New testosterone guideline to help Canadian physicians diagnose and treat patients

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Controversy exists about how to manage patients with low testosterone, and many health care professionals are reluctant to treat testosterone deficiency, but a new guideline aims to provide a road map to help diagnose and treat this health condition. The guideline, created by the Canadian Men's Health Foundation and published in *CMAJ* (*Canadian Medical Association Journal*), targets primary care physicians, general internists, endocrinologists, geriatricians and urologists as well as psychiatrists, nurse practitioners and pharmacists who deal with men at or beyond middle age.

"The use of hormone replacement in both women and men has been a topic of much controversy over the years," states Dr. Alvaro Morales, chair of the guideline group and a urologist in the Department of Urology, Queen's University, Kingston, Ontario. "The situation for men is even more complex than for women since, as opposed to menopause, testosterone deficiency syndrome [TDS] is not an unavoidable age-related occurrence. It is a mistake to extrapolate the experience of hormone replacement therapy for menopause in women to the management of TDS in men."

Although older Canadian men are being treated for testosterone deficiency, many have not been clinically diagnosed with a deficiency. A recent study found that 1 in 90 men over age 65 had been prescribed testosterone replacement therapy, but only 6% of them had a conclusive diagnosis of low testosterone.

Symptoms of testosterone deficiency include fatigue, sexual symptoms, mood changes, weight gain, decrease in muscle mass and strength, sleep disturbance and more. They may be subtle and can be affected by age, other illnesses and medications. Diagnosing testosterone deficiency can be difficult because some laboratory tests have varying degrees of accuracy.

"The task force recognizes that the management of testosterone deficiency syndrome remains highly controversial and that, in many instances, the evidence continues to be of doubtful quality," states Dr. Morales. "However, health professionals must deal with patients presenting with clinical manifestations and biochemical confirmation of the diagnosis."

To address the gap in clinical practice information on testosterone deficiency, the Canadian Men's Health Foundation (CMHF) created the CMHF Multidisciplinary Guidelines Task Force on Testosterone Deficiency with members from diverse clinical areas. Although other guidelines for testosterone therapy exist, this new guideline, based on the latest evidence, was created for a broad multidisciplinary Canadian audience of general and specialist physicians and other health care providers.

"The management of testosterone deficiency syndrome has been controversial for decades and contributes substantially to the uncertainty among clinicians," write the authors. "Prominent among controversial issues are concerns about the diagnostic accuracy of laboratory tests and cardiovascular and prostate health."

Key recommendations:

Diagnosis

- Physicians should conduct a thorough patient history and physical examination to identify patients who should undergo biochemical testing.
- The initial biochemical test should be measurement of total testosterone levels in samples taken in the morning between 7 am and 11 am (or within 3 hours after waking for shift workers).

Treatment and monitoring

- Men with a diagnosis of testosterone deficiency and no contraindications should receive testosterone therapy.
- If symptoms of testosterone deficiency are convincing but laboratory tests are uncertain, a 3-month trial of testosterone replacement therapy is recommended.
- For men who wish to preserve fertility over relieving symptoms, the task force recommends against testosterone therapy.
- Men with testosterone deficiency syndrome and stable cardiovascular disease are candidates for testosterone treatment.
- For men with metastatic prostate cancer, the task force recommends against treatment for testosterone deficiency.
- Assessment of a patient's response to testosterone therapy at 3 and 6 months is recommended, looking at benefits and adverse effects.

"We hope [this guideline] will help physicians and their patients navigate the murky waters of testosterone deficiency," states Dr. Morales.

The guideline authors note that new research will expand the understanding of testosterone deficiency and may help settle the controversy around the condition. They expect to update the guideline in the next three to five years.

To help patients and their physicians make informed decisions, CMHF

has developed two health awareness programs: YouCheck.ca provides a man with his 10-year self-risk assessment of developing six diseases including testosterone deficiency. DontChangeMuch.ca helps men prevent the onset of chronic health conditions by encouraging them to take small steps toward a healthier lifestyle.

In a related commentary , Professor Geoffrey Hackett, a urologist at Heartlands Hospital, Birmingham, United Kingdom, and a researcher in testosterone deficiency, writes, "Testosterone deficiency syndrome is an area fraught with disagreement and controversy. A new Canadian guideline from the Canadian Men's Health Foundation is welcomed in the light of the huge volume of research on this topic over the last five years."

He states that there are many areas of testosterone deficiency syndrome for which there is no consensus about diagnosis and treatment. For example, he recommends a 6-month trial of testosterone therapy rather than the 3-month period indicated by the guideline.

"Many will welcome the clarity provided by the new Canadian guideline and other recently revised guidelines, but many important clinical issues remain unresolved. Unfortunately, it is unlikely that the ideal clinical trials required to provide the highest levels of evidence will ever be done for ethical, practical and financial reasons," Professor Hackett concludes.

More information: Guidelines: www.cmaj.ca/lookup/doi/10.1503/cmaj.150033

Commentary: www.cmaj.ca/lookup/doi/10.1503/cmaj.151208