

## **PATIENT INFORMATION LEAFLET**

*Revised 14.05.2012*

**The Centre for Men's Health** aims to provide a service of excellence for patients suffering from androgen deficiency (specifically the condition known as Androgen Deficiency in the Adult Male or ADAM, Testosterone Deficiency Syndrome or Andropause) and other male health related issues.

It is our intention to continuously monitor and update our procedures in order to give patients the best possible service. To support this process we invite all new patients to give consent for their anonymised data to be included in our clinical audit. If you are willing to do this, you will be asked to sign a short statement to confirm that you give permission for your anonymous data to be used.

### **Testosterone Deficiency**

The following pages provide further information about testosterone deficiency or Andropause and its treatment by testosterone replacement and other methods.

Reduced testosterone activity is common in men from the age of 40 onwards – 20% of men over 50. This causes the loss of energy, libido and potency which are symptoms of Testosterone Deficiency Syndrome (TDS). The condition can usually be helped by carefully monitored Testosterone Replacement Therapy (TRT). TRT has been used over many years and has an excellent safety record. In addition to TRT, a wide range of other treatments to restore potency are available, including Viagra, Cialis and Levitra.

The confidential on-line E-medicine Androscreen Screening Service, an essential part of the Centre for Men's Health assessment procedures, is the basis of a broad approach to maintaining health together with vitality and virility.

The Centre for Men's Health bases its approach on the recommendations of the International Society for the Study of the Aging Male (The Ageing Male, 2009; 12: 1-5) and the Consensus Study of the American Endocrinology Society. The Centre for Men's Health does not accept patients under the age of 21.

### **Testosterone Deficiency Syndrome Recent Research Findings**

Over the last few years, research has shown that low or ineffective testosterone levels are implicated in many of the severe, long term illnesses which assail men with increasing years. Metabolic syndrome and diabetes, Alzheimer's disease, coronary heart disease and angina, and erectile dysfunction are illnesses where it has been shown testosterone deficiency contributes to causation and exacerbation.

Where testosterone is low or levels are ineffective, studies also show that appropriate hormone replacement may help to avert or alleviate symptoms.

In 2005, Professor Shabsigh of Columbia University, New York, presented evidence to suggest that the symptoms of TDS and erectile dysfunction may be early warning markers of important men's health issues, such as cardiovascular disease, diabetes, metabolic syndrome, depression and benign prostatic disease (Shabsigh, Am.J.Cardiol., 2005, v96, 313-321).

This means that early detection of testosterone deficiency and erectile dysfunction (ED) may be a key factor in early diagnosis and treatment of these serious disorders.

It has now been established that the probability of men suffering from erectile dysfunction increases rapidly with age.

Low testosterone levels, or inability to make use effectively of higher levels, results in changes in the penile tissues causing erectile dysfunction (Shabsigh, 2006, Traish, 2006, Foresta 2004). Moderate to long term hormone replacement can reverse these changes and may avert the need for use of more expensive drugs (Yassin, 2006).

Shabsigh suggests that symptoms of sexual dysfunction may be the manifestation that presents an opportunity to detect other disorders and hopefully implement changes to improve men's health.

## **Defining a normal level of testosterone**

Testosterone replacement has continued to be viewed as a controversial treatment for a number of reasons. Definition of the normal pattern of blood levels has remained a stumbling block as many patients exhibiting symptoms of androgen deficiency have apparently normal levels of blood testosterone.

However, it is now generally recognised that three factors undermine the use of total testosterone as an indicator of hormonal sufficiency. Firstly, the level of available and usable testosterone is reduced increasingly with age by the accumulation of sex hormone binding globulin (SHBG) which inactivates the hormone. Other proteins also have a binding effect. To overcome this difficulty, Calculated Free Testosterone is now used as a more accurate alternative (Vermuelen, 1971, 1998).

Secondly, recent papers have revealed the extreme difficulty of obtaining accurate measure of both testosterone and oestrogen using current laboratory techniques. There are large inter-laboratory and inter-method discrepancies which render results unreliable.

Another factor which can influence results is the state of the patient at the time of testing. A heavy drinking bout the night before can lower testosterone. If the patient is fasting, the level will be raised. Finally, variations in the androgen receptor also radically affect the effective use of the hormone in the tissues, combining with other factors to cause androgen resistance, a key factor, similar to the insulin resistance seen in adult onset diabetes, recently put forward by Dr Malcolm Carruthers (Carruthers, J. Sexual Medicine,5,998-1012).

## **Cardiovascular Disease**

A growing body of research now challenges many traditional views concerning the role of testosterone in relation to heart disease. Testosterone has long been considered a dangerous hormone, damaging to the circulatory system, albeit with little evidence. To the contrary, evidence from clinical and laboratory research associates testosterone with cardiovascular health.

Physiological androgen activity may actually be a 'tonic for the heart' and protect the circulatory system against complications that appear to be associated with declining serum testosterone (Channer, 2007).

Testosterone replacement therapy is safe, with no excess adverse events, improving functional capacity and symptoms in hypogonadal men with moderately severe heart failure (Malkin et al, 2006). Testosterone does not increase the risk of thrombosis (Smith et al, 2005)

Testosterone improves ischaemic threshold and quality of life in hypogonadal men with angina (Malkin, Channer et al, 2004) and low doses of transdermal Testosterone therapy improve the angina threshold in men with chronic, stable angina (English et al, 2000)

Age-related decline in testosterone could contribute to the atherosclerotic process and the immune-modulation properties of testosterone may be important in inhibiting atheroma formation and progression to acute coronary syndrome (Malkin et al, 2003; Jones et al, 2005)

Resistance to insulin occurs in chronic heart failure and relates to prognosis. Testosterone improves this, suggesting a favourable effect on an important metabolic component of chronic heart failure (Malkin, Channer et al, 2007)

Low testosterone levels in young men can be detected using measurements of finger length ratios and it has been suggested, could be used to predict those at risk of later circulatory problems and the possible need for replacement in later life (Fink, Manning & Neave, 2006).

## **Alzheimer's Disease**

It is now predicted that cases of dementia could rise from 700,000 to 1.7 million by the year 2050. The Alzheimer's Society refers to this as 'a time bomb' and calls for resources and strategies for care and support. An increasing number of studies suggest that testosterone replacement is a major possibility in treatment of many of these cases.

Available testosterone depletion is a normal consequence of aging in men. Testosterone is frequently lower in AD patients, and one consequence of this is an increased risk for the development of AD (Pike et al, 2006, Rosario 2004).

Testosterone plays a role in regulating toxic beta-amyloid (Abeta) levels but also has both neurotrophic and neuroprotective functions.

Sufferers also may have distortions of the androgen receptor which result in a decreased capacity to use such levels of testosterone as are available to them. So that even apparently normal levels of the hormone are inadequate to protect (Lehmann, Hogervorst et al, 2004).

Overproduction of Abeta peptide is believed to be a key factor in the development of AD. It is neurotoxic probably due to its capacity to cause oxidative stress. The reproductive hormones help to reduce the damaging effects of Abeta (Barron et al 2006).

Oxidative stress has been implicated in AD pathogenesis as well as in other illnesses such as atherosclerosis and Parkinson's (Sicotte, 2006). Many studies show that oestrogen, progesterone, testosterone and luteinizing hormone have a neuroprotective role. Decreasing levels of these hormones during aging are thought to increase risk of AD as a result of reduced protection against oxidation (Hogervorst, 2004). These findings have led to trials evaluating androgen-based therapies for the prevention and treatment of AD (Lim et al, 2003, Tan R., 2003). Initial findings suggest that testosterone could indeed improve cognition, including visual-spatial skills in mild to moderate Alzheimer's disease.

Enhancement of testosterone levels may be an effective method of preventing or ameliorating the disease (Tan R., 2003).

## **Metabolic syndrome**

Metabolic syndrome (which has also been shown to be an indicator of later Alzheimer's disease) is set to reach epidemic proportions. Metabolic syndrome is a cluster of the most dangerous heart risk factors: diabetes and pre-diabetes, abdominal obesity, dyslipidaemia, high blood pressure, and hypercoagulability. The global prevalence is 25% in adults and up to 80% of sufferers of diabetes will die of cardiovascular disease.

Again, low testosterone levels (or possibly ineffective use of available testosterone due to genetic changes in the androgen receptors or increased levels of SHBG), has been flagged up as a factor in this type of illness (Svartberg, 2006). Androgen replacement has given encouraging results as a method of treatment in this area.

Zitzmann (2006) found in several small intervention studies that normalization of testosterone levels reduces fat mass and inflammatory markers, increases lean body mass and shows an overall improvement in the risk factors for the metabolic syndrome and cardiovascular diseases in patients with visceral obesity, cardiovascular diseases and diabetes type 2.

Kapoor, Channer et al (2006) concludes that testosterone replacement reduces resistance and improves glycaemic control in hypogonadal men with type 2 diabetes. In addition, improvements in glycaemic control, insulin resistance, cholesterol and visceral adiposity represent a reduced cardiovascular risk.

## **Prostate Cancer and Safety Issues**

A series of recent publications examining the link with prostate cancer supports the current consensus that testosterone may exacerbate prostate cancer that is already present, with many reasons to doubt the role of testosterone in the initiation of biologically significant cancer (Raynauld, 2006; Feneley, 2006; Morales, 2007; Chen et al, 2003). In fact, there is evidence that high levels of testosterone and adrenal androgens may be associated with lesser risk of aggressive prostate cancer, whereas androgen levels are not associated with non-aggressive disease (Severi et al, 2006).

Aside from potential adverse safety concerns with inappropriate or unmonitored testosterone replacement, overwhelming evidence supports testosterone replacement as one of the safest forms of pharmacology. A survey all forms of testosterone treatment reported to the Medicines Control Agency from 1963 to 2002, gives no adverse reactions in the first 15 years of reporting. Over the next 29 years a total of 214 possible reactions were reported in 185 patients, some having more than one reaction. Of these reactions, half were minor skin reactions, pain at injection sites or loss of pellet implants. There were only three fatalities reported, including one suicide, one overdose and one sarcoma of unknown site. These, of course may or may not have been due to the testosterone. More recent studies (Feneley 2006, Raynaud, 2006) confirm these safety findings.

It should also be noted that low testosterone has now been found to be associated with increased mortality (Shores, 2006).

## **Future Use of Testosterone**

The use of testosterone purely as a cosmetic, anti ageing technique is not acceptable to many practitioners. Nor is the prescribing of testosterone to younger men as an aphrodisiac or a sports aid in any way warranted.

But medicine in the 21<sup>st</sup> century faces a different series of challenges. The ageing population is set to increase markedly over the next few decades. Responsible testosterone replacement may be a way to reduce the predicted large numbers of dependent elderly who are likely to need care from the health services. The watershed which doctors face in the 21<sup>st</sup> century, of metabolic disease, Alzheimer's disease, cardiovascular disease and depression is likely to overwhelm existing health resources. Preventative measures together with the help of these new hormonally based approaches may be part of the solution.

## **Symptoms of Testosterone Deficiency**

There comes a time in many men's lives, sometimes sooner, sometimes later, when they are faced by the "Male Menopause" or "Andropause". This equivalent of the menopause in the female is often less sudden in onset but can be more severe in its long-term consequences.

Fatigue, depression, irritability, and reduced libido and potency are the commonest symptoms. This change is surprisingly often overlooked or ignored, either because the man is so pressurised by the rest of his life that he assumes it is an inevitable part of growing older, or because his sexual partner has lost interest as well. Besides lack of sex drive, there is often loss of drive in professional or business life. Physically there is frequently stiffness and pain in the muscles and joints, symptoms of gout, and a rapidly deteriorating level of fitness. There may also be signs of the accelerated ageing of the heart and circulation which testosterone deficiency can cause.

Research in over 2,000 patients at the Centre for Men's Health has shown over the last fifteen years that the main causes of testosterone deficiency are stress, excess alcohol, overweight, lack of exercise, and vasectomy, added to the general effects of ageing.

We have shown scientifically for the first time that there may sometimes be a low absolute level of testosterone, but more often there is a relative deficiency due to a range of factors stopping it working effectively even when the level of this key hormone is normal - the engine is pushing but the brakes are on!

## **Testosterone Replacement Therapy (TRT) for Men**

TRT - HRT for men using Testosterone - has been shown to be dramatically effective in relieving symptoms and restoring drive, health, potency, and a sense of renewed vitality and virility when given to the right patients in the right doses at the right time.

To ensure its safety and effectiveness however it is essential that a full assessment or "work-up" of each patient is carried out before hormone replacement is started, and that the results of treatment are carefully monitored. For this purpose careful history-taking and a detailed clinical examination need to be carried out.

Both to establish the diagnosis and to monitor the treatment carefully, laboratory measurements of the sex hormones and the complex range of factors regulating their action, together with tests of blood fat, liver, kidney, and prostate function, and changes in red and white blood cells all need to be checked before treatment and at each follow-up visit.

TRT is usually given as a gel or injection for the first two to six months. It is often needed long-term, and can safely be continued in these forms if good symptom relief is maintained, or changed to other types if needed.

Testosterone treatment has been in use for over half a century, and has a remarkably good safety record over that time, as confirmed by the detailed studies at this centre. However, every effort is made to exclude pre-existing prostatic cancer, by clinical examination, and a sensitive blood test, the Prostate Specific Antigen (PSA).

## **Side Effects & Complications**

These are listed on a 'consent for treatments' form given to the patient for signature at the time of initiating treatment, as featured over.

## **The following course of treatment has been advised, with instruction of when and how to take medications.**

### Cialis (Tadalafil) 20mg tablets

Benefits: Treatment of erectile dysfunction

Serious or infrequently occurring risks: dyspepsia, vomiting; headache, flushing, dizziness, visual disturbances and increased intra-ocular pressure, nasal congestion; hypersensitivity reactions (including rash), priapism (painful erection lasting over 4 hours, requiring attendance at AE Department), red eyes, back pain, myalgia.

### Levitra (Vardenafil) 20mg tablets

Benefits: Treatment of erectile dysfunction

Serious or frequently occurring risks: dyspepsia, vomiting; headache, flushing, dizziness, visual disturbances and increased intra-ocular pressure, nasal congestion; hypersensitivity reactions (including rash), priapism (painful erection lasting over 4 hours, requiring attendance at AE Department), red eyes.

### Testosterone undecanoate injections (Nebido): 4ml by intra-muscular injections

Benefits: Relief of symptoms of androgen deficiency

Serious or frequently occurring risks: Discomfort may be experienced for an hour or more after the injection. Occasional elevation of red blood cell count.

### Testosterone undecanoate 40 mg capsules orally, taken as directed, with some fat in the food.

Benefits: Relief of symptoms of androgen deficiency

Serious or frequently occurring risks: Mild loose motions can occur.

### Testosterone enanthate: 250mg/1ml ampoules for injection

Benefits: Relief of symptoms of androgen deficiency

Serious or frequently occurring risks: Infrequent, mild gastrointestinal irritation.

### Testogel: 50mg 1% in 5g sachet (30 sachets per pack)

Benefits: Relief of symptoms of androgen deficiency

Serious or frequently occurring risks: skin rashes are possible.

### Tostran: 2% Gel

Benefits: relief of symptoms of androgen deficiency

Serious or frequently occurring risks: Skin rashes occasionally occur.

### Danazol

Benefits: In low doses can enhance natural testosterone reserves or boost the effects of prescribed testosterone.

Serious or frequently occurring risks: In the low doses prescribed at the center, the only side effect has been a slight weight gain (See Patient information leaflet for further details).

### Arimidex (Anastrozole) 1 mg tablets

Benefits: Used in 0.5mg doses as an anti-oestrogen.

Serious or frequently occurring risks: Diarrhoea, headache, bone pains.

## **Contraindications for treatment**

1. Diagnosed prostate cancer is an absolute contraindication to androgen therapy. (Although medical researchers are increasingly of the opinion that successfully treated prostate cancer patients can with care receive testosterone replacement)

Before starting treatment, the prostate-specific antigen (PSA) is determined together with other tests to rule out cancer of the prostate.

2. Mammary carcinoma (breast cancer) in men, though very rare, is also a contraindication.

3. Erythrocytosis with an increased haematocrit.
4. Men with congestive heart failure, severe liver or kidney dysfunction, epilepsy or migraine are also not eligible for testosterone replacement.
5. Concomitant physical disease, such as thyroid disease, diabetes mellitus with use of medication to control blood sugar, coronary artery disease, hypertension, prior ischaemic attack or minor cerebrovascular accident, are not reasons for exclusion, but need to be carefully monitored.
6. Patients prescribed anti clotting drugs such as Warfarin may not be prescribed Danazol.

## How Hormone Replacement Therapy can Prolong Active Life

Life can be compared to a trip in a glider when, after being catapulted in our teens and early twenties to the peak of our innate physical and mental abilities by a powerful cocktail of hormones, including particularly the sex hormones testosterone and oestrogen, we then go into a variable glide path for the rest of our lives, the rate of descent largely being controlled by the body's hormonal balance.

Some hormones, particularly the stress hormones such as adrenaline, noradrenaline, and cortisol, increase wear and tear and the rate at which we use up our energy, having what is known as a catabolic (or break-down) action. Others, particularly testosterone and oestrogen, have the opposite, or what is called anabolic (or build-up) effect. This can explain why some people burn themselves out and go into a nose dive, their health crashing at the age of 50 or earlier, while others glide gently on into their 80s or even 100 or more.

In general, both physically and mentally, you're as young as your arteries. Testosterone and oestrogen have both been used to prevent and treat heart and circulatory disease. Their beneficial actions have been proved in many research studies and these hormones also maintain the condition of the skin, muscles and bones. Therefore it seems reasonable to expect that, by giving nature a helping hand on a scientifically regulated and carefully monitored basis, we could slow down the ageing processes and prolong active and enjoyable life,

It is the philosophy of the **Centre for Men's Health** that the present careful research in the rapidly expanding field of Hormone Replacement Therapy in both sexes will lay the foundation for preventive medicine in the 21st Century.

## Treatments for Erection Problems

Research at the **Centre for Men's Health** has shown that in around two thirds of cases, by treating the underlying andropausal condition, **testosterone can restore both libido and potency**. In the remaining third, our studies on over 500 patients have shown that combining testosterone with **Viagra (sildenafil)** brings the success rate with erection problems to over 95%. As they become available, the new oral treatments such as **Cialis (tadalafil)** and **Levitra (vardenafil)** are being introduced with our patients here.

Information about side effects of these drugs, if prescribed for you, will be provided during your consultation by your doctor.

## **Prostate Health Programme**

Prostate problems are a very common cause of impaired health in middle-aged and older men. The prostate undergoes benign enlargement in 50% of men over age of 50. This can result in symptoms such as having to get up frequently at night, poor urinary stream, and urgency in having to go to the toilet. In extreme cases, it can result in urinary infections and sudden retention of urine, requiring catheterisation or surgery.

Prostate cancer is also on the increase, with 30,000 new cases being diagnosed, and 10,000 men dying each year in the UK. While the benefits of treatment are disputed ( as it is difficult to tell which tumours are 'tigers' which will advance and spread rapidly, and which are 'pussy-cats', not life threatening in the short term) most people would prefer the luxury of choice of management provided by early diagnosis.

## **The Holistic Approach to Treatment**

Often there are several factors contributing to the vicious circle of testosterone insufficiency leading to feelings of social and sexual inadequacy, producing more stress, leading to attempts to compensate by excess food and alcohol, which then further worsen the hormonal imbalance. As well as giving TRT where it is needed, we try to help reverse this downward spiral by intervention at many levels.

## **Dietary and Related Measures**

As well as giving advice on ways of reducing weight, blood pressure and cholesterol, together with prescribing weight reducing drugs where necessary, we also advise on vitamin and mineral supplements to boost potency and safe-guard the prostate.

## **Stress Management and Relaxation Training**

These effects of stress on hormones make it important to study it carefully in each person, and relieve it where it is excessive. For this reason advice is often given on ways of managing stress.

## **Chaperone Policy**

Because of the nature of the problems presented, in patients attending the Centres for Men's Health we consider there is implied consent to abdominal, genital and rectal examination, though patients may bring someone to act as chaperone if they require.

## **Follow-up Appointments**

For reasons of safety, it is important that your treatment continues to be monitored. You will therefore be offered follow-up appointments at either 2 months for the first six months, and 2, 3 or 6 monthly intervals thereafter.

## **CONSULTATION AND TREATMENT FEES**

### **Laboratory Profile and on-line E-medicine Androscreen©: £175**

Fasting blood samples are taken for a full laboratory profile, including detailed hormone analyses, prostate-specific antigen test, biochemistry, and haematology. This is the same price at all Centres, and needs to be paid for before booking the appointment with the Specialist. For patients attending the Harley Street Centre, the blood sample can be taken before 11am for a same-day afternoon consultation. For patients attending Out-of-London Centres, the fasting samples need to be taken on a Monday to Thursday morning in the week before the appointment with the Specialist, to allow time for the sample to be sent to Quest Laboratories in London for analysis and return of results. There are 10 clinics around the country at which these samples can be taken, contact details for which will be provided after making your payment for the blood test. Alternatively, if you find it more convenient, we can send you the Quest remote blood sampling kit and request form, and you can get any local GP, hospital or private medical facility to take the sample for you, but at your own expense.

### **Initial Specialist Consultation: London £500 - Out of London: £300**

The Specialist goes over the e-medicine Androscreen© questionnaire covering the patient's presenting symptoms, medical history, life-style and habits. Uniquely to the Centre for Men's Health, this questionnaire can be completed on-line from home by the patient himself at leisure before the consultation to save time and give more detail. Alternatively, by request at the time of making the booking, a copy of the questionnaire can be sent for completion at home, and brought with you to the initial consultation. The specialist then carries out a physical examination and goes over the results of the laboratory tests, discussing them with you and making recommendations for treatment and follow up.

### **Follow-up Specialist Consultation: London £300 - Out of London: £150**

This consultation, together with the laboratory profile, is needed every 2-6 months to monitor and optimise the results of treatment, and is part of a general, on-going, men's health maintenance programme.

**Testosterone Treatment:** £30-60 per month according to preparation used.

**The fees are not reclaimable under private insurance schemes**

**To make an appointment to see a Specialist please call Office Manager Jim McGrew on 020 636 8283**

## **Methods of Payment**

Other than on-line fees for blood tests and Androscreen, payment is due at the time of consultation. Credit or debit cards and cheques are accepted. Please make cheques payable to Centre for Men's Health Ltd.

## **Contact with your GP**

A summary of the results of your assessment and the treatment regime agreed will be sent to your GP within 4 weeks unless you formally request that this not be done. In this case, you will need to sign a request that your GP not be informed and the summary will then be sent to you instead unless you request other arrangements to be made.

## **Out of Hours and Emergency Contacts**

If you need to contact your doctor at the center between appointments, you will be informed when he will be available during clinic hours. In the case of an out of hours emergency, you are advised to contact your GP or your local Accident and Emergency Department.

## **Complaints Procedure**

If you should have a complaint about the services provided by this clinic, this should be addressed to the Medical Director or to the Practice Manager.

You will receive a written acknowledgement of your complaint within 2 working days (unless a full response can be sent within 5 working days).

If this is not possible, a full response will be sent within 20 working days, or where the investigation is still in progress, a letter explaining the reason for the delay will be sent and a full response made within 5 working days of a conclusion being reached.

**If you need to complain about the way your grievance has been handled, you should write to the Care Quality Commission (see address at the end of the leaflet).**

## **Access to Records**

All patients have a right to access to their records in line with the Data Protection Act 1998. Should you wish to have access to your records, please discuss this with the Medical Director.

The Centre for Men's Health is registered for data protection with the Information Commissioners Office, Registration.

## **Suggestions and Comments**

If you would like to make suggestions or comments about this leaflet or about the centre, please send your ideas in writing to The Practice Manager. c/o Flat 20 Harmont House, 20 Harley Street, London W1G 9PH.

**London Region, Care Quality Commission, Citygate, Gallowgate. Newcastle upon Tyne NE1 4PA**

**Care Quality Commission Inspections - website [www.cqc.org.uk](http://www.cqc.org.uk).**

CQC inspections were carried out in the Harley Street and Manchester Centres during 2011.