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To screen or not to screen

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Is there undertreatment of male hypogonadism?

Region	Men aged >50 (Millions)	TDS symptoms (Millions)	Total number treated	Symptoms treated (%)	Sympt. + biochem. (Millions)	Symptoms + biochem treated (%)
Whole EU	81.77	16.35	113,000	0.69	4.09	2.76
UK	9.48	1.90	19,000	1.00	0.47	4.00
Ireland	0.54	0.11	1,000	1.10	0.27	4.40
Spain	7.92	1.58	12,000	0.76	0.40	3.04
Italy	10.86	2.17	11,000	0.51	0.54	2.03
France	10.13	2.03	10,000	0.49	0.51	1.97
Germany	13.27	2.65	50,000	1.89	0.66	7.55
America	40.72	8.14	648,000	7.96	2.04	31.84?
Russia	17.00	3.40	18,400	0.54	0.85	2.16
Australia	2.93	0.59	9,100	1.54	0.15	6.17

Number of men over 50, and those expected to be androgen deficient on the basis either of symptoms alone (20%), or with symptoms and low TT and CFT (5%), compared with total number being treated in each region (Based on estimates for 2006).

Numbers treated are based upon 2006–2007 figures from Intercontinental Medical Statistics. (IMS), Bayer-Schering Russia and Medicare Australia

Carruthers M. *Aging Male*. 2009;12(1):21–28.

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Screening for hypogonadism/ androgen deficiency recommendations

ISSM	ISA, ISSAM, EAU, EAA, and ASA	Endocrine Society
▪ Men with erectile dysfunction, hypoactive sexual desire and retarded ejaculation, as well as those with visceral obesity and metabolic diseases, should be screened for TD and treated	▪ T levels should be measured in men with type 2 diabetes with symptoms suggestive of TDS ▪ The initial treatment of all men with ED and/or diminished libido should include determination of serum testosterone	▪ Recommendation against screening for androgen deficiency in the general population ▪ Suggest that clinicians consider case detection by measurements of total testosterone levels in men with certain clinical disorders, in which the prevalence of low testosterone levels is high or for whom testosterone therapy is suggested/ recommended

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Benefits of screening

- Some specialists recommend testosterone screening in all new patients with erectile dysfunction, especially in those with inadequate response to prior PDE5 inhibitors
- Differences in patient populations and comorbid conditions may account for divergent findings
  - One significant difficulty with testosterone screening is that normal ranges for total and free testosterone levels vary even among healthy young men.

Buvat J, Lemarie A. *J Urol.* 1997;158:1764–1767; Johnson AR III, Jarow JP. *J Urol*. 1992;147:1542–1543; Bhasin S, *et al. J Clin Endocrinol Metab*. 2006;91:1995–2010. Shabsigh R. *J Sex Med*. 2005;2(6):785–92.

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EMAS Study: Evidence-based criteria identifying LOH defined

- EMAS Study: 3369 middle-aged and elderly men (aged 40–79 years)
- 9 symptoms were confirmed to be significantly related to total or free T
- Total levels T<11 nmol/L and free T levels <220 pmol/L and the presence of the 3 sexual symptoms were identified as diagnostic criteria for LOH
- The probability of symptoms increased with decreased levels of T
- The presence of the three sexual symptoms correlated most closely with low T levels

Sexual symptoms	▪ **decreased frequency of morning erection** ▪ **low sexual desire** ▪ **ED**
Physical symptoms:	▪ inability to engage in vigorous activity ▪ inability to walk more than 1 km ▪ inability to bend, kneel or stoop
Psychological symptoms:	▪ loss of energy ▪ sadness ▪ fatigue

Wu FC, Tajar A, Beynon JM, *et al. N Engl J Med* 2010;363(2):123-135.

Screening due to comorbidities

- Patients with clinical conditions associated with insulin resistance (obesity, type 2 diabetes and metabolic syndrome) should be screened for TD, since it is often comorbid.
  - It is important to measure sex hormone binding globulin (SHBG) to estimate calculated free testosterone (cFT)

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Conditions with a high prevalence of low testosterone levels: screening recommended

- Sellar mass, radiation to the sellar region, or other diseases of the sellar region
- Treatment with medications that affect testosterone production or metabolism e.g. glucocorticoids, ketoconazole, and opioids
- HIV-associated weight loss
- End-stage renal disease and maintenance haemodialysis
- Moderate to severe chronic obstructive lung disease
- Infertility
- Osteoporosis or low trauma fracture, especially in a young man
- Type 2 diabetes mellitus

Bhasin S, *et al. J Clin Endocrinol Metab.* 2006;91:2000.

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Screening measures

- **Morning serum total testosterone level, which measures free testosterone plus protein-bound testosterone**
  - Morning testosterone values <300 ng/dL (10.4 nmol/L) suggest hypogonadism and should be confirmed by a second assay
  - Diagnosis should be confirmed by repeating the measurement of morning total testosterone and, in some men in whom total testosterone is near the lower limit of normal or in whom SHBG abnormality is suspected by measurement of free or bioavailable testosterone level, using validated assays
- **Luteinizing hormone (LH) should be measured to determine whether the cause is primary or secondary**
  - LH levels <2 ng/mL suggest a hypothalamic lesion (pituitary adenoma, trauma, etc), whereas LH levels >10 ng/mL indicate primary testicular failure
  - Levels within the normal range suggest an age-related, decreased hypothalamic response to declining testosterone levels
  - In addition, serum prolactin should also be measured to rule out the presence of a pituitary tumour

Bhasin S, *et al. J. Clin. Endocrinol. Metab.* 2010 95: 2536-2559,

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Questionnaires

- A number of questionnaires have been proposed to help towards screening
  - Sensitive but not specific
- In subjects with sexual dysfunctions, structured interviews, eg Androtest, demonstrate enough sensitivity/specificity to raise suspicion of TD
- Diagnosis should not be based exclusively on questionnaires/interviews

Buvat J *et al. J Sex Med*. 2010;7:1627-1656.

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ADAM questionnaire

- Researchers at St. Louis University created the Androgen Deficiency in the Aging Male (ADAM) questionnaire, which has been shown to be a **highly sensitive (88%) instrument but with low specificity (66%),** largely due to questions that identify patients with depression.
- However, because many men with hypogonadism don't seek medical attention, instruments such as the ADAM questionnaire can be a useful way to screen for clinical symptoms of androgen deficiency.

ADAM questionnaire

1	Do you have a decrease in libido?
2	Do you have a lack of energy?
3	Do you have a decrease in strength and/or endurance?
4	Have you lost height?
5	Have you noticed a decreased "enjoyment of life"?
6	Are you sad and/or grumpy?
7	Are your erections less strong?
8	Have you noticed a recent deterioration in your ability to play sports?
9	Are you falling asleep after dinner?
10	Has there been a recent deterioration in your work performance?

- A positive questionnaire result is defined as a "yes" answer to
  - questions 1 or 7 or any 3 questions

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Summary

- There is clear under-treatment of hypogonadism
- Screening should be undertaken in certain populations according to recommendations, such as:
  - New patients with erectile dysfunction
  - Clinical conditions associated with insulin resistance (obesity, type 2 diabetes and metabolic syndrome)
- Questionnaires can be helpful to reach out to patients