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Experts issue recommendations to improve testosterone prescribing practices

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New scientific evidence has strengthened the case for reserving testosterone therapy for well-documented cases of hypogonadism, a condition where the body does not produce enough testosterone, Endocrine Society experts concluded in an updated Clinical Practice Guideline released today.

The guideline, entitled "Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline," was published online today and will appear in the May 2018 print issue of The *Journal of Clinical Endocrinology & Metabolism* (*JCEM*), a publication of the Endocrine Society. The availability of new information from some of the largest randomized trials of testosterone, recent improvements in testosterone measurements, combined with the growing public interest in issues related to men's health encouraged the Endocrine Society's initiative to update its testosterone treatment guideline, which was last released in 2010.

The Society debuted the guideline on the opening day of ENDO 2018, its 100th Annual Meeting & Expo. The meeting is taking place in Chicago though March 20.

"In a reflection of the growing attention paid to men's health issues, men's health clinics have mushroomed all over the country," said Shalender Bhasin, M.D., of Brigham and Women's Hospital in Boston, Mass., and chair of the task force that authored the guideline. "Yet recent surveys indicate many men are prescribed testosterone treatment

without an appropriate diagnostic work up or monitoring plan. Some men receiving testosterone therapy do not have adequately documented hypogonadism, while others who have hypogonadism are not receiving the needed treatment."

Testosterone therapy is recommended for hypogonadal men to correct symptoms of testosterone deficiency. Men who are otherwise healthy do not need to be screened for hypogonadism. The guideline calls for avoiding testing and treating healthy men for whom the risks and benefits of testosterone therapy are unclear.

The Society recommends against routinely prescribing testosterone therapy to all men age 65 or older with low testosterone concentrations. The treatment decisions should be individualized and guided by the intensity of symptoms, the presence of other co-morbid conditions, and an explicit discussion with the patient of the long-term risks and benefits of testosterone treatment in older men. The scientific evidence for this recommendation has grown stronger since the 2010 guideline was released.

Men should only be diagnosed with hypogonadism if they display symptoms of a testosterone deficiency and their measurements of total or free testosterone are unequivocally and consistently low. Diagnosing hypogonadism can be challenging because the symptoms are nonspecific and may vary, depending on the individual's age, other medical conditions and factors such as how long the testosterone deficiency has persisted.

Society experts note an individual's testosterone levels can vary greatly over time, so it is important to confirm measurements. About 30 percent of men whose testosterone is measured in the hypogonadal range will have normal concentrations when their levels are retested. In addition, there can be great variability among different testing methods and

laboratories. Clinicians should ideally measure total testosterone levels using an assay certified by the U.S. Centers for Disease Control and Prevention's accuracy-based standardization program or one verified by an external quality control program.

"We hope these recommendations will help clarify and dispel much of the misinformation about testosterone therapy," Bhasin said. "With this updated guideline, we were able to incorporate data from some of the most important randomized trials on testosterone conducted during the past three years. Relying on the latest and highest quality scientific evidence will help men and their healthcare providers determine when testosterone treatment is appropriate and when it is unlikely to benefit an individual's health."

Other members of the Endocrine Society task force that developed this guideline include: Juan P. Brito of the Mayo Clinic in Rochester, Minn.; Glenn R. Cunningham of Baylor College of Medicine in Houston, Texas; Frances J. Hayes of Massachusetts General Hospital in Boston, Mass.; Howard N. Hodis of the Keck School of Medicine at the University of Southern California in Los Angeles, Calif.; Alvin M. Matsumoto of Seattle VA Puget Sound Health Care System in Seattle, Wash.; Peter J. Snyder of the Perelman School of Medicine at the University of Pennsylvania in Philadelphia, Penn.; Ronald S. Swerdloff of Harbor UCLA Medical Center in Torrance, Calif.; Frederick C. Wu of the University of Manchester in Manchester, U.K.; and Maria A. Yialamas of Brigham and Women's Hospital in Boston, Mass.

The Society established the Clinical Practice Guideline Program to provide endocrinologists and other clinicians with evidence-based recommendations in the diagnosis and treatment of endocrine-related conditions. Each guideline is created by a task force of topic-related experts in the field. Task forces rely on evidence-based reviews of the literature in the development of guideline recommendations. The

Endocrine Society does not solicit or accept corporate support for its Clinical Practice Guidelines. All guidelines are supported entirely by Society funds.

The new guideline is co-sponsored by the European Society of Endocrinology.

More information: Shalender Bhasin et al, Testosterone Therapy in Men With Hypogonadism: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism* (2018). DOI: 10.1210/jc.2018-00229