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A Risk Benefit Analysis of Treatments for Cystic Acne

An Honors Thesis
Presented to
The University Honors Program
Gardner-Webb University
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by

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ABSTRACT

Acne is a prevalent skin disorder and is displayed through various different incidences. Cystic acne, a severe form of acne that is difficult to treat, reaches deep into the skin underneath the epidermis layer and produces painful, inflamed cysts that contain sebum, dead skin cells, and *Propionobacterium acnes*, the acne causing bacteria. Because this is an uncomfortable type of acne and is tough to treat, researchers have developed and tested a number of treatments to determine the best course of treatment for reducing and potentially eradicating cystic acne. These treatments are most commonly in the form of systemic or topical treatments, but other types of treatments are still considered as a possible course of action. According to this research, the most effective treatment that is currently available is isotretinoin, commonly known by the brand name Accutane. A short survey of medical professionals was conducted in order to determine what they most frequently prescribe when treating cystic acne and what the benefits and consequences of those treatments are. Their answers were compared to current research and determined that systemic Accutane is the most successful course of treatment for most patients with cystic acne due to the medications ability to reduce and potentially eradicate all cystic acne lesions.

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I would first like to thank God for blessing me with the opportunity to attend Gardner-Webb University. This school is where I was meant to be and has become my home. Thanks to God's guidance, I have been blessed with numerous opportunities during my college career and I feel incredibly fortunate to have had these experiences.

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TABLE OF CONTENTS

- I. INTRODUCTION
- II. THE ANATOMY OF THE SKIN
- III. ACNE VULGARIS
- IV. TYPES OF ACNE
- V. CATEGORIES OF ACNE
- VI. CAUSES OF CYSTIC ACNE
- VII. SYMPTOMS OF CYSTIC ACNE
- VIII. TREATMENTS FOR CYSTIC ACNE
- IX. SURVEY OF MEDICAL PROFESSIONALS
- X. CONCLUSION
- XI. REFERENCES
- XII. APPENDIX

I. INTRODUCTION

Acne is a chronic skin condition that affects many people every year. This skin disorder has a high incidence and prevalence amongst all age groups. Cystic acne is a severe form of acne that causes unpleasant cysts on the face, chest, neck, back, or behind regions of the body and can lead to disfigurement. Determining a treatment for this form of acne may be an extensive and difficult process depending on the patient's response to initial treatments. Because of this, researchers have discovered and developed many forms of treatments for cystic acne from systemic therapy to light therapy. The goal of this thesis is to discuss the basis of cystic acne and to evaluate the diverse treatments that are currently available.

II. THE ANATOMY OF THE SKIN

In order to understand the genesis of acne, one must first understand the anatomy of the skin and the components that allow acne to form. The anatomy of the skin is broken down into three main layers: the epidermis, dermis, and subcutaneous tissue. These layers are listed from most superficial to the deepest layer. (See figure one).

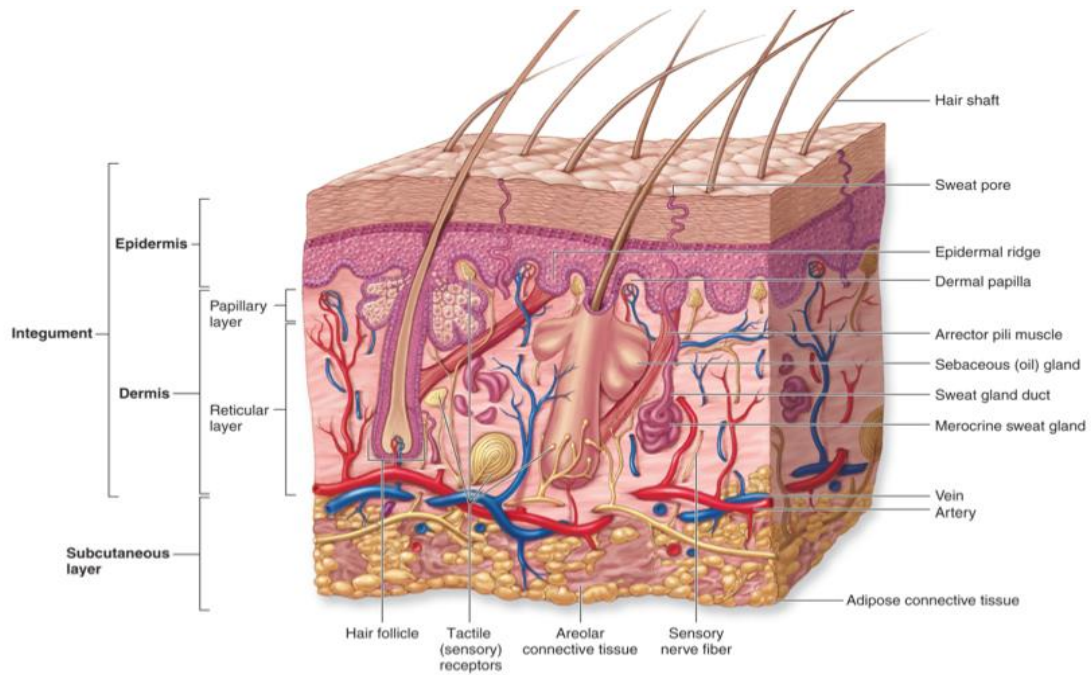
- a. The epidermis layer, the outermost skin layer that can be easily observed, contains the sensory nerve endings as well as the pore openings and hair shaft (McKinley, O'Loughlin, Bidle, 2015). One of the main functions of the epidermis layer is to be the first line of protection from ultraviolet light, infections, and prevent detrimental damage to the integumentary system (Chu, 2012). This layer does not contain blood vessels or capillaries, but it does contain four to five layers of keratinized, stratified squamous epithelium (LeMaster, Matern, Morrison-Graham, etc., 2019). The keratin proteins within the epidermis skin cells assist in protection as well as cell migration, cell growth, transportation of resources, and recovery from injuries to the skin (Genetics Home Reference. 2019).

- b. The dermis layer, which is the middle layer of the skin, is constructed of two layers of connective tissue (LeMaster, Matern, Morrison-Graham, etc., 2019). The dermis contains the nerve fibers with sensory nerve endings branching off of the fibers and stretching into the top of the dermis layer, which is defined as the papillary layer (McKinley, O'Loughlin, Bidle, 2015). The bottom layer of the dermis is the reticular layer, which contains the majority of the appendages within the skin. The nerve fibers and sensory nerve endings allow the body to feel sensations on the skin whether the body is lightly touched or injured (American Academy of Dermatology, 2013). The dermis layer also includes capillaries and the erector pili muscles. The capillaries within this layer provide the nutrients for the epidermis layer since that layer does not have capillaries or blood vessels (LeMaster, Matern, Morrison-Graham, etc., 2019). The erector pili muscles provoke the involuntary process that is observed as the hair on our body to "standing up" and the skin may exhibit a goose bump like texture when someone is cold or frightened. The scientific word for the hair rising is piloerection (Piloerection. (n.d.) Merriam-Webster). The most notable appendages located within the dermis layer of the skin are the sweat glands, sebaceous glands, and the hair follicles. The sweat glands are responsible for releasing sweat through the sweat gland duct to the sweat pore or hair follicle (McKinley, O'Loughlin, Bidle, 2015, pg. 201). Sweating assists the body by excreting sweat in order to cool the body down so that it does not overheat and cause damage (American Academy of

Dermatology, 2013). The sebaceous glands produce sebum, which is an oily secretion that is released onto the hair or within the hair follicle (McKinley, O'Loughlin, Bidle, 2015, pg. 202). This release is motivated by male and female sex hormones during puberty (McKinley, O'Loughlin, Bidle, 2015, pg. 202). Sebum assists in keeping the skin from drying out, creating a waterproof barrier, and may create a level complexion. However; an overproduction of sebum during puberty and other points in the human life span where hormones are produced in excess, such as menopause or pregnancy, may result in acne.

- c. The subcutaneous layer, the deepest layer of the skin, consists of connective tissue such as areolar and adipose connective tissue, which insulate the body (McKinley, O'Loughlin, Bidle, 2015). The adipose tissue provides extra padding around the bodies muscles and bones and it also assists in regulating the body's internal temperature by controlling whether or not heat is retained or released from the body (American Academy of Dermatology, 2013). The connective tissue within this layer is what connects the integumentary system to the body's muscles and bones (American Academy of Dermatology, 2013). The veins and arteries that travel through the integumentary system are also located within the subcutaneous layer (McKinley, O'Loughlin, Bidle, 2015). The nerve cells from the dermis layer extend through the subcutaneous layer and travel through the body in order to relay information of touch and sensations to the brain (American Academy of Dermatology, 2013).

Figure 1: Diagram of the Skin Anatomy:



McKinley, O'Loughlin, Bidle, 2015

III. ACNE VULGARIS

Acne vulgaris is the medical term for common acne (The Free Dictionary). This skin condition is the most prevalent throughout the United States with an estimated number of forty to fifty million people who are affected (American Academy of Dermatology, n.d.). Acne affects approximately 85% of teenaged patients due to their increase in sex hormones during puberty (Ayer, Burrows, 2006). Acne occurs more frequently in teenagers than in middle-aged adults because of the spike in hormone levels, however; anyone may experience acne at any age (American Academy of Dermatology, n.d). Both males and females are affected by acne, however; because women often experience more hormonal changes than men, women are more frequently affected by acne (American Academy of Dermatology, n.d). The changes in hormones in females that could lead to the formation of acne may be attributed to menstruation, pregnancy, menopause, and occasional hormone imbalances.

Acne is caused by an overproduction of sebum and a build up of unnecessary substances on the skin the leads to clogged pores and hair follicles in the dermis layer of the skin (American Academy of Dermatology, n.d.). These unnecessary substances include certain skincare products, make-up, dead skin cells, and the acne causing bacteria, *Propionobacterium acnes* (American Academy of Dermatology, n.d.). These substances become trapped in a pore or a hair follicle along with excess sebum and are unable to escape (American Academy of Dermatology, n.d.). Therefore, this

combination of substances will form an inflamed pimple or nodule-like acne spot on the surface of the skin (American Academy of Dermatology, n.d.).

The reason for an overproduction of sebum and the occurrence of *P. acnes* varies from patient to patient. Genetics, androgens (such as testosterone), stress, and excessive sweating are known causes that may affect the formation of acne (Ayer, Burrows, 2006). Endocrine disorders, such as polycystic ovarian syndrome, a hormone disorder that affects growth and sexual hormones, are also capable of causing an acne breakout (Ayer, Burrows, 2006). Other factors that lead to etiopathogenesis that are not genetic or a part of a natural body function include smoking cigarettes and the ingestion of medicines and chemicals such as oral contraceptives, bromides, corticosteroids, and dioxins (Ayers, Burrows, 2006).

Acne may appear in many different forms and severities depending on the patient's hormone levels and sebum production. The blemishes often occur on the face, chest, neck, shoulders, back, the upper arms, or backside depending on the amount of friction, sweat, and sebum produced on these areas of the body (American Academy of Dermatology, n.d.).

Researchers and medical professionals that work to develop and pinpoint the most effective treatments for acne recommend that this skin condition be treated as soon as possible in order to prevent acne scars and because it is better to determine what is the best method of treatment for the patient early on rather than later (Ayer, Burrows, 2006).

Treating acne is not a short-term situation. In order for patients to be equipped to handle their skin condition, it's best to explore what treatment method would be the most comfortable for them to continue for a long period of time while still treating the skin inflammation caused by the acne lesions (Ayer, Burrows, 2006). The medical professional treating patients with acne should also inform them of appropriate cosmetic and hair products that will not aggravate the pre-existing acne or result in the formation of new acne lesions (Ayer, Burrows, 2006).

IV. TYPES OF ACNE

Acne is displayed in various forms depending on the causes and potential hormone levels of an individual. Researchers have currently identified multiple different types of acne. The simplest known form of acne lesion is a comedo (WebMD), which is a hair follicle that is clogged with sebum and dead skin cells, and they are either an open or closed comedone. (Comedones are the plural form of comedo) (WebMD). An open comedo is also known as a blackhead and a closed comedo is known as a whitehead (WebMD).

Blackheads are clogged pores in the skin that have a dark colored appearance (InformedHealth.org, 2013). The dark color is not due to a build up of dirt, but is a result of the skin pigment melanin reacting with oxygen in the air because blackheads are open comedones (InformedHealth.org, 2013). Blackheads are difficult to extract from the skin because the dead skin cells, sebum, and acne causing bacteria that make up this open comedo are not on the surface of the skin. A whitehead is a closed comedo with a small yellow or whiteish oil-filled bump (InformedHealth.org, 2013). Whiteheads are easier to extract because the oil-filled bump is easily popped by friction or pressure.

Papules are a step up from whiteheads. Papules are the typical inflamed pimple that most people associate with acne, and they occur as small bumps across the affected area (InformedHealth.org, 2013). Another pimple or bump that is more serious than a papule is a pustule. A pustule is a bump filled with

yellow pus, and both papules and pustules may be popped to release the bumps contents (InformedHealth.org, 2013).

A more severe type of acne that is more difficult to treat is nodular acne. The nodules are inflamed painful, reddish bumps on the skin that may feel like knots under the skin (Palmer, 2019). Nodules reach deep into the skin and while they may have a whitehead, they usually cannot be popped and will stay deep under the epidermis layer until the nodule is treated (Palmer, 2019). Another type of severe acne, which is the focus of this paper, is cystic acne. Cystic acne is also an inflamed, red, and tender bump that reaches deep into the skin's layers, however; it occurs as cysts within the skin instead of nodules (de Bellefonds, 2018). This type of acne will be discussed in depth further into the paper.

A form of acne that is less well known amongst the general population is a severe form of acne known as acne conglobata. This type of acne includes multiple irritated nodules that form a connection under the skin and branch towards other nodules on the chest, neck, arms or the bottom regions of those affected (WebMD). Researchers have determined that this form of acne may affect men more often because of steroid or testosterone usage, and it may cause scarring (WebMD).

A more common form of acne is acne mechanica, which occurs due to friction, pressure, and heat against the skin of the forehead due to frequent use of sports helmets and baseball caps (WebMD). Because the main source of this form of acne is related to sports equipment, acne mechanica is

common amongst athletes, and they have been encouraged to use absorbent materials under their helmets or caps and to shower shortly after wearing the equipment (WebMD).

V. CATEGORIES OF ACNE

Dermatologists have narrowed down the types of acne to three different categories based on the amount of whiteheads, blackheads, irritated bumps, and lesions that occur on a person's skin (See figure two). The first category of acne is mild acne, which consists of blackheads and/or whiteheads (InformedHealth.org, 2013). A patient with mild acne will have fewer or smaller pimples than those with more intense acne, and therefore, mild acne will be easier to treat and clear up than others (InformedHealth.org, 2013).

The second category of acne is moderate acne, which is normally treated by a dermatologist with a prescription medication in order to reduce the amount of lesions over time (WebMD). A patient with moderate acne will have more noticeable pimples as well as inflamed papules or pustules and this form of acne will be more difficult to treat (InformedHealth.org, 2013).

The third category of acne is known as severe acne, which consists of papules, pustules, nodules, and cysts (InformedHealth.org, 2013). This category of acne often leads to the formation of acne scars because the types of acne involved are stubborn and difficult to treat (InformedHealth.org, 2013). In order to cure or reduce this form of acne, it has to be treated by a dermatologist who in particular situations, may prescribe strong topical or systemic acne treatments or sometimes inject a corticosteroid into a targeted nodule or cyst in order to reduce the inflammation (WebMD).

Figure 2: Categories of Acne

Figure 2a: Mild Acne:



<https://www.webmd.com/skin-problems-and-treatments/acne/ss/slideshow-acne-dictionary>

Figure 2b: Moderate Acne:



<https://www.webmd.com/skin-problems-and-treatments/acne/ss/slideshow-acne-dictionary>

Figure 2c: Severe Nodulocystic Acne:



<https://www.webmd.com/skin-problems-and-treatments/acne/ss/slideshow-acne-dictionary>

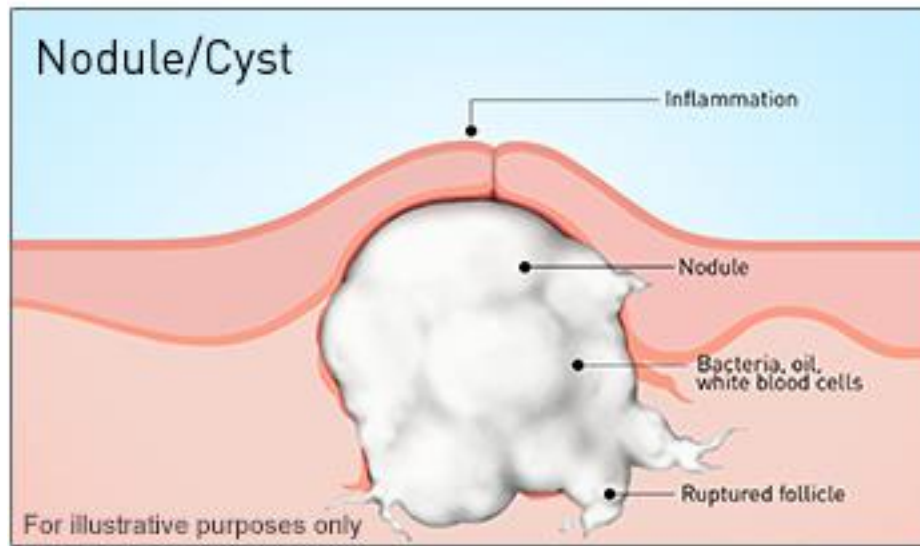
VI. CAUSES OF CYSTIC ACNE

Although there are many types of acne, this research is geared towards the formation and treatment of cystic acne. Cystic acne is defined in medical terms as severe acne with the formation of follicular cysts that are enclosed in a mixture of keratin and sebum, which may rupture and scar (The Free Dictionary). Acne cysts are present on the surface of the skin if the inflammation of the skin continues deep into the affected pore or hair follicle (American Academy of Dermatology, n.d) This inflammation is caused by the previously mentioned unnecessary substances, such as dead skin cells and *P. acnes*, and an overproduction of sebum (American Academy of Dermatology, n.d.). (See figure three)

A universal cause for the overproduction of sebum that causes cystic acne has not been determined yet due to the differences in lifestyles, skin types, and hormone levels. A key factor that may potentially play a role in the formation of acne for some patients is their diet. Researchers are still debating on whether or not an increase in sugar or sugary foods in a patient's diet and an increase of insulin in the bloodstream due to the amount of glucose ingested could lead to acne formation (Huntley, 2003). This increase in insulin could create an increase in the production of endogenous sex hormones, such as testosterone and estrogen, and therefore the cells within the sebaceous glands could be stimulated and begin overproducing sebum, which may result in cystic acne (Huntley, 2003).

Researchers do know that a surge in hormones, such as those during adolescent teenage years, is one of the most prevalent elements that result in an overproduction of sebum and acne causing bacteria (MacGill, 2017). However; cystic acne is not restricted to teenagers and may affect all ages (MacGill, 2017). As previously mentioned when discussing the formation of general acne, certain hormonal fluctuations that are caused by oral and hormonal birth control implants, pregnancy, the menstrual cycle, stress, and other hormone therapies will also increase cystic acne production (MacGill, 2017). High levels of humidity and the usage of lotions, cleansers, and make-up that contain greasy or oily compounds may also result in the formation of cystic acne lesions (MacGill, 2017). If a person who is prone to cystic acne lesions is exposed to chemicals and drugs such as lithium, phenytoin, corticosteroids, and isoniazid he or she may notice an increase in cystic lesions as a form of reaction to these compounds (MacGill, 2017). However, for some cystic acne patients, their acne may occur due to a genetic disposition no matter their environment or exposure to acne triggering products (MacGill, 2017).

Figure 3: Diagram of Nodulocystic Acne Below the Skin:



https://www.getproactiv.ca/on/demandware.static/-/Sites-Proactiv-Library/en_CA/content/images/your-skin/nodule.jpg

VII. DIAGNOSIS & SYMPTOMS OF CYSTIC ACNE

Cystic acne is diagnosed by having the lesions inspected by a medical professional such as a family medicine doctor, a dermatology physician assistant, or most likely, a dermatologist. The medical professional will observe the lesions and determine if they are cystic and also count the other acne lesions (open and closed comedones, papules, pustules, and nodules) to determine the degree of severity for treatment purposes (Cole, 2009). The lesions observed may be on the back, chest, or face of the patient (Cole, 2009). (See figure four).

The superficial symptoms of cystic acne lesions are characteristically described as red, painful to the touch, elevated bumps on the areas of the body that are acne prone (face, chest, and back) (Cole, 2009). A cystic lesion is normally accompanied by smaller lesions around the cyst, and therefore causes the affected area to be painful or sensitive (Cole, 2009). These lesions are also more visible than less severe forms of acne, which may lead to self-esteem issues over one's appearance as well as a decline in mood (MacGill, 2017). This puts patients with cystic acne at a higher risk for psychological problems and emotional distress than those with a less severe form of acne (MacGill, 2017). Cystic acne may also result in permanent damage to the skin by producing scars in the form of either small, deep pits called "icepick scars," shallow depressions in the skin, larger pits, or red, raised scars (MacGill, 2017).

Figure 4: An Example of Cystic Acne:



<https://optinghealth.com/wp-content/uploads/2017/07/Cystic-Acne-1-e1503829566899.png>

VIII. TREATMENTS FOR CYSTIC ACNE

Cystic acne falls under the category of severe acne, and therefore it may be difficult to determine a universally effective treatment for patients that suffer from this type of skin disorder. It may also be difficult to completely eradicate all lesions or scars produced especially if the treatment is not an effective match for the patient. Thankfully, there are many different forms of acne treatments such as systemic (oral antibiotics/medicines), topical (creams or gels), as well as light, vitamin, or herbal therapy.

a. Systemic

Systemic treatments have earned the title of the most common type of treatment for cystic acne because they are known to decrease swelling and reduce the redness that occurs with cystic lesions (American Academy of Dermatology). Some of the oral antibiotics known amongst the medical community that may treat cystic acne are doxycycline, trimethoprim-sulfamethoxazole, and Isotretinoin (Cole, 2017). Female patients may also be prescribed an oral contraceptive, such as norethindrone, which is a progesterone pill used to balance female hormone levels (Cole, 2017).

Oral doxycycline is the most prescribed oral tetracycline in the United States due to this antibiotic being a low risk medication for causing adverse reactions (Rosso, 2015). Doxycycline is a variation of the medication tetracycline, which is an antibiotic that may be used as treatment for various bacterial infections such as acne or sexually

transmitted diseases (Cunha, 2018). Doxycycline is capable of treating moderate-to-severe acne and is sometimes paired with extended-release minocycline tablets in order to increase effectiveness and reduce side effects such as gastrointestinal issues, photosensitivity, and dizziness (Rosso, 2015). Doxycycline works by preventing further bacterial growth, and the medication kills bacteria while reducing the production of acne causing oils in the pores (MedlinePlus, 2017).

Trimethoprim-sulfamethoxazole is another oral antibiotic used for treating moderate-to-severe acne, however; it is known to be a higher risk medication for adverse reactions, so it is only prescribed when other antibiotics, such as doxycycline, are not effective (Huntley, 2003). Trimethoprim-sulfamethoxazole is also used to treat infections such as dysentery, urinary tract infections, pneumonia, and severe cases of chronic bronchitis (McCarty & Rosso, 2011). This medication has been compared to isotretinoin (to be discussed shortly) because it presents a similar response, but does not provide a long-term solution for preventing severe acne once the medication is no longer being administered (Huntley, 2003). Trimethoprim-sulfamethoxazole works by deterring the production of folates, which are salts or esters of folic acid required for bacterial DNA production (McCarty & Rosso, 2011).

Isotretinoin, also known by the brand name Accutane, is defined as an oral acne treatment that is a derivative of vitamin A that exploits retinoid receptors, which are related to vitamin A, and there is no age

restriction on who may be prescribed this systemic treatment (Hitzeman, 2016). This is currently the most effective treatment for treating cystic acne because this drug is able to cutback on the amount of comedone production and sebum production on the surface and the pores and ducts within the dermis layer (Layton, 2009). This prevents the acne causing bacteria from reproducing in a hostile environment (Hitzeman, 2016). Antibiotics (in general) work by decreasing the cell growth within the sebaceous glands and are able to decrease the bacteria *P. acnes* and the inflammation that this bacteria causes (Hitzeman, 2016). Isotretinoin is not recommended as the first course of treatment to be prescribed for patients with moderate-to-severe acne because it is a teratogenic drug that poses a risk to the fetus if a female who is on the medication were to become pregnant (Hitzeman, 2016). Females on isotretinoin who are within childbearing years are required to use two forms of birth control if they are sexually active. They are also required to take two pregnancy tests before this medication is prescribed. This requirement continues every month while they are taking isotretinoin and one month after the patient has completed their prescribed dosage. The patient must also refrain from donating blood while on this medication to protect pregnant or soon to be pregnant women from receiving potentially harmful blood (Hitzeman, 2016).

Common side effects of isotretinoin include dry lips, eyes, and skin, including parts of the body other than those affected by acne lesions (Hitzeman, 2016). The medical professional prescribing this strong systemic treatment will recommend their patient to take the medication for a certain number of months based on the severity of their acne. This will be adjusted based on the patient's progress and once they have completed their prescribed dosage. Isotretinoin is prescribed by medical professionals with hopes of eradicating most of the acne production and to decrease the inflammation of future breakouts (Layton, 2009).

b. Topical

Systemic medications are known amongst the medical community as the most effective for treating severe acne. However; topical acne treatments are used more regularly than systemic ones and are usually prescribed prior to or in combination with systemic treatments (Penna, Ponti, Sparavigna, Tenconi, 2015). Topical acne treatments are typically prescribed to patients who suffer from mild-to-moderate acne, and it often take six to eight weeks to see a response (Freiman, Kraft, 2011). Topical treatments may also be prescribed to prevent the side effects that sometimes occur during the use of systemic medications, such as gastrointestinal issues (Adawiyah, Priya, Roshidah, 2010). The most common side effects of topical acne treatments are skin irritation or dryness where the treatment has been applied (Freiman, Kraft, 2011). These may be soothed by including creams, face lotions, or ointments that are made for remedying dry and irritated skin into the patient's skincare routine (Freiman, Kraft, 2011). Topical acne treatments are also prescribed in various forms of retinoids and antimicrobials (Freiman, Kraft, 2011).

Retinoids are a derivative of vitamin A that are used to bind with nuclear receptors to regulate epithelial cell growth (skin cell growth) and are prescribed in either a gel, liquid, or cream form (American Osteopathic College of Dermatology). These medications encourages follicular keratinocytes in order to inhibit comedone formation by

unblocking clogged pores (American Osteopathic College of Dermatology & Freiman, Kraft, 2011). The topical retinoids that are most frequently prescribed are adapalene, tretinoin, alitretinoin, and tazarotene (American Osteopathic College of Dermatology). Those being treated for cystic acne with a retinoid are requested to apply the medication in small amounts once daily approximately thirty minutes after washing their face (American Osteopathic College of Dermatology). Topical retinoids may also be used to treat hyperpigmentation such as acne scars as well as other skin conditions such as psoriasis (American Osteopathic College of Dermatology). The downfall of these medications is that while they can be used for treatment of inflammation caused by acne and acne scars, they are most commonly prescribed for patients with mild-to-moderate acne are not as effective as other known treatments for cystic acne (American Osteopathic College of Dermatology).

Patients dealing with cystic acne may also be prescribed a topical antimicrobial to treat inflammation (Freiman, Kraft, 2011). The most common topical antimicrobial prescribed is benzoyl peroxide. Benzoyl peroxide assists in counteracting the antibiotic resistance of *P. acnes* while possessing anti-inflammatory characteristics and being able avert the formation of comedones (Freiman, Kraft, 2011). These medications are prescribed in numerous strengths depending on the patient's experience and skin disorder. The strength reaches up to

10.0% benzoyl peroxide concentration, which may be more irritating to those who are not used to the effects of this treatment (Freiman, Kraft, 2011). It is strong enough that it is able to bleach any fabrics with which it may come in contact, so this is a concern that some patients have before using this medication (Freiman, Kraft, 2011). Benzoyl peroxide kills *P. acnes* within the skin by emitting oxygen throughout the affected hair follicles and sebaceous glands (Freiman, Kraft, 2011).

Other topical antimicrobials used include clindamycin and erythromycin because they may be tolerated more easily while still being able to decrease the number of inflamed acne lesions (Freiman, Kraft, 2011). However; when used alone and not in conjunction with benzoyl peroxide, these medications could increase the number of antibiotic resistant *P. acnes* in less than a month of use (Freiman, Kraft, 2011). Even though erythromycin and clindamycin have antimicrobial characteristics, antibiotic resistant *Staphylococcus aureus* and *Staphylococcus epidermidis* may form or increase in numbers in and around the part of the body being treated with one of these topical treatments (Freiman, Kraft, 2011).

c. Light Therapy

Although systemic and topical acne treatments are the most recommended for treating cystic acne, researchers have tested different forms of light therapy for decreasing acne causing bacteria and inflammation. This research did observe patients whose acne had decreased inflammation after they experienced contact with natural sunlight (Adya, Inamadar, Pei, Tsoukas, 2015). It was determined that the porphyrins, which are produced naturally inside of the sebaceous glands by the *P. acnes* bacteria, were capable of absorbing light wavelengths between 400 to 700 nm (Adya, Inamadar, Pei, Tsoukas, 2015). This absorption of light promotes photo-excitation of the porphyrins, which leads to the release of oxygen and free radicals that can cause bacterial suicide within the *P. acnes* (Adya, Inamadar, Pei, Tsoukas, 2015). Researchers have deduced that red lights, which have a longer wavelength, are capable of reaching deeper into the skin towards the sebaceous glands to focus on utilizing cytokine from macrophages to produce anti-inflammatory properties (Adya, Inamadar, Pei, Tsoukas, 2015). Blue lights are also able to decrease inflammation caused by acne, however; they are more effective when used in combination with red light (Adya, Inamadar, Pei, Tsoukas, 2015). In order to determine the efficacy of light therapy, studies were done to compare subjects being treated with blue light or blue-red light therapy to those being treated with either a systemic or topical

treatment (Adya, Inamadar, Pei, Tsoukas, 2015). Studies were also done to test whether or not using light therapy in unison with other well known acne treatments would be beneficial for reducing acne inflammation (Adya, Inamadar, Pei, Tsoukas, 2015). After many experiments were done to compare blue and blue-red light therapy to other types of cystic acne treatment, it was determined that the light therapy was best used for treating mild-to-moderate cases of acne due to the severe inflammation that is caused by cystic acne lesions (Adya, Inamadar, Pei, Tsoukas, 2015). It was also determined that by incorporating light therapy along with, not in place of, systemic or topical acne treatments, a decrease in the number of lesions and severity of the inflammation could occur (Adya, Inamadar, Pei, Tsoukas, 2015). The light therapy was also credited with decreasing the sebaceous gland size and for cutting down sebum production (Adya, Inamadar, Pei, Tsoukas, 2015). However; if the distribution of the treatment is misused, there may be photothermal harm to the sebaceous glands as well as phototoxic damage to the skin due to improper exposure of light (Adya, Inamadar, Pei, Tsoukas, 2015).

IX. SURVEY OF MEDICAL PROFESSIONALS

a. Objective

The objective of the research conducted for this thesis was to evaluate the risks and benefits of the different methods of treatment for patients with cystic acne as well as to determine what treatment is most frequently prescribed to them. A simplified survey of medical professionals such as dermatologists, family medicine doctors, and dermatology physician assistants was performed in order to answer questions like, "Which type of treatment and what treatment method is used on a regular basis when treating cystic acne?" and, "Who treats patients with cystic acne and what do they use?"

b. Methods

The methodology of the interview process with the medical professionals was as follows: the medical professionals were selected from local Shelby medical practices as well as from medical practices in the Lake Norman-Charlotte area. In order to obtain enough data to evaluate, the initial number of intended interviewees was six to eight medical professionals. The professionals were contacted individually and asked if they would like to participate in answering a short survey about their experience with treating acne, specifically cystic acne. They were required to provide verbal consent in order to participate. If they declined, it was politely accepted and the researcher continued on to the next person. If they accepted, they were asked to provide verbal

consent to record the phone call and their answers for the survey questions through voice recording and typed notes. The phone calls were recorded in order to accurately remember their answers. A script was used to ask them for their verbal consent in order to offer reassurance to the professionals that their privacy would be protected and patient information would not be a topic of conversation in order to abide by HIPAA. HIPAA stands for the Health Insurance Portability and Accountability Act (Rouse, 2019). See appendix A to read the verbal consent script. Once verbal consent was acquired, they were asked to answer nine brief questions. See page appendix B to read the blank copy of the survey. If the professionals answered no to questions three or five, the survey ended because they did not have personal experience or treatment methods for cystic acne and their data would not apply to this research. The number of professionals who have treated cystic acne was recorded in a table along with their suggested treatments to determine if there is a link between the treatments. The reason for their recommendations on certain treatments was used to further answer the research questions. The medical professionals will be informed of this during the request for consent. The surveyed professionals are referred to as: subject 1, a dermatologist; subject 2, a dermatology PA; or subject 3, a family medicine doctor and so forth throughout the written and presentation portions of this thesis. Those who answered the survey were not informed of anyone else who was

interviewed or the other survey answers so that their responses were unbiased. The individual answers of the medical professionals are provided in appendix C.

c. Responses

Three medical professionals responded to the survey request and allowed their answers to be recorded. It was noted that three was not the preferred number of participants for this survey, however; the three medical professionals that responded had some diversity amongst their professions.

The first response was from a dermatologist who has been practicing medicine since 1997. He underwent a three-year dermatology residency and after medical school he became board certified. The majority of the dermatologist's patients that have acne are teenagers, however; the dermatologist has also treated patients with acne up to eighty years old. A dermatologist's job largely consists of treating patients with acne. Although other medical professionals are equipped to treat this skin disorder as well, patients with cystic acne are commonly referred to a dermatologist. Based on the dermatologist's experience with treating cystic acne, they recommend systemic and topical acne medications that consist of isotretinoin. As previously mentioned, Accutane is the name brand of isotretinoin. The benefits of Accutane that have been observed by the dermatologist are that this medication is the closest researchers have been to finding a

cure for cystic acne and that 95% of patients who complete their suggested Accutane prescription do not have future breakouts. In order for a medical professional to prescribe Accutane or for a patient to be prescribed this medication, both must have an account with iPledge. iPledge is a program that was created in order to provide necessary information about Accutane such as the potential risks for both male and female patients as well as the potential concerns for depression (iPledge). The only consequences that this dermatologist considered for this medication are the political issues that have occurred due to the creation of iPledge and the stigmas that have been made about the medication potentially causing depression.

The second response to this survey was a physician assistant who has been practicing dermatology since 2009. She went through a six-month dermatology training program once she completed physician assistant school, and she does treat patients for acne in general as well as cystic acne. The average age range of patients that she treats for cystic acne is between thirteen to eighteen years old. When treating a patient that is troubled by cystic acne, the dermatology PA most frequently prescribes isotretinoin because she also believes that this medication can lead to complete clearance of acne. The dermatology PA concluded that the consequences of this treatment include dryness, teratogenicity, mood changes, blood work, and frequent dermatology appointments. She also mentioned that a patient taking Accutane may

have difficulty driving at night and muscle aches, which are two side effects that haven't been discussed in the research collected for this thesis.

The third and last response received for this survey was from a doctor that has been practicing family medicine since 2008. She does treat patients with acne, however; she did not undergo extra training to do so except for the general training they received in medical school and a four-week rotation in dermatology. The family medicine doctor does begin treatment for cystic acne and she commonly treat patients between the ages of twelve to fifty years old for this type of acne. The topical treatments that she frequently prescribes to treat cystic acne include Retin A, benzoyl peroxide, topical clindamycin, and adapalene. If these topical treatments are not effective, the doctor will refer the patient to a dermatologist so that the patient may be treated with Accutane. The doctor claimed that the benefit of topical treatments was that the patient will experience less systemic side effects, but the benefit of oral antibiotics is that they are more effective at treating deep cystic acne. The doctor also claimed that the benefit of Accutane is that it is more capable of eradicating cystic acne and preventing future lesions. She stated that consequence of topical treatments is that they do not entirely resolve the issues with deep cystic acne and that the consequence of oral antibiotics is that using this treatment may result in bacteria that are antibiotic resistant. She also noted that the

consequences of Accutane are the patient's mucous membranes may become dry and that there are issues with teratogenicity in female patients if they become pregnant while on the medication.

d. Conclusion of data

The number of responses for this survey was not preferable for determining a universal treatment for cystic acne. However; there was some variation within medical backgrounds amongst the three professionals that responded. Therefore, the surveys did conclude that three different medical professionals with different levels of experiences all recommended Accutane as the most effective course of treatment for reducing and potentially eradicating cystic acne. Based on the survey responses, it was determined that the medical professionals believed that the outcome of this treatment outweighed the consequences.

All of the professionals provided a verbal or written agreement to answer the survey and also allowed their answers to be recorded for research purposes. Out of the professionals surveyed, none of them answered no to questions number three or five so therefore all three surveys were permitted for use. The surveys provided were edited to provide a clear understanding of the answers, but the integrity of the answers was not disrupted. Overall, those that answered the survey were pleased to be able to provide useful information on this topic and to demonstrate their knowledge on acne treatments.

X. CONCLUSION

Acne, specifically cystic acne, is difficult to treat without the guidance of a trained medical professional so it is helpful to know the options for treatments as well as the benefits and consequences of those treatments. The current treatments that are frequently used for decreasing cystic acne lesions are systemic, topical, and light therapy. As previously mentioned, and based on the research collected through online databases and the survey of medical professionals, systemic Accutane is the best course of treatment for severe, stubborn cystic acne over other acne treatments. This is the best course of treatment because it is the only known medication to this date that provides complete or almost complete clearance in patients with cystic acne. Also, despite the concerns that coincide with systemic medications and the potential side effects of Accutane, this medication received notable praise from the medical professionals that completed the survey used for this research. It was also determined through research that Accutane may not be the best course of treatment for every patient, so it is wise to seek medical advice on an initial medication prior to Accutane. By testing out other systemic or topical medications first, it will determine whether or not Accutane is necessary for that specific patient or not. As researchers and medical professionals continue to observe the effects of other medications, a new medication may later be determined as a more universal course of treatment for severe cystic acne, but for the time being, Accutane is the most effective when aiming to cure a patient's cystic acne.

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XII. APPENDIX

APPENDIX A: VERBAL CONSENT SCRIPT

“Good morning/afternoon Dr./Mr./Mrs. So-and-so. My name is Callie Elliott and I am a senior biology major at Gardner-Webb University. I am currently conducting research for my Honors thesis on treatments for cystic acne and I was wondering if you would do me the honor of participating in a short survey regarding how you treat this form of acne. The answers will be used to answer my thesis question as to who treats cystic acne, which type of treatment is used, and what treatments are most commonly used amongst medical professionals to treat this skin condition. Your name, medical practice, and graduate schools will not be documented and none of my questions will require patient specific answers in order to follow HIPAA regulations.”

IF NO: “I understand, thank you for your time and have a blessed day.”

IF YES: “Thank you for your consent Dr./Mr./Mrs. So-and-so. May I also have your consent to document your answers to the survey in a word document as well as to record this phone call so that I may reference the answers within my thesis?”

IF NO: “I understand, in order to use your answers as a part of my research I will need to document them so that I may recall your methods of treatment when writing my thesis. If that is an issue, I will respect your privacy and I will not be able to conduct my survey with you today. Thank you for your time and have a blessed day.”

IF YES: “Thank you again, I will now proceed with the survey”

APPENDIX B: BLANK SURVEY

1. How long have you been practicing medicine?
2. What is your medical specialty?
3. Do you treat patients with acne?
4. Did you receive extra training to treat patients with acne?
5. Do you treat patients with cystic/severe acne?
6. What age range do you treat most often for cystic acne?
7. What treatment method do you recommend most often for cystic acne (severe)?
8. What are the benefits of that treatment?
9. What are the consequences of that treatment?

APPENDIX C: SURVEY RESPONSES

Answers from the Dermatologist:

1. How long have you been practicing medicine?

He has been practicing medicine since 1997.

2. What is your medical specialty?

Their specialty is Dermatology.

3. Do you treat patients with acne?

Yes, he does treat patients with acne.

4. Did you receive extra training to treat patients with acne?

Yes, he went through three years of a dermatology residency with board certification.

5. Do you treat patients with cystic/severe acne?

Yes, he does treat patients with cystic/severe acne.

6. What age range do you treat most often for cystic acne?

He treats teenagers most frequently for cystic acne, but they may also treat patients up to eighty years old.

7. What treatment method do you recommend most often for cystic acne (severe)?

He recommends systemic, oral antibiotics or topical, isotretinoin

8. What are the benefits of that treatment?

He believes that the benefit of Accutane is that it is the closest to a cure for cystic acne. 95% of patients do not have reoccurrence after following the recommended usage.

9. What are the consequences of that treatment?

He believes that there are no consequences other than the political issues that have occurred due to iPledge and the concerns over Accutane being a teratogenic drug because of societal concerns that have become more prevalent.

Answers from a Dermatology Physician Assistant:

1. How long have you been practicing medicine?

She has been practicing medicine since 2009

2. What is your specialty?

Her specialty is Dermatology

3. Do you treat patients with acne?

Yes, she does treat patients with acne.

4. Did you receive extra training to treat patients with acne?

Yes. She did a 6-month Dermatology training program after Physician Assistant School.

5. Do you treat patients with cystic/severe acne?

Yes, she does treat patients with cystic/severe acne.

6. What age range do you treat most often for cystic acne?

She treats patients in the age range 13-18 years old most frequently for cystic acne.

7. What treatment method do you recommend most often for cystic acne (severe)?

She recommends isotretinoin for treatment of severe acne.

8. What are the benefits of that treatment?

She believes that the benefit of Accutane is that this treatment usually allows for complete clearance of acne.

9. What are the consequences of that treatment?

She concluded that there can be side effects for Accutane which include, but are not limited to, dryness, difficulty driving at night, teratogenicity, muscle aches, mood changes, frequent appointments, and blood work.

Answers from the Family Medicine Doctor:

1. How long have you been practicing medicine?

She has been practicing since 2008.

2. What is your medical specialty?

She practices Family Medicine

3. Do you treat patients with acne?

Yes, she treats patients with acne

4. Did you receive extra training to treat patients with acne?

No, she went through the general training through medical school and residency training, which included a 4-week rotation in Dermatology.

5. Do you treat patients with cystic/severe acne?

Yes, she does start treatment for cystic acne, but often refer patients to a dermatologist if it is severe or not responding to their treatments.

6. What age range do you treat most often for cystic acne?

She treats patients 12-50 years old for cystic acne

7. What treatment method do you recommend most often for cystic acne (severe)?

She recommends topical treatments such as Retin A, benzoyl peroxide, topical clindamycin, and adapalene to start out if the patient is not responding to minocycline or doxycycline. If all these fail, they usually will refer the patient to dermatology to look into Accutane.

8. What are the benefits of that treatment?

The doctor stated that the benefit of using topical treatments only is the patient will experience less systemic side effects. The benefit of oral antibiotics is that they can more effective at eradicating deep cystic acne.

The benefit of Accutane is that it is very effective at eradicating cystic acne and many times it does not return.

9. What are the consequences of that treatment?

The consequence of topical treatments only is that many times they do not completely resolve the deep cystic acne problem. The consequence of oral antibiotics is that bacteria can become resistant to the antibiotics and they no longer work. The consequence of Accutane is side effects of teratogenicity and drying of the mucous membranes

APPENDIX D: IRB APPLICATION



GARDNER-WEBB
UNIVERSITY

Institutional
Review Board

THIS IS TO CERTIFY THAT THE RESEARCH PROJECT TITLED
A Risk Benefit Analysis of Treatments for Cystic Acne

being conducted by _____

has received approval by the Gardner-Webb University IRB. Date _____

Exempt Research

Signed _____

Department/School/Program IRB Representative

Department/School/Program IRB Member

Expedited Research

Signed _____

Department/School/Program IRB Representative

Department/School/Program IRB Member

IRB Administrator or Chair or Institutional Office

Non-Exempt (Full Review)

Signed _____

IRB Administrator

IRB Chair

IRB Institutional Officer

Expiration Date _____

IRB Approval:

_____ Exempt _____ Expedited _____ Non-Exempt (Full Review)



APPLICATION TO CONDUCT RESEARCH WITH HUMAN SUBJECTS

(Researcher must complete this form before request can be submitted to IRB.)

Please save this form to your computer before completing.

Name of Researcher Callie Elliott Date 2-13-19
 GWU ID# 906607 Email Address celliot4@gardner-webb.edu
 Mailing Address PO Box 658 / 110 S Main St., Boiling Springs, NC, 28017
 Phone 704-615-5212
 Department Biology
 Faculty Sponsor (if student research) Dr. Nancy Winker
 Faculty Sponsor Email Address nwinker@gardner-webb.edu
 Phone Number _____
 Title of Research Project A Risk Benefit Analysis of Treatments for Cystic Acne

LEVEL OF IRB REVIEW REQUESTED

In order to identify the level of review you are requesting, please read the descriptions below and select the applicable box(es).

Exempt Review Request

Please review the Exempt categories below and indicate the category that applies to your research. Please note: if your study does not fall into one of the categories below it cannot be reviewed as exempt.

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected

or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- (4) Research involving the collection or study of existing data*, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
*Existing data is defined as materials that are "on the shelf" at the time the research is submitted to the IRB.
- (5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- (6) Research involving taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture

Expedited Review Request

Federal regulations provide that certain types of research may be considered for review through an expedited process (45 CFR 46.110). A primary criterion for expedited review is that the research be of minimal risk. The Office of Human Research Protections (OHRP) defines minimal risk as risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than that ordinarily experienced in daily life or during the performance of routine physical or psychological examinations. In addition, the purpose of the research must fit within a series of categories as stipulated by DHHS regulations.

Please confirm statements A and B are true for your study (by checking the boxes in front of the statement) and indicate the appropriate category under C.

- (A) The research poses no greater than minimal risk.
- (B) The identification of the subjects/and or their responses would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that the risk to privacy and breach of confidentiality are no greater than minimal.

- C) Review the Expedited categories below and indicate the category that applies to your research. **Expedited Categories:**
- (1) Clinical studies of drugs and medical devices.
 - (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from (a) healthy, non-pregnant adults who weigh at least 110 lbs.; (b) other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency of collection. For these subjects, the amount drawn may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week.
 - (3) Prospective collection of biological specimens for research purposes by noninvasive means. For example: hair/nail clippings, external secretions, saliva, mucosal skin collected by buccal swab.
 - (4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. For example: (a) physical sensors that are applied to the surface of the body; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, ultrasound, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. **Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).**
 - (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
 - (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
 - (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- Full Committee Review:** Applications that do not meet the definition of Minimal Risk (see definition above) to the participants or do not meet the qualifications of Exempt or Expedited review must be presented to the Full IRB Committee for discussion and vote.

DESCRIPTION OF RESEARCH

What is your hypothesis/research question(s)?

My main research question is to ask dermatologists, family and internal medicine doctors "Which type of treatment and what treatment method is used on a regular basis when treating cystic acne?" I will also be asking "Who treats patients with cystic acne and what do they use?"

How many subjects do you expect to use, and how will you obtain this sample (describe population)?

I intend on surveying six to eight medical professionals (dermatologists, dermatology PAs, and family medicine doctors). I will obtain this sample by contacting local medical professionals in the Shelby area as well as those who work in my hometown doctors office.

What is your research methodology? Attach any surveys, instruments, or tests to this form with the appropriate references.

The methods for my research will be to first create the survey attached to this form, once approved, I will contact the medical professionals via a phone call during their work hours and conducting a nine question survey regarding their experience with treating cystic acne. It is estimated that the phone call should last between five to ten minutes and I will use my computer to record the conversation with my phone on speaker while also taking note of their responses. If they answer no to question three or five that will be the end of the survey and I will thank them for their time. If they answer yes to questions three and five, then I will continue with the survey and use their answers as data for my thesis.

Describe the research procedure. Attach a copy of the consent form and a copy of the debriefing statement. Describe how and when these will be used.

The research procedure is as followed; the medical professionals will be contacted individually and asked if they would like to participate in answering a short survey for my thesis research about their experience with acne, specifically cystic acne. I will require them to provide verbal consent in order to participate. If they decline I will politely accept their decline and move on to the next person. If they accept, I will also ask for verbal consent to record the phone call and their answers for the survey questions through voice recording and typed notes. The phone call will be recorded in order to accurately remember their answers. See attached script for more detail about how I will ask for consent. Once I have acquired verbal consent to continue with the survey and record the conversation, I will ask them 9 brief questions. If they say no to questions 3 or 5, the survey will end because they will not have personal experience or treatment methods for cystic acne and their data would not apply to my research. The number of professionals who have treated cystic acne will be recorded in a table along with their suggested treatments. The reason for their recommendations will be written out in paragraph form and used to further answer my research question. The notes and audio from the survey will not be saved on iCloud and will be deleted after my thesis is completed.

Does this research pose risk to the subject? If so, what protocol will be enacted to protect the subject?

This research does not pose risk to the subjects being interviewed because their names, practices, locations, and graduate schools will not be included within the documentation / research. The medical professionals will be informed of this during the request for consent. See attached script for the detailed verbiage used to notify the professionals of how their answers will be handled. The surveyed professionals will be referred to as subject 1, a dermatologist; subject 2, a dermatology PA; or subject 3, a family medicine doctor and so forth throughout the written and presentation portions of my research.

Does this research involve deception of any kind? (If applicable, please explain.)

No this research does not involve deception. The questions being asked are straight forward in order to gain the most honest and scientific results. If the medical professional feels deceived, the survey will be explained further and may end at any time based on their wishes.

Will any incentives be used? If so, please explain.

No incentives will be used. The medical professionals may refuse to answer my survey if they wish.

How will you protect the subject's right NOT to participate in your research?

I will inform the medical professional that I am conducting a short survey to collect research for my undergraduate thesis, not conducting a political or sales survey, and that if they wish to answer a few short questions based on their experience with cystic acne, they may. If they wish not to answer the questions, I will politely accept their decline and let them go about their day. I will not contact that professional again in order to respect their wishes.

How will you protect the subject's confidentiality of results? Please indicate how and where data will be stored and secured; please include the process for destruction of data.

As previously mentioned, I will not use the name of the medical professional, their practice, or graduate programs that they attended. They are informed by law (HIPAA) not to use personal patient information so that information will be protected by them. The data from this survey will be password protected on my computer within a word document and a voice recorded document also located on my computer. This data will not be stored on iCloud in order to prevent the data from being viewed by unauthorized parties.

How, when, and where will the research results be reported?

The results of the survey will be voice recorded as well as noted in a word document. That document and voice recordings will be password protected and only viewed by my thesis advisor, Dr. Nancy Winker, and the Director of the Honors Program, Dr. Tom Jones, if need be. The research will be used to give information on what methods the medical professionals use and prefer when treating cystic acne and discussing the effects of those methods within my thesis. The results will be documented in my written thesis and presented during my final presentation at Gardner-Webb University in the Spring of 2019. There is also a possibility that they will be presented at the Southern Regional Honors Conference in March 2019 and at the National Collegiate Honors Conference in November 2019.

If this changes, be sure to contact the IRB with an update. If, for example, a faculty member publishes research results, he/she should forward this information to the IRB.

By March 1st, 2019

When do you anticipate completing this research? _____

Signatures: (Hand-written signatures are required for IRB submission.)

Researcher _____ Date _____

Print Above Name _____

Faculty Research Advisor, please note. In signing this document, you verify that you have reviewed the protocol and approve of the procedures described therein. You also have verified that the Student Researcher is currently IRB certified. Also, in order to act as the Faculty Research Advisor for this student, you must complete the IRB Certification Training. Training is valid for three years.

Faculty Sponsor _____ Date _____
(if student research)

Print Above Name _____

Required attachments:

- Copy of Informed Consent Form
- Copy of Instruments, Surveys, Tests, and Interview Questions, etc.
- Permission to use published instruments (If applicable)
- Signed External IRB Approval Form (If Required)
- Evidence of CITI Certification

Please submit only signed documents to the IRB.