



Body System: Reproductive-Male		
Session Topic: Male Hypogonadism		
Educational Format		Faculty Expertise Required
REQUIRED	Interactive Lecture	Expertise in the field of study. Experience teaching in the field of study is desired. Preferred experience with audience response systems (ARS). Utilizing polling questions and engaging the learners in Q&A during the final 15 minutes of the session are required.
OPTIONAL	Problem-Based Learning (PBL)	Expertise teaching highly interactive, small group learning environments. Case-based, with experience developing and teaching case scenarios for simulation labs preferred. Other workshop-oriented designs may be accommodated. A typical PBL room is set for 50-100 participants, with 7-8 each per round table. <u>Please describe your interest and plan for teaching a PBL on your proposal form.</u>
Professional Practice Gap	Learning Objective(s) that will close the gap and meet the need	Outcome Being Measured
<ul style="list-style-type: none"> Knowledge and practice gaps exist with regard to identifying the primary symptoms and clinical features of patients with hypogonadism, particularly hypogonadism as a comorbidity of other health conditions. Knowledge and practice gaps exist with regard to diagnosing hypogonadism, particularly in the selection of appropriate laboratory tests, imaging studies, bone densitometry, genetic studies, testicular ultrasonography, or performing a differential diagnosis Knowledge and practice gaps exist with regard to developing effective treatment therapy plans for hypogonadism that take into account complications of treatments for other conditions, and that include monitoring and follow-up 	<ol style="list-style-type: none"> Recognize the pathophysiology and the classification of primary and secondary hypogonadism, as well as the causes of HG associated with each classification. Diagnose HG by appropriate laboratory testing, understand when differential diagnosis is required, when to order an MRI as indicated in men with secondary HG, when to order pituitary imaging, when to order bone densitometry studies, and when to refer to an endocrinologist. Recognize and manage HG comorbidities. Develop treatment plans that take into account complications of treatments for other conditions, and that include monitoring and follow-up. 	Learners will submit written commitment to change statements on the session evaluation, indicating how they plan to implement presented practice recommendations.



<ul style="list-style-type: none"> • Knowledge and practice gaps exist with regard to the management of ED. • Knowledge and practice gaps exist with regard to managing ED as a complication of diabetes. • Knowledge and practice gaps exist with regard to managing medical interactions of polypharmacy. • Knowledge and practice gaps exist with regard to providing sexual counseling. • Treatment updates for diabetes are considered by many physicians as their primary need, particularly with regard to appropriate initial (titration) and maintenance dosing with insulin analogs to achieve adequate glycemic control, and for managing associated co-morbid conditions. • There has been a dramatic increase in inappropriate use of testosterone therapy in healthy middle-aged and older men. 		
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ACGME Core Competencies Addressed (select all that apply)

X	Medical Knowledge		Patient Care
X	Interpersonal and Communication Skills		Practice-Based Learning and Improvement
	Professionalism		Systems-Based Practice

Faculty Instructional Goals

Faculty play a vital role in assisting the AAFP to achieve its mission by providing high-quality, innovative education for physicians, residents and medical students that will encompass the art, science, evidence and socio-economics of family medicine and to support the pursuit of lifelong learning. By achieving the instructional goals provided, faculty will facilitate the application of new knowledge and skills gained by learners to practice, so that they may optimize care provided to their patients.

- Provide recommendations to help learners understand the pathophysiology and the classification of primary and secondary hypogonadism, as well as the causes of HG associated with each classification
- Provide recommendations for diagnosing HG by appropriate laboratory testing,



understand when differential diagnosis is required, when to order an MRI as indicated in men with secondary HG, when to order pituitary imaging, when to order bone densitometry studies, and when to refer to an endocrinologist

- Provide recommendations for recognizing and manage HG comorbidities
- Provide strategies for developing treatment plans that take into account complications of treatments for other conditions, and that include monitoring and follow-up.
- Provide strategies and resources for counseling patients regarding pharmacologic and non-pharmacologic (e.g. lifestyle modifications, behavioral, alternative therapies, surgical and procedural) therapies for those with diagnosed erectile dysfunction.
- Provide recommendations for screening patients with diagnosed erectile dysfunction for cardiovascular risk factors.
- Provide an overview of current evidence-based ED pharmacologic and non-pharmacologic therapies, including recommendations for managing medical interactions of polypharmacy.
- Provide evidence-based recommendations for treating low-T as indicated by diagnosis and evaluation.
- Provide recommendations regarding guidelines for Medicare reimbursement.
- Provide recommendations to maximize office efficiency and guideline adherence to the diagnosis and management of hypogonadism.
- Provide an overview of newly available treatments, including efficacy, safety, contraindications, and cost/benefit relative to existing treatments.
- Provide instructions regarding the incorporation and use of the PCMH/ACO/Primary Care Core Measure Set into practice.

Needs Assessment

The prevalence of hypogonadism (HG) is high; however, estimates differ according to the definition used. The crude prevalence in men ≥ 45 years presenting to primary care offices is 38.7%; however, only an estimated 5-35% HG males receive treatment for their condition.^{1,2} Patients with HG have higher direct and indirect medical costs and higher comorbidity rates compared to patients without HG; on average, experiencing risk-adjusted direct costs of \$4,000 per year and indirect costs of \$900 per year more than patients without HG.³ Patients with HG experience significant comorbidities such as such as obesity, type 2 diabetes, hypertension, depression, osteoporosis and metabolic syndrome; thus significantly reduce the quality of life and has resulted in the loss of livelihood and separation of couples, leading to divorce.^{1,4}

During more than 422 million ambulatory office visits in 2010, 27.9% of men presented with hypertension, 12.8% presented with diabetes, 6.8% presented with depression, 6.0% presented with obesity, and 0.7% presented with osteoporosis.⁵ As there is a high prevalence of HG in the older adult male and that segment of the population in projected to rise, family physicians are increasingly likely to have to treat HG and comorbidities of HG in their practice. In fact, there is some evidence that filling a prescription for testosterone therapy is associated with an increased likelihood of experiencing an MI, especially in older men and those with a history of cardiovascular disease.⁶



Testosterone is necessary for normal sexual development in boys and fertility and healthy sexual function in adult men. It is also increasingly recognized as an essential component in biochemical and metabolic pathways affecting muscle mass and strength, fat accumulation, bone density, insulin sensitivity, energy, and mood.⁷ Left untreated, testosterone deficiency may compromise sexual function, bone strength, and body composition, and may increase patients' risk for diabetes and CVD.^{8,9} Testosterone deficiency often goes undiagnosed, for various reasons.¹⁰ For example, nonspecific symptoms are sometimes attributed to other conditions and may confound diagnosis. Testosterone levels may vary widely as a result of episodic secretion, circadian rhythms, and differences in assay methodology, among other causes. In addition, patients may be embarrassed about sexual symptoms and thus reticent to report them; similarly, physicians may hesitate to ask questions about sexual health that might reveal symptoms of testosterone deficiency. Other barriers to recognition include clinical presentations that vary depending on the age of onset and inconsistencies in terminology and definitions for testosterone deficiency and hypogonadism.^{11,12}

Testosterone treatment, used primarily to treat symptoms of sexual dysfunction in men and hot flashes in women, is controversial for men and even more so for women.¹³ Potential benefits may include improved libido, increased bone mass, and increased sense of well-being, not to mention that a growing body of evidence shows a relationship between low serum testosterone levels and the development of chronic disease.¹⁴ However, no consistent relationship has been proven between testosterone levels and symptoms purportedly associated with Low T. Decreased energy, increased body fat, reduced muscle mass and strength, and reduced sex drive are nonspecific symptoms associated with aging. Testosterone may increase libido, but testosterone levels do not correlate with sexual function.¹⁵ However, there has been a dramatic increase in inappropriate use of testosterone therapy in healthy middle-aged and older men. This is likely due, at least in part, to direct-to-consumer advertising encouraging use of testosterone products for nonspecific symptoms, such as decreased energy and sexual interest.¹⁶⁻¹⁹ Also, a recent study that reported an association between testosterone therapy and adverse cardiovascular outcomes had serious methodologic flaws, such as the omission of 1,132 men from the statistical analysis.¹⁴ The use of testosterone treatment continues to be highly debated. Physicians need to be kept up to date on the latest research and evidence-based clinical guidelines, and understand that the diagnosis of testosterone deficiency should be made only on the basis of clinical symptoms and signs consistent with androgen deficiency and consistently subnormal serum testosterone concentrations at 8 to 10 AM on three occasions.

Erectile dysfunction (ED) is the most prevalent sexual problem in men, causing significant negative impact on intimate relationships, quality of life, and self-esteem; and may also be the presenting symptom of undetected cardiovascular disease.²⁰⁻²² In fact, men with ED are at a 65% increased relative risk of developing coronary heart disease and a 43% increased risk of stroke within 10 years, and should therefore be screened for cardiovascular risk factors.^{20,22-24} The National Institutes of Health estimates that ED affects as many as 30 million men in the United States.²⁵ However, ED is under-reported due primarily to patient embarrassment about the issue; particularly among patients who receive care from other sub-specialties for health conditions that impact sexual performance, such as urologists and oncologists.^{26,27} Despite the high prevalence of ED and the recognition of the benefits from treatment, ED is under treated as several barriers to optimal management exist, including physician-patient communication and physician



recognition of patient and partner preferences.^{28,29} Approximately 12.5% to 35% of men with ED have low testosterone (low-T) levels however, research study evidence was insufficient to verify if men with ED had a higher prevalence of hypogonadism or hyperprolactinemia compared with men without ED; therefore, the value of routine hormone testing is uncertain.³⁰

Data from the most recent AAFP CME Needs Assessment Survey indicate that family physicians report having a knowledge gap regarding the management of hypogonadism (HG) and associated comorbidities such as diabetes, obesity, depression, and metabolic syndrome; but gaps also existed in managing pituitary diseases, which are a related cause of secondary acquired HG. This same data also suggest that physicians have knowledge and practice gaps related to the management of erectile dysfunction, sexual counseling, and cardiovascular problems associated with ER.³¹ Lifestyle modification and modifying pharmacotherapy are first-line therapies for ED; however, physicians have knowledge gaps in managing medical interactions of polypharmacy and providing sexual counseling, including inadequate sexual history assessments during the time surrounding the initial prescription of ED medication.^{22,31,32}

More specifically, CME outcomes data from 2013 AAFP Assembly (currently FMX): *Hit Below the Belt: Winning Strategies to Combat Men's Health Issues*, 2014 AAFP Assembly: *Hypogonadism (Male): Evidence-Based Management*, and 2015 AAFP FMX *Erectile Dysfunction and Impotence* sessions suggest that physicians have knowledge and practice gaps with regard to when to sample blood for testosterone deficiency; which testosterone replacement therapy (TRT) provides more stable serum concentrations; the appropriate frequency of hematocrit measurement; identification of low-T symptoms (other than a decrease in spontaneous erections); involving the patient's spouse in treatment considerations; appropriate timing of referral; and monitoring/follow-up after treatment.³³⁻³⁵ Additionally, patients with diabetes are three times more likely to have ED compared to the general population; however, AAFP CME Needs Assessment Survey data indicates that family physicians have a knowledge gap with regard to managing complications of diabetes.^{22,31}

Physicians may improve their care of patients with HG by engaging in continuing medical education that provides practical integration of current evidence-based guidelines and recommendations into their standards of care; including, but not limited to the following:^{11,13}

- Only make a diagnosis of androgen deficiency only in men with consistent symptoms and signs and unequivocally low serum testosterone levels.
- Testosterone supplementation should not be considered in patients with prostate cancer.
- Testosterone supplementation should be considered when treating sexual dysfunction in hypogonadal men.
- Testosterone therapy, as a general policy, should not be offered to all older men with low testosterone levels.
- Men with human immunodeficiency virus infection or acquired immunodeficiency syndrome; who also have diminished mood, strength, libido, and well-being; often benefit from testosterone use.
- Until more consistent data are available, testosterone should be used with caution and only for those indications approved by the FDA.



- Patients receiving testosterone therapy should be evaluated 3 to 6 months after treatment initiation and then annually to assess whether symptoms have responded to treatment and whether the patient is suffering any adverse effects, and to check compliance.
- Repeat bone mineral density of the lumbar spine, femoral neck, and hip after 1 to 2 yr of testosterone therapy in hypogonadal men with osteoporosis or low trauma fracture.

In the management of HG in the primary care setting, family physicians should be able to:^{1,4,13,22,36-42}

- Recognize the primary symptoms and clinical features of HG through the history and physical examination to inform the diagnosis
- Understand the pathophysiology and the classification of primary and secondary hypogonadism, as well as the causes of HG associated with each classification
- Diagnose HG by appropriate laboratory testing, understand when differential diagnosis is required, when to order an MRI as indicated in men with secondary HG, when to order pituitary imaging, when to order bone densitometry studies, and when to refer to an endocrinologist
- Recognize and manage HG comorbidities
- Develop treatment plans that take into account complications of treatments for other conditions, and that include monitoring and follow-up

Physicians may improve their care of patients with ED by engaging in continuing medical education that provides practical integration of current evidence-based guidelines and recommendations into their standards of care; including, but not limited to the following:^{21,22,43-48}

- Diagnostic testing for erectile dysfunction should usually be limited to obtaining a fasting serum glucose level and lipid panel, thyroid-stimulating hormone test, and morning total testosterone level.
- First-line therapy for erectile dysfunction should consist of oral phosphodiesterase type 5 inhibitors.
- Phosphodiesterase type 5 inhibitors are most effective in the treatment of erectile dysfunction associated with diabetes mellitus and spinal cord injury, and of sexual dysfunction associated with antidepressants.
- Additional therapy for erectile dysfunction may consist of psychosocial therapy and testosterone supplementation in men with hypogonadism.
- Testosterone supplementation in men with hypogonadism improves erectile dysfunction and libido.
- Screening for cardiovascular risk factors should be considered in men with erectile dysfunction.
- The American College of Physicians recommends that clinicians initiate therapy with a PDE-5 inhibitor in men who seek treatment for erectile dysfunction and who do not have a contraindication to PDE-5 inhibitor use (Grade: strong recommendation; high-quality evidence).
- The American College of Physicians recommends that clinicians base the choice of a specific PDE-5 inhibitor on the individual preferences of men with erectile dysfunction, including ease of use, cost of medication, and adverse effects profile (Grade: weak recommendation; low-quality evidence).



- The American College of Physicians does not recommend for or against routine use of hormonal blood tests or hormonal treatment in the management of patients with erectile dysfunction (Grade: insufficient evidence to determine net benefits and harms).
- Boosting low testosterone levels into the normal range does not further improve the effectiveness of sildenafil in men with erectile dysfunction.

The guideline, *Hormonal Testing and Pharmacologic Treatment of Erectile Dysfunction*, was developed by the American College of Physicians and was endorsed by the American Academy of Family Physicians. The Canadian Urological Association recently released their *2015 CUA Practice guidelines for erectile dysfunction*. It may be helpful to point out any relevant recommendations that may be considered by U.S. physicians.⁴⁹

Appropriate care has been defined as providing a net health benefit for the patient or providing the right intervention to the right patient in the right setting at the right time. Overuse refers to medical services that are unnecessary, likely to lead to more harms than benefits, or both; such services are responsible for an estimated \$150 billion to \$200 billion in wasted health care spending in the United States each year. Although overuse can involve specialist procedures such as coronary revascularization or colonoscopy, it also occurs in tests or treatments provided in primary care settings.⁵⁰

The American Academy of Family Physicians (AAFP) is committed to supporting the Choosing Wisely® campaign with the goal of ensuring high-quality, cost-effective care for patients.⁵¹ With regard to testosterone therapy, physicians should be familiar with the following recommendations:⁵²⁻⁵⁵

- Don't prescribe testosterone or testosterone products to men contemplating/ attempting to initiate pregnancy.
- Don't prescribe testosterone to men with erectile dysfunction who have normal testosterone levels.
- Don't prescribe testosterone therapy unless there is biochemical evidence of testosterone deficiency.
- Don't prescribe testosterone therapy unless there is laboratory evidence of testosterone deficiency.

These recommendations are provided only as assistance for physicians making clinical decisions regarding the care of their patients. As such, they cannot substitute for the individual judgment brought to each clinical situation by the patient's family physician. As with all clinical reference resources, they reflect the best understanding of the science of medicine at the time of publication, but they should be used with the clear understanding that continued research may result in new knowledge and recommendations. These recommendations are only one element in the complex process of improving the health of America. To be effective, the recommendations must be implemented. As such, physicians require continuing medical education to assist them with making decisions about specific clinical considerations.

The American Academy of Family Physicians Academy has participated in the Core Measures Collaborative (the Collaborative) convened by America's Health Insurance Plans (AHIP) since August 2014. The Collaborative is a multi-stakeholder effort working to define core measure sets



of various specialties promoting alignment and harmonization of measure use and collection across both public and private payers.

Participants in the Collaborative included Centers for Medicare and Medicaid Services (CMS), the National Quality Forum (NQF), private payers, provider organizations, employers, and patient and consumer groups. This effort exists to decrease physician burden by reducing variability in measure selection, specifications and implementation– making quality measurement more useful and meaningful for consumers, employers, as well as public and private clinicians.

With significant AAFP input, a PCMH/ACO/Primary Care Core Measure Set has been developed for primary care. The goal of this set is to decrease burden and allow for more congruence between payer reporting programs.⁵⁶

Resources: Evidence-Based Practice Recommendations/Guidelines/Performance Measures

- Testosterone therapy in men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline¹¹
- Testosterone treatments: why, when, and how?¹³
- Osteoporosis in men⁴²
- Management of erectile dysfunction²²
- ACP Hormonal Testing and Pharmacologic Treatment of Erectile Dysfunction: A Clinical Practice Guideline³⁰
- AUA: The management of erectile dysfunction⁴⁷
- Medication adherence: we didn't ask and they didn't tell⁵⁷
- Engaging Patients in Collaborative Care Plans⁵⁸
- Health Coaching: Teaching Patients to Fish⁵⁹
- Simple tools to increase patient satisfaction with the referral process⁶⁰
- The benefits of using care coordinators in primary care: a case study⁶¹
- Adding health education specialists to your practice⁶²
- Integrating a behavioral health specialist into your practice⁶³
- Are you ready to discuss complementary and alternative medicine?⁶⁴
- FamilyDoctor.org. Erectile Dysfunction | Causes & Risk Factors (patient education)⁶⁵

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