LOW TESTOSTERONE

SO WHAT'S THE PROBLEM?

Mark S Uhlman MD

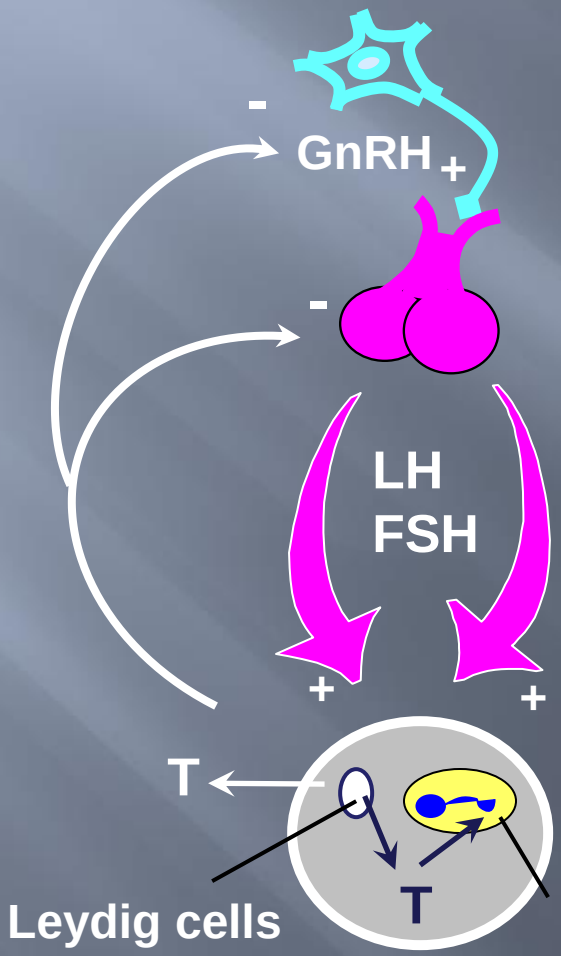
Yakima Valley Medical Conference
March 12, 2022

A Disease with Many Names

- AD – Androgen Deficiency
- ADAM – Androgen Deficiency in Aging Male
- "Andropause" or "Male Menopause"
- LOH – Late Onset Hypogonadism
- Low T – Low Testosterone
- Male Hypogonadism
- TDS – Testosterone Deficiency Syndrome

PHYSIOLOGIC ETIOLOGY OF HYPOGONADISM

Production and Regulation of Testosterone



Hypothalamus

Pituitary

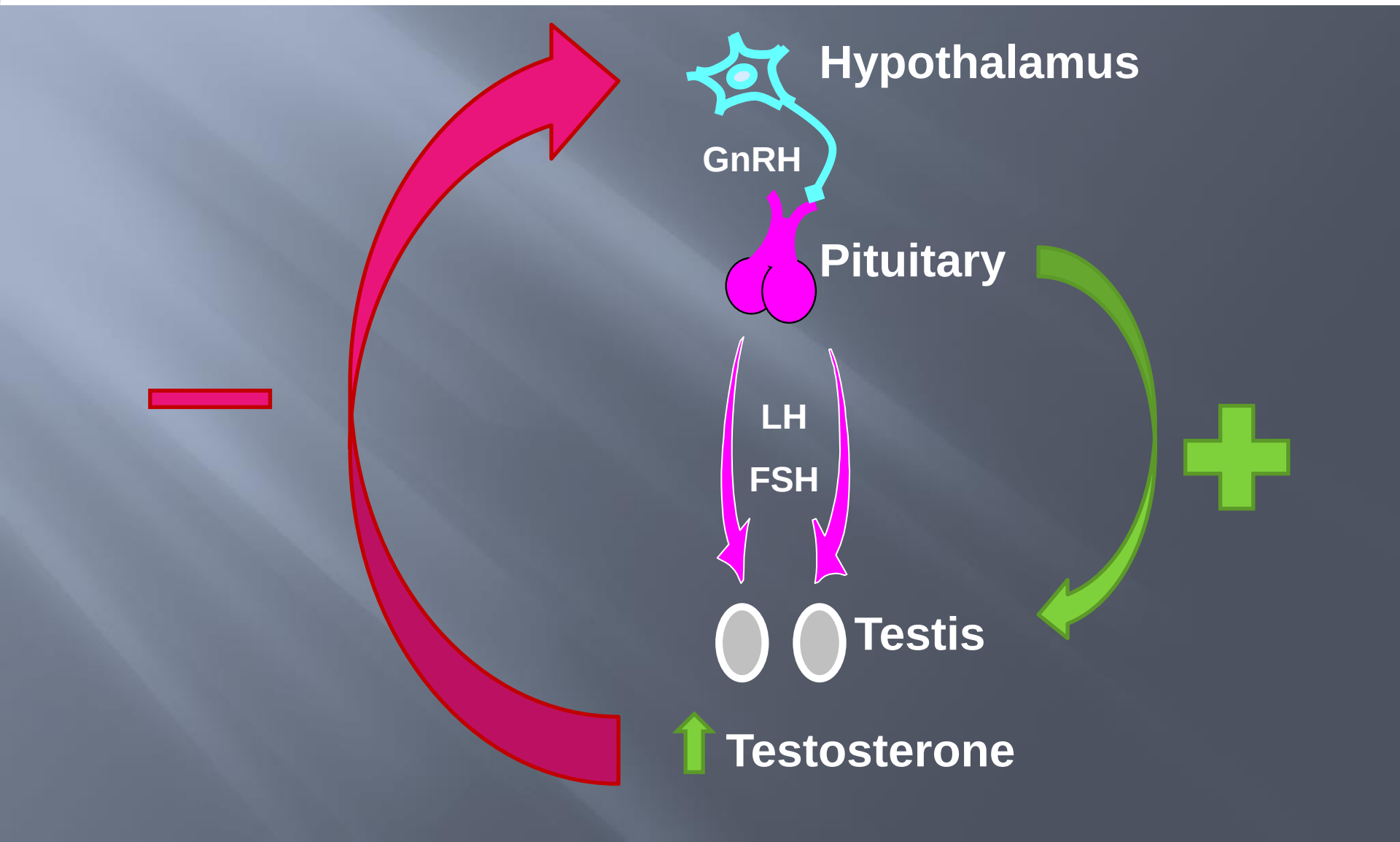
Testis

Definition of Hypogonadism

- "…clinical syndrome that results from failure of the testis to produce physiological levels of testosterone…due to disruption of *one or more levels* of the hypothalamic-pituitary-gonadal (HPG) axis."

H-P-G Axis

NEGATIVE feedback system



H-P-G Axis

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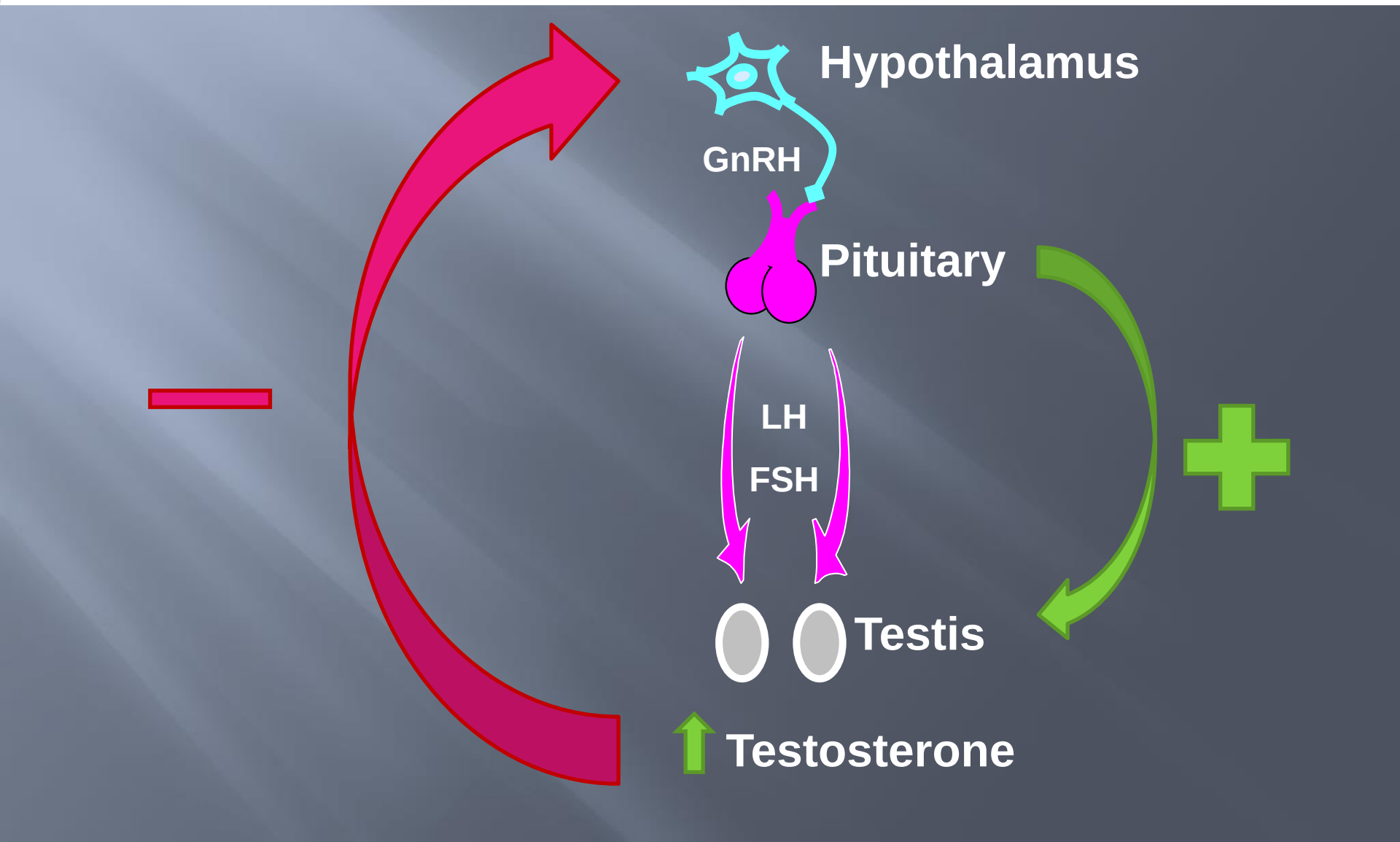
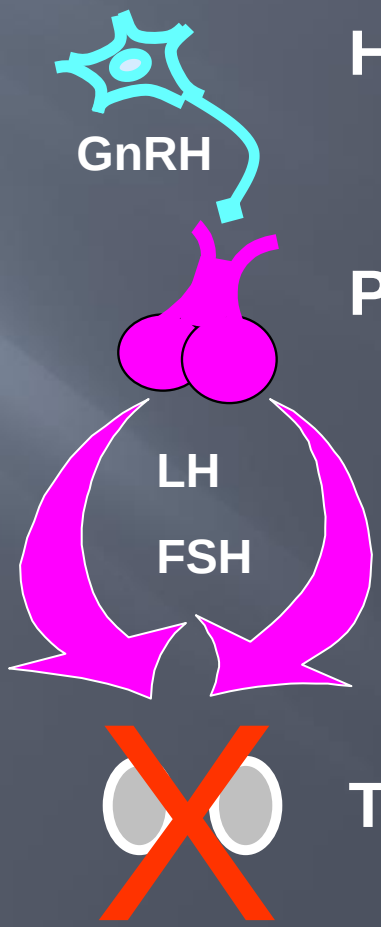


Primary Hypogonadism

Hypergonadotropic Hypogonadism

Increased LH & FSH

Low testosterone
Impaired sperm production



Hypothalamus

Pituitary

Testis

H-P-G Axis

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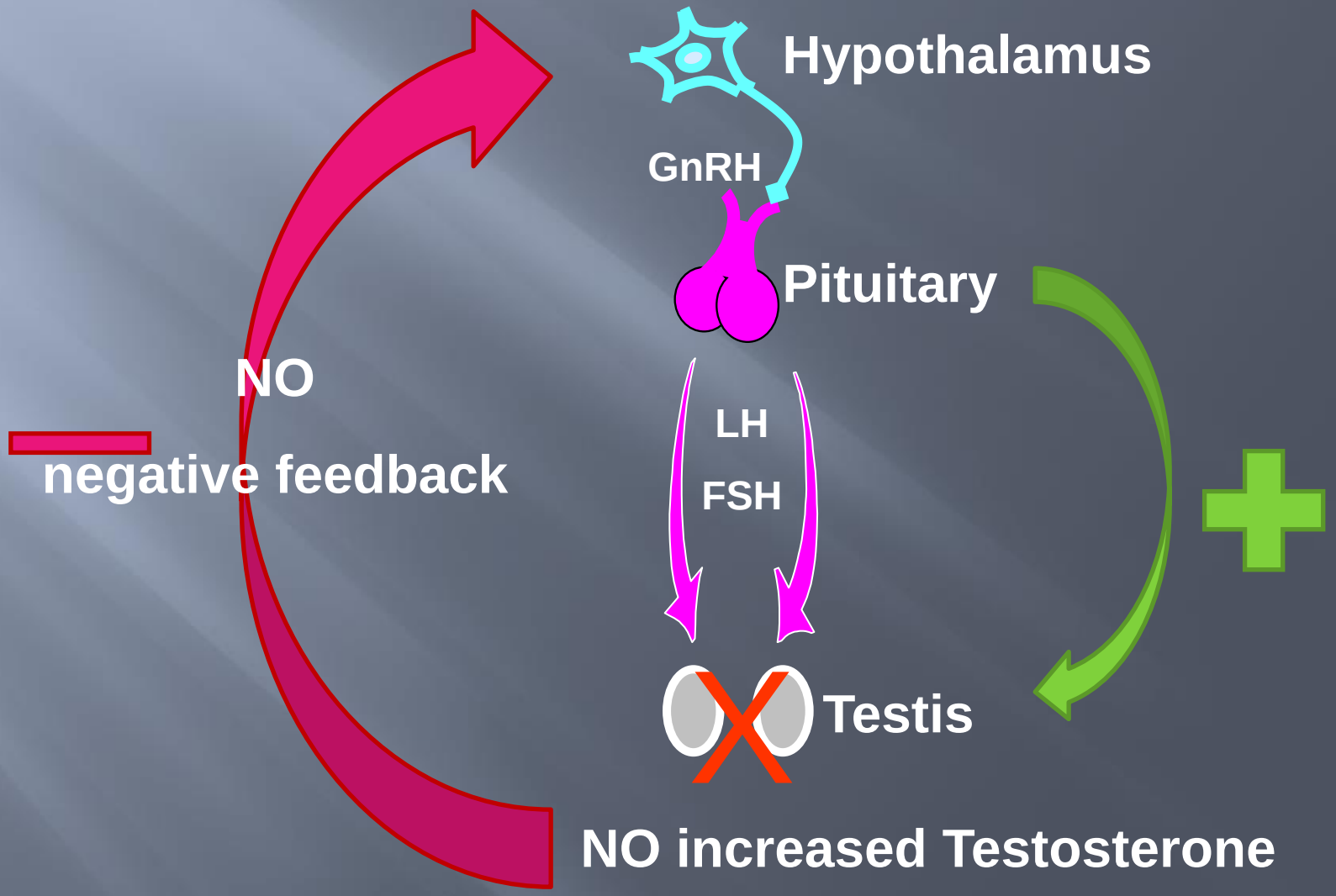
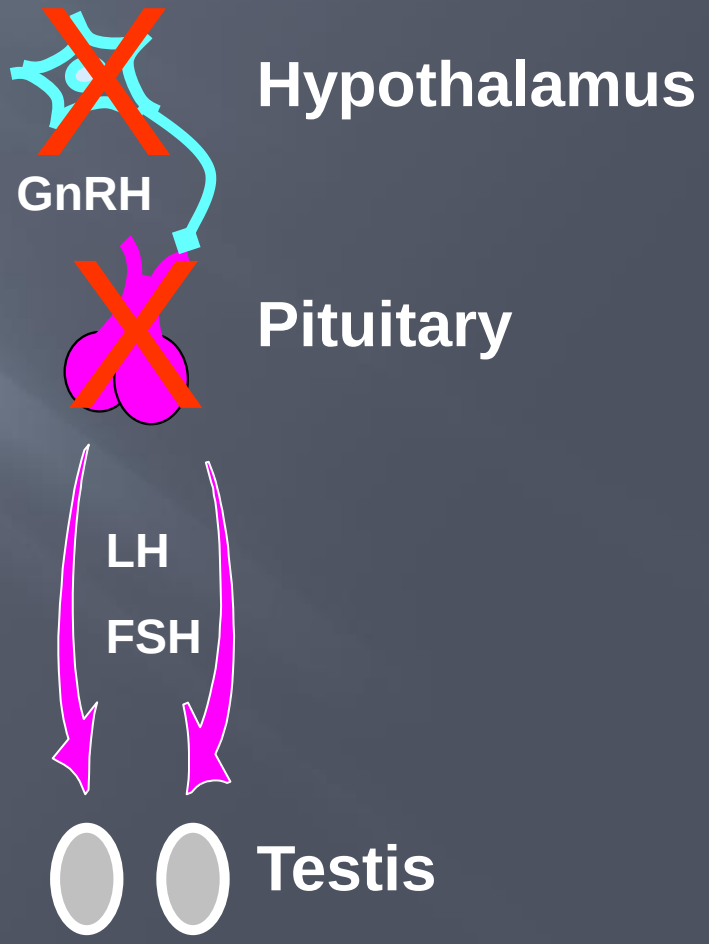


Secondary Hypogonadism

Hypogonadotropic Hypogonadism

Low or low-normal LH & FSH

Low testosterone
Impaired sperm production



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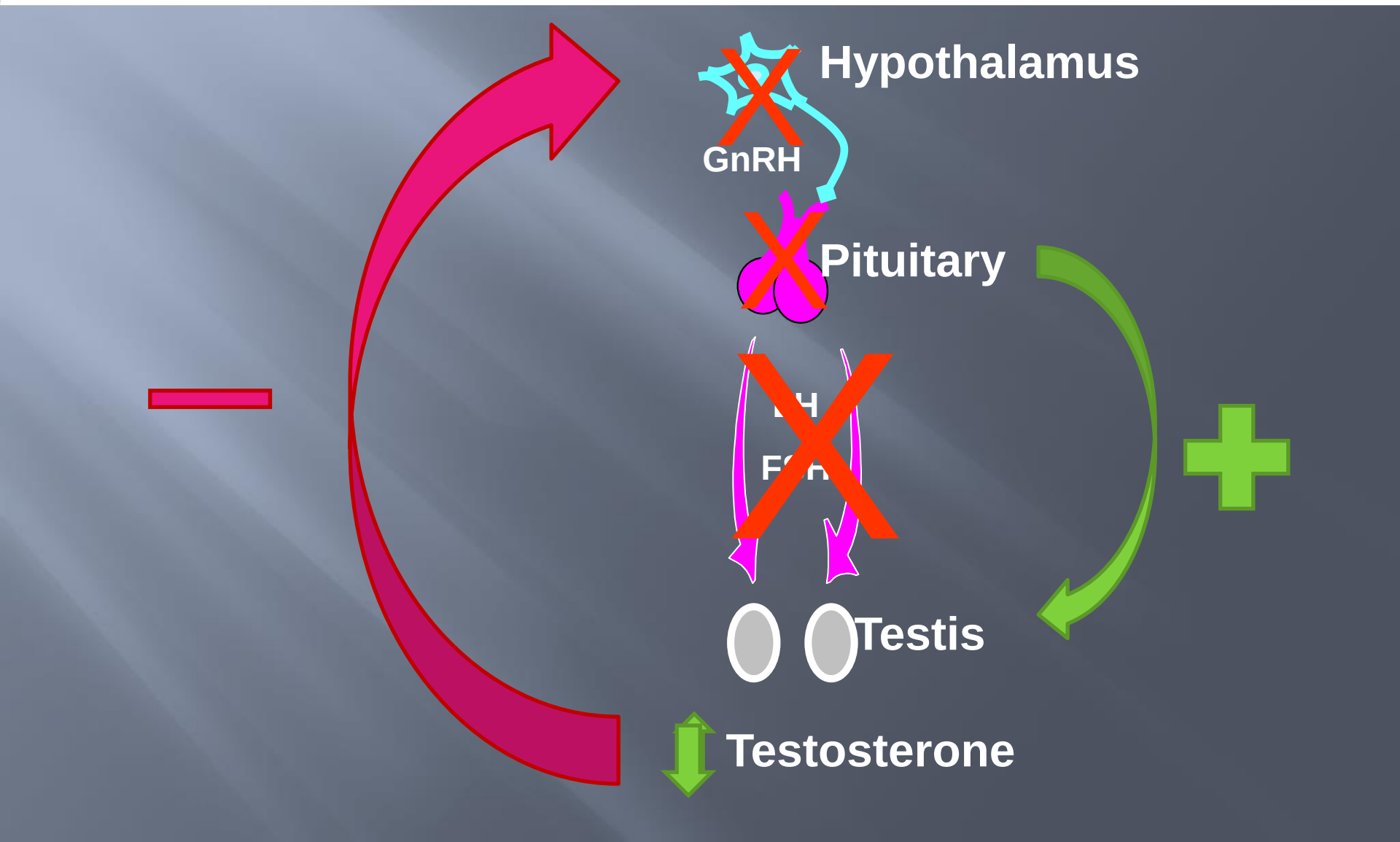


Hypogonadism - Congenital

- Klinefelter syndrome & variants (1/1000 live births)
- Other Chromosomal Abnormalities
  - 46 XY/XO (Turners)
  - Kallmann Syndrome (Hypothalamic Underdevelopment)
- Defects in Androgen synthesis or action
  - 17 alpha hydroxylase
  - 17 beta hydroxysteroid dehydrogenase
- Cryptorchidism / Anorchia
- Myotonic dystrophy
- Sickle cell disease
- Prader-Willi syndrome (Testicular underdevelopment)

Hypogonadism - Acquired

- Trauma / Torsion
- Mumps Orchitis
- Cancer chemotherapy
- Testicular radiation
- Autoimmune syndromes
- Medications
  - Opioids
  - Steroids
  - Ketaconazole
- Severe systemic illness
  - Cirrhosis
  - CRF
- HIV/AIDS
- Aging
- Pituitary disorder
- Hemochromatosis
- Obesity

Hypogonadism

Clinical Diagnosis of Hypogonadism

Early Symptoms and Signs of Androgen Deficiency

- Decreased:
  - Energy
  - Motivation
  - Libido
- Depressed mood, dysthymia
- Poor concentration and memory
- Sleep disturbance, increased sleepiness
- Mild anemia (normochromic, normocytic)
- Increased:
  - Body fat
  - Body mass index (BMI)
- Diminished physical or work performance
- Erectile Dysfunction

Late Symptoms and Signs of Androgen Deficiency

- Incomplete sexual development, eunuchoidism, aspermia
- Breast discomfort, gynecomastia
- Loss of body hair (axillary and pubic), reduced shaving
- Very small or shrinking testes (especially < 5 ml)
- Inability to father children, low or zero sperm counts
- Height loss, low trauma fracture, low bone mineral density
- Reduced muscle bulk and strength
- Hot flushes, sweats

Symptoms and Signs of Androgen Deficiency

- Decreased:
  - Energy
  - Motivation
  - Libido
- Depressed mood, dysthymia
- Poor concentration and memory
- Sleep disturbance, increased sleepiness
- Hypogonadism (normocytic normochromic anemia)
- Increased:
  - Body fat
  - Body mass index (BMI)
- Diminished physical or work performance
- Erectile Dysfunction

Thinking Depression?

Think Hypogonadism

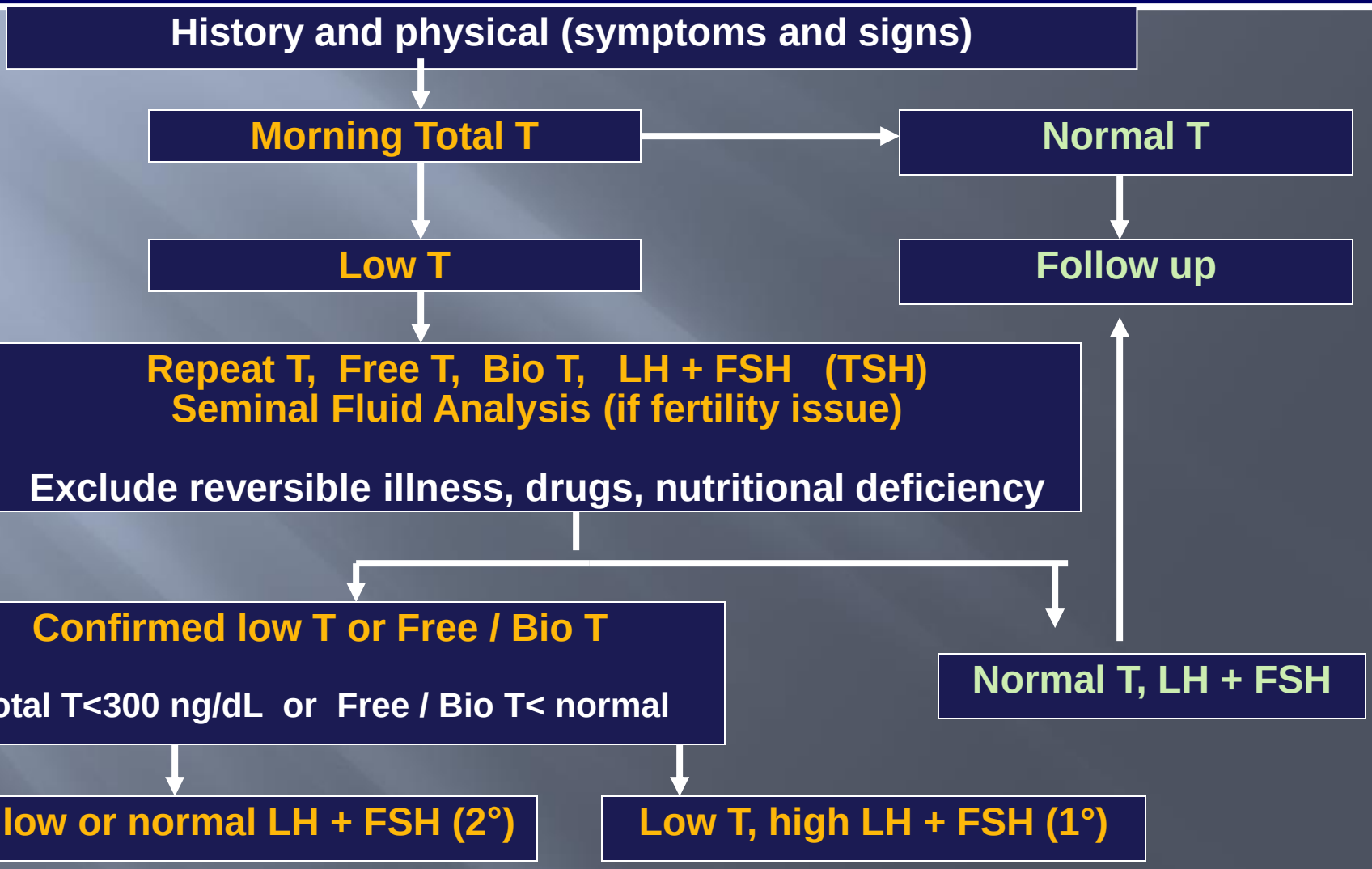
Hypogonadism

Laboratory Confirmation of Hypogonadism

Endocrine Society Recommendations for Diagnosing Androgen Deficiency

- Diagnose only in men with consistent signs/symptoms and unequivocal low T level (TT< 300 ng/dl)
- Measure total T levels in AM
- Confirm diagnosis by repeat measurement (with LH/FSH)
- Recommend against screening in general population
- Consider case detection in men with certain clinical disorders where prevalence of low T is high

Endocrine Society Guidelines
Hypogonadism – Diagnostic Evaluation



Bio T = Free + Albumin bound T

Further Diagnostic Recommendations

- **Primary Gonadal Failure (Low T Elevated LH)**
  - Karyotype to rule out Klinefelter Syndrome
- **Secondary Gonadal Failure**
  - Measure serum Prolactin, Pituitary hormones
  - Consider MRI if:
    - Severe 2º hypogonadism (T < 150ng/dL w/ low or normal LH)
    - Hyperprolactinemia
    - Other pituitary hormone deficiency
    - Age < 35-40y/o
    - Symptoms/signs of Pituitary tumor mass effect
      - Headache or visual disturbance

Further Diagnostic Recommendations

- **Primary Gonadal Failure**
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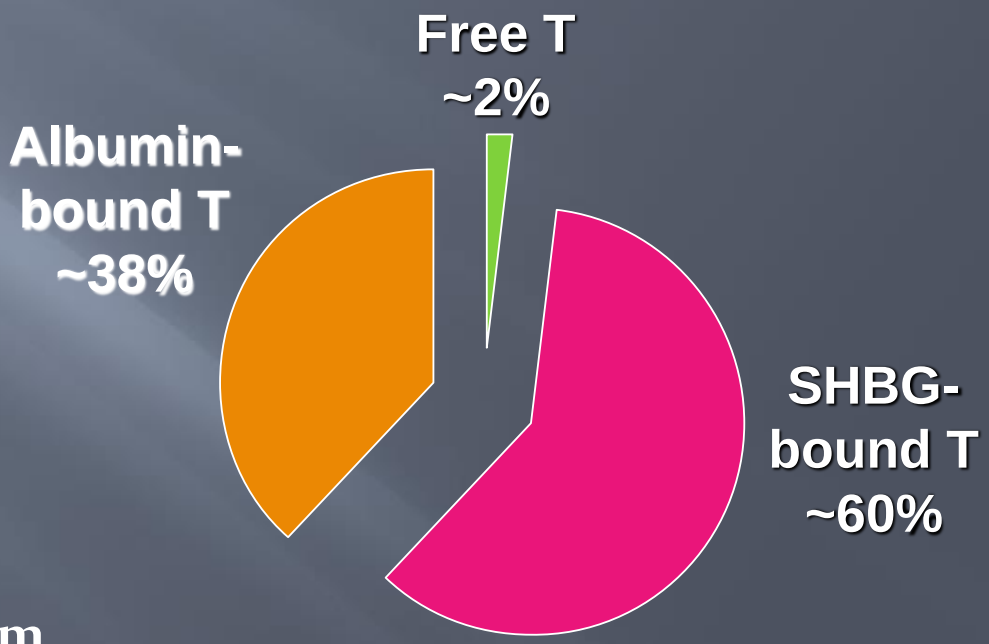
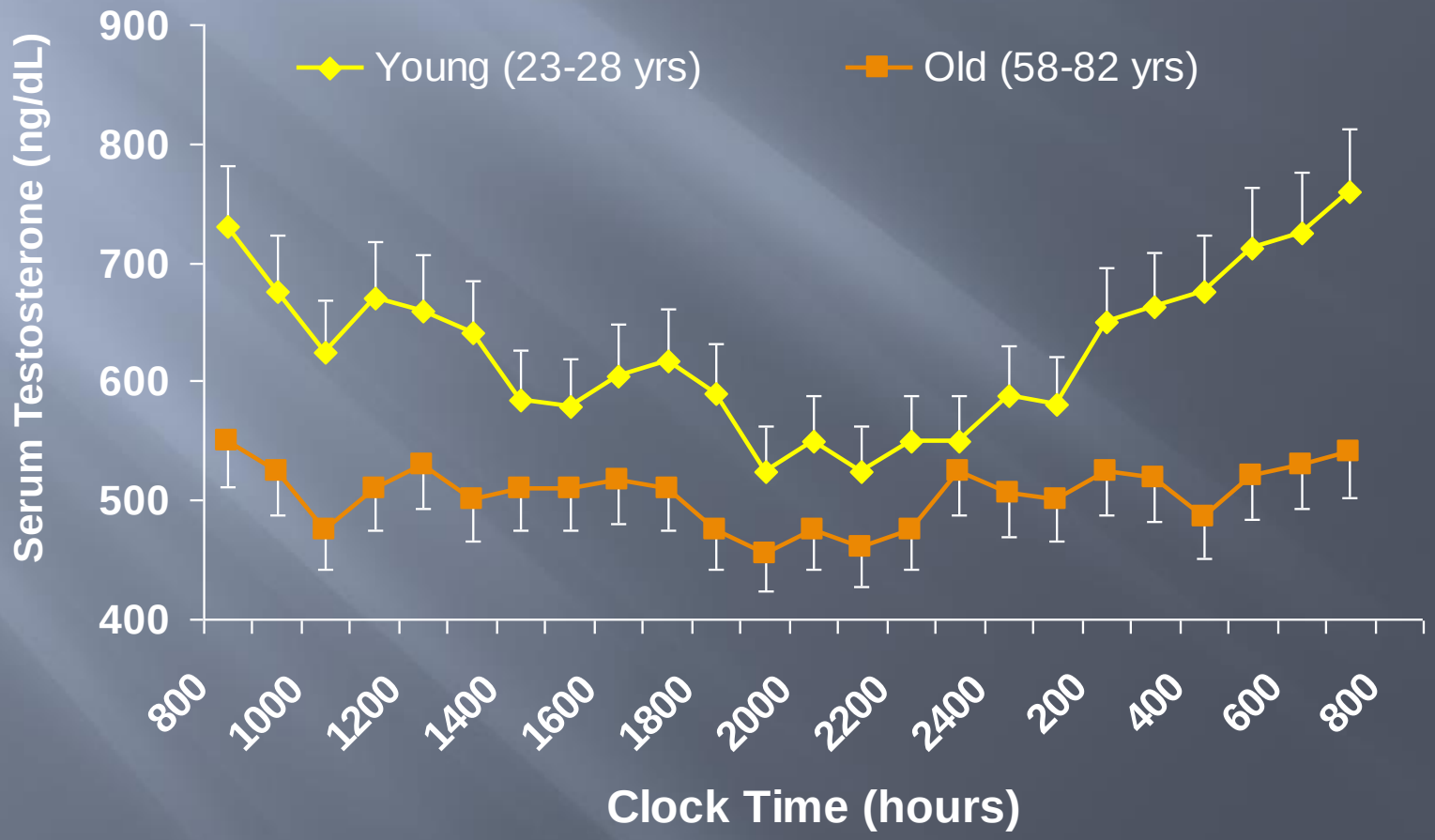
TESTOSTERONE MEASUREMENT

Testosterone Ranges

- Total Testosterone
  - Free and protein bound
  - 300 - 1100 ng/dL
- Free Testosterone
  - 50 - 210 pg/ml
- Bioavailable Testosterone
  - Free and albumin bound
  - < 70 ng/dL = hypogonadism



Diurnal Rhythms in Serum Testosterone in Normal Males



Calculated Free Testosterone (cFT)

- **Calculated from labs routinely obtained (SHBG, albumin, T)**
  - Requires knowledge of SHBG and albumin association constants
  - Correlates strongly with free T via Equilibrium Dialysis (r = 0.919 $P<0.001$)

LOW TESTOSTERONE:

PREVALENCE AND CO-MORBIDITIES

Mark S Uhlman MD

March 10, 2022

Hypogonadism in the Aging Male

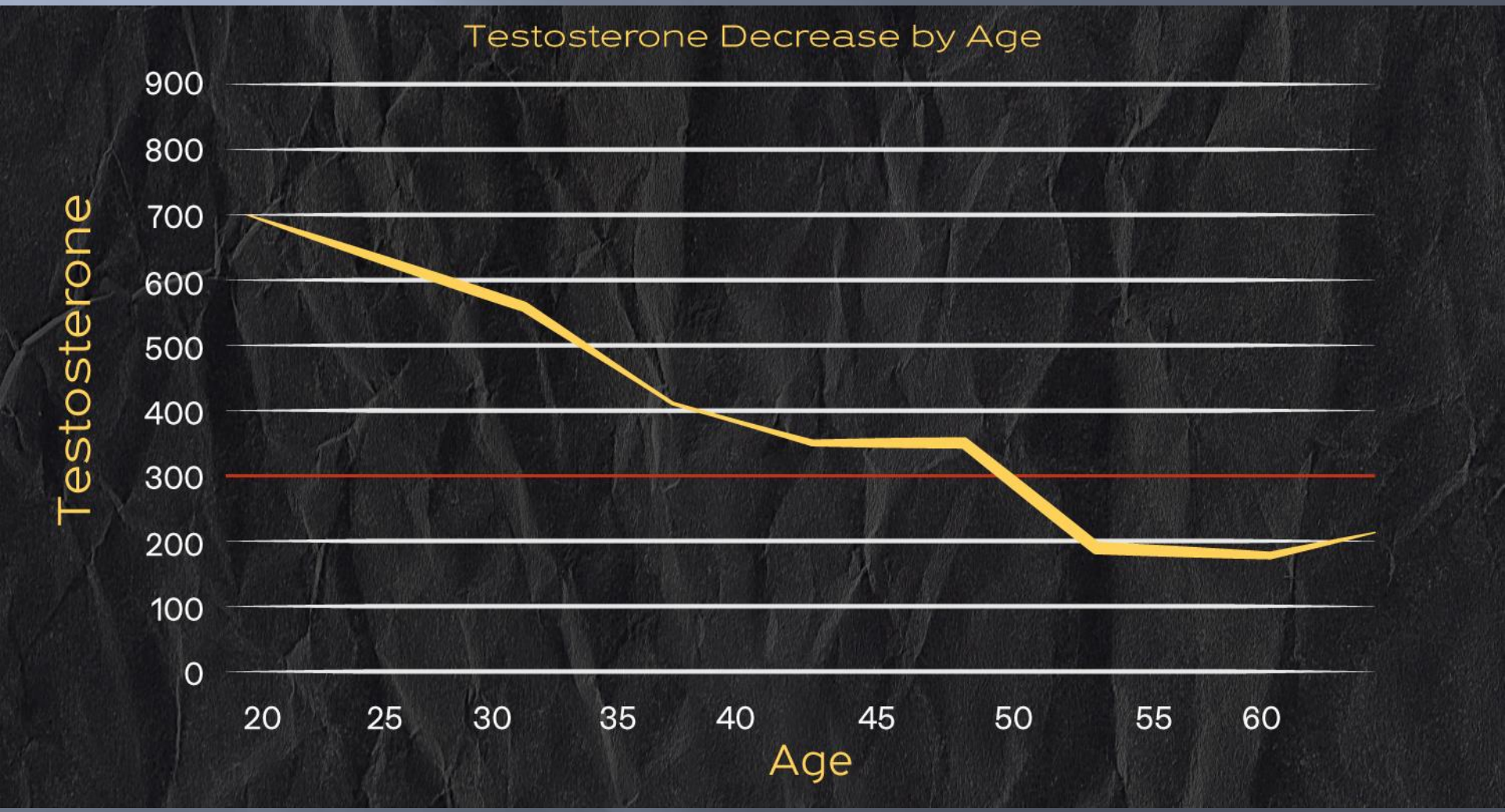
- **Total, free, and protein bound testosterone (T) all decline with normal aging**
  - Decline in Leydig cell count
  - Decrease in testosterone production ~ 1-3% per year after age 40
  - Increase in sex hormone binding globulin (SHBG) levels
- Symptoms and Signs
  - Decreased energy and fatigue
  - Reduced sexual desire (libido) and activity
  - Depressed mood
  - Erectile Dysfunction
  - Reduced muscle bulk and strength
  - Increased body fat, BMI Weight gain
  - Anemia

Estimates of the Prevalence of Hypogonadism by Age

Age	% Prevalence (95% CI)
45 – 54	34.0 (30.6, 37.4)
55 – 64	40.2 (36.6, 43.8)
65 – 74	39.9 (35.4, 44.4)
75 – 84	45.5 (39.0, 52.1)
≥ 85	50.0 (32.7, 67.3)
Crude Rate	**38.7 (36.6, 40.7)**

CI = Confidence Interval

Hypogonadism in the Aging Male



Hypogonadism in Males (HIM) Study

- **Objective**
  - To estimate the prevalence of Hypogonadism in a general population sample of men age ≥ 45 y
- **2165 patients, 95 sites, 25 states**
- **Screened and assessed by a single morning blood draw:**
  - Total testosterone
  - Free testosterone
  - Bioavailable testosterone
  - SHBG
- **Hypogonadism**
  - Single total testosterone level <300 ng/dL ***or*** patients on current androgen therapy previously diagnosed as hypogonadal

Estimates of the Prevalence of Hypogonadism

	% Prevalence (95% CI)	
	Enrolled Patients (n = 2162)	Untreated Patients (n = 2085)
Crude Rate	38.7 (36.6, 40.7)	36.3 (34.2, 38.4)
Age-adjusted Rate*	38.4 (36.3, 40.5)	36.1 (34.0, 38.2)

Data collected over 2 week period from 95 sites, All male patients seen prior to 12PM

Sites:

47 family practice,

44 IM,

3 endocrinology,

1 urology

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Chronic Diseases or Conditions Associated with Decreased T

- Infertility
- Type 2 diabetes
- Obesity
- Rheumatoid arthritis
- HIV infection
- Cancer
- COPD/respiratory illness
- Corticosteroid use
- Chronic liver disease
- Chronic renal failure
- Chronic opioid exposure

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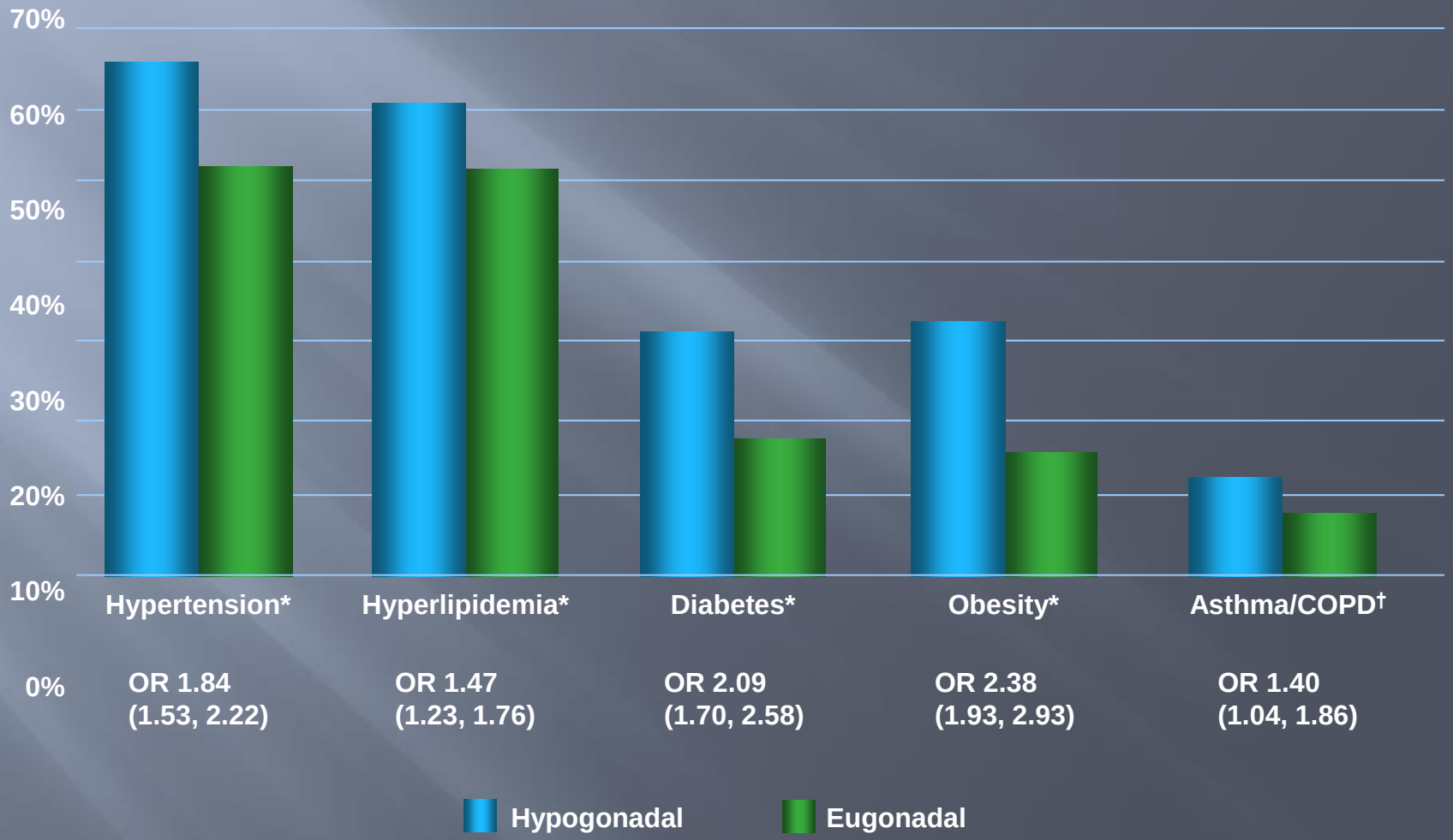
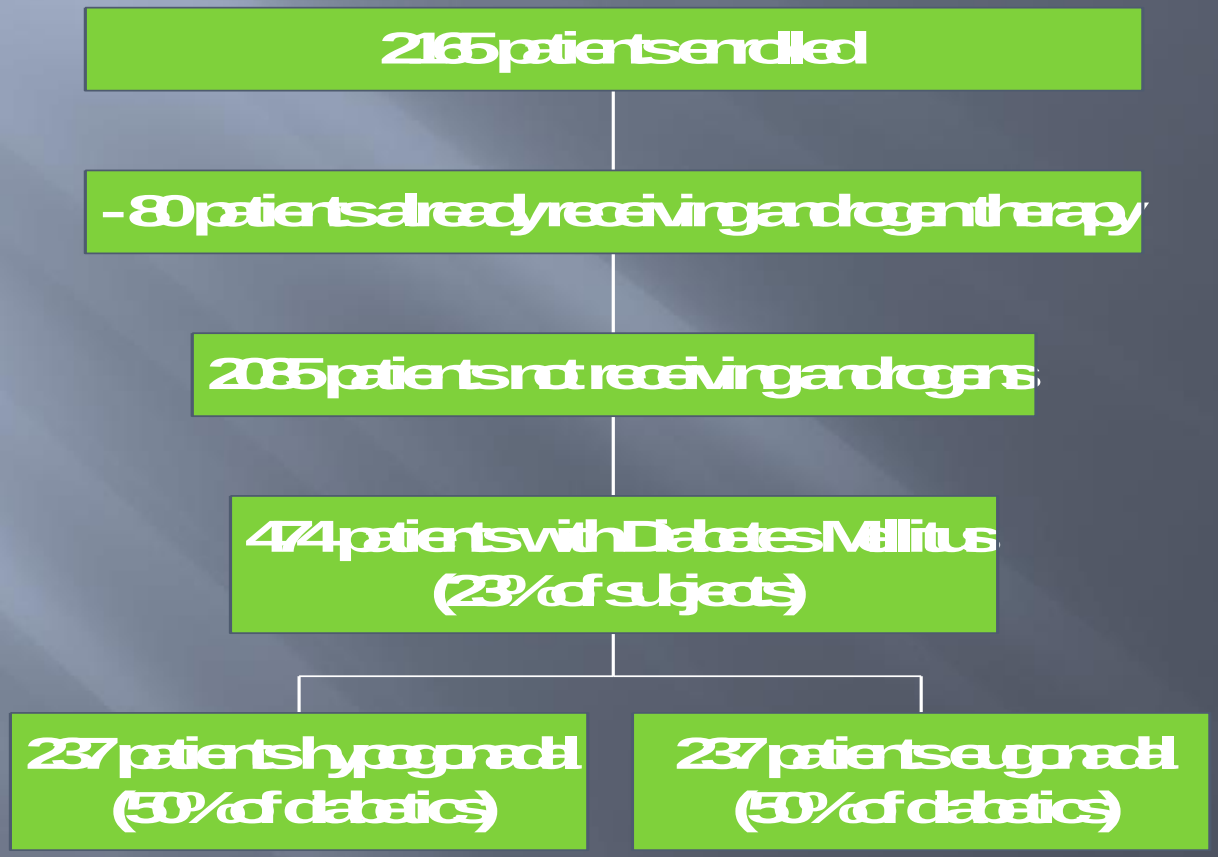
Co-morbidities in Hypogonadal Men

HIM Study



HIM: Diabetic Patient Population

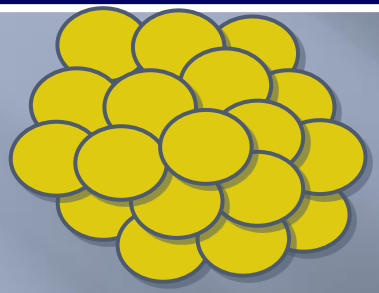


Low T Symptoms in Diabetic Males*

Signs and Symptoms	Hypogonadal Patients (%) (n = 237)	Eugonadal Patients (%) (n = 237)	p value
Decrease in ability / frequency to perform sexually	153 (64.6)	125 (52.7)	0.009
Decrease in sexual desire / libido	128 (54.0)	98 (41.4)	0.006
Physical exhaustion / lacking vitality	82 (34.6)	62 (26.2)	0.046
Decrease in muscular strength (feeling of weakness)	71 (30.0)	70 (29.5)	NS
Decline in general feeling of well-being	66 (27.8)	60 (25.3)	NS
Depressed mood	42 (17.7)	44 (18.6)	NS

*Untreated with androgens
NS = Not significant

Hypogonadism, Obesity and Insulin Resistance



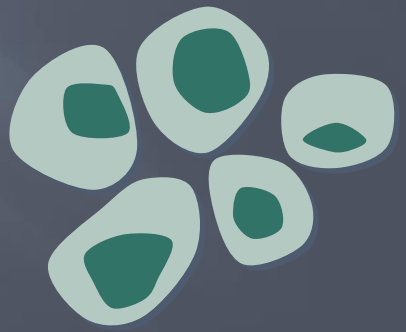
Body Fat

Insulin Sensitivity

Endogenous T

T → E2

Aromatase



Altered Leydig cell function

E2 = Estradiol

Screening for Low T

The Androgen Deficiency in Aging Males (ADAM) Questionnaire

1. Do you have a decrease in libido (sex drive)?
2. Do you have a lack of energy?
3. Do you have a decrease in strength and/or endurance?
4. Have you lost height?
5. Have you noticed a decreased enjoyment of life?
6. Are you sad and/or grumpy?
7. Are your erections less strong?
8. Have you noticed a recent deterioration in your ability to play sports?
9. Are you falling asleep after dinner?
10. Has there been a recent deterioration in your work performance?

If answer is yes to question 1 or 7, or at least three of the other questions, low testosterone may be present.

CASE PRESENTATION

Case Presentation

History of Present Illness

- 52 year-old male
- ED, loss of libido x 2 years
- Unsatisfactory response to sildenafil 50 mg & 100 mg
- Recent weight gain

Past Medical History

- Type 2 diabetes
- Hypertension
- Mild neuropathy
- Absent ankle reflexes
- No retinopathy

Case Presentation

Medications

- Glipizide
- Metformin
- Rosiglitazone
- Valsartan
- Aspirin

Physical Exam

- **BMI 32 kg/m^2**
- **Waist circumference 40 inches**
- **BP 155/90 mm Hg**

Q. What are the first steps and what labs would you order?

Endocrine Society Guideline - Diagnosis

SIGNS AND SYMPTOMS

Include fatigue, loss of libido, depressive mood, poor concentration, increased body fat, decreased muscle mass, decreased bone mineral density (BMD)

MEASURE TOTAL TESTOSTERONE (TT)

Test in the morning

LOW TT <300 ng/dL

EXCLUDE REVERSIBLE ILLNESS, PITUITARY DISORDERS, DRUGS, NUTRITIONAL DEFICIENCY

These factors can lower testosterone levels transiently

REPEAT TT, MEASURE LH and FSH

CONFIRM LOW T

(TT <300 ng/dL)

LH = Luteinizing Hormone, FSH = Follicle Stimulating Hormone

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Laboratory Tests

❑ Hgb and Hct	Hgb 14.8 g/dL, Hct 39.6%
❑ Hemoglobin A1c	8%
❑ Cholesterol	TC 250 mg/dL, LDL 179 mg/dL, HDL 37 mg/dL, TG 220 mg/dL
❑ Serum Total Testosterone	TT 205 ng/dL, FT 5.0 ng/dL
❑ FSH and LH	FSH 2.9 IU/L, LH 3.5 IU/L
❑ SHBG (10-57)	22 nmol/L
❑ Serum Prolactin (2-18)	12 ng/mL
❑ TSH	1.5 microIU/mL
❑ PSA	1.1 ng/mL

Diagnosis

Q1. Is this patient hypogonadal?

Q2. Would you consider treatment with appropriate T therapy?

Diagnosis

Q1. **Is this patient hypogonadal? YES**

Q2. **Would you consider treatment with appropriate T therapy?**

Diagnosis

Q1. Is this patient hypogonadal? YES

Q2. Would you consider treatment with appropriate T therapy? YES

Hypogonadism

Treatment Options

(Should we treat?)

Long Term Considerations

- Sexual dysfunction
- Osteoporosis
- Memory loss and Cognitive decline
- Lean body mass deterioration
- Fatigue
- Anemia

Testosterone Replacement Therapy
Potential Benefits

- Normalization of T levels
- Improved libido
- Positive effects on fatigue (improvement in energy level)
- Improved mood, sense of well-being
- Increase in lean body mass and strength
- Decrease in body fat mass
- Improved bone mineral density (effects on fracture risk are currently unknown)

Testosterone Replacement Therapy
Contraindications and Precautions

- Known or suspected prostate cancer
- Breast cancer
- History of Thromboembolic disease
  - Doubles risk of VTE – more prolounced first 6 months and in younger men
- Known or suspected sensitivity to ingredients used in T delivery systems
- Unexplained PSA elevation
- Hematocrit >50%
- Severe BPH symptoms
  - AUA prostate symptom score >19
- Unstable severe heart failure
  - Studies are equivocal
- Untreated prolactinoma

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- Hematocrit >50%
- Severe BPH symptoms
  - AUA prostate symptom score >19
- Unstable severe heart failure (Class III or IV)
  - Studies are equivocal
- Untreated prolactinoma

Hypogonadism

Treatment Options (TRT)

Testosterone Replacement Therapy
Recommended Dosing and Administration

Intramuscular - Short acting (1-2 weeks)

- Testosterone enanthate or cypionate
- 75-100 mg weekly or 150-200 mg every 2 weeks

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Intramuscular - Long acting (6-10 weeks)

- AVEED® (testosterone undecanoate)
- 750 mg/3 mL (250 mg/mL)

Testosterone Replacement Therapy
Recommended Dosing and Administration

Oral (non age related hypogonadism)

- JATENZO® (testosterone undecanoate – 158-237mg BID)

Transdermal Gels 1% – 1.62%

- 25-100mg Testosterone applied daily

Transdermal Patches

- 2.5-7.5 mg applied nightly for 24 hours*

SQ Pellets (Testopel)

- 150-450 mg implanted SC every 3-6 months†

SC = Subcutaneous

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*****DO NOT confuse this oral medication with older halogenated oral testosterone preparations such as Methyltestosterone (Testred) or Fluoxymesterone (Halotestin)…… High incidence of Liver Toxicity**

*****Older halogenated Testosterone preparation play NO ROLE IN TREATMENT OF HYPOGONADISM**

Testosterone Replacement Therapy
Recommended Dosing and Administration

Oral Clomiphene Citrate (LH/FSH Stimulation)

- Clomid 25-50mg daily

*Secondary Hypogonadism

*Younger Patients who wish to retain fertility

* Prolactin related hypogonadism on DA therapy

* Studies show Clomiphene Citrate to be safe and effective with Testosterone levels similar to topical gel application

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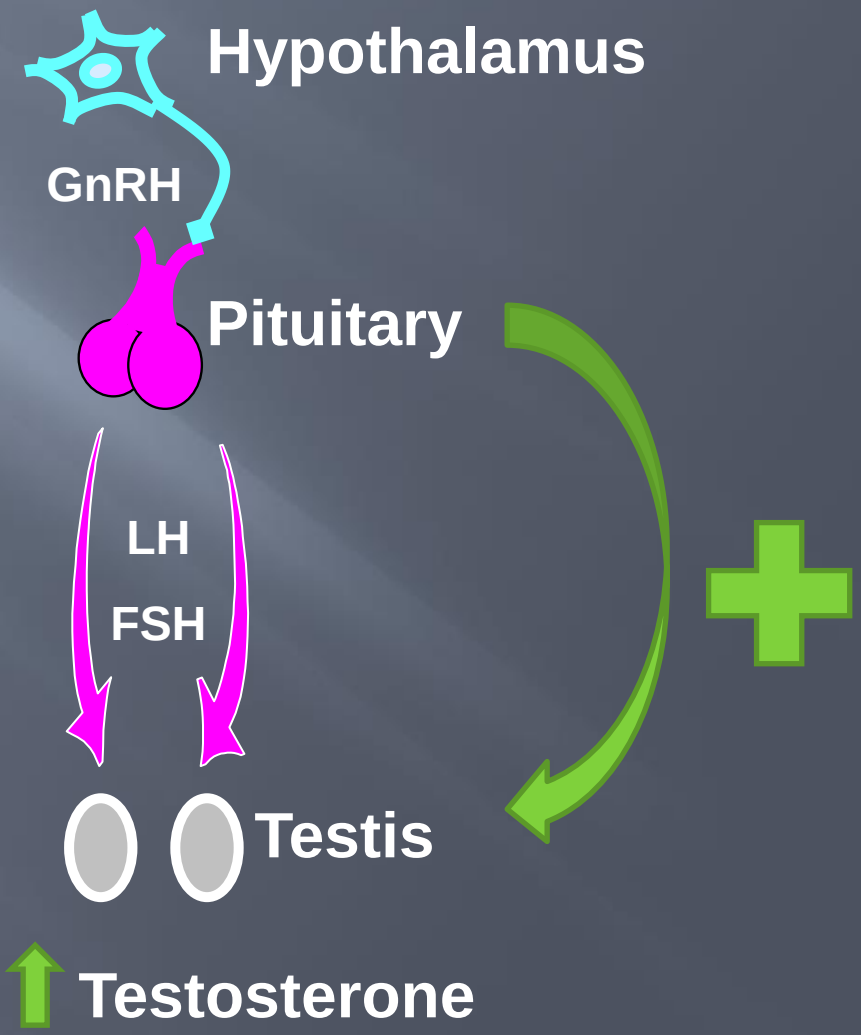
NEGATIVE feedback system



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Endocrine Society Guideline
Formulation Specific Adverse Events

Oral
- Cost - Proprietary
- Erythrocytosis

Intramuscular - Short acting
- Peaks and valleys in serum T levels
- Fluctuation in mood or libido
- Pain at injection site
- Excessive Erythrocytosis

Intramuscular – Long acting
- POME *30 minute wait*
- Erythrocytosis

Transdermal Gels
- Risk for transference to others (2-4 hour ruboff risk)
- Erythrocytosis

Transdermal Patches
- Skin irritation at application site
- Erythrocytosis

SQ Pellets
- Infection
- Pellet expulsion
- Office placement only
- Erythrocytosis

POME – Pulmonary Oil Micro Embolism

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- Fluctuation in mood or libido
- Pain at injection site
- Excessive Erythrocytosis

Intramuscular – Long acting
- POME *30 minute wait*
- Erythrocytosis

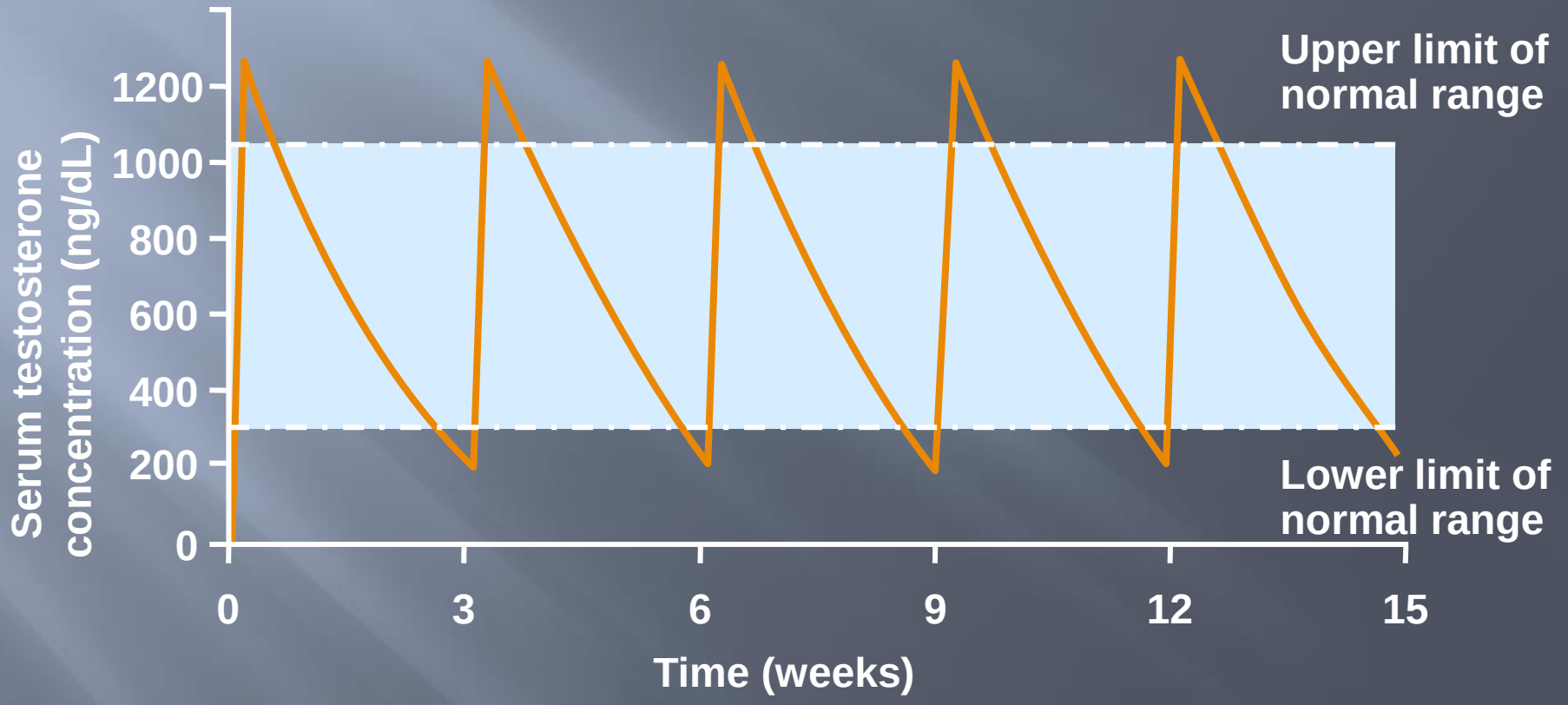
Transdermal Gels
- Risk for transference to others (2-4 hour ruboff risk)
- Erythrocytosis

Transdermal Patches
- Skin irritation at application site
- Erythrocytosis

SQ Pellets
- Infection
- Pellet expulsion
- Office placement only
- Erythrocytosis

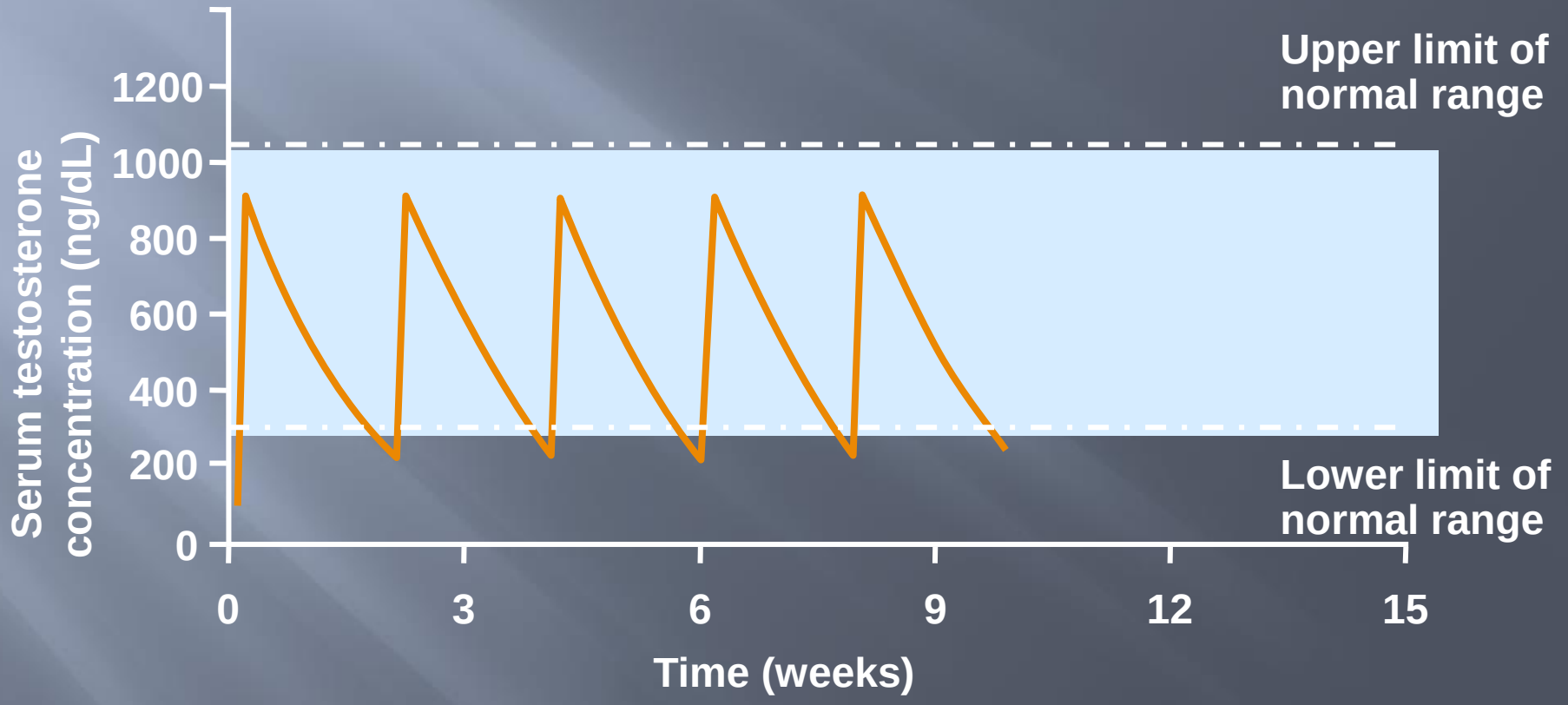
POME – Pulmonary Oil Micro Embolism

Testosterone Enanthate 250 mg Administered IM Every 3 Weeks



IM = Intramuscular

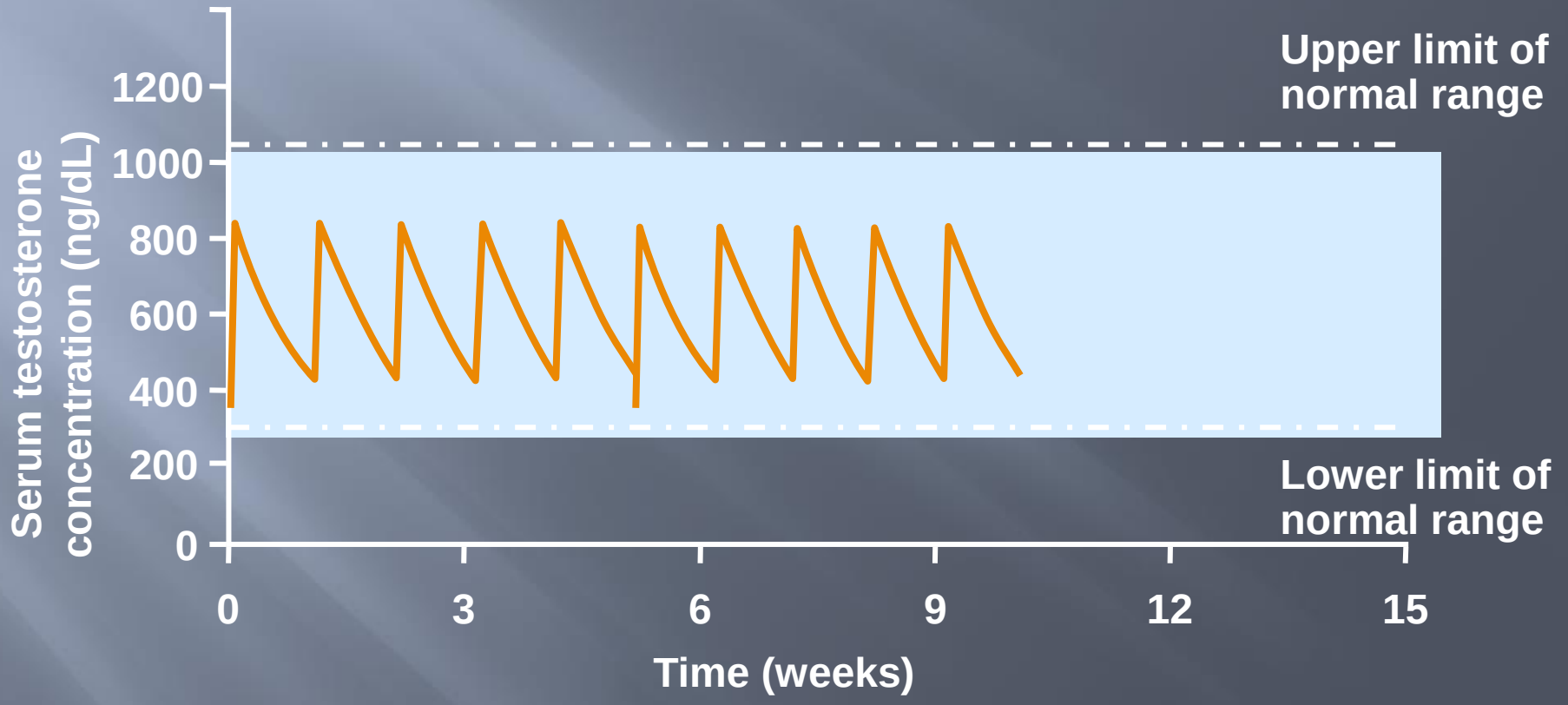
Testosterone Enanthate 250 mg Administered IM Every 2 Weeks *



IM = Intramuscular

* Illustration only

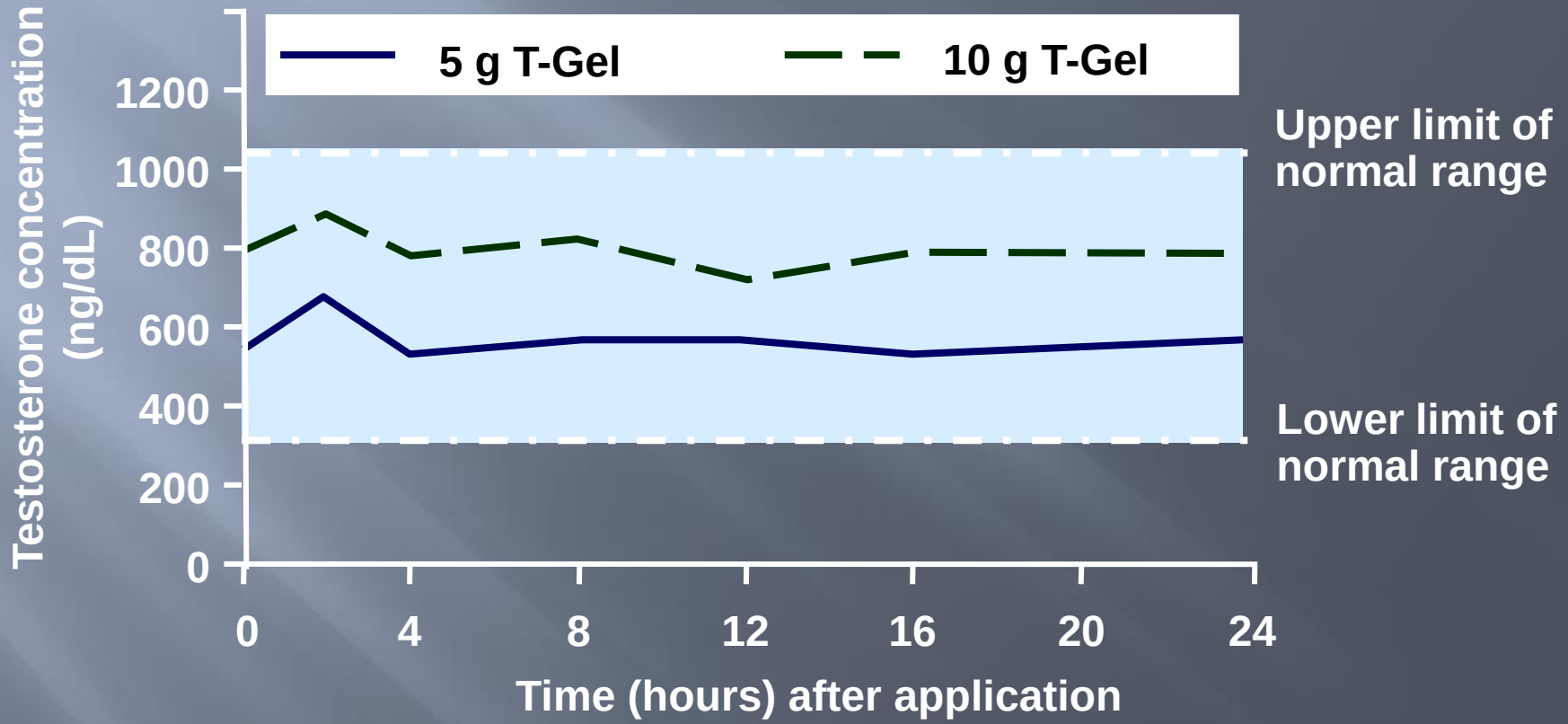
Testosterone Enanthate 250 mg Administered IM Every Week *



IM = Intramuscular

* Illustration only

Testosterone Gel Mean Steady State Concentrations on Day 30



Testosterone Replacement Therapy
Potential Risks

- Stimulation of growth in previously undiagnosed prostate cancer*
- Increased risk of bladder outlet symptoms due to increase in prostate volume*
- Erythrocytosis
- Precipitation or worsening of sleep apnea
- Acne
- Decreased sperm production
- Edema in patients with preexisting cardiac, renal, or hepatic disease
- VTE Risk is likely 2X from baseline
- Cardiac event risk may or may not be increaseed

Clomid Therapy

Potential Risks

- Stimulation of growth in previously undiagnosed prostate cancer*
- Increased risk of bladder outlet symptoms due to increase in prostate volume*
- Erythrocytosis
- Precipitation or worsening of sleep apnea
- Acne
- ~~Decreased sperm production~~
- Edema in patients with preexisting cardiac, renal, or hepatic disease
- VTE Risk is likely 2X from baseline
- Cardiac event risk may or may not be increaseed

Testosterone Replacement Therapy
Monitoring recommendation

Evaluate patient 3 months after testosterone initiation, then every 6-12 months for response to treatment and symptom resolution

	Baseline	2-3 Months	6-12 months
T Concentrations	✓	✓	✓
Hematocrit	✓	✓	✓
PSA and DRE	✓	✓	In accordance with prostate cancer screening guidelines, depending on the age and race of the patient
BMD	✓*		After 1-2 years of T therapy in hypogonadal men with osteoporosis or low trauma fracture consistent with regional standard of care

DRE = Digital Rectal Exam BMD = Bone Mineral Density

Questions?

LOW TESTOSTERONE

SO WHAT'S THE PROBLEM?

Mark S Uhlman MD

March 12, 2022