

Trends in Testosterone Prescription and Public Health Concerns



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KEYWORDS

- Testosterone supplementation therapy • Hypogonadism • Testosterone replacement therapy
- Late-onset hypogonadism

KEY POINTS

- Testosterone supplementation therapy has become increasingly popular since the turn of the century.
- In the U.S., most testosterone prescriptions are written by primary care providers, endocrinologists, or urologists.
- Due to conflicting results regarding the efficacy and safety of testosterone supplementation, the US Food and Drug Administration has asked manufacturers to clarify the labeling of these products and requested further research into the long term use of testosterone products.
- Results from these studies will help define the appropriate population for testosterone supplementation therapy going forward. It is hoped that these data combined with physician and public education will minimize inappropriate prescribing and allow those likely to benefit from testosterone supplementation therapy to receive it.

"It is important not to conclude that every old man who is tired is suffering from the male climacteric. This diagnosis should be made only after the most careful search has been carried out to discover some other cause for the symptoms."¹ This statement is from an article entitled Uses and Abuses of the Male Sex Hormone published in *The Journal of the American Medical Association* in 1946, when age-related hypogonadism was referred to as *climacteric*. The struggle to define what is appropriate use of testosterone supplementation therapy (TST) and what constitutes misuse of these drugs has

been present since the hormone was first synthesized in 1935.²

The intensity of public scrutiny has increased with the approval and marketing of various testosterone formulations since the turn of the century. In 2002, recognizing the public interest in testosterone products, the National Institute of Aging and the National Cancer Institute requested the Institute of Medicine conduct an assessment of clinical research on TST. The study concluded that uncertainties remain regarding the use of TST in older men.³ Further developments in both the popularity and risk profile of these medications

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have led to increasing public health concerns in recent years.

TRENDS IN THE PRESCRIPTION OF TESTOSTERONE

The continued research and development of a diverse range of testosterone formulations will continue to benefit men with hypogonadism. Much of the concern about the use of TST, however, has arisen because of the rapidly increasing number of men using TST in the United States (Table 1) and worldwide. Many of these men are prescribed testosterone for age-related decreases in testosterone (subsequently referred to as *late-onset hypogonadism* [LOH]) rather than classic androgen deficiency caused by pathologic conditions such as Klinefelter’s syndrome, orchiectomy, and chemotherapy. The trend of increasing use of TST has been documented in a variety of ways ranging from commercial insurance claims data to integrated health care systems.

Commercial Insurance Claims Data

Layton and colleagues⁴ used a commercial health insurance database, MarketScan Commercial Claims and Encounters, to evaluate trends in testosterone initiation in the United States from 2000 to 2011. The authors evaluated 410,000 men older than 18 years who initiated testosterone therapy each year. They calculated the population rates of testosterone initiation by using person-years of eligibility as the denominator (calculated by summing the continuously enrolled person-time for men in each year). The annual rate of testosterone initiation increased from 20.2 per 10,000 person-years in 2000 to 75.7 per 10,000 person-years in 2011—a nearly 4-fold increase—with an accelerating rate after 2008. Most men initiating testosterone therapy were relatively young (74% were between the ages of 40 and 64); however, commercial health insurance databases are limited by undersampling of men older than 65 who use Medicare as their primary source of health care coverage.

Baillargeon and colleagues⁵ used data from Clinformatics DataMart, one of the largest commercial health insurance populations, to examine testosterone-prescribing practice patterns from the years 2001 to 2011. The authors restricted the study to men age 40 years and older to focus on the issue of testosterone use in men with LOH. The database included more than 10 million men in this age group, with at least 1 million men covered by insurance every year of the decade studied. They found that testosterone use increased 3-fold between 2001 and 2011. In 2001, 0.81% of men older than 40 years were using TST compared with 2.91% in 2011. Use of topical gel formulations of testosterone had the largest increase with a 5-fold increase during the decade. Again, one limitation of this report is its reliance on commercial health insurance, which undersamples men older than 65 years.

Pharmacy Sales

Using data obtained from IMS Consulting, the 2002 Institute of Medicine study reported that although sales of testosterone products were steady at approximately \$18 million per year until 1988, the annual sales of these products was \$400 million by 2002.⁶ The number of testosterone prescriptions written increased from 648,000 in 1999 to 1.75 million in 2002, a 170% increase.³ The first gel preparation of testosterone was approved for use in the United States in 2000.

The US Food and Drug Administration (FDA) held a joint meeting between the Bone, Reproductive, and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee on September 17, 2014. During the meeting, Mohamed A. Mohamoud from the FDA’s Office of Surveillance and Epidemiology presented recent prescription sales data using the Symphony Healthcare Solutions Anonymous Patient Longitudinal Database.⁷ This database captured unique patients filling a prescription for testosterone at outpatient pharmacies throughout the nation. National projections from these data estimated that the number of men filling

Table 1 Percentage increase in the use of TST in the United States						
Study	Database Type	Population	Number	Years Studied	% Increase	
Baillargeon et al, ⁵ 2013	Commercial insurance	>40 y	10,739,815	2001–2011	359	
Layton et al, ⁴ 2014	Commercial insurance	>18 y	410,019	2000–2010	374	
Jasuja et al, ⁸ 2015	Veteran Affairs	>20 y	111,631	2009–2012	78	
Nguyen et al, ⁷ 2015	Outpatient pharmacy	All ages	7,246,013	2010–2013	183	

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