

## ORIGINAL RESEARCH

## The International Society for Sexual Medicine's Process of Care for the Assessment and Management of Testosterone Deficiency in Adult Men

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DOI: 10.1111/jsm.12952

### ABSTRACT

**Introduction.** In 2014, the International Society for Sexual Medicine (ISSM) convened a panel of experts to develop an evidence-based process of care for the diagnosis and management of testosterone deficiency (TD) in adult men. The panel considered the definition, epidemiology, etiology, physiologic effects, diagnosis, assessment and treatment of TD. It also considered the treatment of TD in special populations and commented on contemporary controversies about testosterone replacement therapy, cardiovascular risk and prostate cancer.

**Aim.** The aim was to develop clearly worded, practical, evidenced-based recommendations for the diagnosis and treatment of diagnosis and management of TD for clinicians without expertise in endocrinology, such as physicians in family medicine and general urology practice.

**Method.** A comprehensive literature review was performed, followed by a structured, 3-day panel meeting and 6-month panel consultation process using electronic communication. The final guideline was compiled from reports by individual panel members on areas reflecting their special expertise, and then agreed by all through an iterative process.

**Results.** This article contains the report of the ISSM TD Process of Care Committee. It offers a definition of TD and recommendations for assessment and treatment in different populations. Finally, best practice treatment recommendations are presented to guide clinicians, both familiar and unfamiliar with TD.

**Conclusion.** Development of a process of care is an evolutionary process that continually reviews data and incorporates the best new research. We expect that ongoing research will lead to new insights into the pathophysiology of TD, as well as new, efficacious and safe treatments. We recommend that this process of care be reevaluated and updated by the ISSM in 4 years. **Dean JD, McMahon CG, Guay AT, Morgentaler A, Althof SE, Becher EF, Bivalacqua TJ, Burnett AL, Buvat J, El Meliegy A, Hellstrom WJG, Jannini EA, Maggi M, McCullough A, Torres LO, and Zitzmann M. The International Society for Sexual Medicine's process of care for the assessment and management of testosterone deficiency in adult men. J Sex Med 2015;12:1660–1686.**

**Key Words.** Testosterone Deficiency; Hypogonadism; Etiology of Hypogonadism; Assessment of Hypogonadism; Treatment of Hypogonadism

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## Introduction

In March 2014, the International Society for Sexual Medicine (ISSM) Testosterone Deficiency Guideline Committee met in New York for 3 days. The leadership of ISSM felt there was a need to publish a process of care for the diagnosis and management of testosterone deficiency (TD) based on increased awareness of the impact of TD on sexual and general health, and because of substantial scientific advances. Sexual medicine healthcare providers are particularly suited to provide care to men with TD as several of the most prominent symptoms are sexual in nature. The intended audience for this process of care is the general medical practitioner, although we believe other healthcare providers may benefit as well.

The 18 committee members were selected by peer recommendation and further vetted to provide a diversity of discipline, balance of opinion, knowledge, and geography. The committee was drawn from internationally recognized experts on TD in adult men and comprised 10 urologists, 1 psychologist, 2 endocrinologists, 2 primary care physicians, 1 sexual medicine physician, 1 genitourinary physician, 1 internal medicine physician, and 1 radiation oncologist.

All committee members were required to declare in advance any potential conflicts of interest with their participation in the committee's work. Committee members were asked to review all available evidence, not just the articles provided by the ISSM researchers, and prepare a presentation for the meeting on specific topics related to the guideline. The committee employed evidence-based medicine grading as the means of integrating individual clinical expertise with the best available external clinical evidence from systematic research. Table 7, with the *Conclusion* of this article, contains a summary of the relevant evidence-based recommendations of the Committee. In addition, recommendations are bold highlighted throughout the text. Quality of evidence was graded using the Oxford Centre of Evidence-Based Medicine system (March 2011) and the strength of recommendation with the GRADE system (2007).

The meeting was supported by an unrestricted grant from Repros Therapeutics Inc. However, ISSM required complete independence from industry during the development of the guideline and related resources. There were no industry representatives at the meeting and there was no attempt by industry to influence any part of the development or writing process at any time. The views or interests of the funding body, Repros Therapeutics Inc., have not influenced the final recommendations of the committee.

## Evidence Acquisition

MEDLINE, Web of Science, PsychINFO, and EMBASE and the proceedings of major international and regional scientific meetings were searched for publications or abstracts using the words in the title, abstract or keywords "testosterone," "hypogonadism," "testosterone deficiency," "testosterone replacement." This search was then manually cross-referenced for all articles. The substantial amount of evidence derived from this search was distilled by the members of the committee to a collection of key and seminal publications.

## Definition and Nosology

Defining TD is an essential prerequisite to diagnosis and clinical management. Achieving a generally accepted definition has been complicated by previous inconsistency in nosology, with terms that include *hypogonadism (primary, secondary, mixed, hypergonadotropic, hypogonadotropic subtypes), late-onset hypogonadism, androgen deficiency, and andropause* being used to describe some or all types of TD state.

ISSM recommends that the term "testosterone deficiency" is universally adopted and used in clinical practice, along with the following definition:

Testosterone deficiency is a clinical and biochemical syndrome characterized by a deficiency of testosterone, or testosterone action, and relevant symptoms and signs.

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