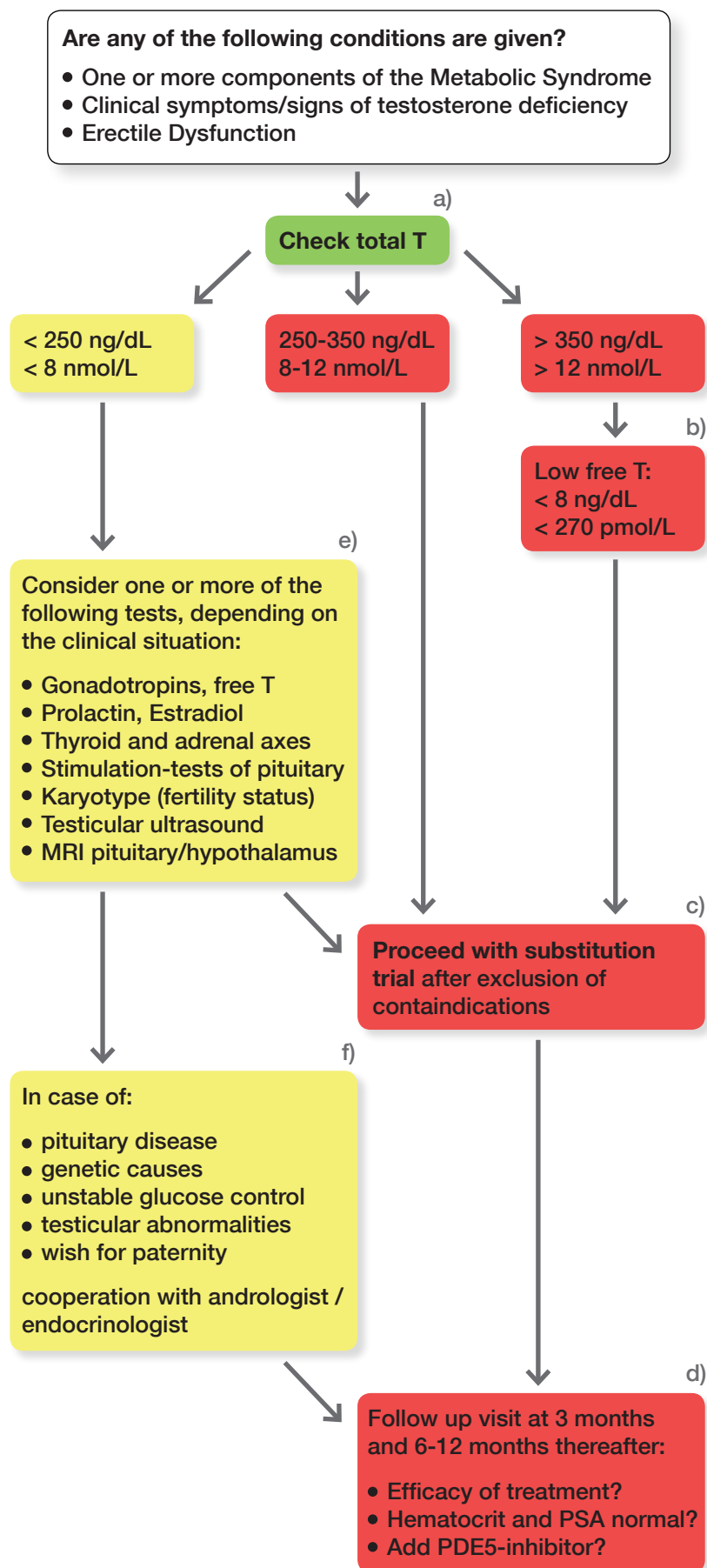


Testosterone Management Recommendation¹

STEPS



NOTES

Conditions:

Total T:

Low free T:

Considered tests:

Contraindications:

Special conditions:

Notes on follow up:

Testosterone Management Recommendation

(a) Total testosterone (T) has been the traditional method to diagnose testosterone deficiency. A number of suggested thresholds have been published.^{2,3} However, T assays produce highly variable results, and treatment must be individualized based on a combination of clinical presentation and biochemical results. Genetic variation may lead to symptoms of T deficiency in men with normal total T results.

(b) Free T can be of diagnostic help in cases where total T does not correspond with clinical presentation. Clinical use of free T is complicated by the availability of a number of assays, and a lack of consensus regarding threshold values. We suggest 8 ng/dl (270 pmol/L) for calculated free T. The analog free T assay^{4,5} shows good correlation with calculated free T, corresponds with biological outcomes, and in our experience has clinical utility, albeit controversial. Values 1.5 mg/dL (52 pmol/L) obtained by the analog free T assay have been suggested as indicating the lower limit of normal.

(c) Men with a suspicious prostate examination, or elevated prostate-specific antigen (PSA) should be referred to a urologist for consideration of prostate biopsy before initiation of T therapy. The use of T therapy in men with a prior history of prostate cancer has historically been an absolute contraindication to T therapy. This is an area of active investigation, with recent evidence suggesting the risk is considerably lower than once believed.

However, we recommend that the nonspecialist refrain from initiating treatment in such men until there is clearer information as to which men with prior history of prostate cancer may be safely offered T therapy. Contraindications include the presence of elevated hemoglobin or hematocrit at baseline and the desire to initiate a pregnancy within the next 12 months.

(d) A symptomatic response to T therapy is generally seen within 3 months. Monitoring should occur at least 2-3 times during the first year, and 1-2 times per year thereafter. Monitoring should include serum T, PSA levels, and hematocrit/hemoglobin. There is no need to measure liver or renal function tests for any of the routine T-therapy formulations.

(e) Severe reductions in total T, (ie, 250 ng/dL (8 nmol/L)) are usually accompanied by symptoms or objective measures of T deficiency. Additional diagnostic studies may be indicated depending on the clinical presentation, for example, to exclude the presence of a pituitary mass, or genetic tests.

(f) In cases of pituitary disease, genetic causes, unstable glucose control, testicular abnormalities, or the wish for paternity, a specialist should cooperate with the treating physician. PDE-5 = phosphodiesterase type-5.

References

1. Traish A et al., Testosterone Deficiency, *The American J of Medicine* (2011) 124:578-587.
2. Bhasin S, Cunningham GR, Hayes FJ, et al., Testosterone therapy in men with androgen deficiency syndromes: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab.* (2010) 95:2536-2559.
3. Wang C, Nieschlag E, Swerdloff R, et al. Investigation, treatment, and monitoring of late-onset hypogonadism in males: ISA, ISSAM, EAU, EAA, and ASA recommendations. *J Androl* (2009) 30:1-9.
4. Morgentaler A. Commentary: guideline for male testosterone therapy: a clinician's perspective. *J Clin Endocrinol Metab* (2007) 92:416-417.
5. Moreno S, Shyam A, Morgentaler A. Comparison of free testosterone results by analog radioimmunoassay and calculated free testosterone in an ambulatory clinical population. *J Sex Med* (2010) 7:1948-1953.

Additional notes (not included in the referenced publication)

For complete safety monitoring recommendation according to Prescribing Information:

Safety monitoring during testosterone replacement therapy

- Periodic check-ups during long-term androgen therapy are recommended for prostate disease, haemoglobin, haematocrit and liver function tests.
- After starting testosterone therapy, careful and regular monitoring for prostate disease should be performed in accordance with recommended standard of care methods