Low Dose Isotretinoin - What Does the Literature Say?

The Pathogenesis of Acne

Hormonal Treatment of Acne

Post Acne Scarring in Pigmented Skins

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EDITOR’S NOTE

Acne affects up to 75% of all teenagers and between 5% and 20% of adults, mainly in females. The severity varies, and ethnic factors play a role. The old adage that “acne scars the psyche as well as the soul” is still appropriate, perhaps even more so in some social settings which have high image consciousness.

All family practitioners will, therefore, see a large number of acne sufferers. Old myths such as food and dietary influences aggravating acne have largely been discounted. The pathogenesis of acne is better understood and hormonal influences better defined.

There have been significant changes in the use of drugs such as Isotretinoin. Lower dose regimens are being used by many, but often without adequate evidence-based information. Dr Selwyn Schwartz reviews this thorny issue.

We last dedicated an issue to acne some years ago, and with all the changes mentioned above, it was time to revisit the problem and look at more recent advances.

The articles in this issue have either been updated or specially written for us.

Great news is that our website is finally up and running. Please visit www.samedicalreviews.co.za to log onto the latest as well as archived editions. It is also linked to the Dermatology Society website’s journal room.

Getting your CPD points online is a bit challenging initially, and a step-by-step “how to do it” is included in this issue as well as on the website.

Robert Weiss

Chief editor
South African Dermatology Review
ADCOCK INGRAM LAUNCHES NEW DERMATOLOGY DIVISION

In line with its vision of being a leading, world-class, focused healthcare company, Adcock Ingram has established a new dermatology business unit which offers a range of prescription dermatological products.

“Adcock Ingram Dermatology is committed to improving the quality of patients’ lives and providing dermatologists with additional solutions for their patients’ needs,” says recently appointed head of Adcock Ingram Respiratory and Dermatology, Gary Vine.

Vine says the establishment of Adcock Ingram Dermatology will ensure therapeutic alignment across Adcock Ingram’s product range. The therapeutic areas that Adcock Ingram Dermatology will focus on include: eczema, acne, psoriasis, and skin infections. “Through strategic collaboration with our valued partners including LEO Pharma, Novartis, MSD and Roche, we are now able to offer healthcare professionals and our patients a wide range of prescription dermatological brands,” says Vine.

Some of the key brands within these areas include: Elidel®, Elocon®, Roaccutane®, Dovobet®, Famvir®, Fucidin®, Fucidin® H and Quadriderm®.

For further information, please contact Nicolette Kotze: Dermatology Brand Manager Tel: 011 635 0627 or Shakti Pillay: Dermatology Brand Manager Tel: 011 635 0642

CETAPHIL® RESTORADERM™ FROM GALDERMA

Cetaphil® by Galderma, is one of the world’s leading dermatological therapy brands, and the brand of choice for many. The launch of its two revolutionary new skincare products, Cetaphil® RESTORADERMTM Skin Restoring Body Wash and Cetaphil® RESTORADERMTM Skin Restoring Body Moisturiser, is good news for atopic dermatitis sufferers, as they will do much to reduce redness, dryness and irritation which are common symptoms of this skin condition.

Both contain patented ceramide and flaggrrin technology which helps replenish the skin’s natural lipids and restore moisture to help rebuild the damaged skin barrier. Clinically proven to be non-irritating, these products are highly tolerable and fragrance free, with studies showing that they can be used in children as young as three months with atopic skin.

These products when included in the daily cleansing and moisturising regimen, will do much to provide increased tolerability.

For further information, please contact Peter McGill on 011 706 2339 or email peter.mcgill@galderma.com

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Vichy Laboratoires has discovered the central role of the Derm Source, the layer of the dermis that, alone, commands the regeneration of the entire skin. The Derm Source is located in the upper part of the dermis, immediately beneath the dermo-epidermal junction.

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For further information, please contact Natalie da Silva on 011 286 0700.
EVOLUTION

Use of isotretinoin has evolved since it was first launched. It is now being widely used earlier in the course of disease. The recommendations for regular laboratory monitoring of liver functions and triglycerides while on treatment have been diminished. An increased need for safeguards against pregnancy for the duration of therapy and one month thereafter has developed. The list of indications for use of isotretinoin has expanded and is no longer reserved for cases of nodulocystic or refractory acne. It is now also used for cases of moderate acne relapse or less than fifty percent improvement after a course of antibiotics or hormone therapy of four months, significant psychosocial impairment as a result of the acne, marked concomitant seborrhoea, gram negative folliculitis and scarring or persistent dyschromia from the acne process. Lower dosage schedules are also now being widely used.

EXPECTATION OF THERAPY

The expectation of isotretinoin treatment is longterm treatment free remissions. White et al looked at recurrence rates after a first course of standard isotretinoin treatment and reported a longterm remission rate of 39% after a standard course of isotretinoin 1mg/kg in 179 patients at three years post treatment.

A further course of isotretinoin was used in 19%, whereas topical therapy was used in 17% and oral antibiotics in 25%. Layton et al published a study of ten year’s experience of oral isotretinoin in which they studied 88 patients over ten years. Forty percent of patients remained cured, whereas a further 21% required further topical therapy, 16% oral antibiotics and 23% required further isotretinoin therapy. They also concluded that patients with higher cumulative doses had significantly better responses to treatment.

PRESCRIPTION TRENDS

Isotretinoin usage increased by twenty five percent from 1992 to 2000 in the USA, whereas post 2002 usage decreased by 23% mainly ascribed to more stringent legislation procedures enforced prior to commencing and during treatment.

South Africa has seen increased usage of isotretinoin with further increase in recent years due to generics being launched, decreased price, increased prescriptions for it and increased use by non - dermatologists.

ARTICLES

LOW DOSE ISOTRETINOIN - WHAT DOES THE LITERATURE SAY?

Dr Selwyn Schwartz, MBChB FCDerm(SA)
Dermatologist in private practice, Rosebank, Johannesburg

Isotretinoin (Roaccutane from Roche) was first introduced on the market in 1982. It has become the gold standard of acne treatment. This form of acne therapy is the only approach with possible “cure” or longterm remission from acne.

Use of isotretinoin has evolved since it was first launched. It is now being widely used earlier in the course of disease. The recommendations for regular laboratory monitoring of liver functions and triglycerides while on treatment have been diminished. An increased need for safeguards against pregnancy for the duration of therapy and one month thereafter has developed. The list of indications for use of isotretinoin has expanded and is no longer reserved for cases of nodulocystic or refractory acne. It is now also used for cases of moderate acne relapse or less than fifty percent improvement after a course of antibiotics or hormone therapy of four months, significant psychosocial impairment as a result of the acne, marked concomitant seborrhoea, gram negative folliculitis and scarring or persistent dyschromia from the acne process. Lower dosage schedules are also now being widely used.

The aim of this article is to evaluate whether there is scientific basis in the literature for the use of low dosage isotretinoin schedules in acne therapy.

Low dose isotretinoin use was first described in patients with persistent adult acne for many years. It has since become widely used for acne which flares when conventional therapy is discontinued. Usage was first described in the literature in “pensioner’s acne” where dosages of 0.25mg/kg/day or intermittent 1 in 4 week schedules was used.
ARTICLES

TERATOGENICITY

Isotretinoin would not receive FDA approval today due to its teratogenic potential. Concerns with low dosage schedules are more treatment failures, much longer courses and therefore less awareness of side-effects, more complacency and laxity with pregnancy prevention.

LOW DOSE ISOTRETNINOIN

Use of low dose isotretinoin is off-label. The recommended dose of isotretinoin is 120mg/kg/course. Low dose isotretinoin results in much longer time periods required to reach the target cumulative dose. According to Micromedex Healthcare series, a greater number of patients receiving a lower dose of 0,1mg/kg/course required re-treatment in a study done on 150 patients with nodulocystic acne. The authors concluded that doses of 0,1mg/kg/course could not be recommended for nodulocystic acne.

A dose-related decrease in sebum production was reported in a double-blind trial on 14 patients in Micromedex Healthcare series where patients were treated with 0,1, 0,5 or 1 mg/kg/day for 12 weeks. No difference in clinical efficacy was reported between the three groups. A 90% decrease in sebum production was reported in the 1mg/kg group at 8 weeks. Sebum production had returned to normal 8 weeks post-treatment in the 0,1mg/kg/day group.

Goulden et al from Leeds in the UK published a study in which they looked at 80 patients over the age of twenty five who were unresponsive or had relapsed after three courses of conventional acne therapy. They treated patients with 0,5mg/kg/day for one in four weeks for six months. Eighty eight percent of patients resolved with this treatment, but thirty nine percent relapsed by one year post-treatment. Patients with truncal acne & higher sebum secretion had higher relapse rates.

Seukeran and Cunliffe studied the response to low dose isotretinoin in the elderly. Ten patients aged 50 - 70 years old with chronic acne were treated with a dose of 0,25mg/kg/day for six months. All were clear at six months (six by 3-4 months). All except one were clear 36 months post-treatment.

In Cunliffe et al’s article on Roaccutane treatment guidelines in 1997, he reported a good response to low dose intermittent isotretinoin in older patients when using 0,5mg/kg for 10 out of 28 days.

Palmar et al reported continuous use of extremely low doses of isotretinoin in patients who relapse quickly when ceasing standard isotretinoin treatment. A dose of 20mg once to twice a week was used in 8 patients.

Enormous psychological benefit was reported. The patients and dermatologist all perceived conventional measures of treating relapse as inferior to isotretinoin in this dosage. The cumulative dose is less than 15mg/kg/year.

Kaymak and IIter from Ankara, Turkey treated sixty patients with mild to moderate acne with 0,5 - 0,75mg/kg/day for 1 out of 4 weeks for six months. Forty one (68,3%) completed treatment and of those thirty four (82,9%) had complete improvement. All adverse effects were mild and no discontinuation was necessary.

Mandekou-Lekafi et al from Thessaloniki, Greece compared low dose and high dose regimens to assess the therapeutic effect and tolerance of the lower doses. They recommended treating up to 120mg/kg total dose for optimal results. The low dose schema was associated with fewer adverse effects and a beneficial effect on pre-existing scarring.

Amichai et al from Ashkelon, Israel studied the effect of a dose of 20mg/day for six months in a group of 638 patients between 12 and 35 years old. They concluded that this dose was effective for moderate acne, with a low incidence of side-effects and at lower cost than higher doses. They reported a good response in 94,8% of patients in the less than twenty year old group and 92,6% in the older group. Treatment failed in 5,2% and 7,4% of these two groups. Elevated serum lipids were reported in 4,2% of patients and abnormal liver functions in 4,8%.

Sardana et al from New Delhi, India studied the safety and efficacy of low dose isotretinoin plus topical 1% cindamycin gel in the treatment of moderate acne in the light of the potentially serious side-effects of standard isotretinoin doses. Three hundred and twenty adults were enrolled in this study and given doses of 20mg alt days for six months with topical cindamycin gel. Very good results were achieved in 68,2% and good results in a further 19,34%. There was a treatment failure of 12,46% with relapse in 16,39% of patients. Relapses were commoner in females, and over 86% of these had polycystic ovarian disease. The group concluded that six months of treatment with fixed-dose, alternate day isotretinoin 20mg with cindamycin topical was effective in moderate acne treatment with a low incidence of side-effects.

Sardana and Garg from New Delhi (who were part of the Indian group who published the study above) analysed various trials using low-dose isotretinoin 0,5mg/kg/day with or without topical therapy and compared the results, efficacy and relapse rates with the standard regimen of 1mg/kg/day, and concluded results were comparable. They concluded that the grade of acne should dictate the dose of administration of isotretinoin and the standard dose of 1mg/kg/day is an unnecessary overtreatment for mild to moderate grades of acne.
CONCLUSION

Low dose isotretinoin is a more acceptable treatment option for the patient. It is associated with fewer mucocutaneous side-effects and is less costly.

It is not for severe cases, but rather for mild to moderate unresponsive acne or chronic grumbling acne. The standard dose of 1mg/kg/day is an unnecessary overtreatment for mild to moderate grades of acne. A concern of low dose isotretinoin use is that due to longer treatment periods, there is a widened window of opportunity for pregnancy.

REFERENCES

1. EXCESSIVE SEBUM PRODUCTION

It is known that acne appears during puberty when sebaceous gland development occurs as hormone levels increase. Sebum is secreted by the sebaceous glands and new insights into the role of sebum secretion in the pathogenesis of acne were published in 2009 in an update from the Global Alliance to Improve Outcomes in Acne Group.

It has been shown that the peroxidation of sebum lipids can activate inflammatory mediators, including IL-6 and lipoxygenases. Oxidised squalene can also stimulate hyperproliferative behavior in keratinocytes thereby perhaps being partly responsible for the formation of comedones.

Androgens are the main hormonal drive of the sebaceous follicles. The gonads and adrenal glands are the main source of androgens. It was previously thought that high overall androgen production or increased availability of free androgen because of deficiency in sex-hormone-binding globulin was responsible for the stimulation of high levels of sebum secretion that occurs at puberty. At the 2002 World Congress of Dermatology, Professor Cunliffe stated that most patients have a normal endocrine profile and that the disease-related seborrhoea is more likely to be an end-organ hyper response of the sebaceous follicles to normal levels of circulating androgens.

It is now understood that the development of acne is associated with the increased sensitivity of sebaceous glands to Dihydrotestosterone (DHT). The effects of DHT are stimulated by insulin-like growth factor (IGF-1). IGF-1 levels rise during puberty, in girls at age 15 and boys at age 18.

In addition insulin and IGF-1 can also stimulate the proliferation of keratinocytes, which can lead to the formation of comedones. Of note is that high Glycaemic diets can increase insulin and IGF-1. Diet may therefore be a possible influencing factor in the pathogenesis of acne.

There are various factors that play a role in the pathogenesis, hence the confusion that often emerges. It is vital to understand the pathogenesis of acne because effective and focused therapy is based on such an understanding.

There are four central pathogenic factors:

1. Excessive sebum production secondary to androgen stimulation;
2. Abnormal follicular keratinisation resulting in follicular plugging;
3. Proliferation of Propionibacterium acnes, an anaerobic organism normally resident in the follicle; and
4. Inflammation following chemotaxis and the release of various proinflammatory mediators.

1. EXCESSIVE SEBUM PRODUCTION

Acne vulgaris is a common dermatological disease evolving within the pilosebaceous unit. Comedones, erythematous papules, pustules and, less frequently, nodules and cysts are characteristic lesions seen in acne.

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Dr Sian Hartshorne – MBBCh (Wits), FC Derm (SA), MMED Derm (Wits)

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2. Abnormal follicular keratinisation resulting in follicular plugging;
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4. Inflammation following chemotaxis and the release of various proinflammatory mediators.
Emotional stress may aggravate acne. This may be caused through changes in the pituitary-adrenal axis. Corticotrophin-releasing hormone levels change in response to stress. Sebaceous gland function is influenced by corticotrophin-releasing hormone. This relationship may help to explain the link between stress and acne.

2. ABNORMAL FOLLICULAR KERATINISATION

The formation of the comedone is central to the development of acne. The initial changes leading to the formation of the comedone are observed in the lower portion of follicular infundibulum. The primary change is an alteration of keratinisation in which the normally loosely organised keratinous material changes to more dense keratinous material. There is an increase in the production of keratinocytes lining the follicle and then a retention of these cells within the follicle. The abnormally desquamated cells and the excess sebum build up within the follicle to form a comedone.

3. PROLIFERATION OF PROPIONIBACTERIUM ACNES

*Propionibacterium acnes* is an anaerobic, pleomorphic diptheroid predominant in the follicular flora.

Other less important organisms found in the follicle include *Propionibacterium granulosum*, coagulase-negative micrococi and the yeast, *Pityrosporum ovale*.

The sebum rich environment of the comedone is ideal for the proliferation of *P. acnes*.

Prolific numbers of *P. acnes* have been found in patients with acne between the ages of 11 and 20 whereas those without acne have practically no *P. acnes*. The same does not hold true for older patients, as those with and without acne have the same numbers of organisms.

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**Table 1**

<table>
<thead>
<tr>
<th>SUMMARY OF PATHOGENESIS OF ACNE</th>
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<tr>
<td><strong>Genetic Influences</strong></td>
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<tr>
<td>Excessive Sebum Production</td>
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<td>Abnormal Follicular Keratinisation</td>
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<tr>
<td>COMEDONE</td>
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<tr>
<td><em>P. acnes</em></td>
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<tr>
<td>Release enzymes eg. Lipase</td>
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<tr>
<td>Release free fatty acids</td>
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<tr>
<td>Irritant to follicle</td>
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<tr>
<td>Inflammation</td>
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<tr>
<td>Release cytokines</td>
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<td>Attract neutrophils</td>
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*Table 1*
4. INFLAMMATION

*P. acnes* produces many enzymes, including three proteases, lipase, phosphatases and hyaluronate lyase, all of which have, in theory been implicated to lead to inflammation. Lipases liberate free fatty acids, which may in turn lead to marked inflammation. The presence of *P. acnes* in the dermis has been shown experimentally to induce only a slight to moderate infiltration of polymorphonuclear leukocytes. However, within the comedone, *P. acnes* secreted chemotactic factors escape from the follicle and attract polymorphonuclear leucocytes. Hydrolytic enzymes are released from the polymorphonuclear leucocytes as they ingest *P. acnes*. This results in producing follicular damage and inflammation.

REFERENCES


THE PATHOGENESIS OF ACNE

Which of the following statements is/are true?

1. Sebum production is one of the pathogenic factors of acne that appears during puberty, at age 15 in boys and age 18 in girls.
2. Corticotrophin-releasing hormone plays no role in the pathogenesis of acne.
3. *Pityrosporum ovale* is one of the organisms which plays a role in the pathogenesis of acne.
4. The enzymes secreted by *P. acnes* are lipase, phosphatase and hyaluronate lyase.
5. The effects of Dihydrotestosterone are stimulated by insulin-like growth factor.

CPD ACCREDITATION

If you are a subscriber to SA Dermatology Review please register on-line at [www.samedicinalreviews.co.za](http://www.samedicinalreviews.co.za) to access your CPD questionnaire and get your CPD points and relevant certificate.
Acne is a chronic condition and while mild cases clear spontaneously after 3-4 years at least 15% of acne sufferers will have the disease for 8-12 years. In the majority of individuals acne will have cleared by the age of 25 years. However, in 7% of patients, acne persists for much longer, into the 3rd and 4th decades, and exceptionally into the 5th, 6th and even 7th decades. Furthermore, there is a small group of individuals, mainly women, who develop late onset acne, starting for the first time after the age of 25 years.

**PATHOGENESIS OF ACNE**

There are various factors that play a role in the pathogenesis of acne. Genetic factors have been shown to influence the development of acne and 40% of acne patients have a family history of acne in first or second degree relatives.

There are four major factors involved in the pathogenesis of acne:

1. Increased sebum production secondary to androgen stimulation
2. Abnormal follicular keratinisation
3. Abnormal proliferation of *Propionibacterium acnes*, an anaerobic organism normally resident in the follicles
4. Inflammation due to the release of pro-inflammatory mediators

While there are various regimes available for treating acne, including topical preparations, oral antibiotics, oral isotretinoin and hormonal options this article will concentrate on the latter only.

**HORMONAL TREATMENT OF ACNE**

Active sebaceous glands are a pre-requisite for developing acne and sebaceous gland activity is predominantly dependant on androgenic sex hormones.

1. **Androgens**

Androgens are responsible for the development and maintenance of sebum production in males and females. At birth sebum production is similar to that of adults, but the sebaceous glands then involute and become minute. At puberty they enlarge enormously and sebum production increases dramatically.

In males the testes produce most of the testosterone, while in women testosterone is derived i) partly, directly from the ovaries ii) mainly, from the conversion of adrenal and ovarian androstenedione to testosterone. (See Figure 1)

Circulating androgens, in particular testosterone, are bound to sex-hormone binding globulin (SHBG), and it is the 1-2 % free testosterone that dictates sebaceous gland activity.

Once delivered to the pilosebaceous cells, androgens and especially testosterone are converted to 5α-dihydrotestosterone (DHT) by the enzyme 5α– reductase type 1.

Androgens exert their effect via androgen receptors in target cells and therefore blocking these receptors, and decreasing the amount of free circulating testosterone, forms the basis of hormonal therapy in women with acne.

2. **Oestrogens**

Oestrogens depress sebaceous gland activity. There is some argument as to their site of action, but they probably act on the sebaceous glands themselves, suppressing the uptake of testosterone and inhibiting its conversion to DHT.

Furthermore oestrogens increase SHGB.
3. Progestogens

The effect of progestogens on sebaceous glands is a matter of dispute. It is known however that progestogens inhibit SHBG production. The fluctuation of sebum production in women during their menstrual cycle has been blamed on progesterone but remains unproven.

HORMONAL TREATMENT OF ACNE IN WOMEN

Hormonal treatment of acne in women is indicated where:
1. Antibiotic regimes have failed or are undesirable.
2. Concomitant period control and/or contraception is needed together with acne therapy.
3. Oral isotretinoin (Roaccutane, Oratane, Acnetane) is inappropriate, contraindicated or not available.
4. Treatment of polycystic ovarian syndrome (PCOS) is required.

When faced with a female patient with acne, certain clinical conditions should always be excluded:
1. Polycystic ovarian syndrome (PCOS)
2. Congenital adrenal hyperplasia (CAH): these patients will have evidence of virulisation (acne, hirsuitism, deep voice, receding hairline and male escutcheon, enlarged clitoris, abnormal menstrual cycle) and virulisation suggests abnormally high testosterone levels which requires investigation. The two most common forms of CAH are 21-hydroxylase CAH (90-95%) and 11 hydroxylase CAH (5%).
3. Hypothyroidism: this results in decreased SHBG and increased levels of free testosterone.
4. Cushing’s disease and Cushing’s syndrome
5. Adrenal tumours
6. Masculinising ovarian tumours
7. Anabolic steroids
8. Menopause
POLYCYSTIC OVARIAN SYNDROME (PCOS)

Polycystic ovarian syndrome (PCOS) is one of the most common female endocrine disorders affecting approximately 5%-10% of women of reproductive age (12–45 years old) and is thought to be one of the leading causes of female subfertility.

While there is some evidence of a genetic predisposition, the aetiology of PCOS remains uncertain and insulin resistance, diabetes, and obesity are all strongly correlated with PCOS.

The principal features are obesity, anovulation (resulting in irregular menstruation or amenorrhea), acne, and excessive amounts or effects of androgenic hormones. The symptoms and severity of the syndrome vary greatly among women and there are many patients with minor forms of this syndrome who are not overtly overweight and have little or no facial hair. These women can easily be overlooked and can only be diagnosed by doing appropriate blood tests and ultrasound of the ovaries.

PATHOPHYSIOLOGY OF PCOS

Recent evidence supports the hypothesis that decreased insulin sensitivity and consequent hyperinsulinaemia are pivotal in the pathogenesis of PCOS. The exact mechanism(s) for insulin resistance is uncertain but a post-receptor defect in adipose tissue has been identified.

Despite peripheral insulin resistance the ovary remains relatively sensitive to insulin, and both insulin and insulin-like growth factor 1 have stimulatory effects on the ovarian theca. This stimulation, in combination with elevated luteinising hormone (LH), leads to thecal hyperplasia, increased androgen secretion, arrest of follicular development, and therefore anovulation along with menstrual disturbances.

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**LABORATORY TESTS FOR POLYCYSTIC OVARIAN SYNDROME (PCOS)**

- FSH (Follicle Stimulating Hormone), will be normal or low with PCOS
- LH (Luteinising Hormone), will be elevated
- LH/FSH ratio. This ratio is normally about 1:1 in premenopausal women, but with PCOS a ratio of greater than 2:1 or 3:1 may be considered diagnostic
- Prolactin will be normal or low
- Testosterone, total and/or free, usually elevated
- DHEAS (may be done to rule out a virilising adrenal tumor in women with rapidly advancing hirsutism), frequently mildly elevated with PCOS
- Oestrogens, may be normal or elevated
- Sex hormone binding globulin, may be reduced
- Androstenedione, may be elevated
- hCG (Human chorionic gonadotropin), used to check for pregnancy, negative
- Lipid profile (low HDL, high LDL, and cholesterol, elevated triglycerides)
- Fasting glucose, may be elevated
- Fasting insulin, often elevated
- TSH (Thyroid stimulating hormone)

Table 1
Hyperandrogenism is a key feature of PCOS. While the adrenal glands might contribute, hyperandrogenism is primarily ovarian in origin. For a diagnosis of PCOS there should be elevated serum androgens (testosterone [total and/or free], DHEAS) and/or biological expression of hyperandrogenism (acne and/or hirsuitism).

The laboratory tests that should be done for PCOS can be seen in Table 1.

While the hormonal medication for treating acne and PCOS is discussed below, it is important to note that the hyperinsulin problem must be addressed.

Three approaches are used:
1. Calorie restricted diet
2. Exercise
3. Oral hypoglycaemics: until recently metformin was the drug of choice in PCOS - 500 or 850 mgs twice a day. The most common side effect is usually nausea. Recently a new oral hypoglycaemic agent, rosiglitazone (Gelvus) was launched in South Africa. It is usually prescribed together with metformin: 50 mgs bd. The combination has several advantages: decreased insulin levels, weight loss and an improved lipid profile.

Most women with acne have normal hormone levels, regular periods, normal female hair patterns and no problems with conception and pregnancy. Many of these women who take low-dose combined oral contraceptives (COC) experience improvement in their acne. While these “pills” are not specifically anti-acne, the clinical response is due to an increased level of SHBG and inhibition of hormone production by the ovaries.

Certain contraceptive pills offer better acne therapy

1. Diane 35/Ginette/Minerva/Diva: the active tablets contain 35 ugn of ethinyl oestradiol and 2 mgs of the progestogen, cyproterone acetate. Cyproterone acetate is primarily anti-androgenic: it is a competitive inhibitor binding to the same cytoplasmic receptors that DHT binds to.

While most women tolerate Diane very well, side effects such as weight gain, mastalgia, increase in breast size, mood changes and depression may limit its use.

2. Yasmin: here a smaller dose of ethinyl oestradiol (3u gms) is combined with drosperinone (DRSP) 3mgs, a newer progestogen that has anti-mineralocorticoid properties making it more similar to endogenous progestogens. Drosperinone is able to counteract the “weight increasing” tendency of oestrogen and most women do not gain weight while taking Yasmin, and a few have even reported mild weight loss. It is also effective in women who retain water as part of the pre-menstrual syndrome. In addition, drosperinone also has effective anti-androgenic activity (competitive antagonist) and is beneficial in women with mild to moderate acne. While the side-effect profile of Yasmin is better than Diane’s, Diane is a more potent anti-acne medication.

3. Yaz: the oestrogen content has been further reduced to 2 ugm while the amount of drosperinone remains the same as that of Yasmin ie 3mgs. The other difference is that there are 24 active pills in this pack with only 4 placebos. The control of acne is the same as with Yasmin while there are certainly some advantages:
   i) less chance of chloasma
   ii) less chance of weight gain
   iii) shorter period
   iv) less menstrual flow

The only negative feature of Yaz is that a greater number of women experience spotting and menstrual irregularities.

4. Cyproterone acetate (CA) (Androcur/ Cipla cyproterone acetate/Cyprolex): should the anti-acne response to Diane / Yasmin/Yaz or any other contraceptive pill be unsatisfactory, additional cyproterone acetate can be added to these pills. The initial dose should either be 10 mgs for 14 days or 25 mgs for 10 days always starting on the 5th day of the menstrual cycle. This combination is continued until a satisfactory clinical response is obtained. Thereafter it is worthwhile trying to reduce the dose of cyproterone acetate, sometimes even stopping it altogether. Should the acne recur, CA can always be re-introduced.

There are two other medications worth mentioning, that while they are not hormones themselves, they do have an effect on circulating hormones and can be useful in treating acne in women.
Spironolactone

Spironolactone is potassium-sparing diuretic used primarily to treat heart failure. Due to its antiandrogen effect, it can also be used to treat acne in women: it is thought to block the androgen receptors on the sebaceous glands.

The starting dose is 25 -50 mgs per day. This can be titrated up to 100 mgs a day. It is a very useful medication and popular in the USA.

Flutamide

Flutamide is an oral nonsteroidal antiandrogen drug primarily used to treat prostate cancer. It competes with testosterone and its powerful metabolite, dihydrotestosterone (DHT) for binding to androgen receptors in the prostate gland and the sebaceous glands. Flutamide has been largely replaced by a newer member of this class, bicalutamide (Casodex), due to a better side-effect profile. Flutamide may also be used to treat excess androgen levels in women - especially those with PCOS. It is marketed under the brand name Eulexin.

CONCLUSION

As outlined above there are many different choices available to doctors treating women with acne. The hormonal options are many and with experience, it is usually fairly easy to control the acne in these patients, while at the same time limiting the side effects.

REFERENCES

*Supplied on request*
## ACNE TREATMENT ALGORITHM

<table>
<thead>
<tr>
<th>Comedonal</th>
<th>Papular/ Pustular</th>
</tr>
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<tbody>
<tr>
<td><strong>1st Choice¹</strong></td>
<td><strong>Topical Retinoid</strong></td>
</tr>
<tr>
<td><strong>Alternatives¹</strong></td>
<td><em><em>Alt. Topical Retinoid or Azelaic Acid</em> or Salicylic Acid</em>*</td>
</tr>
<tr>
<td><strong>Alternatives for Females¹,⁴</strong></td>
<td><strong>See 1st Choice</strong></td>
</tr>
<tr>
<td><strong>Maintenance Therapy</strong></td>
<td><strong>Topical Retinoid</strong></td>
</tr>
</tbody>
</table>

¹ Consider physical removal of comedones;
² With small nodulas (>0.5 - 1cm);
³ Second course in case of relapse;
⁴ For pregnancy, see text;
⁵ See text
* There was not consensus on this alternative recommendation, however, in some countries Azelaic acid prescribing is appropriate practice.
### Articles

<table>
<thead>
<tr>
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<td>Oral Antibiotic + Topical Retinoid + BPO</td>
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<tr>
<td>Oral Antiandrogen&lt;sup&gt;5&lt;/sup&gt; + Topical Acid* +/- Topical Antimicrobial</td>
<td>Oral Antiandrogen&lt;sup&gt;5&lt;/sup&gt; + Topical Retinoid +/- Oral Antibiotic +/- Alt. Antimicrobial</td>
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<td>Topical Retiniod +/- BPO</td>
<td>Topical Retiniod +/- BPO</td>
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</table>
POST ACNE SCARRING IN PIGMENTED SKINS
AN ANALYSIS OF THE PHYSICAL AND PSYCHOLOGICAL EFFECTS IN 101 SOUTH AFRICAN PATIENTS

Mosam A, Vawda NM*, Nkwanyana E Gondhan AH, Aboobaker J. Departments of Dermatology and Medically Applied Psychology*, Nelson R Mandela School of Medicine, University of Natal, South Africa and Medical Research Council of South Africa

OBJECTIVES
- To assess the degree of scarring in acne patients with pigmented skins.
- To assess the psychological impact of and quality of life in these patients.

METHOD
A prospective study of acne patients attending a tertiary hospital in Durban, South Africa. All patients had Fitzpatrick skin types 4-6 and were of African or Asian origin. Acne was graded by the Global acne Grading Scale (GAG). A novel system of grading scarring was used. Grade 0 = pigmenitary change; grade 1 = fine ice-pick / follicular scars and/or pigmented nodules; grade 2 = profuse ice-pick or follicular scars and grade 3 = keloids. Psychological morbidity was assessed by the General Health Questionnaire (GHQ) and quality of life using the Dermatology Specific Quality of Life Questionnaire (DSQL).

Results
The total sample size was 101 with a female to male ratio of 3.8:1. There were 53 (52.5%) Asian and 48 (47.5%) African patients. Clinically, 42.5% had mild, 45.8% moderate and 7.9% severe acne. All 101 patients had scarring; 6(5.6%) grade 0, 48 (47.5%) grade 1 (mild), 39 (38.6%) grade 2 (moderate) and 8 (7.9%) grade 3 (severe) scarring. On the GHQ, 46 (45.5%) were not distressed (ND), 21 (20.8%) were psychologically distressed (PD) and 34 (33.7%) suffered severe psychological distress (SPD). Of the total sample 55 (54.5%) were distressed. Of those with severe scarring, 87.5% were PD. There was a positive correlation between PD and all aspects of the patient’s QOL (p < 0.05).

Conclusion
Acne grading systems should take into account scarring and current scarring grades should include pigmentary change. Acne patients with pigmented skin suffer significant psychological distress and are affected in the quality of their lives. Therapy should be timeous and aggressive as the sequelae of acne are preventable.

BACKGROUND
Acne vulgaris is the commonest cutaneous condition treated by physicians and is estimated to affect 95-100% of 16-17 year old boys and 83-85% of 16-17 year old girls. Scarring occurs in up to 95% of patients attending a dermatologist. The distressing effects of scarring on the facial appearance and hence adverse psychological health and social well being have been documented. A recent study of the spectrum of skin disease occurring in a black population in London described acne as the commonest reason for consultation among black adults.

Often, the most common reason for seeking a dermatological opinion is the marked associated hyperpigmentation which is of major concern. It is a well established fact that in darker-skinned patients the post inflammatory change can be more alarming to the patient than the underlying disorder.

These factors: the ubiquitous nature of acne and post-acne scarring, its predilection for the face, occurrence in adolescence, the non-reversible nature of scars and their potential for creating emotional distress argue the point for timeous therapy.
The dermatology unit at King Edward VIII Hospital, KwaZulu-Natal, Durban serves a majority of African patients, followed by Asians and a minority of coloured (mixed origin) and white patients. Hence dark-skinned patients (African and Asians) are the majority seeking help. Since they are more prone to and scar more severely than their white counterparts it may be a considerable source of distress in addition to the inflammatory lesions. Even when the active acne has burnt out, these tell tale signs remain a therapeutic challenge in the patients that we serve. Therefore a patient with severe scarring secondary to acne may still seek help and experience psychological difficulties.

**METHOD**

This was a prospective study carried out in the dermatology outpatient department of King Edward VIII Hospital, a major tertiary referral hospital in KwaZulu- Natal, South Africa.

The study was carried out over a 3 month period, August to October 1998. All patients diagnosed with acne vulgaris who consented to the study were first assessed by one of two dermatology trainees for their Fitzpatrick skin types. This was based on sun tolerance and facultative tanning determined by history as well as racial origin. Only those with Fitzpatrick types 4-6 were included in the study. Acne was graded according to the Global acne Grading Scale (GAG).

In this grading system the face, upper back and chest are divided into 6 areas. A factor is given for each depending on the density of pilosebaceous units.

Lesions are given the following scores:
0- no lesions;
1- 1 comedone;
2- 1 papule;
3- 1 pustule and
4- 1 nodule.
The most severe lesion in each area determines the local grade which is then multiplied by the factor for that area to give the local score. The summation of all the local scores for each of the 6 regions gives the global score. This global score is categorized as follows: 1-18 mild; 19-30 moderate and 31-38 severe acne.

The demographic details of patients were recorded in addition to completing a General Health Questionnaire (GHQ), a 30 item self-report psychometric instrument, which is a general measure of emotional distress, anxiety, depression and social dysfunction. A score of < 5 indicates no distress (ND); 5 to 10 Psychological distress (PD) and > 10 Severe Psychological Distress (SPD).

Patients were also administered a quality of life instrument, the Dermatology Specific Quality of Life Questionnaire (DSQL). It is a multiscale, disease specific, self-report measure of the impact of the patient’s acne on the various parameters of daily living i.e physical symptoms, daily activities, social activities and functioning, work/school performance, self-perception and overall mental health.

RESULTS

Data collected from the questionnaires was analysed using the Statistical analysis System (SAS). Categorical data were assessed using Chi-squared and Fischer’s exact test and questionnaire data using analysis of variance. The total sample size was 101. Of these, 80 were female (79.2%) and 21 male (20.8%).

The female to male ratio was 3.8:1. Ages ranged from 12 to 47 years with a mean age of 22 years. With respect to the racial distribution, 53 (52.5%) were Asian and 48 (47.5%) African patients. The clinician’s rating of acne severity using the GAG scale found 42.5% had mild, 45.8% moderate and 7.9% severe acne.

Scarring was assessed on a scale of 0-3. All 101 patients had scarring; 6 (5.6%) grade 0, 48 (47.5%) grade 1 (mild), 39 (38.6%) grade 2 (moderate) and 8 (7.9%) grade 3 (severe) scarring. On the GHQ, 46 (45.5%) were not distressed (ND), 21 (20.8%) were psychologically distressed (PD) and 34 (33.7%) suffered severe psychological distress (SPD).

Of those with mild scarring, 53.7% were distressed, 48.7% of those with moderate scarring were distressed and 87.5% of those with grade 3 (severe) scarring were distressed. See Table 3 for correlation of scarring with GHQ.

There was a positive correlation between all domains of the DSQL and PD on the GHQ (p<0.05)

DISCUSSION

Acne vulgaris is a chronic inflammatory disease of the pilosebaceous units characterised by the formation of comedones, papules and pustules, less frequently nodules and pseudocysts. The commonest site affected is the face (99%), to a lesser extent the back (60%) and chest (15%).

Scarring occurs in up to 95% of patients attending a dermatologist but severe scarring in 22%. Scarring has been described secondary to papular and not only severe nodular and cystic acne. The distressing effects of scarring on the facial appearance and hence adverse psychological health and social well being have been documented. Post-acne scarring has been implicated as a risk factor for suicide. These factors: the ubiquitous nature of acne and post-acne scarring, its predilection for the face, occurrence in adolescence, the non-reversible nature of scars and their potential for creating emotional distress argue the point for timeous therapy.

Several acne grading systems are in place to assess acne. However, none of these current systems assesses scarring as part of the score.

Acne scarring grades that have been used are the following:
1. Assessment of scarring using a lesion count based scoring system which counts each scar type (ice-pick, macular atrophic and follicular macular atrophic) and allocating a score of 1-6 according to the number of scars present as in Table 1.

   Scarring was assessed using the following scale:
   0) pigmentary change
   1) fine pitted scars (ice-pick or follicular), pigmented nodules
   2) profuse ice-pick or follicular scars
   3) keloidal scarring

   Keloids and hypertrophic scars are assessed independently and allocated a score of 2-6 according to their number as in Table 2.

2. Another system presented by Jacob et al in 2001 as the only accepted standard classification system to date divides scars into 3 types (icepick, rolling and boxcar) forming the basis for a treatment algorithm.

None of the above take into account the post-inflammatory hyperpigmentation secondary to scarring or that inflammatory lesions may coexist with scars. The classification by Jacob et al and most other references to scarring have been devised purely to direct therapy.
ARTICLES

**ALLOCATION OF SCORE ACCORDING TO NUMBER OF ICE-PICK, MACULAR ATROPHIC AND FOLLICULAR MACULAR ATROPHIC SCARS PRESENT (MAXIMUM SCORE 18)**

<table>
<thead>
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<tr>
<td>51-100</td>
<td>5</td>
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<tr>
<td>&gt;100</td>
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*Table 1*

**ALLOCATION OF SCORE ACCORDING TO NUMBER HYPERTROPIC AND KELOID SCARS PRESENT**

<table>
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<th>Number of scars</th>
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<tr>
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<tr>
<td>&gt;7</td>
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*Table 2*

**CORRELATION OF SCARRING GHQ**

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<th>Scarring</th>
<th>ND (%)</th>
<th>PD (%)</th>
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<td>0</td>
<td>4 (66.7)</td>
<td>0 (0.00)</td>
<td>2 (33.3)</td>
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</tr>
<tr>
<td>1 mild</td>
<td>20 (41.6)</td>
<td>10 (20.8)</td>
<td>17 (35.4)</td>
<td>48</td>
</tr>
<tr>
<td>2 moderate</td>
<td>21 (53.8)</td>
<td>7 (17.9)</td>
<td>12 (30.7)</td>
<td>39</td>
</tr>
<tr>
<td>3 severe</td>
<td>1 (12.5)</td>
<td>4 (50.0)</td>
<td>3 (37.5)</td>
<td>8</td>
</tr>
</tbody>
</table>

ND = no psychological distress
PD = psychological distress
SPD = severe psychological distress

*Table 3: Correlation of Scarring and GHQ*
ARTICLES

PATHOGENESIS OF SCARRING

A review of post-acne scarring by Goodman describes the pathogenesis of scars secondary to inflammation. The extent and depth of perifollicular and dermal inflammation incites repair and this is associated with contraction of the scar, which with maturation results in an indentation. He grades scarring into atrophic (superficial macular, deep dermal, perifollicular and fat atrophy) and hypertrophic.

Post inflammatory hyperpigmentation is thought to be due to mediators of inflammation (leucotrienes, prostaglandins and thromboxanes) which stimulate melanogenesis. In the epidermal type there is increased transfer of melanin to keratinocytes whereas the dermal type is characterised by pigment laden macrophages, melanophages, in the dermis. Biopsies done in black patients with acne vulgaris have found most postinflammatory hyperpigmentation to be of the epidermal type.

SCARRING IN PIGMENTED SKINS

It is well known that pigmented skins have some characteristics which are uniquely different from white skin. Although the number of melanocytes per unit area is the same compared to white skin it is the number and type of melanosomes and their distribution to keratinocytes that distinguishes it from white skin. Since the melanocytes of dark-skinned patients seen in African and Asian skin tend to be hyperreactive, it is associated with greater pigment lability.

Cutaneous inflammation or injury such as acne presents as irregular darkly pigmented spots reported to persist for months but which eventually disappear.

However, disfigurement may be severe in patients with highly pigmented skin. In addition, black skin is prone to enhanced mesenchymal response following trauma. This genetic predisposition. In the face of inflammatory acne lesions sets the scene for unsightly hypertrophic scars and keloids.

The preponderence of acne as being 3.8 times more common in our female subjects may reflect the greater premium that female patients place on facial appearance. Previous studies on scarring in acne patients have not highlighted racial differences which may be significantly different especially since dark-skinned patients are known to be more likely to scar, either with post-inflammatory hyperpigmentation or keloids.

In this study the true prevalence of hyperpigmentation may have been underreported as it occurred alone in 5.6% of patients. However, if it occurred in association with ice-pick or follicular lesions, it was given a more severe grade. Hence, hyperpigmentation co-existing with other types of scarring has been underestimated.

The reason a novel system was devised was to avoid the lesion counting which can be tedious as described by Layton et al as well as to include hyperpigmentation. This was given a grade of 0 as it is reversible but thought to be significant as it can persist for months post acne. Keloids were given a score of 3 as they were thought to be the most severe and most resistant to therapy post-acne as was done by Layton et al. However it was not given a separate grading system as was done by the previous authors for ease of use.

Ice-pick and follicular atrophic scars were graded as 1 and 2 depending on their number, few as opposed to profuse, respectively. Pigmented nodules were also given a score of 2
as these were thought to be more persistent than macular hyperpigmented lesions. Overall the system is easy to use, can be applied to all skin types, and is a useful adjunct to acne grading systems.

In our study, of those with mild (grade 1) scarring, 58.8% were psychologically distressed. Of those with moderate (grade 2) scarring, 47.5% were distressed and of those with severe (grade 3) scarring, 80% were distressed.

Many of our patients present with pigmentation in addition to inflammatory lesions and there is no grading for scarring system currently which includes this complication. The study makes an important statement that scarring should be considered in future grading scales.

The limitation of this study is that it may be difficult to separate out the effects of inflammatory lesions and scarring on the psyche of patients as these lesions often co-exist. Future studies are required to assess the effects of these variables on psychological distress independently.

CONCLUSION

“Acne should not be dismissed as being of no consequence....... for the psychological scars and trauma are often deeper and more disastrous than the blemishes themselves.”

It is imperative that clinicians provide aggressive therapy since the scars are not merely “skin deep”.

REFERENCES

ARTICLES

30. Fitzpatrick TB. The validity and practicality of sun-reaction skin types I through VI. Arch Dermatol 1988; 124:869-71

CPD ACCREDITATION

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POST ACNE SCARRING IN PIGMENTED SKINS

Which of the following statements is/are true?

1. Acne and acne scarring is amongst the commonest reasons for a dermatology consultation.
2. Post-inflammatory pigmentation is not a problem in darker complexions.
3. In this study, more than one third of patients with mild acne scarring admitted distress from post acne pigmentation.
4. Traditional acne scarring grading systems do not include post inflammatory pigmentation.
5. Post inflammatory pigmentary scarring is permanent.
2011 GUIDELINES FOR THE TREATMENT OF ACNE:
TOPICAL AND ORAL AGENTS

De Robert Weiss, Dermatologist in Private Practice, Johannesburg

Acne is a common disorder of adolescence and early adulthood affecting up to 40% of adolescents and up to 15% of females in early adulthood. It is a condition that must be taken seriously as the old adage “acne damages the skin as well as the psyche” remains true today.

Management of acne is a challenge as one is often dealing with adolescents with additional peer pressure and other teenage issues, or adult females who are frustrated by a disease they thought was confined to teenagers. Treatment needs to be individualised. While some patients have relatively mild acne, potential to scar or more significant social awareness may encourage more aggressive therapy. Whatever the nature of the condition, take it seriously. Acne is not a trivial disorder to be treated only for the “matric dance.” Scarring can have long term consequences for the self esteem of the sufferer and studies have shown job opportunities are affected by scarring.

Adequate management includes taking the time to explain the nature of the condition, the treatment options and the duration of treatment and possible outcomes. Parents also need to be counselled. A discussion as to the relative importance or otherwise of diets, washing, cosmetic use and sun exposure should be included.

AIMS OF TREATMENT

• Prevent scarring
• Limit duration of acne
• Decrease psychological impact

CLINICAL ASSESSMENT

History

• Duration
• Aggravating factors e.g. premenstrual flares, diet, medications, heat
• Previous therapy: topical, oral, OTC, homeopathic
• Medications: steroids, anticonvulsants, hormonal therapy.
• Family history or history of acne in infancy
• Allergies

Examination

1. Confirm the diagnosis: few problems in most cases but exclude other conditions involving pilosebaceous unit e.g. keratosis pilaris. Look in particular for classic primary lesions such as comedones, papules and pustules.

2. Take an adequate history: exclude drug-induced acne (anticonvulsants, steroids etc).

3. Note severity and extent of lesions:
   - Grading (see Table 1) This can be recorded according to existing grading scales or your own scale, so long as it is consistent and comparisons can be made each visit to assess results of treatment. Photographic follow-up is helpful to convince patients that improvement is occurring as initially, patients are impatient and need reassurance that therapy is working.
   - Extensive involvement of the face as well as chest and back will usually require oral treatment.

4. Types of lesions are important in deciding which treatment to use.
   - Non-inflammatory lesions:
     Open comedones (blackheads)
     Closed comedones (whiteheads)
     Non-inflammatory papules or nodules
   - Inflammatory lesions:
     Pustules
     Inflamed papules or nodules
ARTICLES

Figure 1: Mild acne - note numerous comedones are present

Figure 2: Mild acne with open and closed comedones

Figure 3: Mild to moderate acne (Grade 2)

Figure 4: Moderate acne (Grade 2.5)

Figure 5: Moderate grade 3 acne with papules, pustules and comedones

Figure 6: Infantile acne
ARTICLES

ACNE SEVERITY GRADING

<table>
<thead>
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<th>PREDOMINANT LESION</th>
<th>OVERALL SEVERITY</th>
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<td>papules, pustules</td>
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<td></td>
<td>nodules</td>
</tr>
<tr>
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<td></td>
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</tr>
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<td></td>
<td>pigmentedary change</td>
</tr>
<tr>
<td>Psychosocial impact</td>
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</table>

- Mixed pattern: combinations of above
- Deep nodules, cysts and scars:
  These will not respond to topical therapy alone and oral treatment must be started from the outset.

The severity of the acne should be assessed. A scoring system is shown in Table 1.

TREATMENT

Topical preparations

Although acne is frequently treated initially with topical agents, little thought is given as to which agent should be used. Topical preparations have different actions and side effects and patients need to be told how to use each product properly in order to obtain optimal benefit. Each must be used for sufficient time before deciding whether they are effective or not. Combinations of creams and lotions are sometimes of great benefit provided each is chosen with a specific purpose in mind and an understanding that the drying effects of most topical products may be aggravated. Your climate must also be considered. In dry climates, the drying effects of most topical therapies must be kept in mind, while those in humid areas will want to limit occlusive therapies Sun sensitivity to some preparations such as retinoids must be kept in mind.

The guidelines given below are designed to give the practitioner a better understanding of the use of topical acne preparations.

General considerations

- Topical treatment remains the cornerstone of treatment for mild acne vulgaris.
- Mild acne can be managed with topical therapy alone.
- Topical therapy needs to be used in addition to most oral therapies to achieve best results.
- Topical treatment often needs to be maintained after oral therapy has cleared the acne to prevent relapse.
- Cream or gel? Gel more helpful for greasy skins, creams for the most other skin types and use in the dry climates.

Advantages: relatively inexpensive, few side effects, may reduce the incidence of antibiotic resistance

Disadvantages: Irritant effects, poor compliance, slow onset of action

Directions

- Apply creams as directed. Overuse may irritate skin while some creams do not work efficiently if applied infrequently.
- Topical applications must be applied to all involved areas, not only to individual spots.
- Minor irritation: can be expected with all topical treatments especially at the onset of treatment and in those with sensitive skin.
- Moisturising creams used sparingly will help dryness or irritation and do not “clog up pores”.
- Different creams have different effects – it is important to choose a cream according to the clinical assessment of the patient i.e. the predominant type of lesion and the severity of the problem.
WHAT'S AVAILABLE?

Comedolytic agents

These are most helpful in predominantly non-inflammatory types of acne. Comedolytic agents play a pivotal role in the management of acne by helping to loosen the microcomedones, which are present in the initial stage of development of all other lesions. Most of the comedolytic agents are retinoids. They play a pivotal role in the management of acne. Topical retinoids are used at all stages of acne to prevent micro-comedone formation.

Side effects of most of these products are drying, desquamation and irritation. Moisturisers may be used in the day if needed.

They can be used on all affected areas including the face, chest and back.

There is some controversy in the use of topical retinoids in pregnancy. Recent evidence suggests they are safe and that the teratogenic dose is in the region of 4 million times the amount absorbed with normal usage!

Products on the SA Market in 2011

• Retinoic acid / Tretinoin: (Retin-A® / Ilotycin A®/ Retacnyl®). This is the prototype retinoid. It is available in both a 0.5% cream and 0.25% gel formulations. It is an effective comedolytic agent however may cause irritation of sensitive skins especially in dry climates. Sun sensitivity was thought to occur, but this has been disproved. It is however noted by patients using all forms of retinoids that they have a sensation of increased burning in the first few weeks of therapy. This wears off in time. It is just as well to advise use of sunscreens if outdoors. The affected area must be washed and allowed to dry completely prior to application. Concomitant use of abrasive soaps, drying medicated soaps and other potentially irritating preparations should be avoided.

• Adapalene (Differin®): This is a chemically stable retinoid-like compound formulated in a hydrophilic gel or a less drying cream formulation. It is particularly effective in non-inflammatory acne and clinical trials have shown it to be moderately effective in reducing inflammatory lesions. The hydrophilic gel causes less drying than conventional retinoids and photosensitivity has not been reported.

• Isotretinoin (Isotrex®): Isotretinoin gel is less irritant than retinoic acid and although photosensitivity is not a problem, the manufacturers recommend that it be used at night. It should be applied after drying the affected area thoroughly to prevent dilution of the cream. It is predominantly of benefit in comedonal acne but has mild keratolytic effects. Its use in seborrhoea alone is poor.

• Azelaic acid (Skinoren®) is comedolytic, causes alterations in the free fatty acid composition of the skin surface lipids and decreases bacterial counts. It may cause irritation and has a slow onset of action so that use must be extended over at least 4 – 6 months to obtain maximum benefit. Application twice daily is recommended. The use of azelaic acid for hyperpigmentation has been reported but in practice this benefit is disappointing. Skinoren is available in a cream and more recently in a gel formulation.

• Tazarotene (Zorak®) This is a novel new type of retinoid better known for its use in psoriasis. It is available in a 0.1% gel and a 0.05% gel formulation. The 1% gel is are no longer available in SA. Several studies have shown it to be as effective as retinoic acid for the management of comedolytic acne. It tends to be very drying and several protocols have been used to minimize this problem. These include starting with alternate day treatment for the first month.

Alternatively, short contact treatment has been used, with the gel being applied initially for a few minutes, increasing this on a weekly basis as tolerance builds up.

Topical antibiotics

There has been some concern that the frequent use of topical antibiotics will encourage the development of resistant organisms. Interestingly however, the concentrations of antibiotic achieved using topical treatment often exceed even the resistance of resistant bacteria. One reason for resistance may be the lower concentrations of the antibiotic at the edges of the application area.

In light of this issue it is recommended that benzoyl peroxide be used intermittently with topical antibiotics, which may restrict growth of resistant bacteria. Allergy to topical antibiotics used in acne is uncommon.

Topical erythromycin clindamycin and tetracycline are available for use in inflammatory acne especially if there are pustules present.

Preparations available include:

Erythromycin preparations:
• Ilotycin lotion® (erythromycin)
• Erymycin lotion®
• Eryderm®

Clindamycin preparations
• Dalacin –T lotion
## TOPICAL THERAPY

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>TRADE NAMES</th>
<th>NON-INFLAMMATORY</th>
<th>INFLAMMATORY</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Comedolytic agents</strong></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Tretinoin</td>
<td>“Retin A” 0,025% gel 0,05%</td>
<td>++</td>
<td>-</td>
<td>Irritating in dry climates, photosensitising, avoid in pregnancy</td>
</tr>
<tr>
<td>Isotretinoin</td>
<td>“Isotrex”</td>
<td>++</td>
<td>+</td>
<td>Not photosensitising</td>
</tr>
<tr>
<td>Adapalene</td>
<td>“Differin”</td>
<td>++</td>
<td>-</td>
<td>Not photosensitising, less irritant for dry skin</td>
</tr>
<tr>
<td>Benzoyl Peroxide</td>
<td>“Panoxyl”</td>
<td>+</td>
<td>++</td>
<td>May bleach clothing, irritant in dry climates, start with short application times</td>
</tr>
<tr>
<td></td>
<td>“Benzac AC 5”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>“Brevoxyl”</td>
<td>+</td>
<td>++</td>
<td>Less irritant effect due to hydrophase BP</td>
</tr>
<tr>
<td><strong>Topical antibiotics</strong></td>
<td></td>
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<td></td>
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<tr>
<td>Erythromycin</td>
<td>“Erycette” / “Eryderm”</td>
<td>-</td>
<td>+</td>
<td>May be effective even if resistant bacteria due to high concentration</td>
</tr>
<tr>
<td></td>
<td>“Ilotycin” / “Stiemycin”</td>
<td></td>
<td></td>
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<tr>
<td>Clindamycin</td>
<td>“Dalacin T”</td>
<td>-</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td><strong>Combination Products</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Benzoyl Peroxide</td>
<td>+micanazole</td>
<td>+</td>
<td>+</td>
<td></td>
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<tr>
<td></td>
<td>“Acneclear” / “Acnedazil”</td>
<td></td>
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<tr>
<td></td>
<td>+hydroxy-</td>
<td></td>
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<tr>
<td></td>
<td>quinolene</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>“Quinoderm”</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Erythromycin</td>
<td>+zinc</td>
<td>+</td>
<td>+</td>
<td>Well tolerated by most skin types</td>
</tr>
<tr>
<td></td>
<td>“Zineryt”</td>
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</tbody>
</table>

*Table 2*
Benzoyl peroxide is a potent oxidising agent and is available in many preparations in concentrations from 2.5% - 10%. It does not induce resistance and is most helpful in predominantly inflammatory acne. The main adverse reactions are drying of the skin and bleaching of clothing. Occasional contact dermatitis is reported. Benzoyl peroxide has a mild comedolytic effect.

**Preparations available include:**
- Panoxyl® (5% / 10% gel)
- Benzac Ac 5® (5% cream)

**COMBINATION PRODUCTS**
- BP+ miconazole nitrate (Acneclear®, Acnidazil®) and BP+ hydroxyquinolene sulphate (Quinoderm®).
- Zineryt® (Erythromycin + zinc)

Other combination products are due to be released later this year pending registration.

The predominant actions of these products are summarised in Table 2.

### CHOICE OF ANTIBIOTIC

<table>
<thead>
<tr>
<th>DRUG</th>
<th>DOSE</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetracyclines</td>
<td>Initial 500 mg bd</td>
<td>Maintenance 250 mg bd</td>
</tr>
<tr>
<td>Tetralysal</td>
<td>300 mg bd</td>
<td>150 mg bd</td>
</tr>
<tr>
<td>Minocycline</td>
<td>50-100 mg bd</td>
<td>50 mg bd</td>
</tr>
<tr>
<td>Doxycycline</td>
<td>100 mg bd</td>
<td>50-100 mg/day</td>
</tr>
<tr>
<td>Cotrimoxazole</td>
<td>2bd</td>
<td>1 bd/2 daily</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>500 mg bd</td>
<td>250 mg/day</td>
</tr>
</tbody>
</table>

Table 3

**Topical keratolytic agents**
- Benzoyl peroxide is a potent oxidising agent and is available in many preparations in concentrations from 2.5% - 10%. It does not induce resistance and is most helpful in predominantly inflammatory acne. The main adverse reactions are drying of the skin and bleaching of clothing. Occasional contact dermatitis is reported. Benzoyl peroxide has a mild comedolytic effect.

**Preparations available include:**
- Panoxyl® (5% / 10% gel)
- Benzac Ac 5® (5% cream)
ARTICLES

SYSTEMIC THERAPY

There are three accepted approaches to systemic therapy: antibiotics, hormonal preparations and Isotretinoin. The first two are suppressive in nature and prolonged courses are usually required. Isotretinoin has a cure rate of about 70% if used in the recommended doses. This article only deals with antibiotics and the other two modalities are dealt with elsewhere in this issue. It is important to stress to all patients that there is a delayed onset of action of the drugs prior to visible cosmetic improvement and in some cases and initial flare up may be experienced. Compliance with therapy is essential in achieving satisfactory results.

Indications
- Moderate to severe acne
- Poor response to topical therapy after reasonable trial (4 months)
- Psychological i.e dysmorphophobic or peer pressure
- Persistent hyperpigmentation (especially black patients)

ANTIBIOTIC THERAPY (See Table 3)

Mechanism of action
- Decrease P.acnes concentration
- Inhibition of bacterial lipases
- Decrease concentration of surface fatty acids by up to 50%
- Inhibition of neutrophil chemotaxis

Antibiotic resistance
Increasing resistance to tetracyclines, erythromycin and clindamycin found in both P.acnes and Staph. epidermidis.

Resistance to minocycline is uncommon but increasing.
- Topical therapy has no effect on gut bacteria and controversy whether use topically increases bacterial resistance. Some evidence suggests that the concentration of antibiotic applied topically overcomes the resistance of even the most resistant bacteria.
- Failure to respond is often unrelated to bacterial resistance but related to increased sebum excretion rates with resulting decrease in the concentration of antibiotic.
- There is no evidence of increased sepsis apart from gram-negative folliculitis even when used long term.

Prevention of antibiotic resistance
- Combination therapy
- Adequate doses for sufficient duration
- Topical benzoyl peroxide or zinc acetate used intermittently reduces the chances of resistance

Interaction with oral contraceptive pill
- Possible mechanisms by which antibiotics reduce OCP effect include increased urinary or faecal excretion, decreased enteropathic circulation resulting in reduced recirculation of oestrogen or increased liver degradation.

Recent meta-analysis has confirmed that there is no risk of interaction of the pill and antibiotics, and this is not a contraindication to use.

Dose
- Use of adequate dose essential
- Use of antibiotic for sufficient time to get response
- Compliance with instructions on taking drug correctly, i.e. with/without meals, periodicity etc.

Which antibiotic?
Most of the drugs recommended in this schedule have similar effects. The decision as to which product to use must be based on side effect profile and cost as well as patient factors, e.g. response to previous therapy, allergies and compliance.

Duration and changing antibiotic choice
If sufficient response is not seen after three months, change to another drug for another 3 months. If the response is still not adequate, consider alternative option, i.e. Isotretinoin or hormonal approach in suitable patients. If a satisfactory response is observed, the dose should be tapered by halving the dose monthly for three months, i.e. dose should be tapered and not stopped suddenly.

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GUIDELINES FOR THE TREATMENT OF ACNE: TOPICAL AND ORAL AGENTS

Which of the following statements is/are true?
1. The primary lesions of acne include closed comedones, inflammed papules and comedones.
2. Topical treatment may need to be combined with oral therapy.
3. Most comedolytic agents contain bezoyl peroxide.
4. Frequent use of topical antibiotics encourages follicular occlusion.
5. Recent data suggest that oral antibiotic use in acne does not inactivate contraceptive pills.
The Consumer Protection Act 68 of 2009 (CPA) was fully implemented on 31 March 2011. The Regulations were effective from 1 April 2011. The CPA and its Regulations have far-reaching implications for contracts. This article briefly reviews some of those provisions pertaining to contracts.

An “agreement” as defined in the CPA is “an arrangement or understanding between or among two or more parties that purports to establish a relationship in law between or among them”. The doctor-patient relationship is contractual in nature and the provisions of the CPA are therefore relevant. In this contractual relationship the doctor would be regarded as the supplier of services and the patient, the consumer as defined in the CPA. Medical practitioners also often enter into agreements with other entities such as medical schemes (e.g. Designated Service Provider [DSP] agreements), pharmaceutical companies and managed care companies.

Medical practitioners are entitled to structure their practices as incorporated practices, which are juristic persons. Certain provisions of the CPA do not apply to juristic persons, namely:

- The provisions of section 14 in respect of fixed-term agreements do not apply between juristic persons; and
- If a juristic person qualifies as a “consumer” in terms of the CPA, but its turnover exceeds R2 million, most of the provisions (including the provisions relating to contracts) will not apply and therefore provide any protection to such a juristic person.

VERBAL OR WRITTEN CONTRACTS

The CPA provides in section 50 that the Minister of Trade and Industry may prescribe which categories of consumer agreements must be in writing. This has not occurred to date.

Written consumer agreements (whether prescribed by the Minister or voluntarily entered into) apply irrespective of whether or not the consumers have signed them. The supplier is, however, required to provide the consumers with free copies or free electronic access to the terms and conditions of such agreements, which must

- Be in “plain language” as defined in section 22. This means that an ordinary consumer of the class of persons, for whom the document is intended with average literacy skills and minimal experience as a consumer of the relevant goods or services, could be expected to understand the content without undue effort. The form, style, vocabulary, sentence structure, illustrations and headings would amongst others be used to determine whether a document was written in plain language; and
- Contain an itemised break-down of the consumer’s financial obligations in terms of the agreement.

In addition, the CPA requires that where a consumer agreement is not in writing, the supplier must keep a record of the transaction entered into over the telephone or in any other recordable form that may be prescribed.

Doctor-patient contracts are generally verbal agreements. However, doctors often enter into written agreements with their patients, which mainly contain the payment terms and conditions for services to be rendered. Such agreements would now have to comply with the “plain language” requirements stated above.

It should also be noted that in terms of section 40 it would be unconscionable (or unethical) for a supplier to knowingly take advantage of the fact that a patient was substantially unable to protect his/her own interests because of a physical or mental disability, illiteracy, ignorance, inability to understand the language of an agreement or any other factor. If medical practitioners intentionally take advantage of the fact that consumers are illiterate or do not understand the language of the relevant documents, their conduct would be unconscionable within the purview of section 40.
AGREEMENTS WITH PERSONS LACKING LEGAL CAPACITY

A person must have legal capacity to enter into an agreement with another person. In medical practice the person agreeing to pay for the services of the doctor must have such legal capacity.

The CPA provides that an agreement to supply any goods or services to a consumer will be:

• Void if the consumer has been declared mentally unfit by a court and the supplier knew or could reasonably determine such fact; and
• Voidable at the option of the consumer if he/she was an unemancipated minor (i.e. the patient was under the age of 18, unmarried and has not been declared an adult by the courts), no consent was obtained from the responsible adult and the agreement was not ratified as specified.

The aforementioned provisions will, however, not be applicable if a supplier was induced to believe that the consumer had unfettered legal capacity to contract or there was an attempt to obscure or suppress that fact.

It should be noted that legal capacity for contracting purposes differs from a person’s ability to consent to medical treatment and procedures. A person may be legally able to consent to treatment e.g. a child of 12 years under certain circumstances. However, such a child does not have legal capacity to enter into a contract.

FIXED-TERM AGREEMENTS

Section 14 of the CPA regulates the term, renewal and cancellation of agreements of a specific duration, i.e. fixed-term agreements. As pointed out above this section does not apply to transactions between juristic persons regardless of their annual turnover or asset value. Therefore a fixed-term agreement between for example, an incorporated company of doctors and a medical scheme would fall outside the ambit of the CPA.

A fixed-term agreement may not exceed 24 months from the date of signature of the agreement. A longer period is only permitted:

• If it is expressly agreed to by the consumer and the supplier can demonstrate that the longer period will be of financial benefit to the consumer; or
• Where authorised by a regulation or an industry code in respect of a specific type of agreement, type of consumer, sector or industry.

A consumer is entitled to cancel the agreement when the term expires or at any other time provided that the supplier was given 20 business days written notice. Where the consumer cancels the contract before the expiry date, the supplier is entitled to recover any outstanding amounts as well as a reasonable cancellation fee. However, a supplier may not charge a fee that would have the effect of negating the consumer’s right to cancel an agreement as provided for in terms of the CPA.

The following aspects must be taken into account to determine what constitutes a reasonable cancellation fee:

• Amount owed by the consumer up to the date of cancellation;
• Value of the transaction up to cancellation;
• Value of the goods, which will remain in the possession of the consumer after cancellation;
• Value of the goods that are returned to the supplier;
• Duration of the consumer agreement as initially agreed;
• Losses suffered or benefits accrued by the consumer as a result of entering into the agreement;
• Nature of the goods or services that were reserved or booked;
• Length of the cancellation notice;
• Reasonable potential for the service provider, acting diligently to find an alternative consumer between the time of receiving the cancellation notice and the time of the cancelled reservation; and
• General practice of the relevant industry.

The supplier may also cancel a fixed-term agreement with a consumer where it can be shown that there is a material failure by the consumer to comply with the agreement. In these circumstances, the supplier must give the consumer 20 business days written notice to rectify the failure, failing which the agreement may be cancelled.

The CPA also requires the supplier to notify the consumer of the impending expiry of the agreement of at least 40 business days, but no more than 80. This must be done in writing or in any other recordable form. The notice must amongst others include:

• Any material changes that would apply if the agreement was to be renewed or continued beyond the expiry date; and
• The options available for the consumer in terms of terminating the agreement or renewal.

At the expiry of the fixed-term agreement, the contract will automatically continue on a month to month basis, until the consumer either cancels or renews the agreement for another fixed-term.
Doctor-patient agreements will in general not qualify as fixed-term agreements. However, an agreement between a doctor and a medical scheme or a pharmaceutical company could qualify as a fixed-term agreement.

**CONTRACT TERMS**

Section 48 prohibits suppliers (e.g. medical practitioners) to enter into any agreement for the supply of goods or provision of services at a price or on terms that are unfair, unreasonable or unjust. The following terms are amongst others regarded to be unfair, unreasonable or unjust:

- Terms that are excessively one-sided in favour of a person other than the consumer;
- Terms so adverse to the consumer that they are unfair;
- Instances where a consumer relied upon a false, misleading or deceptive representation provided by or on behalf of the supplier; and
- When the consumer’s attention was not drawn to them as required in section 49. These contract terms include those that
  - Limit the risk or liability of the supplier or any other person;
  - Constitute an assumption of risk or liability by the consumer;
  - Impose an obligation on a consumer to indemnify the supplier;
  - Constitute and acknowledgement of any fact by a consumer; or
  - Concern an activity or a facility that involves a risk of unusual nature of which the consumer could not reasonably be aware of or that could result in serious injury or death.

Terms and conditions that would fall in the aforementioned categories are for example indemnifications of doctors, where the consumer acknowledges a fact e.g. that the charges of a particular doctor are reasonable or when a patient agrees to participate in a clinical trial. These provisions must be written in plain language and their nature and effect must be pointed out to a consumer in a conspicuous manner before the earlier of the consumer entering into the agreement, engaging in the activity, entering the facility or paying for the goods or services. The consumer must always be given an adequate opportunity to receive and comprehend the condition in the circumstances.

In the event of an activity or facility involving a risk of unusual nature, the consumer must also in writing assent to such a provision or act in a manner that demonstrates acknowledgment and acceptance of that risk.

Section 51 specifies a list of prohibited terms, which may not appear in contracts such as those that:

- Defeat the purpose of the CPA;
- Mislead or deceive the consumer;
- Deprive a consumer of a right in terms of the CPA;
- Exempt a supplier from liability for any loss directly or indirectly attributable to the gross negligence of the supplier; or
- Authorise the supplier to do anything, which is unlawful in terms of the CPA.

Furthermore, Regulation 44 contains 28 terms, which are presumed to be unfair, if they appear in a contract related to the business of a supplier acting on a for-profit basis and a consumer and the contract is wholly or mainly unrelated to the consumer’s business or profession. This list of terms is, however, neither exclusive nor exhaustive.

**Examples of these terms are those that**:

- Exclude or limit the liability of the supplier for death or personal injury of the consumer caused by an act or omission of that supplier. It would appear that doctors would therefore not be allowed to require patients to indemnify them for medical treatment or procedures;
- Limit the supplier’s vicarious liability for its agents. In terms of section 113 an employer or principal is jointly and severally liable for the acts or omissions of his/her employees or agents (excluding criminal liability). A doctor would therefore also not be able to limit his/her liability for acts or omissions of for example his/her employees or contracted staff;
- Enable the supplier to unilaterally alter the terms of the agreement, including the characteristics of the product or service. This would for example prohibit the doctor to unilaterally change the payment terms of an agreement with a patient; and
- Prohibit a consumer from taking legal action against the supplier.

**POWERS OF THE COURT**

The courts have broad powers in respect of contracts under the CPA. They are amongst others compelled to interpret any contract (also standard forms or documents prepared by a supplier) to the benefit of the consumer.

Furthermore, if a court determines that an agreement was in entirely or partially unconscionable, unjust, unreasonable or unfair it may amongst others
• Make a declaration to that effect;

• Make an order, which is just and reasonable in the circumstances, which could include:

• Restoration of the consumer’s money;
• Compensate the consumer for losses or expenses related to the agreement or the proceedings of the court;
• Require the supplier to cease or alter any practice, form or document;
• Declare an agreement void;
• Sever any unlawful provision in terms of the CPA from the agreement; or
• Alter any unlawful provision in order to render it lawful.

CONCLUSION

Medical practitioners need to ensure that all contracts comply with the provisions of the CPA and related Regulations. In addition to the powers a court has in respect of agreements, contraventions of the CPA may also result in a fine and/or imprisonment for a period not exceeding 12 months, if an offence is committed. Offences include failure to comply with a compliance notice, i.e. a notice requiring a supplier to comply with the CPA. The National Consumer Tribunal may also impose administrative fines for contraventions of the CPA. The maximum fine that may be imposed is the greater of 10% of the supplier’s annual turnover during the preceding financial year or R1 million.

REFERENCES

2. Consumer Protection Act Regulations, General Notice Number 9515 published as Government Gazette Number 34180 on 1 April 2011
ARTICLES

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