# REFRAMING MEN'S HEALTH: IS AUSTRALIA FALLING BEHIND?

TESTOGEL® testosterone


## Defining testosterone deficiency

Definitive diagnosis of testosterone deficiency (TD) requires the presence of characteristic clinical features combined with biochemical evidence of reduced serum testosterone levels.[1-5] It is recognised that deficient androgen levels can negatively affect multiple organ systems and quality of life,[1-3] yet Australian recommendations (last updated in 2016) are not as broad as international guidelines when it comes to screening and treatment.[1,6]

## Screening is simple – but are we looking?

Testosterone levels should be measured in men who exhibit clinical signs and symptoms of TD – that much is obvious. The more signs and symptoms the more likely the diagnosis will be TD.[1-5] International guidelines have identified clinical signs and symptoms suggestive of testosterone deficiency that are broader than the Australian guidelines. The Endocrine Society of Australia's recommendations are limited to signs and symptoms of 'pathological hypogonadism' and therefore the guidance is restricted to this group.[2,4,6] This begs the question – how many patients who could be benefiting from testosterone therapy are being overlooked in Australia?

With increasing evidence linking low testosterone levels to obesity and metabolic dysfunction, and a high prevalence of low testosterone levels among patients with a wide range of other conditions, international guidelines are now recommending broader screening criteria, sometimes even in the absence of key clinical signs and symptoms of TD.[1-5]
The broader criteria of international guidelines include:[1-5]

- Type 2 diabetes or metabolic syndrome
- Obesity, specifically body mass index >30 kg/m2 or waist circumference >102 cm
- Long-term use of opiates, antipsychotics, anticonvulsants, or corticosteroids
- Unexplained anaemia
- Infertility
- Osteoporosis, bone density loss, or low-trauma fracture
- Exposure to chemotherapy or testicular radiation
- HIV/AIDS
- Pituitary dysfunction or exposure to pituitary radiation

Despite differing recommendations on who to screen for TD, all experts agree that a diagnosis should be confirmed by low fasting morning serum testosterone levels measured on at least 2 occasions using a reliable and accurate method like mass spectrometry.[1-6]

## Treatment is straightforward

Despite differing recommendations, it's a matter of providing testosterone therapy to men who meet the clinical criteria for diagnosis of TD. The aim is to return testosterone to normal physiologic levels. While there is no exact 'normal' level, average serum testosterone levels of approximately 15–20 nmol/L are recommended.[1-5,7] The Australian guidelines have various 'normal' values, depending on the age and reproductive function of the patient, while other international guidelines have slightly broader ranges (Table 2).[1-6]

**Table 2:** Comparison of 'normal' serum testosterone values from Australian vs international guidelines.

| AUSTRALIAN (ESA) GUIDELINES*[6] | INTERNATIONAL GUIDELINES[1-5] |
|---|---|
| **Age 21–35 years with normal reproductive function:** 10.4–30.1 nmol/L | **Normal range:** 8 nmol/L – 31.8 nmol/L |
| **Unselected young men:** 7.4-28.0 nmol/L | |
| **Very health mean aged 70–80 years:** 6.4–25.7 nmol/L | |

*Serum testosterone levels measured using mass spectrometry

For men with total testosterone levels in the lower normal range (8–12 nmol/L) with clinical symptoms of TD, further biochemical evaluation is indicated to tease out the underlying androgen imbalance and a trial of testosterone therapy may be appropriate.[1-4]

Testosterone therapy is not indicated in men with:

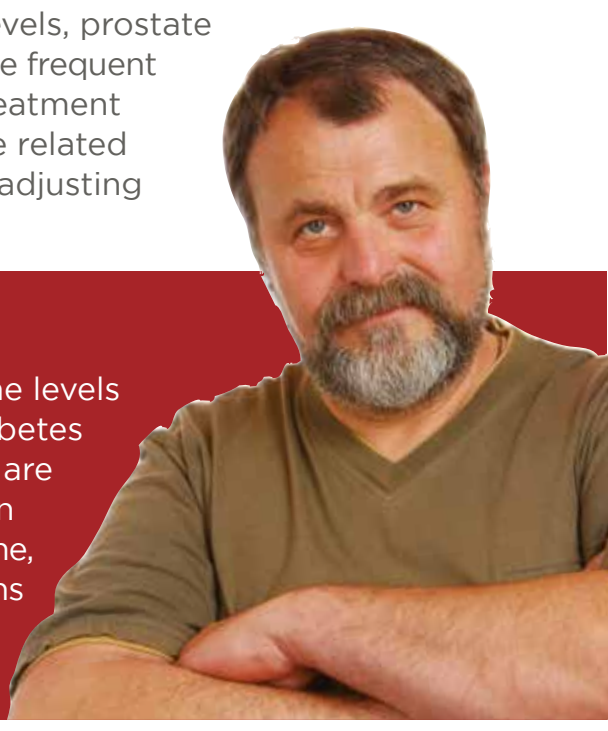
- Active plans for children
- Locally advanced or metastatic prostate cancer
- Male breast cancer
- Elevated haematocrit levels (>48–54%) or
- Severe chronic heart failure.

While not contraindicated, patients with increased prostate specific antigen levels, untreated sleep apnoea, severe lower urinary tract symptoms, or recent cardiovascular events should be carefully evaluated before initiating testosterone therapy.[2-6] Before initiating testosterone therapy, all patients should receive haematologic, prostate, breast, and cardiovascular risk assessments, and ensure secondary prevention is optimised in men with existing cardiovascular disease.[2,3,5]

## Monitoring testosterone therapy is not difficult

Testosterone therapy should be trialled for a minimum of 6 months, as maximal benefit is often not seen until after 12 months of treatment.[2,3]

After initiation of testosterone therapy, patients should be evaluated at 3, 6, and 12 months, and then annually to assess serum testosterone levels, confirm symptomatic improvement, evaluate any adverse effects, and monitor haematocrit levels, prostate specific antigen levels, and cardiovascular risk factors. More frequent follow-up may be required for patients with suboptimal treatment response or safety concerns.[2-5,7] Some adverse events are related to excess testosterone levels, which can be managed by adjusting testosterone dose or switching formulation.[2,4,7]



## Are we falling behind?

There is still debate surrounding whether low testosterone levels in men with obesity, metabolic syndrome, and type 2 diabetes represent true hypogonadism; however, some guidelines are now specifically recommending testosterone treatment in patients with TD associated with obesity, metabolic syndrome, and type 2 diabetes in conjunction with lifestyle modifications and treatment of comorbidities.[1-3] The ESA guidelines don't include these recommendations.[6]

REFERENCES: 1. Al-Sharefi A, Quinton R. Current National and International Guidelines for the Management of Male Hypogonadism: Helping Clinicians to Navigate Variation in Diagnostic Criteria and Treatment Recommendations. *Endocrinol Metab (Seoul)*. 2020;35:526-540. 2. Hackett G, Kirby M, Edwards D, Jones TH, Wylie K, Ossei-Gerning N, *et al.* British Society for Sexual Medicine guide¬lines on adult testosterone deficiency, with statements for UK practice. *J Sex Med.* 2017;14:1504-23. 3. Dohle GR, Arver S, Bettocchi C, Jones TH, Kliesch S. Male hypogonadism. Arnhem: European Association of Urology; March 2018. https://uroweb.org/guideline/male-hypogonadism. Accessed: November 2020. 4. Bhasin S, Brito JP, Cunningham GR, Hayes FJ, Hodis HN, Matsumoto AM, et al. Testosterone therapy in men with hy-pogonadism: an Endocrine Society clinical practice guide¬line. *J Clin Endocrinol Metab.* 2018;103:1715-44. 5. Mulhall JP, Trost LW, Brannigan RE, Kurtz EG, Redmon JB, Chiles KA, *et al.* Evaluation and management of testos¬terone deficiency: AUA guideline. J Urol. 2018;200:423-32. 6. Yeap BB, Grossmann M, McLachlan RI, Handelsman DJ, Wittert GA, Conway AJ, et al. Endocrine Society of Australia position statement on male hypogonadism (part 1): assessment and indications for testosterone therapy. *Med J Aust.* 2016;205(4):173-8. 7. Yeap BB, Grossmann M, McLachlan RI, Handelsman DJ, Wittert GA, Conway AJ, *et al.* Endocrine Society of Australia position statement on male hypogonadism (part 2): treatment and therapeutic considerations. *Med J Aust.* 2016;205(5):228-31.

BESINS HEALTHCARE
Innovating for Wellbeing

Besins Healthcare Australia Pty Ltd. ABN 68 164 882 062.
Suite 5.02, 12 Help St Chatswood NSW 2067.
Office phone (02) 9904 7473.
For medical information call 1800 BESINS (237 467). www.besins-healthcare.com.au
TES-1318. Approval date November 2021.

TESTOGEL® testosterone