priority. According to a survey of over 1600 American Academy of Pediatrics physicians, over 90% of pediatricians acknowledge the necessity for counseling patients on sun safety measures, however most admitted to rarely following through due to time constraints.[2] Furthermore, common misconceptions regarding sun protection factor (SPF), ultraviolet radiation (UVR), and the mechanism of action of SPF drug ingredients remain prevalent among healthcare providers.

The Food and Drug Administration (FDA) has produced several monographs on sunscreen since 1978, with significant activity in 2011. This article aims at providing practitioners with a simplified yet comprehensive review of over-the-counter (OTC) sunscreen drug products and the most recent FDA sunscreen monograph. In addition, the authors have addressed common misconceptions about SPF, such as measured efficacy and areas of debate requiring the provider's clinical judgment on a case-by-case basis.

ULTRAVIOLET RADIATION

The light emitted by the sun's rays, as classified by its wavelength on the electromagnetic spectrum, ranges from the longer wavelengths of visible light to the shorter wavelengths of ultraviolet (UV) light. Ultraviolet light is further subdivided into three potentially skin-damaging subcategories: UVA (315-400nm), UVB (290-315nm), and UVC (270-290nm).[3] Although sources slightly differ on cutoff endpoints, wavelengths shorter than 300nm typically do not result in skin damage because they are absorbed by the earth's ozone layer.[3] Therefore humans have minimal radiation exposure to UVC light.

Ultraviolet radiation, through the depletion of antioxidants and initiation of DNA damage, activates a complex cascade that leads to immunosuppression, inflammation, and free radical generation. The resultants of these cumulative processes are reactive oxygen species (ROS) that create oxidative damage to proteins, lipids and carbohydrates. These broken down molecules accumulate in the dermal and epidermal layers of the skin and aid in the process of photoaging.[4]

Both UVA and UVB radiation are known causes of cellular damage, which may result in cutaneous changes such as aging and skin cancer. However, due to their respective wavelength spectrums, their primary effect on the skin differs. As a general rule of thumb, the longer wavelengths of UVA light penetrate through the epidermis and into the dermis, producing a delayed tanning effect as well as alterations in dermal collagen,

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leading to signs of photoaging. Light from UVB, on the other hand, does not penetrate beyond the epidermis and has been shown to produce primarily a sunburn reaction.[5] Until recently, it was believed that only UVB rays produced skin cancer.[6] In comparison to the shorter wavelengths of UVB, UVA is able to penetrate through glass and reach the deeper layers of the skin. It has been found that 90-95% of UVA light and 5-10% of UVB light emitted by the sun will penetrate the skin, and that 20-50% of UVA light and 9-15% of UVB light will reach melanocytes.[7]

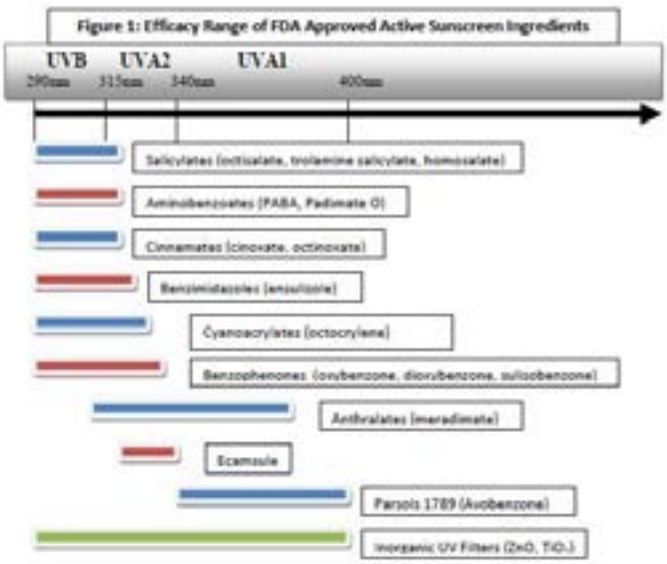
For these reasons, it is essential to use a sunscreen that provides both UVA and UVB protection, such as broad spectrum sunscreen discussed in greater detail below.

THE ACTIVE INGREDIENTS IN SUNSCREEN

There are two categories of sunscreen ingredients: organic UV filters, commonly known as chemical blockers, and inorganic UV filters, often referred to as physical blockers. Organic UV filters contain chromophores that absorb a range of UV wavelengths, triggering a series of molecular changes that ultimately result in a conversion of the absorbed energy into heat, which is transepidermally eliminated. Essentially, the chemical change that occurs from UV light interacting with chromophores prevents radiation from penetrating the skin.[6] The current FDA approved organic UV filter ingredients are: Parsol 1789 (avobenzone), dioxybenzone, oxybenzone, sulisobenzone, para-aminobenzoic acid (PABA), padimate O, ecamsule (Mexoryl SX), meradimate, cinoxate, octinoxate, octisalate, trolamine salicylate, homosalate, ensulizole, and octocrylene.[8] The chromophores within organic filters are composed of π-electron systems resulting in greatest effectiveness against the shorter wavelengths of UVB light.[3] Most of these ingredients are either ineffective or minimally effective against UVA light, however, ecamsule, which is capable of absorbing short UVA wavelengths (320-340nm), and Parsol 1789, which protects against longer UVA wavelengths (340-400nm), may be utilized for broad spectrum chemical protection (see Figure 1).[6]

Inorganic UV filters, the second category of sunscreens, are metal oxide powders that reflect UV radiation (UVR) away from the skin, thereby acting as a physical protective barrier.[6] The current FDA approved inorganic UV filters are: titanium dioxide (TiO2) and zinc oxide (ZnO). These ingredients are capable of diffusing wavelengths larger than 370nm and, therefore provide protection against UVA and a portion of UVB radiation.[6] The primary disadvantage of these ingredients is that they appear thick and chalky on the skin, making them aesthetically unappealing to consumers.

The majority of OTC sunscreen products consist of a combination of organic and inorganic UV filter ingredients.



Combination formularies are often preferable due to the fact that they offer protection against a larger UVR wavelength spectrum. Another benefit to combination products is increased durability. Organic UV filters have limited photostability under normal environmental conditions; therefore inorganic UV filters are typically added for their durability throughout prolonged periods of sun exposure.[6, 8-9]

Two proprietary sunscreens have been approved by the FDA: Helioplex, produced by Johnson & Johnson Neutrogena, and Mexoryl SX (La Roche-Posay), created by L'Oreal Paris. Both products utilize the broad spectrum, yet photo-unstable, azobenzone and combine it with oxybenzone to enhance resiliency. These proprietary sunscreens are advantageous in that they are broad spectrum, photostable and non-irritating.[2]

SUNSCREEN EFFICACY

Efficacy of sunscreen drug products is measured by two key components: sun protection factor (SPF) and UVA protection profile. The SPF of a sunscreen is measured by in vivo laboratory testing. Volunteers with Fitzpatrick skin types I-III skin types receive a sunscreen density of 2mg/cm^2 and are subsequently administered increasing doses of UVR.[3,9] The "minimal erythema dose" (MED) is defined as the least amount of UVR required for visible erythematous skin changes with distinct and clear borders 16-24 hours following UV introduction.[3] In theory, the MED correlates to the amount of time the sunscreen product protects the skin against the reddening effects of UVB, as opposed to the amount of time that erythema would occur without protection.[10] For instance, if your patient normally sunburns after 10 minutes in the sun, applying SPF 15 with an appropriate application thickness (2mg/cm^2) will protect an individual from sunburn for 150 minutes (2.5 hours). It is essential to note that SPF specifically refers to UVB protection alone, and that this testing model has many limitations such as inter-laboratory variability and

genetic or sensitivity variability of the volunteers.[11]

The method of measuring the second component of sunscreen efficacy, UVA protection profile, varies worldwide. In the United States, the FDA included in their most recent monograph a mandate for in vitro critical wavelength assessment. In this test, the product being evaluated is placed at a density of 0.75 mg/cm^2 in polymethylmethacrylate plates.[3] Ultraviolet doses starting at 290nm are then administered until the sum of the product's total absorbance reaches 90% of that product's total absorbance in the UVA spectrum (290-400 nm).[3,11] A sunscreen's critical wavelength is thus a measurement of the product's range of UVA protection.

THE NEW FDA MONOGRAPH FOR OTC SUNSCREEN PRODUCTS

The U.S. FDA recently published guidelines for over-the-counter sunscreen labels with a compliance deadline of December 2012.[8] According to these guidelines sunscreen products that adequately provide both UVA and UVB protection may garnish the label "broad spectrum." Adequate UVB protection has been defined as a minimum SPF of 15, whereas, satisfactory UVA protection, according to the FDA, has 90% of its absorbance at the critical wavelength of 370nm or greater.[8-9,12]

On sunscreens that have been deemed broad spectrum, the FDA now allows manufacturers to add the following claim to their product: "if used as directed with other sun protection measures…decreases the risk of skin cancer and early skin aging caused by the sun."[8] In the same light, sunscreens that do not meet the critical UVA wavelength and/or have an SPF of less than 15 are now required to print the following warning: "Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or skin aging."[13]

Prior to the FDA guidelines, there was an epidemic of uncorroborated claims regarding length of protection and durability of sunscreen products in high moisture environments. Now, claims such as "all-day protection", "waterproof" and "sweat-proof" are replaced with strict time limitations of either 40 or 80 minutes. For instance, sunscreens that have proven resiliency against water for 40 minutes following application, now state on the bottle "water resistant (40 minutes)."[14]

In addition to the new monograph, the FDA proposed a regulation that, if finalized, limits SPF to 50+. Advocates of the proposal argue that higher SPF values increase exposure to potentially irritating chemicals while providing minimal additional UVB protection.[12] The claim that little benefit is gained from SPF values greater than 30 stems from the absorbance equation, A=1-1/SPF, which demonstrates a logarithmic curve with UVB absorbance plateauing at SPF 30 (see Figure 2).[9]

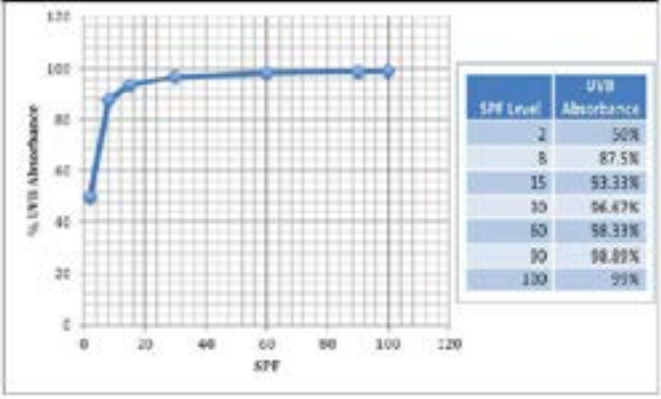
Opponents of the FDA's proposed SPF limit argue that the measurement of 'minimal erythema' utilized in the determination of SPF only evaluates for a visible erythematous response and does not take into consideration potential damage on the cellular or molecular level.[10] The ability for UVR doses below the minimal erythema level to cause long-term skin damage such as aging, immunosuppression, and skin cancer, has been well documented in the literature.[10] Furthermore a study, by Cole et al, found that a photostable SPF 55 offered cellular and molecular protection proportional to the SPF level.[10] However, this study compared the cellular changes of unprotected skin exposed to UVR to SPF 55 protected skin exposed to UVR. Despite these findings, there remains a lack of research comparing the cellular and molecular changes of UVR-exposed skin with SPF levels of 30 to that of higher SPF levels. A second counterargument to the FDA proposed SPF cap is that consumers average a sunscreen application thickness of 25-50% of the FDA recommended 2mg/cm^2 application density, thus resulting in actual SPF protection values significantly lower than labeled.[15-16] A recent study by Ou-Yang, et al that compared the actual SPF value of six sunscreens (with varying labeled SPF values between 30-100) at four application densities, found that broad spectrum SPF > 70 products were required when applying at a low application density of 0.5 mg/cm^2 in order to provide the FDA's minimal required protection for broad spectrum of SPF 15.[15] The FDA has not yet published guidelines for high SPF sunscreen and has stated that it will continue to review submitted data on sunscreens with SPF > 50.

CLINICAL CONSIDERATIONS & RECOMMENDATIONS

The new FDA monograph does not pertain to all forms of over-the counter sunscreens. Only oils, creams, lotions, gels, butters, pastes, ointments, sticks and sprays are considered eligible for inclusion. All other formularies, such as body washes, towelettes, powders, shampoos, etc., must apply for consideration from the FDA on a case-by-case basis.[12-13]

Regarding spray products, the FDA has requested additional information on their effectiveness and they plan to further investigate potential health consequences secondary to incidental inhalation.[13] A study by McKinney et al detected cardiovascular and pulmonary damage secondary to inhalation of spray TiO2 particles.[17] Therefore, spray sunscreen products are of particular concern in patients, particularly children, with known respiratory disease as asthma exacerbations may occur. Additional drawbacks to

Figure 2: Absorbance of UVB radiation as related to SPF level



SPF Level	UVB Absorbance
2	50%
8	87.5%
15	93.33%
30	96.67%
60	98.33%
90	98.89%
100	99%

using spray products include the requirement of manually rubbing in the product for complete coverage. Consumers are unable to safely assume that spraying the product and walking away will provide adequate sun protection coverage. Healthcare professionals should keep the above information in mind, along with their clinical judgment, when providing recommendations regarding sunscreen formularies to their consumer patients.

For patients of all age groups, long sleeve shirts, sunglasses, and wide brim hats in concert with careful avoidance of sunlight during the peak hours of 10am-2pm should be the mainstay of photoprotection methodology.[3] In adults, a broad spectrum sunscreen with SPF > 30 applied to sun exposed skin every two hours during periods of sun exposure is recommended.[18]

Unfortunately, due to limited research, pediatric guidelines are not as straightforward. Pediatrics, particularly infants, have a significantly larger body surface area to volume ratio than adults lending to the potential for increased chemical absorption when applied topically. For this reason, sunscreen drug products should be avoided in infants < 6 months of age and parents must be counseled on proper sun avoidance techniques.[16] The FDA determined in the new monograph that sunscreen is now considered safe in patients > 6 months old.[9] However, only inorganic UV filters are advised for children between 6 months and 2 years of age due to the fact that they are less irritating to the skin and less readily absorbed.[2,9,16] Keep in mind that inorganic filters do not provide the same range of UVB protection as combination sunscreens, thus further necessitating limited sun exposure along with protective clothing as the primary methods of UVR protection.

PATIENT EDUCATION

It is imperative to educate patients on the importance of purchasing broad-spectrum sunscreens. Sunscreens than do not don the "broad spectrum" label do not offer protection while driving or sitting near windows due to their lack of UVA absorbance. Although SPF 15 is eligible to be considered broad spectrum by the FDA, the American Academy of Dermatology (AAD) maintains a recommendation of SPF 30, reapplied every two hours when outdoors.[18] Furthermore, the FDA conducts SPF testing with a standard application of 2 mg/cm^2 of sunscreen product to the skin. According to previous studies, consumers average an application thickness less than 50% of that amount.[4,19-20] This suggests that, without proper physician instruction, consumers are often not receiving full SPF protection despite the use of sunscreen. A simple method physicians may use for patient education is to instruct their patients to squeeze a golf ball sized amount of sunscreen product into the palm of their hand and then thoroughly rub all of that product evenly onto exposed skin.

Another necessary topic for patient education is sunscreen shelf life. Current FDA regulations do not mandate the publication of expiration dates on OTC drug products without dosage limitations that are stable for a minimum of three years.[13] Nevertheless, it is commonly advised that sunscreen products be discarded after three years of use. Moreover, products purchased prior to the December 2012 FDA compliance deadline may not provide substantiated evidence regarding UVA protection, durability, and water resistance.

Lastly, since peek daylight hours and outdoor activities often go hand in hand, it is important to discuss the topic of combining bug repellants and SPF drug products with your patients. N,N-diethyl-m-toluamide (DEET), the most frequently used active ingredient in bug repellents, is estimated to decrease the SPF of a sunscreen by approximately 33%.[21] Therefore, in order to obtain the same degree of sun protection, sunscreen must be reapplied even more frequently and in greater amounts. Another health concern that arises with the topical co-administration of sunscreen and insect repellants is resulting higher transdermal absorption of the repellant product.[22] Currently, the CDC recommends that consumers apply SPF and insect repellants separately and that insect repellants be reserved for patients over 2 months of age.[23]

ON THE HORIZON

As consumers are becoming increasingly more conscious of the harmful effects of UVR, technological advancements in photoprotection are rapidly enhancing our ability to prevent skin cancer. One of the newest technologies developed is nanoparticle polymer spheres, ZnO and TiO2 particles reduced to sizes less than 100nm diameter.[5] The nanoparticles are easily incorporated into makeup and clothing for a multitude of potential uses without leaving the characteristic chalky residue of their larger sized counterparts. However, these particles are easily absorbed resulting in controversy regarding their safety.[5]

Heliocare, Fernblock and Sunpill are oral supplements containing polypodium leuctomos, an extract that has demonstrated modest evidence of antioxidant, immunomodulating, and photoprotection properties.[5] However, the sample sizes studied were small and the products are not intended to replace sunscreens, but instead to work in concert with topical SPF 30 products. The FDA has not provided their recommendations on these new products. Still, some are available to consumer patients, potentially prompting them to seek the advice of their physician.

CONCLUSION

In 2012, the FDA revised their guidelines on sunscreen in an attempt to cease the misleading and unsubstantiated claims commonly published on sunscreen product labels. The new guidelines deem products providing a minimum of SPF 15 and UVA protection as "broad spectrum." However, clinicians should be conscious that the AAD upholds their SPF 30 recommendation.

Under application, failure to reapply sunscreen every two hours, and misconceptions regarding the meaning of SPF are common reasons for sunscreen failure. Due to the increased incidence in skin cancer worldwide, physicians should educate consumer patients on the method of application in order to reduce the damaging cutaneous effects of UVR. Additionally, physicians should be familiar with the sunscreen formularies and active ingredients in order to provide evidence based recommendations to their consumer patients.

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REVIEW ARTICLE

Funding and Other Resources for Beginning Researchers

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KEYWORDS:

Research Proposal

Research Support

Research Personnel

Grant Writing

Despite the fact that osteopathic research is essential for the continued advancement of our profession, such research is lacking. One barrier is the attainment of funding resources to launch and continue quality research studies. In the present article, the authors outline resources for the early stages of research and provide guidance for grant proposal preparation, if it is determined that external funding is needed. Free and low-cost resources for obtaining preliminary data and sources of external funds are described. An overview of grant writing and information on where to obtain training is presented. Information on proposal writing basics, tips to increase the chances of success, the grant application process, and basic proposal and budget requirements is provided. Potential funding sources appropriate for beginning investigators are listed, as well. Suggestions are offered for revising and resubmitting unsuccessful proposals.

INTRODUCTION

The osteopathic medical profession needs to substantially increase its engagement in clinical research if it is to remain a viable healthcare system, according to many authorities.[1-14] Research, both basic science and clinical, is being conducted at most osteopathic medical schools.[15] Researchers at these institutions are knowledgeable about how to do research and how to obtain resources. Research can also be conducted in residency programs, but at a less advanced level. However, to expand the research base, it is necessary to increase research at osteopathic medical schools and residency programs. Clinical faculty, residents, and students typically are not trained in research, as evidenced by the fact that DO researchers accounted for less than 12% of research grant awards to osteopathic medical schools between 2004 and 2009.[15] It is these clinicians and their trainees who must increase the research output.

Research is a multistep process that begins with developing an idea, formulating the research question, reviewing the literature, establishing the objectives and hypothesis, and constructing the methods.[16] As the research question is developed and refined, a comprehensive literature search helps to establish whether the idea is original, avoid unnecessary duplication, and build the background and rationale for the proposed study.[16] In addition to searching MEDLINE, PubMed, and other medical literature databases, many researchers use clinicaltrials.gov to identify studies that are ongoing in a particular field (thereby avoiding unnecessary duplication), find topics for potential research, and locate collaborators.[17]

Some research requires few resources, including but not limited to funding, to continue and gain momentum. Educational and survey research, medical chart reviews, and analyses of existing data sets are examples of research that is not resource intensive. This article will identify some free and low-cost resources to help beginning researchers learn and understand the research process and obtain preliminary data.[18] It also provides guidance for proposal preparation, if it is determined that external funding is needed. If the decision to seek funding has already been made, preliminary data will be needed (even if the grant announcement says otherwise) to demonstrate the principal investigator's experience relevant to the research and describe the groundwork that is likely to lead to a successful funded project.[19,20] Gathering preliminary data may require only the free and low-cost resources described below. Despite starting with a shoestring budget or no budget at all, the investigator(s) may be able to continue to make progress while preparing to apply for funding or awaiting the sponsor's decision. Several months' lag time between the application deadline, award notification, and project start dates should be expected.[21]

In addition to getting money, some compelling reasons to seek external support include developing and advancing knowledge, enhancing training opportunities, contributing to the prestige of the program and institution, and furthering the investigator's career.[22]

A wise novice researcher will seek the advice of someone with experience in writing successful grant proposals as a mentor.[23] The institution's research and sponsored programs office can assist in identifying potential sources of funding

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and preparing proposals for submission,[24] and may also help in identifying a mentor. For those without access to such an office, local institutions of higher learning (with or without a medical school) may have altruistic faculty willing to provide advice and guidance. This article provides a blueprint for novice researchers for writing and submitting research grant proposals.

FINDING FREE RESOURCES

Many resources are available to reduce the expenses related to collecting data. Government databases and websites and medical charts are excellent sources of historic comparative data.

To evaluate a new drug or procedure, using historical controls instead of an active control group may be an option. Historical controls are people "followed at some time in the past or for whom data are available through records who are used for comparison with subjects being treated concurrently."[25] A control group of living individuals may not be needed, for example, if the disease/condition and its course are well documented. Historical controls are also useful when randomization to an untreated control group is not ethical. Because of advances in medical care and changes in demographics and other factors, use of historical controls may not always be appropriate. This option should be discussed with a statistician.

Free databases are available from many federal agencies. The National Institutes of Health (NIH) maintains an extensive list of federal, nonfederal, and international databases at www.nlm.nih.gov/hsrinfo/index.html, a sample of which is presented in Figure 1.

The public registry clinicaltrials.gov is an excellent resource for those who wish to learn more about clinical trials and observational studies, including specific ongoing research projects. A database containing results of completed clinical studies is also available on the site.

The National Center for Biotechnology Information (NCBI) provides access to databases and tools containing biomedical and genomic information. For example, the Bookshelf collection (www.ncbi.nlm.nih.gov/books) has biomedical textbooks and other scientific titles that can be searched directly or through other NCBI databases.

Individual government agency websites have additional databases. For example, the Agency for Healthcare Research and Quality (AHRQ) has links to the Medical Expenditure Panel Survey (MEPS), National Healthcare Quality Report, and United States Health Information Knowledgebase, along with a guide on which resource to use for a particular purpose (www.ahrq.gov/data/dataresources.htm). The Centers for Disease Control and Prevention has many data sets on children and adults, including the National Health and Nutrition Examination Survey (NHANES) and the Behavioral Risk Factor Surveillance System. Free databases may also be available from state or local departments of health and Area Health Education Centers.

These websites and databases have varying degrees of complexity. The databases can be huge, but many have user-friendly report generators for the basics that will often suffice, such as numbers or percentages of people with a given health condition. The help of a statistician should be enlisted for complex databases without a report generator function or for more sophisticated (inferential) statistics.

Medical charts and electronic medical records are an excellent resource, provided their use is permitted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Medical chart data on diagnoses among specific populations may be obtained using ICD-9 codes. Chart data can also be obtained on medical procedures using CPT codes. Hospital medical records staff can assist with database queries. Prospective studies can often use test results data gleaned from medical records, if the tests were performed as part of standard of care. Such tests may not need to be repeated for the research.

Regardless of the source, all research involving data from human subjects, including research on existing data, requires review by an Institutional Review Board (IRB), even if informed consent is not required. The research office, IRB, or other impartial individual or entity knowledgeable about human subject protections must make this determination. The investigator does not have this authority.[26]

FIGURE 1:

Sample databases linked from the NIH website

- FastStats A-Z from the Centers for Disease Control and Prevention (CDC)
- Health Data Interactive from the CDC's National Center for Health Statistics
- Health Indicators Warehouse
- Quality of Life Instruments Database
- County Health Rankings
- Global Health Observatory from the World Health Organization GlobalHealthFacts.org

FINDING ECONOMICAL RESOURCES

Much research requires resources other than data to bolster the success of the project. Assistance from experts, manpower, devices, equipment, laboratory tests, and internal funds can be very important assets to the research. Some sources are described below, based on the authors' experiences.

Colleges and universities are a good source of help that can be free or inexpensive. Graduate students in epidemiology, statistics, and other fields can help with the project. Many times, these students will work for low wages or free (especially if they can obtain academic credit towards their degree). Co-authorship on publications or posters is a motivating factor for collaborators. Some schools have formal programs that match students with research projects.

Representatives from pharmaceutical and equipment companies may be able to provide items for standard care (wrist braces, placebos, medications, etc.) for the control group in the study. Equipment loans can also be arranged if "old" equipment is being replaced by a state-of-the-art model. Leasing newer equipment is a less expensive than purchasing option if it will only be needed for a portion of the study.

It is unethical and possibly illegal to bill subjects' medical insurance for labs and tests conducted solely for a research study. Clinical labs and other providers should be contacted about obtaining discount or free lab tests, x-rays, etc. Providers may be willing to offer investigators a lower rate to conduct specific tests needed for research, which will help to reduce expenses.

Some medical schools and large hospitals have small amounts of money, such as departmental budgets, student or alumni scholarships, OPTI/GME (Osteopathic Postgraduate Training Institute/Graduate Medical Education) budgets, a Dean's Fund, or research reinvestment funds. Although internally funded, there may still be a competitive application process.

Those wishing to become involved in clinical research may wish to join a Practice-Based Research Network (PBRN). PBRNs focus on health care problems in the context of primary care[27] and collect large amounts of patient encounter data by pooling smaller volumes of information from practice sites within the network.[28] The PBRN at the University of North Texas Health Science Center, called the Consortium for Collaborative Osteopathic Research Development–Practice-Based Research Network (CONCORD-PBRN), has 16 member clinics.[28] CONCORD-PBRN uses a unique approach that distinguishes it from most other PBRNs. Physicians receive training in research design and biostatistics through a fellowship program before becoming engaged in research.[29]

Training in clinical research is essential for all investigators, including those joining an existing project. FDA regulations mandate that the IRB review the qualifications of clinical investigators to perform and supervise the proposed research. In so doing, the IRB is fulfilling its responsibility to ensure that risks to subjects are minimized.[30]

SOURCES OF EXTERNAL FUNDS

Some research requires larger funding amounts to implement a quality project. Sources of funding external to hospitals and colleges and universities may need to be explored. Such sources include collaborations on ongoing research projects that have already received funding, foundations, voluntary health organizations, fellowships, and professional associations. It may be possible to find a collaborator who already has funding for a project similar to the beginning investigator's interests. Supplemental grants may be available that allow researchers or research trainees to "piggyback" onto ongoing studies.

Free federal databases of funded projects include the National Institutes of Health's Research Portfolio Online Reporting Tool Expenditures and Results (RePORTER) (http://projectreporter.nih.gov/reporter.cfm) and the National Science Foundation's NSF Award Search (www.nsf.gov/awardsearch/). RePORTER has a number of searchable fields (e.g., by city, state, and keyword) and provides the grant number; project title; principal investigator's name, e-mail, and academic title; project abstract; thesaurus (keyword) terms; grant start and end dates, and other information for each funded project. NSF Award Search contains information similar to NIH RePORTER, and includes free text search capability. There is also the newly launched Federal RePORTER (http://federalreporter.nih.gov/), which includes projects funded by NIH and other agencies, such as the Centers for Disease Control and Prevention, Congressionally Directed Medical Research Programs within the Department of Defense, Department of Veterans Affairs, and Food and Drug Administration.[31]

Other federal agencies and many private funding organizations provide lists of funded projects and are worth reviewing for ideas and for potential support.

The first consideration should be where to apply for funds. Funding agencies, also called funding sources or sponsors, are like sports teams in that they are seeking the best "players" among the many candidates. Internal or intramural funds are like college sports: a considerable number of positions or opportunities are available, but the money available is relatively small and there is little or no requirement for a record of previous successes. Private sponsors are like the

minor leagues: there are fewer positions or opportunities, but more money is available; the requirements for a history of success are more stringent, but not unattainable. Lastly, federal sponsors are like the major leagues: there are very few opportunities, but the rewards are much greater and the prospects are favorable only for those with a proven record of consistent success. Research proposals with data from a preliminary study are more likely to attract funding, supporting the eventual move from the minor leagues to the big leagues.

The following is an overview of types of sponsors appropriate for those who are at the beginning stages of funding exploration (in other words, not ready for the major leagues).

Private and corporate foundations are an excellent source of funds for beginning researchers. Foundations can be identified through the Foundation Center (http://foundationcenter.org/search/), which offers beginning grantseekers free searches on the 10,000 largest U.S. foundations. Some foundations fund projects nationwide, while others have geographic or subject area restrictions.[21]

Corporate foundations often limit their giving to areas in which they have facilities. Corporate foundations award grants based on an ongoing relationship with the investigator and will expect him or her to conduct research in a partnership with the company. There are literally hundreds of thousands of companies, including pharmaceutical companies, with funds that may be available to individual investigators.[21]

There are also services that research and sponsored programs offices subscribe to on behalf of the institution, such as SPIN™, Illinois Researcher Information Service (IRIS), and Community of Science. Search engines, such as Google and Bing™, can also be useful in identifying foundations and other private funding agencies.

Voluntary health organizations fund health-related research, such as disease prevention (e.g., heart disease, diabetes, cancer), health education, and patient services projects. Opportunities from voluntary health organizations can be explored through a general Internet search or a more focused search using the institution's subscription to a service such as SPIN or IRIS.

The American Osteopathic Association funds both research and training (fellowship) grants. Research grants are limited to proposals to study unique characteristics of osteopathic medicine, particularly osteopathic manipulative medicine (OMM)/osteopathic principles and practices (OPP).[32] Fellowships are available for undergraduate (DO) students and postdoctoral osteopathic medical students (interns, residents, or research fellows). Fellowships are for conducting and completing a research project under the direction of a faculty sponsor. Instructions and forms are available at www.osteopathic.org (keyword search "research handbook"). The American Academy of Osteopathy also has a small amount of funds to support OMM/OPP research. Information is available on their website: www.netforum.avectra.com/eweb/DynamicPage.aspx?Site=AAO&WebCode=ResearchGrantProcess.

The American Association of Colleges of Osteopathic Medicine has an annual grant cycle for medical education research. Visit www.aacom.org/InfoFor/educators/Pages/aacomgrants.aspx for details.

The Osteopathic Heritage Foundations have endowed several centers and chairs throughout the U.S. to enhance osteopathic training and medical research. Each has a specific focus, such as aging or neuromusculoskeletal disease research. The Funding Priorities section of www.osteopathicheritage.org/ lists specific information. While priority is usually given to researchers at the grantee institution and its OPTI partners, some endowments may have provisions for others to conduct research or obtain research training on site with a faculty mentor from the institution.

The National Center for Complementary and Integrative Health (NCCIH) within the National Institutes of Health funds research on complementary and alternative medicine (CAM) and training of CAM researchers.[33] Osteopathic manipulative medicine is considered a form of complementary medicine by NCCIH. NCCIH is particularly interested in funding research on the effect of CAM modalities on chronic pain processes and in supporting health and wellness. NCCIH is also prioritizing research grant applications from early stage or new investigators. More information on specific types of research career development and training opportunities are described in the Training tab on the NCCIH website.[33]

Some professional associations offer seed money grants for research focused on the medical specialty of the association. Eligibility is limited to members of the association or specialty college. One example is the Foundation for Physical Medicine and Rehabilitation (http://foundationforpmr.org/).

Several types of grants may be suited to the specific type of project. For example, some opportunities are for training on how to do research, while others are for the research itself. There are specific opportunities to support new ideas and/or new investigators with little or no preliminary data. These grants are available from a variety of ssponsors and therefore use various terms, such as rapid response, new investigator, early stage investigator, beginning investigator, young investigator, and scientist development or exploratory/developmental grants. There are even grants available to

perform sophisticated analyses of existing databases (in collaboration with a statistician, of course).

The search for funding opportunities can be tailored according to the research interests and type of project. Reviewing the list of projects funded in the last few years will help to determine if the sponsor or specific funding opportunity is well matched to the proposed project.[21,23] For foundations, the current grantees may be listed directly on the website or in a newsletter or annual report linked via the website.[21,23] NIH grantees can be identified by combining keywords with the appropriate check boxes for funding mechanisms and fiscal years in the query function of NIH REPORTER (http://projectreporter.nih.gov/reporter.cfm). RePORTER also has data on current funding levels by NIH center or institute, disease category, location of project, and award type that will indicate what is of greatest interest to NIH. There is also the weekly NIH Guide for Grants and Contracts, available at http://grants.nih.gov/grants/guide/index.html. Speaking with funded researchers and program officers at professional meetings can also provide valuable insight into current and future funding possibilities.[21]

TRAINING ON GRANT WRITING

The most common way to obtain external funding is to write a grant proposal. Grant writing is a specialized skill for which training opportunities are available. The Foundation Center provides free online training on grant writing or low cost (currently under $200) classroom training in various cities. Visit http://foundationcenter.org/getstarted/learnabout/proposalwriting.html. Many professional society meetings include preconference workshops on grant writing. An OPTI may also provide training programs for proposal development.

There's no shortage of workshops offered for $400 a day and more, but they're often focused on NIH proposals and therefore too advanced for beginning grant seekers. In addition, NIH in its best years was funding about 30% of grant proposals. After a combination of funding cuts and increased competition (ie, more proposals submitted) in the past few years, fewer than 14% of the most common types of research proposals were funded.[34] That means that over 86% of proposals were not funded.

GRANT WRITING BASICS

Grant proposal writing is a process in which the investigator makes a persuasive case to the sponsor. Some experts suggest having a one-page mini-proposal or executive summary ready at all times in order to be ready to respond on short notice to new announcements.[21,24] Grant writing takes time, talent, training, and practice. Continuing with the sports analogy, a couch potato can't wake up one day and decide to get a college scholarship, make the minor leagues, or be a professional sports superstar.

A basic tenet of grant writing is that funding should help the investigator and/or the institution to do something bigger, better, faster, and in an innovative manner. In other words, the money should clearly make a difference in advancing a project that is already in progress. "Give us money and we'll do great things" is not an approach that is likely to succeed. Demonstrating that the activities for which funding is being requested are an integral part of an existing project will increase the chances of success and help to lay the groundwork for future funding proposals.[21]

It is important to make sure that the project is a good match for the sponsor's objectives. Don't "stretch" to make the idea fit. If unsure, a call (or e-mail to set up a time) to chat with a program officer at the funding agency to get their feedback (and possible buy-in to the ideas) is in order.[21] The research office staff or mentor can help with preparation before making the actual contact. Many foundations require that the initial contact be in the form of a letter of inquiry and do not accept telephone calls.[21] Guidance on how to write a letter of inquiry is available from the Foundation Center (http://grantspace.org/Tools/Knowledge-Base/Funding-Research/Proposal-Writing/letters-of-inquiry).

Proposal writing should start at least 4 months in advance of the sponsor's submission deadline. Serious writing should be well under way 3 months in advance. The most successful grant applicants allow ample time for this process and routinely share drafts with others inside and outside their immediate area of expertise at least 2 months before they submit their proposals.[35] All revisions should be completed no later than 1 week before the submission deadline.

The importance of writing clearly and concisely cannot be overstated.[21,23,36] At least one person who is not involved with the project should be asked to read and comment on the proposal (and preferably on several drafts of the proposal) at least 1 month before it is submitted to allow time for revisions.[35] Grant reviewers typically have several proposals to read and rate. An axiom among grant writers and reviewers is that "good writing will not save bad ideas, but bad writing can kill good ones."[37] Telling a good story that readers can follow and that answers the questions listed in Figure 2, will improve the chances of getting funded.[36]

Engaging a mentor to advise in grant writing and review drafts is extremely valuable for those new to grant writing. The mentor may have been a grant reviewer and may even have small amounts of money to support related research, as noted above. The research office can help to identify faculty with successful funding histories who can serve as grant writing mentors.

Consider partnering with a more experienced researcher as a co-PI (co-principal investigator). This will be especially helpful if the research project has multidisciplinary aspects. Regardless, a team approach is often more effective than a single PI because most research requires at least some collaboration among investigators.[21] Collaborators can augment the research skills and resources provided by the investigator and the institution and can reassure reviewers that a capable research team is in place.[24]

The time and other resources required to prepare the proposal, obtain approvals for working with human subjects and/or their data, receive an answer from the sponsor, conduct and complete the research, and write the final report for the sponsor must all be considered.

PROPOSAL DEVELOPMENT

Each sponsor and funding opportunity will have specific requirements, but a good general outline is provided in Figure 2, along with questions to be kept in mind when writing a proposal.[38] It is imperative to think of the answers in terms of the sponsor's perspective.

It is absolutely vital to read and follow instructions carefully! A primary reason that proposals are rejected immediately or not considered for peer review is failure to comply with formatting and content requirements.[23, 39]

The abstract may be the most important part of a grant proposal.[21] It is the only part of the proposal that some reviewers read because they are assigned to conduct an in-depth analysis of other proposals. For reviewers assigned to read the entire document, the abstract is the first impression they receive. The abstract should serve as a concise and accurate description that allows the project to be understood without reading the entire proposal. It should include the goals, objectives, design and methods, and relevance to the sponsor's interests. Some sponsors require the abstract to be written in lay terms.[20]

The introduction or background presents the problem and how it relates to the applicant's and sponsor's priorities. It elucidates how the current project logically flows from previous work and provides a bridge to the needs assessment (preliminary studies).[20] The needs assessment summarizes the literature in the field and the applicant's relevant work to date.[21] Data should be provided to document the scope of the problem and to show the expertise of the individual applicant, the research team, and/or the host institution.[20]

The goal (or purpose) is the overall intention and expected results of the project, linked to the identified need.[20,22] The objectives are specific, measurable steps that will lead to achieving the program goals.[40] Objectives explain who will do how much of what by when. Specific aims are a concise list of the project objectives, e.g., to test a stated hypothesis, create a unique design, address a specific problem, or address a significant obstacle to progress in the field.[20] The specific aims also summarize the anticipated outcomes, usually in relation to a hypothesis.[20]

The plan of operation (Methods) gives reviewers substantial, detailed information about the interventions or experiments to be completed.[20,22] They should link directly and logically to the hypothesis and to the needs and objectives. If the aims include testing a hypothesis, it is important to clearly delineate how the procedures section will address the hypothesis. Organizing the plan so that it follows the same order as the needs and objectives section (eg, Method 1 matches Objective 1 and Need 1)[22] is helpful for the investigator(s) and those who will be reading the proposal.

Key personnel contribute in a significant and measurable way to the design, performance, or evaluation of the project.[20] Faculty, administrative staff, research assistants, consultants, and others may fit into this category. Their relevant accomplishments, such as publications and experience, should be highlighted and their role in the project (eg, PI, coordinator, statistician) described.[20] This information should be specific; stating that the individual is a department chair does not provide information on his/her research background. It may be helpful to include an organization chart specific to the project.[41] Information should be provided on the institutional commitment to the project in terms of resources, relevant work done to date, and the capacity to conduct the project. Salaries and fringe benefits for some of the project personnel, along with their office and/or laboratory space, may form part of the institutional commitment.[20,41]

The expected outcomes of the project should be described and related to the goals and objectives.[20] The outcomes section details how the results expected will contribute to solving the problem identified in the needs assessment.

Even small, private sponsors expect an evaluation component.[24] A strong research team, or at the very least the involvement of someone with credentials in epidemiology, statistics, or a related field, will strengthen the proposal and greatly enhance the chances of receiving funding. An experienced evaluator will ensure that the study design, sample size, and analyses are appropriate for the stated hypotheses and anticipated results.[23] For projects that involve an intervention, such as a health education program or clinical study, evaluation during the project is crucial. Without evaluation, there is no accurate way to determine whether the intervention is having a positive effect, a negative effect, or no effect at all.[40] The evaluation plan should include measurements/instruments, data collection and analysis, potential project challenges and

FIGURE 2:

Basic proposal outline and questions to answer

A. Abstract (Summary)

1. What is the problem or need to be addressed?
2. What are the overall goals and objectives of the project?
3. What research design will be used?
4. What are the planned methods?
5. Why is the project important to the funder?

B. Introduction (Background)

1. What need will the project address or what problem will it solve?
2. How is the project relevant to the health of the target population?
3. Needs Assessment (Preliminary Studies)
4. What data are available to demonstrate the need?
   a. Literature review
   b. Studies conducted by the investigator
   c. Government reports
   d. Task force or advisory committee recommendations

C. Goal

1. What is the overall purpose of the project?
2. How is it linked to the needs assessment?
3. How is it linked to the funder's goals?

D. Objectives (Specific Aims)

1. What are the specific, measurable objectives (aims)?
2. Do the objectives specify who will do how much of what by when?
3. Do the objectives specify results and how they will be measured

E. Plan of Operation (Experimental Design and Methods)

1. Where will the project be conducted?
2. What will the investigator do that matches the type of activity the sponsor is interested in funding?
3. How will the investigator conduct the study?
4. What study design has the investigator selected?
5. How will data be collected, stored, and analyzed?

F. Key Personnel

1. Who will do the project?
2. What are their qualifications relevant to the proposed activities?

F. Institutional Commitment

1. What resources (employees, data, space, equipment, etc.) will the institution contribute?
2. What other, similar projects have the investigator and the institution done successfully?

H. Expected Outcomes

1. How is the project expected to improve the health of the target population?

I. Evaluation

1. How will success be measured both during the project and at the end of the funding period?

J. Timeline

1. What is the timeline for the project, including data analysis?

K. Dissemination

1. How will the results be shared with others?
   a. Presentations
   b. Publications
   c. Websites

L. Resources and Facilities

1. What resources are already available?
2. What is the institution's capacity to conduct and complete the project?
3. What resources are needed?

M. Project Continuation

1. How will the work continue after funding ends?
   a. Other grants
   b. Incorporated into the institutional budget (specify in support letter)
   c. Program income

N. Budget and Narrative/Justification

1. How do the expenses link to project goals, objectives, and activities?
2. How much money is being requested?
3. What is being provided by the institution?

proposed solutions, evaluation resources, and the intervals at which evaluations will be conducted.[42]

A timeline for project tasks, including evaluation and dissemination, should be included. The timeline can be something as sophisticated as a PERT chart or Gantt chart[20] or as simple as a table or spreadsheet with quarterly milestones. The timeline should be an overview rather than an exhaustive list of every task. If space and technical capabilities allow, the lead person for each task should be listed.

Dissemination is a key component of any project. The sponsor needs to be assured that the results of the project will be communicated to others interested in addressing the problem, not be put on a shelf and forgotten. The professional society meetings at which posters or papers will be presented and journals to which manuscripts will be submitted should be stated specifically.[43]

The sponsor wants to know that the money will be well spent, the institution and the PI are truly committed to the project, and that the project will not end when the funding does. The project continuation or sustainability plan addresses these issues.[23,44] Among the most common ways to ensure project sustainability are to incorporate the activities into routine practices (and possibly the organization's budget), create a toolkit that is then provided to others for a fee, or to apply elsewhere for funding. For the latter, it is important to be as specific as possible about sources of continuation funding. The continuation or sustainability section is the sequel to the story that's been told throughout the proposal.[36]

Although the budget is the least favorite part of the proposal for some applicants, it is one of the most important parts for the sponsor and the reviewers. First, it is important to stay within the budget limits and types of allowable expenses for the funding opportunity.[21, 23] The project activities should be feasible given the budget considerations, and the budget should accurately reflect what is needed without overestimating or underestimating.[21] A clear, concise budget narrative (or budget justification) should be provided.[21, 23]

The budget is the estimated finances required to complete the project. It is an important part of the proposal and can make or break the chances of getting funded. A carefully prepared budget can help those who make the funding decisions to understand the project.[21, 23] It can also reassure them that the investigator understands the project.[36, 41] This does not mean that it is necessary to agonize over every hour potentially devoted to the project or to prepare an exhaustive list of every paper clip the project may require. The budget is a reasonable approximation of costs, typically divided into the following categories[41]: personnel (salaries and fringe benefits), consultant costs, supplies, equipment, travel, patient costs, and contractual costs.

Many find it helpful to start by estimating all but the personnel expenses rounded to the nearest $1,000. Personnel expenses should be estimated more accurately, in part because they may be the largest component. Next, resources that are needed and those that are already in place should be identified. For those with access to a research and sponsored programs office, the staff can provide guidance on which items must be exact and those that can be estimated and can often provide examples of other proposal budgets and narratives. Most institutions have policies requiring internal approvals for all proposals.[21] Starting the budget preparation and review process early, eg, as soon as the specific aims are finalized, will help this process to go smoothly and quickly. Approvals are required several days or even weeks in advance of the sponsor's submission deadline.

Direct costs are everything associated with the project to which a specific dollar amount can be assigned.[21,41] This includes personnel (inside the institution), consultants (outside the institution), expendable supplies, equipment, travel, etc. It is important to provide accurate salary and fringe benefit information for everyone listed, including those listed as "To Be Hired." Fringe benefits are part of direct costs and include vacation and sick time, health insurance, retirement contributions, etc.[45] Fringe benefits are usually a composite rate of the various benefits, which may vary depending on job category (faculty, postdoctoral fellow, staff, etc.). Stipends are also taxable as income by the federal government.[45] Local payroll taxes may also have to be deducted by the institution. The research office for should be consulted for specific information.

In-kind contributions are existing funds or staff time provided by the institution in support of the project. The most common example is salaries and fringe benefits. For example, if the principal investigator is dedicating 30% to the project, but only 20% of his/her salary and fringe benefits is requested in the proposal budget, then there is a 10% in-kind contribution from the institution.[21, 23] This should be stated in the budget justification to emphasize the institution's commitment[21] and, as previously noted, that the sponsor is not being asked to "give us money and we'll do great things." Policies regarding what may be included as an in-kind contribution or must be part of the request for funding from the sponsor vary among institutions.[21] Any proposed in-kind contributions should therefore be specified in the budget that is submitted for institutional approvals.

Indirect costs (also called overhead or facilities and administrative (F&A) costs) are those costs that are not easily

identified as being related to a particular project, but are nonetheless important and necessary to the administration of the project.[43] Examples include utilities, maintenance, grant accounting, and payroll processing. Indirect costs are calculated as a percentage of some or all of the direct costs. The percentage varies, depending on factors such as sponsor policies, institutional policies (eg, for clinical trials sponsored by pharmaceutical companies), or the rate negotiated between the institution and the federal government.[43] If the sponsor has a policy that allows only a certain indirect cost rate or no indirect costs at all, documentation of this should be provided along with the budget and budget narrative when submitting the materials for internal approvals.

Tips for proposal budget calculations are provided in Figure 3.

A carefully prepared budget will help to plan the project and manage it once funding is secured. Budget planning can help to avoid unpleasant surprises in the future by ensuring that all project expenses have been considered and provided for.[21]

For a tutorial on budget basics, visit http://foundationcenter.org/getstarted/tutorials/prop_budgt/pbb_descrip.html.

THE APPLICATION PROCESS

In many cases, funding must go to an institution, rather than an individual.[21] The institution is the steward of the money on behalf of the individual investigator. Significant additional lead time may be required to obtain permission to submit a proposal through an institution of which the investigator is not a full-time employee.

As noted above, there may be internal deadlines in addition to those set by the funding agency. Faculty members and department chairs rarely have the authority to sign or submit on behalf of the institution.[21] The office of research and sponsored programs can identify who has the authority to sign and who is responsible for obtaining the signature(s).

Other items that may be required before the proposal can be submitted, all of which take varying amounts of time to obtain, are listed in Figure 4.[21]

Letters of commitment, sometimes called support letters, are needed when a formal arrangement with another institution will be required if the proposal is funded, when consultants will participate in the project, or when an external entity will be providing access to a key resource (e.g., equipment or a particular population).[21] It is not uncommon for the requestor to provide a draft letter of commitment that contains the specific information on the expected contribution. Letters from elected officials are not necessary unless the purpose of the project is service delivery to their constituents.

The investigator should meet with the staff in the research and sponsored programs office and/or the faculty mentor early and often. They can help identify funding opportunities,

FIGURE 3:

How to work backwards from a fixed amount for budget calculations

Tip 1: If the sponsor has a total allowable cost for salaries and fringe benefits, to calculate base salaries to allow for fringe benefits at a rate of 30% (for example):

- total divided by 1.30 = base salary amount

Tip 2: If the sponsor has a fixed total budget, to calculate direct costs to allow for indirect costs at a rate of 10% (for example):

- total divided by 1.10 = direct costs subtotal

FIGURE 4:

Additional proposal elements

Letters of commitment

- Collaborator(s)/Mentor(s)
- Consultants (required as part of the proposal by some sponsors)
- Department chairs/Program directors
- Other "higher ups," such as the dean and/or president

Statement of Intent for multi-institutional proposals*

Certificate of Confidentiality/Nondisclosure Agreement for collaboration with other scientists outside the institution*

Other institutional policies and procedures

- Internal approvals for the activity itself from department chair(s)
- Internal approvals of the budget and budget justification (described above)
- Faculty sponsor or full-time faculty member as principal investigator for trainees and other nonfaculty

*It can take several weeks to obtain the required signatures from the official at each institution.

provide guidance on budgeting, help with forms and other aspects of the application process, and advise about any internal approvals and deadlines.[21, 23]

Depending on the sponsor, it may be possible to identify who the potential reviewers of the proposal will be.[21, 23] A simple literature search on the reviewers should be conducted. If appropriate, information from their work should be incorporated into the literature review and/or methods sections with citations to demonstrate the investigator's knowledge of the subject matter.[22, 23] The investigator may be able to recommend reviewers.[21] If so, the list can be derived from among the authors of key publications cited. The mentor should be consulted to determine if there are any researchers who should not be reviewers, usually because of a potential conflict of interest.[22] The mentor can help to craft polite wording in a cover letter to the sponsor explaining any conflicts.

THE WAITING GAME

Once the proposal is submitted, there is generally nothing more to do other than wait to hear from the sponsor. Contacting the sponsor's program staff or potential reviewers is not advisable, as this could be construed as an attempt to unduly influence the review process.[20, 24] Many proposals, especially to large funding entities, are approved, but not selected for funding.[21] Therefore, it is wise to refrain from making any announcements until an official award notice is received.

WHEN THE PROPOSAL IS NOT FUNDED

First, it is important to not take it personally.[46, 47] Even experienced researchers, including those who have or had funding, do not get funded every time.[21, 23, 47] Some sponsors will only issue a generic rejection letter, while others will provide feedback. If feedback is given, the research and sponsored programs office and/or the grant writing expert can offer an objective opinion on the comments and whether the proposal should be revised and resubmitted to this sponsor. NIH and some private sponsors have program officers who can offer guidance and read between the lines of the reviewers' comments.[46, 47] It may be better to submit to another potential funder. A detailed explanation of reading, interpreting, and responding to reviewer critiques is provided in the 2008 article in *Hematology* by Chao.[47]

As with the initial proposal, the sponsor's guidelines should be followed carefully when making changes. The funder may require a cover letter, a page within the proposal summarizing the changes, special formatting of revisions, or all of the above.[21] If the comments are useful, the appropriate changes should be incorporated into the revised proposal. If the comments are not useful or the research team disagrees with them, the investigator should solicit help in how to respectfully and clearly address the next steps.[46, 47]

SUMMARY

This article identified free and low-cost resources and provided guidance for proposal preparation. Potential funding sources appropriate for beginning investigators include:

- Collaborators with Funding
  - National Institutes of Health's Research Portfolio Online Reporting Tool Expenditures and Results (RePORTER)
  - National Science Foundation's NSF Award Search
- Private and Corporate Foundations
  - Foundation Center
  - Subscription services, if available
- Voluntary Health Organizations (e.g., American Heart Association)
- American Osteopathic Association
- American Association of Colleges of Osteopathic Medicine
- Institutional Support
  - Department budgets
  - OPTI/GME budget
  - Dean's funds, if applicable
  - Research reinvestment funds
- Osteopathic Heritage Foundation-funded Centers

Research studies require resources to continue and gain momentum. Compelling nonmonetary reasons to seek external support include developing and advancing knowledge, enhancing training opportunities, contributing to the prestige of the program and institution, and furthering the investigator's career. Nonfederal sponsors are more appropriate for less experienced researchers. It is essential to read and follow instructions carefully to ensure the proposal is not rejected before being assigned to peer reviewers. If the proposal is not funded, it should be revised and resubmitted. As with any acquired skill, grant writing requires practice.

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ADDITIONAL RESOURCES

Agency for Healthcare Research & Quality. Data Sources Available from AHRQ www.ahrq.gov/data/dataresources.htm

American Academy of Osteopathy Louisa Burns Osteopathic Research Committee

American Association of Colleges of Osteopathic Medicine www.aacom.org/InfoFor/educators/Pages/aacomgrants.aspx

American Osteopathic Association. AOA Research Handbook www.osteopathic.org/inside-aoa/development/quality/research-and-grants/Documents/Research-Handbook-rev.07-2011.pdf

Foundation Center. Learn About Proposal Writing www.foundationcenter.org/getstarted/learnabout/proposalwriting.html

Foundation Center. Proposal Budgeting Basics www.foundationcenter.org/getstarted/tutorials/prop_budgt/pbb_descrip.html

National Information Center on Health Services Research and Health Care Technology (NICHSR) www.nlm.nih.gov/hsrinfo/index.html

National Institutes of Health, Office of Extramural Research. Developing Your Budget http://grants.nih.gov/grants/developing_budget.htm

National Institutes of Health, Office of Extramural Research. Strategy for NIH Funding www.niaid.nih.gov/researchfunding/grant/strategy/pages/default.aspx

National Institutes of Health. Research Portfolio Online Reporting Tool Expenditures and Results (RePORTER) www.projectreporter.nih.gov/reporter.cfm

Office of Research Integrity. Writing Skills: Grantsmanship www.ori.hhs.gov/education/products/wsu/writing_gra.html

Osteopathic Heritage Foundations Funding Priorities: Enhancing Osteopathic Training and Medical Research www.osteopathicheritage.org/AboutUs/FoundationEndowedChairs.aspx

REVIEW ARTICLE

Assessing the Immediate Effect of Osteopathic Manipulation on Sports Related Concussion Symptoms

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KEYWORDS:
Concussion
Osteopathic Manipulation
Sports

Background: Osteopathic manipulative therapy has been reported to improve dizziness and neck pain, which are symptoms commonly seen in concussion. Conceivably OMT could be used to treat similar symptoms secondary to concussion. To our knowledge there has not been any studies that linked OMT to the reduction of concussive symptoms. **Objective:** To retrospectively examine the effect of OMT in reducing concussive symptoms in athletes. **Methods:** Records included in this retrospective chart review were those that had a diagnosis of concussion sustained during athletics and required that the patient had completed the symptom checklist found on the Standardized Concussion Assessment Tool (SCAT2) prior to the visit as well as completing another SCAT2 symptom checklist following OMT. Scores from each patient's pre-treatment SCAT2 assessment were then compared to their post-treatment scores. **Results:** A total of 26 patient charts met selection criteria and were included in this retrospective study. Summary descriptive statistics were generated. Paired sample t-tests revealed that OMT improved each of the 22 self-reported symptoms listed on the SCAT2, with 10 symptoms (45.4%) demonstrating statistically significant improvement ($p<.05$). These symptoms included: headache, pressure in head, blurred vision, sensitivity to light, feeling in a fog, don't feel right, difficulty concentrating, fatigue or low energy, irritability, and sadness. **Conclusion:** OMT was effective at reducing overall symptoms related to concussion. A substantial subset of concussive symptoms on the SCAT2 had significant reduction with the use of OMT. The integration of OMT into concussion management appears to immediately reduce symptom burden.

INTRODUCTION

Concussion has become an increasingly common and pervasive injury associated with high energy sports such as football and soccer. Large numbers of athletes who participate in such sports at the professional, collegiate, or even high school level- suffer from concussive injury. The Centers for Disease Control and Prevention reported that out of the 2.5 million concussions that occurred in the United States in the year 2010, 300,000 occurred from sports and recreational activities.[1,2] Sport-related concussions present clinicians with unique challenges regarding diagnosis, treatment and return to play decisions.[3,4]

Numerous factors unique to the patient, such as age, gender, prior history of concussion and other preexisting neurological or psychosocial conditions, can affect diagnosis, prognosis and treatment.[5] A current deficit in the medical community is that no gold standard has been established concerning the diagnoses and management of concussion.[6] The Standardized Concussion Assessment Tool (SCAT) is currently used by sports clinicians for the diagnosis and management of sport related concussion. The second edition of the SCAT (SCAT2) is divided into eight components that assess severity of symptoms, cognition, balance, neurological signs and the Glasgow Coma Scale.[6] The symptom assessment portion is comprised of 22 symptoms measured by a 7 point Likert scale. Most commonly reported symptoms following concussion include headache, dizziness, neck pain and nausea.[7] The 4th international conference on concussion in Zurich, Switzerland stated that a concussion is caused by a direct blow to the head, face, neck or elsewhere on the body with an impulsive force transmitted to the head.[8] Impulsive impacts transmitted through the body to the head or from the head to the body can result in an array of somatic and vestibular dysfunction.

Treatment of vestibular dysfunction and dizziness with osteopathic manipulation and vestibular rehabilitation has been shown to be helpful at improving impairments in eye-head coordination, standing static balance, and ambulation.[9] Dizziness is also a common complaint without history of impact or concussion and has been treated successfully with osteopathic manipulative therapy (OMT).[10,11,12] OMT has been shown to be useful at treating cervical somatic dysfunction, neck pain, and balance difficulties, which are all commonly reported symptoms following concussion.[10] Conceivably, OMT could be useful at treating symptoms related to concussion.

Presently, the recommended management of concussion includes a period of physical and cognitive rest immediately

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following the injury and a graded program of physical exertion once symptoms have subsided.[5] No consensus has been reached on whether rest and light exercise are beneficial to the athlete's return to play progression. However, recent literature suggests that individualized treatment of symptoms may reduce time lost due to concussion.[5] The majority of concussions (80%-90%) resolve in 7-10 days with 10%-15% persisting longer.[6] It has been recommended that sport related concussions in which symptoms persist longer than 10 days be managed in a multidisciplinary manner.[6] OMT has the potential to be easily integrated into existing concussion treatment and management plans. Thus the question explored in this study became: Did OMT reduce symptom burden? If symptom burden prevents progression to a graduated return to play protocol then reduction of that burden may result in a quicker return to play.

OBJECTIVE

To examine the effectiveness of OMT at reducing concussive symptoms in athletes who were diagnosed with a concussion.

HYPOTHESIS

OMT is effective at reducing symptoms related to concussion

MATERIALS AND METHODS

DESIGN

This study was a retrospective chart review of cross-sectional medical information collected on symptomatic athletes diagnosed with concussion during a visit to the physician's sports medicine practice. Institutional Review Board (IRB) permission was obtained to review patient records.

SETTING

All charts contained data on patients who were evaluated at the physician's main office and the athletic training facility at Ohio University. Both are located in Athens, Ohio.

POPULATION/SAMPLE

Each patient whose chart was selected was a high school or collegiate athlete in a small Midwestern community. These athletes were involved in high energy sports and diagnosed with concussion. Twenty-six charts were extracted from the spring sport season of 2013 and fall sport season of 2013.

INCLUSION AND EXCLUSION CRITERIA

All data from charts are representative of athletes who were evaluated and treated for a sports-related concussion. In order to be considered, the patient must have completed the SCAT2 symptom checklist prior to physician evaluation, received osteopathic manipulation and filled out another SCAT2 symptom checklist following the physician encounter. All chart data without a completed pre and post-treatment SCAT2 symptom checklist or a non-sports related concussion were excluded from the review.

INSTRUMENTS

The SCAT2 was used to assess concussion symptoms. The SCAT2 is a standardized assessment tool that measures self-reported symptoms and neurocognitive functioning following a suspected concussion. Each patient evaluated was asked to complete the symptom log that contains 22 symptoms commonly seen in concussed individuals. The log prompts the patient to rank each symptom on a 0-6 scale with 0 being no symptoms and 6 being severe symptoms. Self-reported scores were obtained as literature suggests that self-reported scores are more consistent than if the patient were asked about their symptoms in an interview style.[13, 14] The SCAT2 symptom list is shown in Appendix 1 (page 34).

PROCEDURE

Each patient chart contained a subjective portion of the SCAT2 that was completed upon arrival for an appointment with the physician. During the course of the evaluation, each patient was treated with osteopathic manipulation by the physician or by one of two OMM/NMM Plus-One Residents under the direct supervision of the physician. Osteopathic treatments were individualized based upon the patient's complaint and location of somatic dysfunction. Osteopathic techniques used to treat somatic dysfunction was left to the discretion of the treating practitioner but included both direct and indirect technique. At the close of the appointment the patient was asked to fill out another SCAT2 symptom checklist which was placed in the chart. Once data was collected the pre-treatment scores were compared to post-treatment scores to determine whether osteopathic manipulation had an effect on the participants' SCAT2 scores.

DATA ANALYSIS

Summary descriptive statistics (mean, standard deviation, and range) were generated for continuous variables such as age and the number of days post-injury treatment occurred. Furthermore, descriptive statistics were generated for SCAT2 scores pre and post OMT. Frequencies were generated for the categorical variable, gender. Paired sample t-tests were used to determine pre-post differences in the SCAT2 scores for each of the symptoms as well as an overall summative SCAT2 symptom score. Where appropriate a chi-square test of proportions was used. Statistical significance was set at $p < .05$.

RESULTS

In all, 26 records of athletes met the inclusion criteria. Complete data on gender was available on 25 patients—there was one missing data point for gender. Out of the 25, 16 (64%) were male while 9 (36%) were female. Participants' average age was 19.56 (± 2.873 s.d.) years with a range of 15 to 26 years. Post-injury to treatment period was on average 6.50 (± 4.926 s.d.) days with a range of 1 to 19 days (Table 1). When post-injury period was categorized for the 20 records for which data was recorded, 12 (60%) had post injury time of seven days or less and 8 (40%) had higher than seven days. However, these proportions of patients were not significantly different with respect to the post-injury time categories, $p = .371$.

All the SCAT2 score differences (post minus pre) of the 22 symptoms had a negative sign indicating that the self-reported pre-treatment scores were higher than the reported post-treatment scores. This suggested that treatment (OMT) provided improvement for all symptoms. However, statistically significant improvements were observed in 10 out of the 22 (45.4%) symptoms as well as the overall summative symptoms score of the SCAT2 listed in Table 2. Table 2 provides a summary of the statistically significant ($p<.05$) SCAT2 symptoms scores.

TABLE 1

Age and Number of Days Post-Injury of Patients

	N	Min	Max	Mean	Standard Deviation
Age	25	15	26	19.56	2.873
Number of days post injury	20	1	19	6.50	4.926

TABLE 2

Mean Differences, Standard Errors, Confidence Intervals, and p-Values of the Statistically Significant SCAT2 Symptom Scores

Symptom	Mean Difference (post - pre score)	Standard Error of Mean Difference	95% Confidence Interval		p-value (2-tailed)
			Lower	Upper	
Headache	-0.731	0.226	-1.196	-0.266	.003
Pressure in head	-0.615	0.229	-1.087	-0.143	.013
Balance problems	-0.462	0.194	-0.861	-0.062	.025
Sensitivity to noise	-0.615	0.193	-1.012	-0.218	.004
Feeling like in a fog	-0.731	0.219	-0.280	-3.340	.003
Don't feel right	-0.615	0.272	-1.176	-0.055	.033
Difficulty concentrating	-0.808	0.309	-1.444	-0.171	.015
Fatigue or low energy	-0.615	0.208	-1.044	-0.187	.007
Irritability	-0.462	0.194	-0.861	-0.062	.025
Sadness	-0.500	0.224	-0.961	-0.039	.035
Overall symptom	-10.846	3.769	-18.608	-3.085	.008

Conversely, the non-statistically significant pre-post differences in symptom scores are shown in a table in Appendix 2 (page 35). While the differences were not statistically significant, they all had a negative sign, which implied that there was a reduction in the severity of the symptoms reported following OMT. The SCAT2 scale ranged 0-6 where 0 signified no symptom and 6 signified severe symptoms. Hence, a negative difference between post- and pre- scores would suggest a diminution in reported severity of symptoms following the use of OMT as a treatment intervention.

COMMENT

To our knowledge, this is the first reported study of its kind to examine the effects of OMT on concussive symptoms. Many symptoms listed on the SCAT2 are common to other medical conditions and have been shown to be treated effectively with OMT. In this study, all 22 symptoms trended toward improvement immediately following OMT. There was a subset of symptoms that showed significant improvement as shown in Table 2.

Our hypothesis that OMT results in a reduction of concussion related symptoms as recorded by concussed athletes on the SCAT2 was substantiated by the data. Furthermore, OMT significantly improved a subset of 10 symptoms as reported by the SCAT2 scores. Therefore, it is feasible that stratification of patients into treatment groups, such that those patients presenting with symptoms most responsive to osteopathic manipulation, would receive the greatest benefit from OMT. Patients with symptoms that do not show significant improvement with OMT could then be effectively managed by standard treatment protocols.

Although encouraging, this retrospective study had the limitation of a small data set. It did not take into account patient randomization into a treatment group, a control group or a sham treatment group. As there was not a control group that did not receive OMT, we cannot conclude that the positive changes observed were secondary to OMT. Furthermore, this study also involved the results from multiple treating physicians. The multiple physicians involved in providing the OMT could provide variability in the treatments that was not accounted for. Future studies should have a single osteopathic physician to reduce variability in OMT techniques. Although a formal protocol would have created a uniform treatment, it is important to note that variability coincides with the theories of osteopathic medicine, which is to resolve structural imbalances to improve overall function of the body.[10] In future studies, it may be useful to record the location and severity of somatic dysfunction in order to determine patterns as they relate to concussion. This could potentially help determine treatment protocols, which could then be implemented by clinicians treating concussion.

Results suggest that a certain subset of concussive symptoms can be immediately reduced with individualized OMT. One encouraging outcome was the fact that quite a number of symptoms were significant despite the small sample size. Notably, it would be expected that a higher number of symptoms to be significant with a larger sample size. Although, there are certainly limitations, the results appear promising and should provide a starting point for further research on OMT as an option in the concussion treatment repertoire. Such studies are becoming increasingly more important and necessary secondary to the paucity of recommended treatment options for concussion.

CONCLUSION

The use of OMT following concussion had a positive impact on symptoms as measured by SCAT2 symptom scores. The impact of OMT in reducing the burden of concussive symptoms was significant for 10 of the 22 symptoms on the SCAT2. Future prospective studies are needed to provide more compelling evidence of the effectiveness of OMT in the management of concussive symptoms. Implementing OMT into the management of concussive symptoms decrease the overall symptom burden experienced by the athlete, which may result in a timely return to activity.

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APPENDIX 1

SCAT2 Symptom Evaluation List

	None	Mild		Moderate		Severe	
Headache	0	1	2	3	4	5	6
"Pressure in head"	0	1	2	3	4	5	6
Neck Pain	0	1	2	3	4	5	6
Nausea or vomiting	0	1	2	3	4	5	6
Dizziness	0	1	2	3	4	5	6
Blurred vision	0	1	2	3	4	5	6
Balance problems	0	1	2	3	4	5	6
Sensitivity to light	0	1	2	3	4	5	6
Sensitivity to noise	0	1	2	3	4	5	6
Feeling slowed down	0	1	2	3	4	5	6
Feeling like you're in a fog	0	1	2	3	4	5	6
Don't feel right	0	1	2	3	4	5	6
Difficulty concentrating	0	1	2	3	4	5	6
Difficulty remembering	0	1	2	3	4	5	6
Fatigue or low energy	0	1	2	3	4	5	6
Confusion	0	1	2	3	4	5	6
Drowsiness	0	1	2	3	4	5	6
Trouble falling asleep	0	1	2	3	4	5	6
More emotional than usual	0	1	2	3	4	5	6
Irritable	0	1	2	3	4	5	6
Sadness	0	1	2	3	4	5	6
Nervous or Anxious	0	1	2	3	4	5	6

APPENDIX 2

Table of Statistically Non-Significant SCAT2 Pre-Post Scores Differences

Symptom	Mean Difference (post – pre score)	Standard Error of Mean Difference	95% Confidence Interval		p-value (2-tailed)
			Lower	Upper	
Neck pain	-0.538	0.320	-1.197	0.120	.105
Nausea or vomitting	-0.308	0.173	-0.665	0.049	.088
Dizziness	-0.500	0.243	-1.001	0.001	.051
Blurred vision	-0.269	0.197	-0.674	0.136	.183
Sensitivity to light	-0.269	0.239	-0.761	0.223	.271
Feeling slowed down	-0.308	0.247	-0.816	0.200	.224
Difficulty remembering	-0.462	0.310	-1.100	0.177	.149
Confusion	-0.462	0.237	-0.949	0.026	.063
Drowsiness	-0.462	0.243	-0.963	0.039	.069
Trouble falling asleep	-0.385	0.222	-0.843	0.073	.096
More emotional	-0.308	0.222	-0.761	0.146	.175
Nervous or anxious	-0.423	0.243	-0.923	0.077	.094

CLINICAL IMAGES

Pyogenic Granuloma

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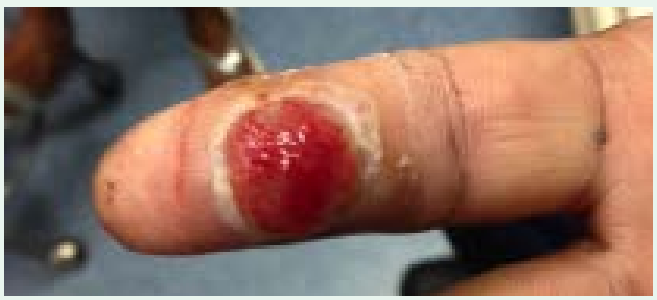
47-year-old African American male presents to the emergency department with a lesion on the distal, palmar aspect of his right second digit. Three weeks previously, the patient noticed a scab on his finger due to unknown trauma. One week ago he picked off the scab and after prolonged bleeding the subsequent lesion developed (Figure 1 and 2). He denies drainage, fevers, chills or previous episodes of similar lesions. No other lesions are present elsewhere on the body. He does note that the lesion is mildly painful and he has a small amount of surrounding swelling.

FIGURE 1

FIGURE 2



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QUESTIONS

1. The lesion depicted above is consistent with a

   a. Nevus
   b. Pyogenic granuloma
   c. Melanoma
   d. Basal cell carcinoma
   e. Furuncle

2. A 32-year-old female presents to your office with a similar lesion. Which of the following medications that she is on may make her prone to lesions such as this?

   a. Glipizides
   b. Beta-blockers
   c. Acetaminophen
   d. Oral contraceptives
   e. Daily Vitamins

3. What is the preferred plan of care?

   a. Apply Neosporin twice daily for 2 weeks
   b. Tie off the lesion at the stalk
   c. Spontaneous regression
   d. Shave excision and electrodesiccation
   e. Cryosurgery

See page 38 for answers and discussion.

ANSWERS

1. The lesion depicted above is consistent with a:

Answer B: Pyogenic granuloma

Explanation: Nevus is a pigmented spot of skin such as a mole that would not have developed as rapidly as the lesion depicted and would have a different appearance. A melanoma is larger than a common mole with borders that are irregular and poorly defined. Color ranges from tan to dark brown shades on a pink background. They have irregular borders that may include notches. They may fade into surrounding skin and include a flat portion level with the skin.[1] A basal cell carcinoma would also not have appeared so quickly, tends to appear on heavily sun exposed areas of the skin, and does not have a stalk like appearance.[2] A furuncle is a skin infection caused by staphylococcal infection. It is smaller and more superficial than subcutaneous abscesses. The case history and image is not consistent with a furuncle.[3]

2. A 32-year-old female presents to your office with a similar lesion. Which of the following medications that she is on may make her prone to lesions such as this?

Answer D: Oral contraceptives

Explanation: Medications have been shown to increase the incidence of pyogenic granuloma including some classes of chemotherapeutics, retinoids, oral contraceptives and protease inhibitors.[4, 5]

3. What is the preferred plan of care?

Answer D: Shave excision and electrodesiccation

Explanation: Shave excision and electrodesiccation are the preferred procedures.[6] Removal must be of a complete thickness in an effort to reduce the rate of recurrence, which is about 0.2-5%.[4, 7]

DISCUSSION

A pyogenic granuloma is a benign proliferation of the capillaries found on both skin and mucus membranes of an unknown etiology, likely related to a discrepancy between angiogenic promoters and inhibitors.[6, 7, 8] It often occurs after an injury or with prolonged irritation.[6] The lesion initially grows rapidly in size over days to weeks before reaching a more stable size later in its course.[9] Despite the name, a pyogenic granuloma is neither an infectious nor a granulomatous process. As such, lobular capillary hemangioma has been proposed as a more accurate designation.[6]

The diagnosis of a pyogenic granuloma is clinical. This lesion is commonly brought to a physician's attention due to its characteristically profuse and easy bleeding.[6, 8] Viewed as a solitary friable, smooth red "raw" nodule, it is usually painless and reaches an average size of 6.5 mm.[4, 6] A history of trauma often heralds the appearance of the lesion.[4] On the skin, the lesion's boarders are well demarcated, commonly forming a hyperplastic epidermal ring called an epithelial collarette.[5, 6] The surrounding tissue is frequently normal in appearance.[5] The head/neck and upper limbs are the most common locations to find lesions.[7]

Age is a significant risk factor for the development of pyogenic granulomas. Although seen at any age, children with a median age of 6.7 years old are most commonly effected.[5, 9] Pregnancy is another noteworthy risk factor. Pyogenic granuloma of the oral mucosa during pregnancy, known as a granuloma gravidarum or a "pregnancy tumor," occurs in 0.2-5% of pregnancies.[4, 7, 8, 10] Found on the maxillary intraoral surface, they often resolve after a pregnancy when the increased levels of vascular endothelial growth factor seen during pregnancy declines.[6] Medications have also been shown to increase the incidence of pyogenic granuloma including some classes of chemotherapeutics, retinoids, oral contraceptives, and protease inhibitors.[4, 5]

Pyogenic granuloma can, albeit rarely, regress spontaneously.[9] Given that they are friable and in cosmetically sensitive areas, dermatologist referral and subsequent removal is the currently favored treatment plan. Shave excision and electrodesiccation are the preferred procedures.[6] Removal must be of a complete thickness in an effort to reduce the rate of recurrence, which is about 5%.[4, 7] Histological findings help both confirm the diagnosis and also rule out other more serious processes like an amelanotic nodular melanoma, which can only be differentiated from a pyogenic granuloma via histological examination.[10] Histologically, a pyogenic granuloma demonstrates a lobular organization of benign proliferating capillaries with neutrophils and notable edema.[11] Cryosurgery and laser removal are alternative removal methods but less favored as these procedures can require multiple treatments and offer little advantage over typical management.[6] Topical Timolol and Imiquimod have been used off-label in the past with success, but surgical removal still remains the mainstay of treatment today.[12, 13]

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2015 Calendar of Events

July 10-12, 2015

Direct Primary Care Summit
InterContinental Kansas City at the Plaza
Kansas City, MO
www.dpcsummit.org

July 22-26, 2015

ALOMA 25th Annual Emerald Coast Conference
Hilton Sandestin
Destin, FL

July 29 - August 2, 2015

Florida Society ACOFP 35th Annual Convention and Family Medicine Update
Hilton Bonnet Creek
Orlando, FL

July 29 – August 2, 2015

MAOFP Summer Family Medicine Update Conference
Grand Traverse Resort
Acme, MI
www.maofp.org/cme

August 4-9, 2015

TOMA-Texas ACOFP 2015 Joint Annual Convention
Omni Bay Front, Corpus Christi, TX

August 6-9, 2015

CA-ACOFP 39th Annual Scientific Medical Seminar
32 1-A AOA CME hours anticipated
Disneyland Hotel | Anaheim, CA
www.acofpca.org

August 7-9, 2015

POFPS 40th Annual CME Symposium
Hershey Lodge, Hershey, PA
www.poma.org

August 12-16, 2015

AOMA 30th Annual State Convention
Chateau on the Lake
Branson, MO
www.arosteopathic.org

August 13-16, 2015

CSOM Summer CME & Membership Program
Vail, CO
coloradodo.org

August 14-16, 2015

NC Society of the ACOFP Annual CME Meeting
Pinehurst Resort
Pinehurst, NC
www.nc-acofp.org

August 21-23, 2015

ACOFP Intensive Update & Board Review
Loews Chicago O'Hare
Rosemont, IL
www.acofp.org

August 28-31, 2015

KMA Annual Meeting
Hyatt Regency Louisville
Louisville, KY
www.kyma.org

September 18-20, 2015

OPSO Annual Primary Care CME
Downtown Portland Embassy Suites
Portland, OR
www.opso.org

October 17-21, 2015

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WVOMA 113th Annual Fall CME Conference
The Greenbrier Resort
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MAY/JUNE 2015 ANSWERS: **1.** C **2.** B **3.** B **4.** C **5.** B **6.** C **7.** D **8.** C **9.** C **10.** A

OFP Patient Education Handout

Peter Zajac, DO, FACOFP, Author • Amy J. Keenum, DO, PharmD, Editor
Ronald Januchowski, DO, FACOFP, Health Literacy Editor

SUNSCREEN

More than 2 million people are diagnosed with skin cancer each year. Protecting yourself from the sun's rays can help prevent skin cancer. Water resistant sunscreens with a Sun Protection Factor (SPF) rating of 30 or greater help to protect the skin from sunburn, early skin aging, and skin cancer. A SPF rating indicates how long a sunscreen will remain effective on the skin. For example, if you normally develop sunburn in 10 minutes without wearing a sunscreen, a sunscreen with a SPF rating of 30 will protect you for 300 minutes - 10 minutes times the SPF of 30. Water resistant sunscreens should maintain the SPF level after 40 minutes of being in water. Everyone of any skin tone should use a sunscreen when outdoors. People who have had skin cancer or have a very fair skin should use a SPF of greater than 30 for extra protection when outside in the sun.

Sunscreen Basics:

- Apply a sunscreen to dry skin 15 minutes before going outdoors.
- Reapply a sunscreen every two hours or after swimming or sweating heavily to all exposed skin.
- Wear sun protective clothing and avoid sun exposure from 10 AM to 2 PM year around.
- Exercise extra caution near sand, snow, or water as they reflect the damaging rays of the sun which can increase the chance of sunburn. Even on cloudy days, up to 80% of the sun's harmful ultraviolet (UV) rays can enter the skin.
- Avoid tanning beds. UV light from tanning beds also can cause skin cancer and wrinkling. If you want to look tan, consider using a self-tanning product along with a sunscreen.
- Skin cancer also can form on the lips. To protect your lips, apply a lip balm that contains sunscreen with a SPF of 30 or higher.
- Sunscreen options include: Lotions and creams which are best for dry skin and the face. Gels are good for hairy areas such as the scalp and male chest. Sticks are good to use around the eyes. Sprays are preferred by parents since they are easy to apply to children. There are also sunscreens made for sensitive skin and kids.
- Avoid sun exposure and do not use sunscreens on infants younger than 6 months of age.
- Use sunglasses, select hats with front and back flaps, and shady areas to provide protection from the sun's rays as well.

Medical Care and Treatment Options:

If you develop sunburn or notice anything changing, growing, or bleeding on the skin call your family doctor. Skin cancer is treatable when caught early. Likewise, if you have any questions about which sunscreen would be best for you or your children please contact your Osteopathic Family Doctor.

Source(s): American Academy of Dermatology, Sunscreen.gov, Up-To-Date, and Web MD.

For additional patient related educational material please visit our website at www.acofp.org

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