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Testosterone Replacement Therapy

A Clinical Primer for Testosterone-Naive Male Patients

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Audience: This protocol is intended for clinicians (MDs, DOs, NPs, PAs) with a foundational understanding of physiology and pharmacology who are seeking to expand or solidify their knowledge base regarding the initiation and management of testosterone replacement therapy for adult male patients.

Scope: This document focuses on the straightforward initiation and monitoring of TRT in **testosterone-naive male patients**. It does not cover complex scenarios such as managing fertility, addressing anabolic steroid abuse history, or navigating significant comorbidities that may complicate treatment.

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Institution: Testosteronology Society™ Clinical Review Board

Date: October 2025

1. The Typical Patient Requiring TRT 6
Common Patient Profile: 6
2. Signs and Symptoms of Hypogonadism[2] 6
Category 6
Common Signs & Symptoms 6
Sexual 6
Physical 6
Cognitive/Mood 7
3. Typical Laboratory Values for Diagnosis[2] 7
Initial Required Bloodwork: 7
Lab Test 7
Typical Reference Range (Adult Male) 7
Key Findings & Interpretation 7
Total Testosterone 7
Free Testosterone 7
Luteinizing Hormone (LH) 7
Follicle-Stimulating Hormone (FSH) 8
Complete Blood Count (CBC) 8
Comprehensive Metabolic Panel (CMP) 8
Sex Hormone Binding Globulin (SHBG) 8
Ancillary Supporting Lab Panel: 8
Lab Test 8
Typical Reference Range 8
Rationale 8
Estradiol (E2) 8
Prostate-Specific Antigen (PSA) 8
Lipid Profile (including ApoB and Lp(a)) 8
Iron Profile 9
Serum Iron: 9

TESTOSTERONOLOGY®

Vitamin D, 25-Hydroxy 9
Prolactin 9
Hemoglobin A1c (HbA1c) 9
TSH & Free T4, T3 9
Semen Analysis 9
IGF-1, fasting insulin, bioavailable T, Free T3, thyroid antibodies 9
Estrogen is an important monitoring tool. However, caution should be practiced with using aromatase inhibitors (AIs) as a method to control estrogen. 9
4. Common Differential Diagnoses 10
Condition 10
Overlapping Symptoms 10
Key Differentiating Factors / Workup 10
Depression/Anxiety 10
Hypothyroidism 10
Obstructive Sleep Apnea (OSA) 10
Nutrient Deficiencies 10
Chronic Illness / Stress 10
Cancer and Chemotherapy[4] 10
Substance Use[5] 10
Chronic Corticosteroids[2] and Cushing's Syndrome 10
5. Monitoring and Adjustment of Therapy (The ABCDEs) 11
A — A1C (Impaired Fasting Glucose, Impaired Insulin Sensitivity Prediabetes, and Diabetes)[6] 11
Medication Considerations: 11
Preferred: 11
Avoid: 11
B — Blood Pressure (BP)[11] 11
Medication Considerations: 12
The 2025 AHA guidelines removed race-based recommendations for use of ACEi and ARBs[12]. 12

TESTOSTERONOLOGY®

C — Cholesterol and Cardiac Health[13] 12
Medication Considerations: 12
D — Deposition (Heme) 12
Management of Erythrocytosis: 12
Contributing Factors: 13
E – Experience[14]: 13
S – Screening: 13
6. Dosing and Administration 13
Generic 14
Brand 14
Strength 14
Route 14
Half Life 14
Dosing 14
Pearls 14
Testosterone Cypionate[18] 14
Testosterone Enanthate[19] 14
References are unclear 14
Testosterone Undecanoate Oral Capsule[20-22] 14
Testosterone Esters[23] 15
Formulated in Peanut oil (ALLERGIES) 15
7. Drug-Drug Interactions[18]: 15
8. Figures 16
9. References: 18

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1. The Typical Patient Requiring TRT

The patient presenting for evaluation for TRT is typically a male between **30 and 60 years old**. While hypogonadism can occur at any age, this range captures the period where age-related decline in testosterone production often intersects with a patient's awareness of symptoms impacting their quality of life[1].

Common Patient Profile:

- **Age:** Most commonly in their late 30s to 50s.
- **Lifestyle:** May range from sedentary to active, but often reports a decrease in energy and performance that is inconsistent with their perceived level of effort.
- **Chief Complaint:** Often presents with vague, non-specific complaints such as "I just don't feel like myself anymore," "I'm tired all the time," or "I've lost my edge."
- **Motivation:** Seeking to improve energy levels, libido, cognitive function, and overall sense of well-being.

2. Signs and Symptoms of Hypogonadism[2]

The presentation of low testosterone is often multi-faceted, affecting physical, sexual, and cognitive domains. It's crucial to conduct a thorough review of systems, as patients may not initially connect all their symptoms to a potential hormonal deficiency.

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Category	Common Signs & Symptoms
Sexual	• Decreased libido (sexual desire) • Erectile dysfunction (difficulty achieving/maintaining an erection and decreased frequency of morning erections)
Physical	• Persistent fatigue and low energy levels • Increased body fat, particularly visceral adiposity • Decreased muscle mass and strength • Reduced exercise tolerance and recovery • Hot flashes or sweats (less common) • Lower Urinary Tract Symptoms

COGNITIVE/MOOD	• "Brain fog" or difficulty with concentration and memory • Decreased motivation and drive • Irritability or mood swings • Difficulty sleeping or reporting non restful sleep • Symptoms of depression or dysthymia • Anxiety

- Common ICD-10 codes that can be used for insurance billing

3. TYPICAL LABORATORY VALUES FOR DIAGNOSIS[2]

Laboratory testing is essential for confirming hypogonadism. Blood samples must be drawn **between 7 AM and 10 AM** on at least two separate occasions.

INITIAL REQUIRED BLOODWORK:

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LAB TEST	TYPICAL REFERENCE RANGE (ADULT MALE)	KEY FINDINGS & INTERPRETATION
TOTAL TESTOSTERONE	300 - 1000 ng/dL[3] (Figure 1-4) You can use this tool to convert units.	A testosterone level **<300 ng/dL** is generally considered the diagnostic threshold. For insurance coverage, two separate test results below this level are typically required.
FREE TESTOSTERONE	5 - 21 ng/dL (varies by lab) Or 50 - 210 pg/mL	Low free T can be clinically significant even with low-normal total T.
LUTEINIZING HORMONE (LH)	1.5 - 9.3 mIU/mL	Differentiates primary (high LH) vs. secondary (low/normal LH) hypogonadism.

Follicle-Stimulating Hormone (FSH)	1.4 - 18.1 mIU/mL	Assessed alongside LH to evaluate the HPG axis.	Ancillary
Complete Blood Count (CBC)	Hgb: 13-17 g/dL Hct: 42-52% RBC: 4.5-6.1 million cells/mcL WBC: 4-10 K cells/mcL Plt: 150-400 K/mcL	Baseline to monitor for erythrocytosis (Hct >50% is a relative contraindication).	
Comprehensive Metabolic Panel (CMP)	Varies	Assess baseline liver and kidney function.	
Sex Hormone Binding Globulin (SHBG)	10 - 50 nmol/L	Helps interpret total testosterone levels.	

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Supporting Lab Panel:

This panel includes tests that are important to consider based on the patient's specific clinical presentation and risk factors.

Lab Test	Typical Reference Range	Rationale
Estradiol (E2)	< 50 pg/mL	Baseline to monitor aromatization. (High-normal laboratory values while on TRT are not indicative of hyperestrogenism.)*
Prostate-Specific Antigen (PSA)	< 4.0 ng/mL	serum PSA concentration **greater than 1.4 ng/mL within the first 12 months** of starting testosterone treatment should prompt a urology referral and consideration of TRT
Lipid Profile (including ApoB and Lp(a))	**Total Cholesterol** <200 mg/dL **LDL** <100 mg/dL **HDL** >60 mg/dL	Establishes baseline cardiovascular risk; TRT can affect lipid parameters.

	TG <150 mg/dL **ApoB** < 90 mg/dL **Lp(a)** < 75 nmol/L or < 30 mg/dL	*Note: A patient achieving optimal parameters is rare, but this is the goal.*
Iron Profile	**Ferritin:** 30-300 ng/mL Serum Iron: Males: 65 to 175 mcg/dL Females: 50 to 170 mcg/dL **TIBC:** 240 to 450 mcg/dL **TSAT:** 20-45%	Baseline to assess iron stores before monitoring for erythrocytosis and crucial to rule out hemochromatosis
Vitamin D, 25-Hydroxy	30 - 80 ng/mL	Deficiency is common and can cause overlapping symptoms like fatigue and low mood.
Prolactin	< 20 ng/mL	Crucial for workup of secondary hypogonadism to rule out a prolactinoma.
Hemoglobin A1c (HbA1c)	< 5.7%	Assesses for underlying insulin resistance or diabetes, which are linked to low T.
TSH & Free T4, T3	TSH: 0.4-4.0 mIU/L	Screens for hypothyroidism, a key differential diagnosis with overlapping symptoms. Low thyroid is correlated with lower SHBG, T and E.
Semen Analysis	Varies	Baseline for assessing fertility before starting TRT
IGF-1, fasting insulin, bioavailable T, Free T3, thyroid antibodies	Varies	Conflicting consensus. Can order if s/sx point towards it.

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Estrogen is an important monitoring tool. However, caution should be practiced with using aromatase inhibitors (AIs) as a method to control estrogen.

4. Common Differential Diagnoses

The symptoms of hypogonadism are non-specific and overlap with several other common conditions. It is imperative to consider and rule out these diagnoses before attributing symptoms solely to low testosterone.

Condition	Overlapping Symptoms	Key Differentiating Factors / Workup
Depression/Anxiety	Low mood, anhedonia, fatigue, decreased libido, poor concentration.	A validated depression screen (e.g., PHQ-9). Symptoms may persist despite normalized testosterone levels.
Hypothyroidism	Fatigue, weight gain, cognitive slowing ("brain fog"), hair loss, decreased libido.	TSH and Free T4 testing. Physical exam may reveal thyromegaly, bradycardia, or delayed reflexes.
Obstructive Sleep Apnea (OSA)	Severe fatigue, poor concentration, irritability, erectile dysfunction, obesity.	Epworth Sleepiness Scale, STOP-BANG questionnaire. Definitive diagnosis via polysomnography (sleep study).
Nutrient Deficiencies	Fatigue, weakness, mood changes.	Check Vitamin D, Vitamin B12, and iron studies (ferritin, iron, TIBC).
Chronic Illness / Stress	Fatigue, low motivation, poor recovery.	Thorough history. Elevated cortisol and inflammatory markers may be present.
Cancer and Chemotherapy[4]	Fatigue, weakness, muscle loss, sexual dysfunction.	Thorough history
Substance Use[5]	Heavy alcohol intake, chronic opioids, and AAS can all cause hypogonadism	Thorough history including social history.
Chronic Corticosteroids and Cushing's Syndrome	Identified by the endocrine guidelines as a cause for hypogonadism	Thorough history and physical exam.

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5. Monitoring and Adjustment of Therapy (The ABCDEs)

Once TRT has been initiated, ongoing monitoring is crucial to ensure efficacy and safety. The "ABCDEs" framework helps to systematically manage key cardiometabolic parameters.

A — A1C (Impaired Fasting Glucose, Impaired Insulin Sensitivity Prediabetes, and Diabetes)[6]

- **Guidelines:** Refer to current American Diabetes Association (ADA) guidelines for diagnosis and management. Updated yearly.
- **Lifestyle:** Per ADA guidelines, at least 150 minutes of moderate intensity exercise every week is recommended to help achieve glycemic goals. A healthy diet is also recommended.

Medication Considerations:

Preferred:

- **GLP-1 receptor agonists:** Ideal for patients with obesity, and/or associated comorbidities such as DM2, or OSA. Also has evidence supporting fatty liver disease improvement, kidney disease improvement, and cardiovascular benefits.
- **SGLT2 inhibitors:** Offer cardiovascular and renal protection. SGLT2is are one of the four pillars of HF and are indicated in CKD. SGLT2is have been shown to cause minor increases in erythrocytosis[7-10]. Extra H/H monitoring can be considered especially in patients with known or uncontrolled AIE.
- **Metformin:** A valid first-line option for diabetes due to cost of GLPs and SGLT2is. Start 500 mg daily, titrate weekly by 500 mg/day to a target of 1000 mg BID. ER formulation can mitigate GI side effects. Metformin is renally adjusted. Do not initiate and decrease dose by 50% in eGFR 30-45 mL/min. Discontinue if eGFR < 30 mL/min.
- **Insulin:** Consider adding insulin when HbA1C is 10% or more or if not meeting glycemic goals despite maximally tolerated first line options. Consider closer monitoring of BG when using insulin and testosterone together. Start long-acting insulin at 0.2-0.3 units/kg QDAY and self-titrating every 3 days to a fasting BG of 80-130 mg/dL initially. Moderate consensus on starting insulin earlier to achieve rapid glycemic control. Will be discussed extensively in the A1C guidelines.

Avoid:

- **TZDs:** Can exacerbate water retention, a potential side effect of TRT. Contraindicated in HF.
- **Sulfonylureas:** TRT can improve insulin sensitivity, increasing the risk of hypoglycemia with these classes of medication. Although evidence is lacking, counsel patients on signs and symptoms of hypoglycemia.

B — Blood Pressure (BP)[11]

- **Goal:** A stricter end goal of **< 120/80 mmHg** is recommended when androgens are on board, compared to the standard < 130/80 mmHg provided that patients do not exhibit signs and symptoms of hypotension.
- **Lifestyle:** A heart healthy diet, at least 150 minutes of moderate intensity aerobic exercise per week or 75 minutes of vigorous aerobic activity, and resistance training at least 2 days per week.

Medication Considerations:

- **Telmisartan:** Start 20-40 mg daily. Offers unique benefits through PPAR-gamma agonism and may mitigate erythrocytosis (class effect for ARBs). Adjust dose every 4 weeks based on home BP readings.
- **Nebivolol:** Start 2.5-5 mg daily. Promotes nitric oxide release, which can be beneficial for endothelial function. Adjust dose every 2 weeks based on HR and BP response. Nebivolol is also less likely to cause depression and weight gain compared to other beta blockers but may cause fatigue.

The 2025 AHA guidelines removed race-based recommendations for use of ACEi and ARBs[12].

C — Cholesterol and Cardiac Health[13]

- **Goal:** Lower is better for LDL, tailored to the patient's individual cardiovascular risk.
- Recommend an Echocardiogram for all TRT patients and CAC score Men over 30 years old not under aggressive medical management of ABCs. Mainly HLD. Anything > 0, start aggressive management of cholesterol.
- **Lifestyle:** A healthy diet and exercise are recommended to control cholesterol.

Medication Considerations:

- **Preferred:** A high-intensity statin (e.g., **Rosuvastatin**) is preferred due to potent LDL lowering and pleiotropic anti-inflammatory effects. Combination therapy with **Ezetimibe** and/or **PCSK9 inhibitors** may be necessary.
- **Alternatives:** Bempedoic acid and/or Inclisiran can be considered for statin-intolerant patients or as add-on therapy.

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D — Deposition (Heme)

- **Monitoring:** Check Hemoglobin (Hgb) and Hematocrit (Hct) at 3 months, 6 months, and then annually. Patients should be assessed on a case-by-case basis.
- **Threshold:** A Hgb > 18.0 g/dL or Hct > 54% is the **"pause point."** At this level, the dose of testosterone should be reduced **and the cause investigated.**

Management of Erythrocytosis:

- **Lifestyle:** A healthy diet, weight loss and exercise is recommended to help control erythrocytosis.
- **Therapy Modification:** Dose reduction, increase in frequency of injection, switching to SubQ injections, or switching testosterone formulations can be considered to control AIE.
- **Iron Studies:** Always check ferritin, iron, and TIBC before phlebotomy. Avoid phlebotomizing an iron-deficient patient.
- **When to Phlebotomize:** Therapeutic phlebotomy is indicated for symptomatic patients or those with persistently elevated Hct despite dose reduction and lifestyle modifications.
- **When NOT to Phlebotomize:** Do not phlebotomize if the elevation is due to dehydration or if the patient is iron deficient. Address the underlying cause first.
- **Donating Blood vs. Medical Phlebotomy:** Donating blood is the standard unless patients are taking medications that prevent them from donating blood.

Contributing Factors:

- **Hypoxic Drive:** Investigate for undiagnosed sleep apnea, which can drive erythrocytosis independently.
- **Geographic Location:** Patients living at high altitudes may have a higher baseline Hct.
- **Poly-pharmacy** with multiple androgens. Alcohol can increase erythrocytosis.

E – Experience[14]:

- **Hypogonadism Impact of Symptoms Questionnaire – Short Form (HIS-Q-SF):**Integration of validated patient-reported outcomes (PROs) will help add a standardized symptom tool to integrate with biologic and physiological. HIS-Q-SF was chosen due to its specificity to the domains that are affected by TRT and having less overlap with other conditions.
- HIS-Q-SF assessment is not designed as a diagnostic tool but can be a very useful tools for monitoring and guiding clinical decision making when changing dosing.
- Note: Avoid using the initiate sexual activity portion of the questionnaire as a sole guide to decision making as it doesn't take into account the initiator to reciprocator spectrum of libido that men can fall into,
- Monitoring.HIS-Q-SF should be used at 3 points:
    - **Baseline:** Document initial symptom burden in sexual, energy, sleep, mood, and cognition domains.
    - **Diagnosis:** Clarify that HIS-Q-SF complements, but does not replace biochemical confirmation.
    - **Monitoring:** Re-administer HIS-Q-SF at 3 and 6 months to track patient response alongside labs and safety markers.

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S – Screening:

- **Skin Cancer:** Insufficient evidence to assess the benefits and harms of clinical visual examination of asymptomatic individuals per The US Preventive Services Task Force. The American Academy of Dermatology recommends self examination especially for high risk individuals. Suspicious skin changes require prompt medical evaluation using their ABCDE rule[15].
- **Colorectal Cancer:** Refer to NCCN Guidelines for Colorectal Cancer Screening[16]
- **Prostate Cancer:** Refer to NCCN Guidelines for Prostate Cancer Early Detection[17]
    - When androgens are on board, first PSA check after 6 months and follow up on a patient to patient basis. Encourage all men > 52 years old to have urology on board.

6. Dosing and Administration

Generic	Brand	Strength	Route	Half Life	Dosing	Pearls
Testosterone Cypionate[18]	Depo-Testosterone Azmiro	200 mg/mL Or 100 mg/mL	IM or SubQ	~8 days	Starting dose for most men **70-100 mg every 5-7 days.** Moderate consensus for twice weekly. Dose on an individual basis but frequency should be **every 7 days at the longest.**	Gold Standard for TRT. Cheap and Easy to access. Potential for high peaks and low troughs due to long half-life
Testosterone Enanthate[19]	Delatestryl, Xyosted	200 mg/mL	IM or SubQ	4.5-7 days IM References are unclear	Dose on an individual basis but frequency should be **every 7 days at the longest.** Xyosted: Start 75 mg SubQ every 7 days Target nadir 350-650 ng/dL total T. Increase by 25 mg/week if < 350 and decrease by 25 mg/week if trough >= 650 ng/dL.	Some insurance issues may arise with Xyosted if prescribed at a higher frequency than every 7 days.
Testosterone Undecanoate Oral Capsule[20-22]	Jatenzo/Kyzatrex/Tlando	Jatenzo: 158, 198 and 237 mg capsules. Kyzatrex: 100, 150, and 200 mg capsules. Tlando: 112.5 mg capsule	PO	2 hours	Jatenzo: 158-396 mg BID with food Kyzatrex: 100-400 mg BID with food Tlando: 225 mg BID with food	Different formulations are not interchangeable. Higher exposure to testosterone higher fat content in meal taken with capsules except Kyzatrex.. No Hepatotoxicity noted PO is the easiest route of administration for adherence.

TESTOSTERONE ESTERS[23]	Sustanon 250	250 mg/mL Contains 30 mg/mL propionate, 60 mg/mL phenyl propionate, 60 mg/mL isocaproate, 100 mg/mL decanoate	IM	Variable due to variety of esters	Should be injected every 7 days[24]	FORMULATED IN PEANUT OIL (ALLERGIES) Available outside the USA

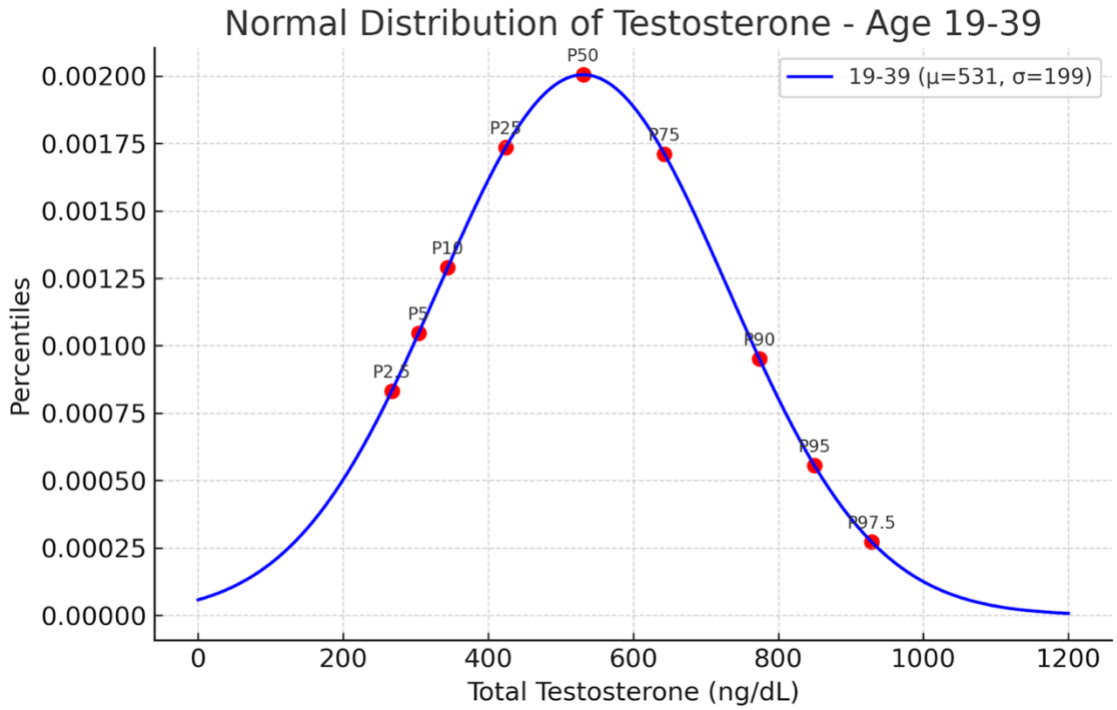
- Testosterone is formulated using different concentrations depending on what manufacturer or compounding pharmacy is formulating it.
- Patients have different levels of health literacy, some might have difficulty measuring the correct dose. We recommend utilizing syringes in the office and showing the patient what the dose should look like on their syringe.
- Utilize the teachback method by asking patients to simulate measuring the correct dose in office or on video if utilizing telehealth.
- The following resource can be utilized to teach patients how to inject IM or SubQ[25]

7. DRUG-DRUG INTERACTIONS[18]:

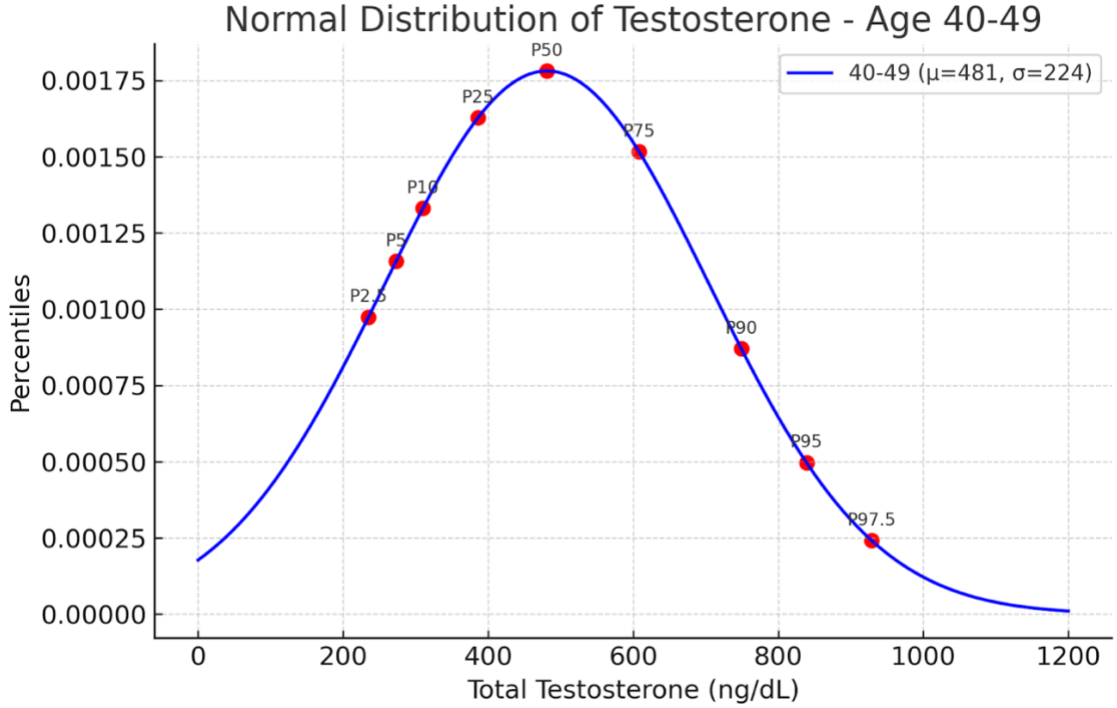
- Insulin and antidiabetic agents: Testosterone can decrease blood glucose and insulin requirements in patients with diabetes
- Oral anticoagulants (especially warfarin): Testosterone can increase the risk of bleeding or thrombosis with Vitamin K antagonists.
- Corticosteroids: Can increase fluid retention from testosterone.
- Medications that can increase BP: Testosterone can further increase the hypertensive effects of these agents.

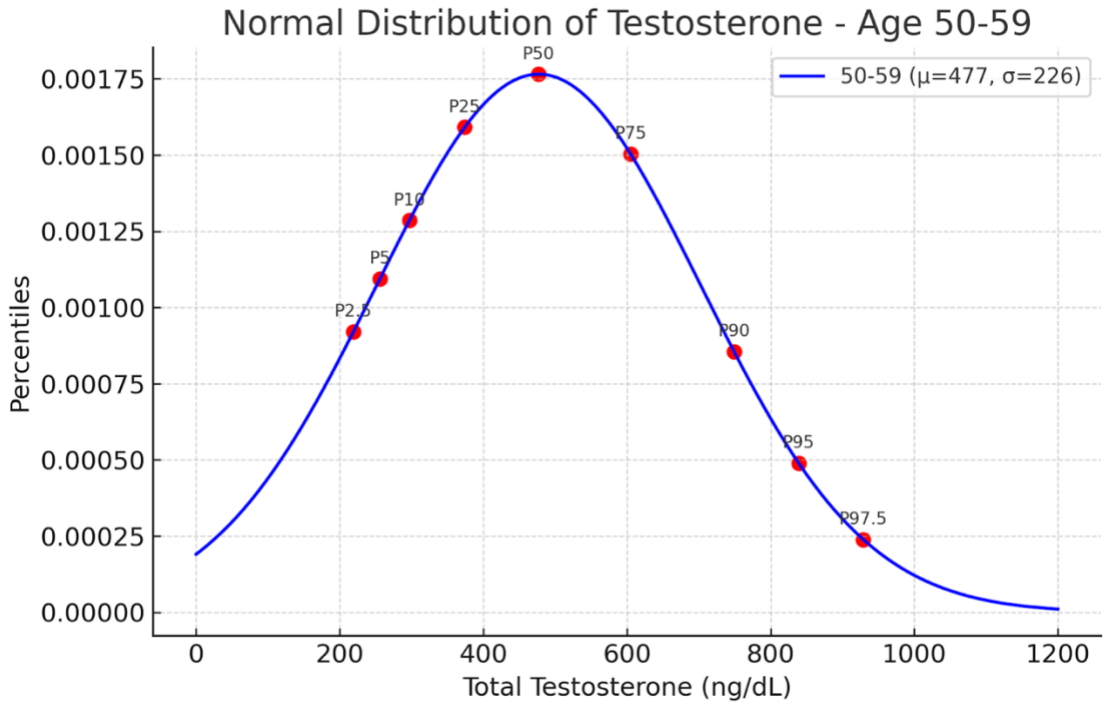
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8. FIGURES:

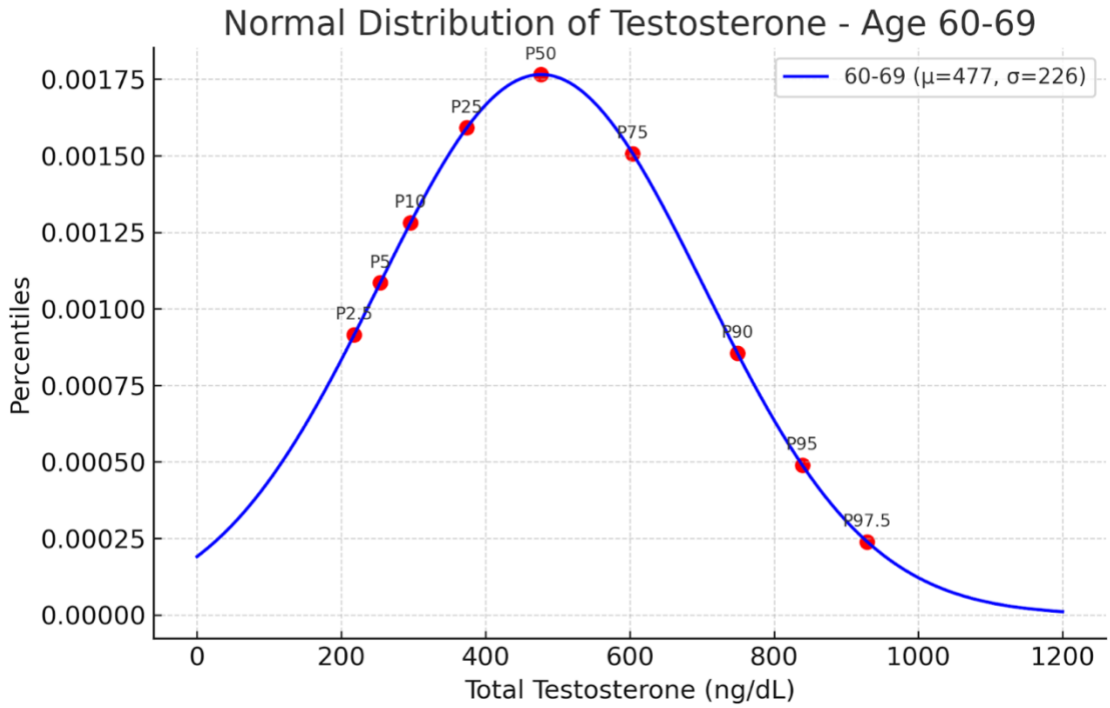


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