# Men's Health Primer: Contemporary Approach to Erectile Dysfunction, Peyronie's Disease, Hypogonadism & More

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University of Colorado Medicine

# Jeff Morrison, M.D. – CU Medicine Urology

## Education

- Medical School: University of Pennsylvania
- Residency: University of Colorado
- Fellowship: UCLA

## Specialties

- Men's Health
- Erectile Dysfunction
- Peyronie's Disease
- Testosterone Replacement
- Male Fertility

## Locations

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303-265-3940

**Anschutz Medical Campus**
Anschutz Outpatient Pavilion, 3rd Floor
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720-848-1800

# Disclosures

- None

## Objectives

- Highlight the purpose and importance of Men's Health Programs.
- Review pathophysiology and management of common men's health diagnoses including Erectile Dysfunction, Peyronie's Disease, and Hypogonadism
- Summarize updates in Prostate Cancer Screening.

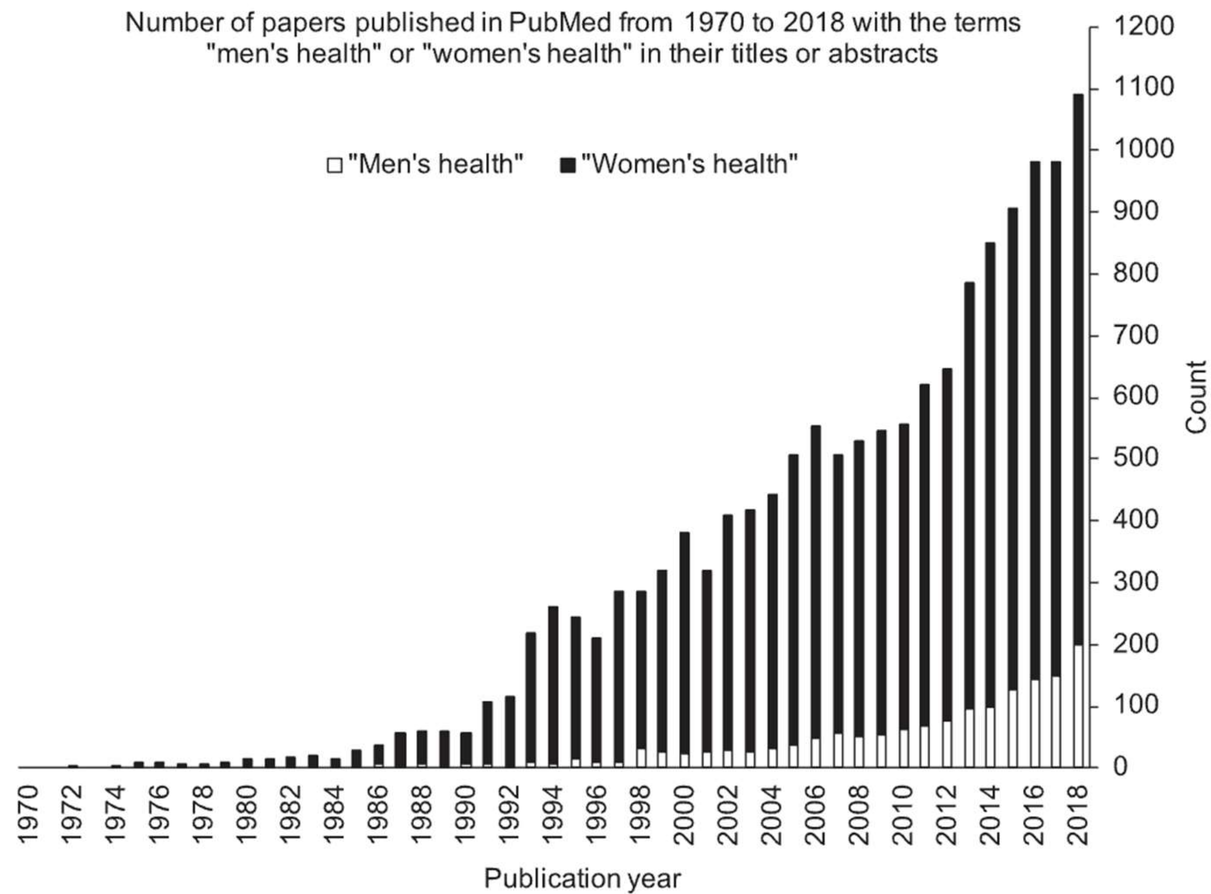
# Men's Health:
# What is it and why does it matter?

## Men's Health – 5 Facts

1. Men are significantly less likely than women to see a HCP
2. Only 60% of men see a HCP on annual basis
3. Men face 41% higher mortality compared to women
4. 31% of men suffer depression, but only 1/4th of these men talk to a HCP
5. Over 39 million American men suffer from erectile dysfunction, which is linked with increased risk of CVD, DM and death

Bernie H, Indiana University
Nuzzo et al The Aging Male 2019
Basaria et al 2019 The Journals of Gerontology

# The Men's Health Paradox




Nuzzo et al The Aging Male 2019

# The Men's Health Paradox

**Table 1.** List of men's and women's offices in national health agencies within the United States government.

| Government agency | Women's office | Men's office* |
|---|---|---|
| National Institutes of Health | Office for Research on Women's Health (est. 1990) | None |
| Department of Health and Human Services | Office on Women's Health (est. 1991) | None |
| Centers for Disease Control and Prevention | Office of Women's Health (est. 1994) | None |
| Food and Drug Administration | Office of Women's Health (est. 1994) | None |

*An attempt was made to establish an Office for Research on Men's Health within the National Institutes of Health in 2009, but the relevant bill, the Men's and Families Health Care Act of 2009, died in subcommittee.

→ Men represent an underserved minority in plain sight

→ Sexual and Reproductive Health issues = big motivators bringing men into the healthcare system!

Nuzzo et al The Aging Male 2019

# Men's Health: Urology Perspective

- Sexual and Reproductive Issues I specialize in:
  - *Reproductive Health: Male Infertility, Vasectomy, Vasectomy Reversal, Microsurgical Varicocele Repair, Surgical Sperm Retrieval for IVF*
  - *Sexual Health: Erectile Dysfunction, Peyronie's Disease, Low T*

- *Broader health conditions I diagnose weekly:*
  - *Diabetes*
  - *Cardiovascular Disease*
  - *Obesity*
  - *Sleep Apnea*

## Men’s Health Outreach

*Men’s Health represents an opportunity to reach men and engage them into the broader health system*

# Erectile Dysfunction

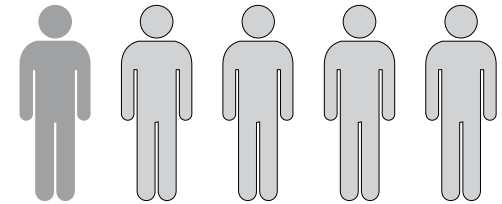
# Erectile Dysfunction

The inability to attain and/or maintain penile erection sufficient for satisfactory sexual performance[1]

[1]2018 American Urologic Association (AUA) Guidleines on Erectile Dysfunction

# Prevalence of ED

**1 in 5** American men
≥ 20 years old[1]

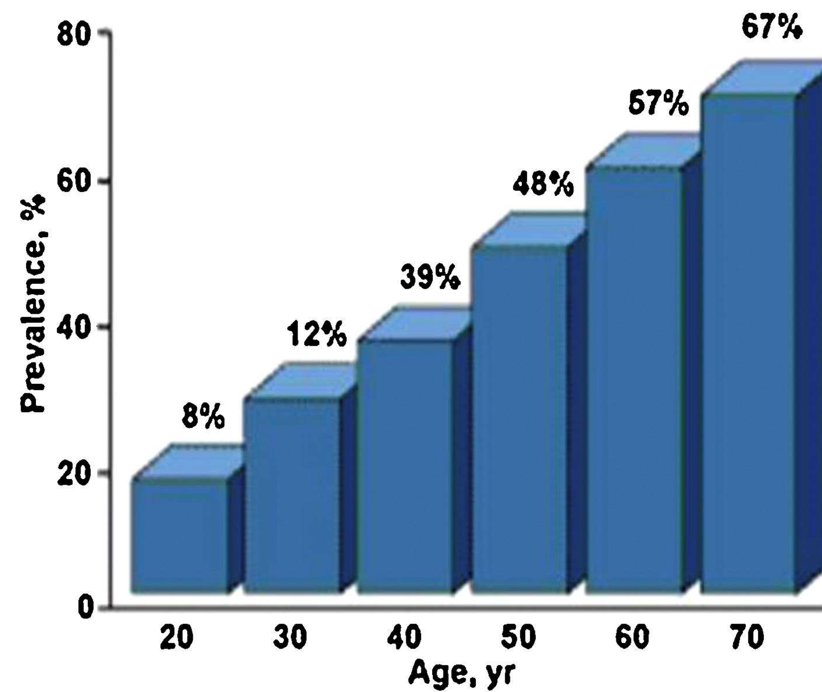


**Over 39 million** American men[2]

**More than half** of men over 40
have some degree of ED[3]

# Prevalence of ED

- ED is common and increases with age!




Colson et al 2018

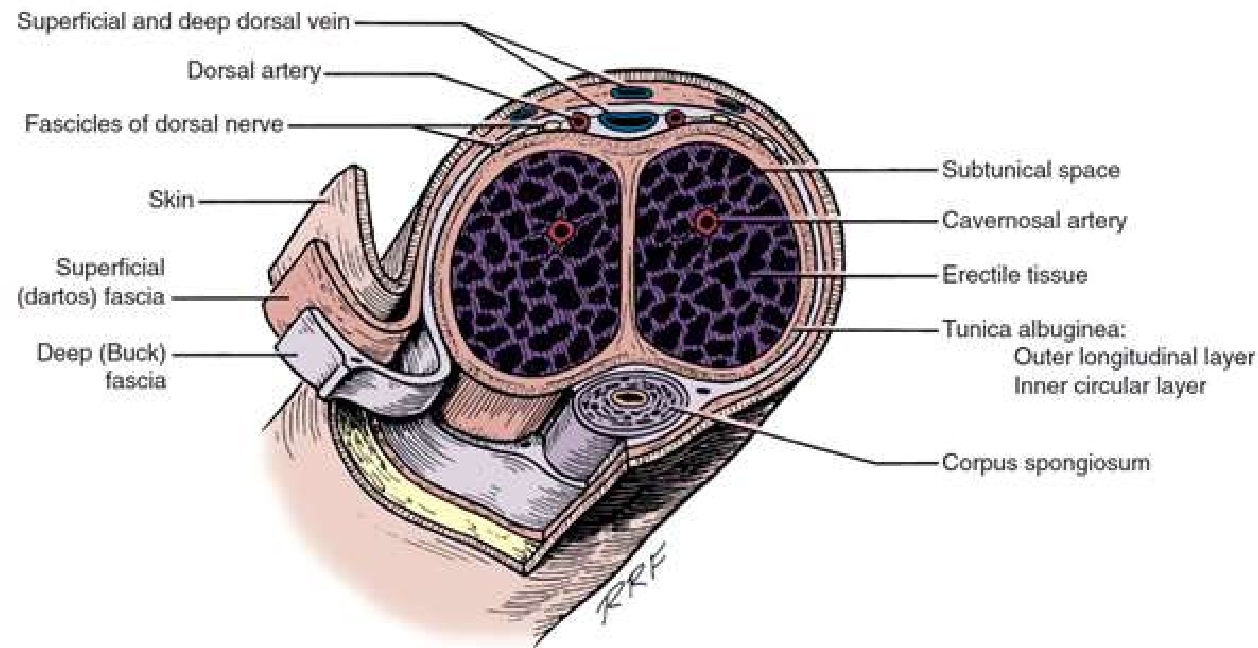
## ED Pathophysiology

Four main categories of ED:

1. **Vascular**
2. Neurologic
3. Hormonal
4. Psychogenic

# ED Pathophysiology - Vascular

- Vascular Causes of ED
  - Hypertension
  - Hyperlipidemia
  - Diabetes mellitus
  - Obesity
  - Tobacco use
  - Metabolic syndrome




Campbells 12th Edition, 2021

# ED Pathophysiology - Vascular

- ED as harbinger of cardiovascular disease
  - ED often pre-dates diagnosis of clinically-significant vascular disease by 2-3 years[1]
  - Men with ED (vs. men without ED) have a significantly increased risk of:
    - CV events by **44%**
    - MI by **62%**
    - Overall mortality by **25%**

[1]Araujo et al 2009 - Massachusetts Male Aging Study

OPTIONAL SLIDE

# ED as Harbinger of Cardiovascular Problems

**E**rectile **D**ysfunction

**E**ndothelial **D**ysfunction

**E**arly **D**eath

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# ED Pathophysiology

Four main categories of ED:

1. Vascular
2. **Neurologic**
3. Hormonal
4. Psychogenic

# ED Pathophysiology - Neurologic

- Neurogenic ED:
  - Injury to **cavernous nerve**
    - Pelvic surgery (radical prostatectomy)
    - Diabetes
  - Damage to spinal nerve routes: **S2-4**

# ED Pathophysiology

Four main categories of ED:

1. Vascular
2. Neurologic
3. **Hormonal**
4. Psychogenic

# ED Pathophysiology – Hormonal

- Hormonal causes of ED:
  - **Hypogonadism**
  - Hyperprolactinemia
  - Hypothyroidism
  - Hyperthyroidism
  - Diabetes
  - Cushing syndrome

# Medical causes of ED

**Table 3. Medications and Substances That May Cause or Contribute to Erectile Dysfunction**

| | |
|---|---|
| Alcohol, nicotine, and illicit drugs (e.g., amphetamines, barbiturates, cocaine, marijuana, opiates) | Antipsychotics (e.g., chlorpromazine, haloperidol, pimozide [Orap], thioridazine, thiothixene) |
| Analgesics (e.g., opiates) | Cardiovascular agents (e.g., digoxin, disopyramide [Norpace], gemfibrozil [Lopid]) |
| Anticonvulsants (e.g., phenobarbital, phenytoin [Dilantin]) | Cytotoxic agents (e.g., methotrexate) |
| Antidepressants (e.g., lithium, monoamine oxidase inhibitors, selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, tricyclic antidepressants) | Diuretics (e.g., spironolactone, thiazides) |
| Antihistamines (e.g., dimenhydrinate, diphenhydramine [Benadryl], hydroxyzine, meclizine [Antivert], promethazine) | Hormones and hormone-active agents (e.g., 5-alpha-reductase inhibitors, androgen receptor blockers, androgen synthesis inhibitors, corticosteroids, estrogens, gonadotropin-releasing hormone analogs, progesterones) |
| Antihypertensives (e.g., alpha blockers, beta blockers, calcium channel blockers, clonidine, methyldopa, reserpine) | Immunomodulators (e.g., interferon alfa) |
| Antiparkinson agents (e.g., bromocriptine [Parlodel], levodopa, trihexyphenidyl) | Tranquilizers (e.g., benzodiazepines) |

Rew et al 2016 (Am Fam Physician)

# ED Pathophysiology

Four main categories of ED:

1. Vascular
2. Neurologic
3. Hormonal
4. **Psychogenic**

# ED Pathophysiology – Psychogenic

- Psychogenic ED
  - Anxiety, depression, or partner-related difficulties
  - Sudden-onset of symptoms
  - Situational
  - No issues with self-stimulated erections
  - Good quality spontaneous morning erections

# ED Pathophysiology – Psychogenic

Important to assess for other etiologies beside "psychogenic"!

**Direct-To-Consumer Internet Prescription Platforms Overlook Crucial Pathology Found During Traditional Office Evaluation of Young Men With Erectile Dysfunction**

Robert H. Shahinyan, Arash Amighi, Alson N. Carey, Dar A. Yoffe, Devyn C. Hodge, Matthew E. Pollard, Justin J. Nork, Jesse N. Mills, and Sriram V. Eleswarapu

**Urology 2020**

- Patients <40 years seen for ED at UCLA Men's Clinic, 2016-2019
  - n = 388 patients
  - Mean age: 29.5 years
  - Comorbidities:
    - **15% obesity**
    - **20% prediabetes or diabetes**
    - **54% dyslipidemia**
    - **20% hypogonadism**

# ED Workup

# Evaluation of ED

- History
  - Onset, severity, context, etc
  - Psychosexual history
  - Questionnaires
    - Single-question impotence assessment
    - IIEF-5 / SHIM
  - PMHx/PSHx
    - Prior prostate cancer treatment
- Exam
  - Vital signs, BMI
  - GU: secondary sex characteristics & testis size, Peyronie’s plaques?
- Tests:
  - Testosterone level
  - Consider BMP, A1c, lipids
  - Consider **Penile Duplex Doppler US**

    → not for most patients

# ED Questionnaires

**Table 1. Single-Question Assessment of Erectile Dysfunction**

Impotence means not being able to get and keep an erection that is rigid enough for satisfactory sexual activity. How would you describe yourself?

A. Not impotent: always able to get and keep an erection good enough for sexual intercourse.

B. Minimally impotent: usually able to get and keep an erection good enough for sexual intercourse.

C. Moderately impotent: sometimes able to get and keep an erection good enough for sexual intercourse.

D. Completely impotent: never able to get and keep an erection good enough for sexual intercourse.

*Information from reference 4.*

Am Fam Physician 2016

**The IIEF-5 Questionnaire (SHIM)**

**Please encircle the response that best describes you for the following five questions:**

| Over the past 6 months: | | | | | |
|---|---|---|---|---|---|
| 1. How do you rate your confidence that you could get and keep an erection? | Very low<br>1 | Low<br>2 | Moderate<br>3 | High<br>4 | Very high<br>5 |
| 2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration? | Almost never or never<br>1 | A few times (much less than half the time)<br>2 | Sometimes (about half the time)<br>3 | Most times (much more than half the time)<br>4 | Almost always or always<br>5 |
| 3. During sexual intercourse, how often were you able to maintain your erection after you had penetrated your partner? | Almost never of never<br>1 | A few times (much less than half the time)<br>2 | Sometimes (about half the time)<br>3 | Most times (much more than half the time)<br>4 | Almost always or always<br>5 |
| 4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse? | Extremely difficult<br>1 | Very difficult<br>2 | Difficult<br>3 | Slightly difficult<br>4 | Not difficult<br>5 |
| 5. When you attempted sexual intercourse, how often was it satisfactory for you? | Almost never or never<br>1 | A few times (much less than half the time)<br>2 | Sometimes (about half the time)<br>3 | Most times (much more than half the time)<br>4 | Almost always or always<br>5 |

**Total Score:** ________________

1-7: Severe ED 8-11: Moderate ED 12-16: Mild-moderate ED 17-21: Mild ED 22-25: No ED

American Urologic Association

# ED Treatment

# ED Treatment

## First-line

- Lifestyle changes (weight loss, exercise counseling, smoking cessation)[1,2]
- Phosphodiesterase 5 inhibitors

## Second-line

- Vacuum devices
- Intracavernosal Injections (ICI)
- Intraurethral alprostadil
- Penile Prosthesis Surgery

[1]Eposito et al 2009 J Sex Med
[2]Janiszewski et al 2009 J Sex Med

# ED Treatment – Phosphodiesterase Inhibitors (PDE5i)

## Mechanism

- Competitive inhibitors of PDE5
- Promote high levels of cGMP in penile vasculature
- Causes smooth muscle relaxation and increased penile blood flow

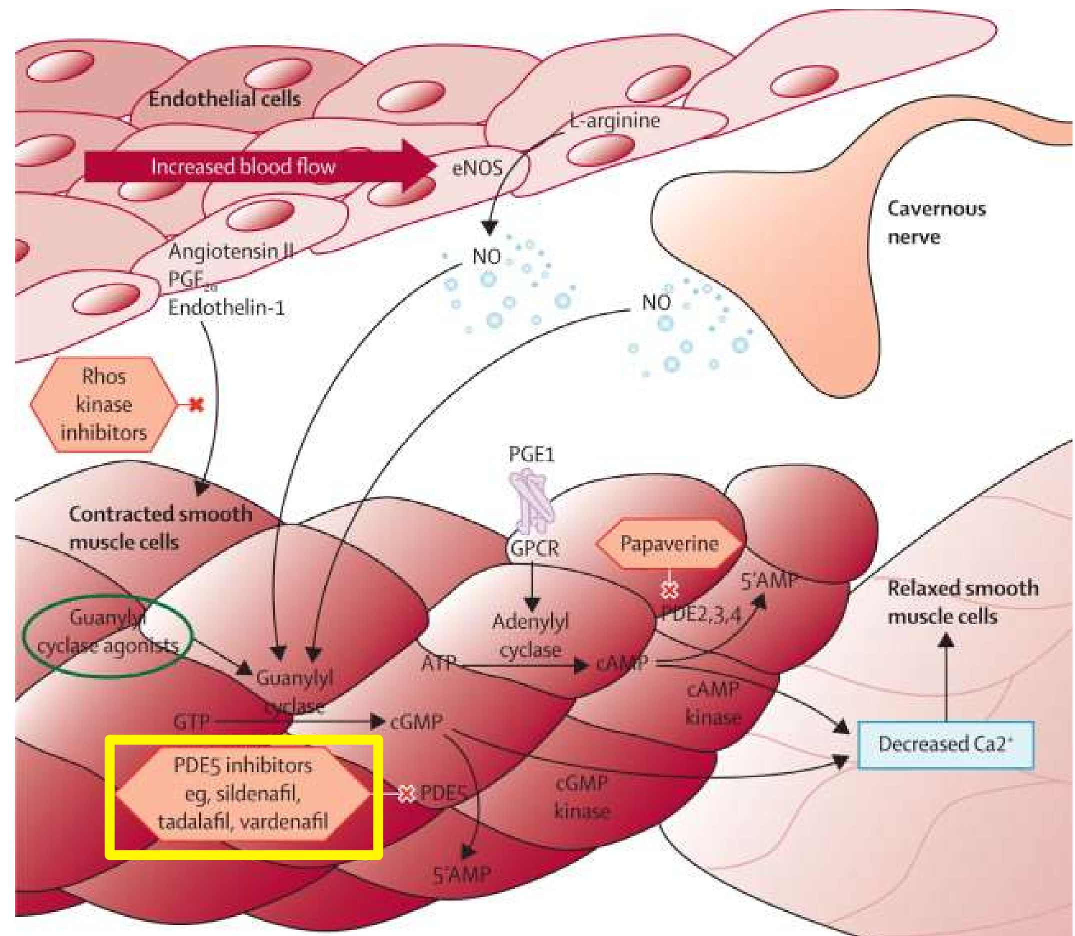

**Table 1: Phosphodiesterase Type 5 Inhibitors**

| Drug Name | Trade Name | Tmax (hours) | Serum Half Life (hours) | Dosage (mg) |
|---|---|---|---|---|
| ★Sildenafil | Viagra®, Revatio® | 1 | 3 - 5 | 25-100 |
| Vardenafil | Levitra®, Staxyn® | 1 | 3 - 5 | 5-20 |
| ★Tadalafil* | Cialis® | 2 | 18 | 5-20 |
| Avanafil | Stendra™ $$$ | 0.5 - 1.5 | ~6 | 50-100 |

*tadalafil pharmacokinetics not affected by ingestion of fatty meal

AUA Core Curriculum 33

# PDE5i Pearls

Generally well-tolerated, safe medications

- Good success rates: 60-75%[1]
    - Long-term, sustained effect (no tachyphylaxis)
- Still require sexual arousal
- Some men who fail one PDE5i may have better response to another

[1]Smith WB et al 2013

# PDE5i Contraindications

- One strict contraindication: **nitrates**
- Relative contraindications:
  - Decrease dose if concurrent use of alpha blockers
- For vardenafil/Levitra:
  - Avoid in patients with congenital QT syndrome
  - Avoid with class IA or III antiarrhythmics (amiodarone, sotalol, quinidine)



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## PDE5i Side Effects

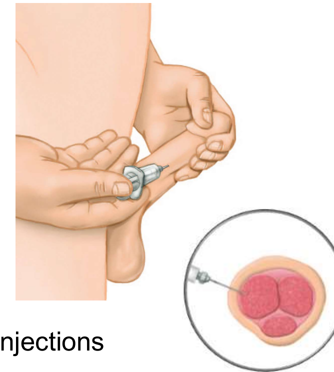
- Headache
- Facial flushing
- Dyspepsia/heartburn
- Nasal congestion
- Visual changes (sildenafil & vardenafil)
- Myalgias (tadalafil)

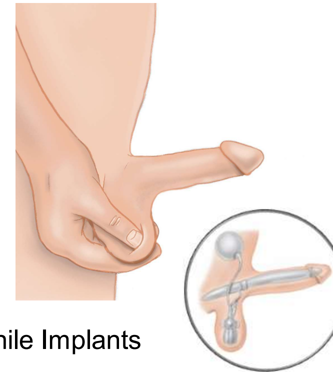
# CU Men's Health ED Regimen:

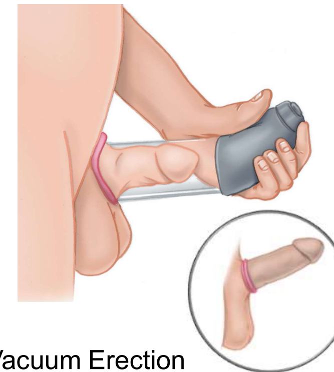
- **Our go-to regimen:**
  - Tadalafil 5mg daily + 5-15mg as needed two hours prior to sex
- **Recommended pharmacy:**
  - **CostPlusDrugs.com**: 90-day supply of 5mg tadalafil tabs: ~$20

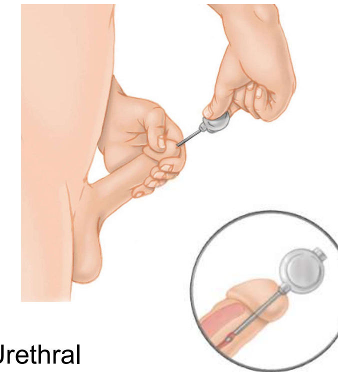
# Other Treatments for ED

- Vacuum Erection Devices (VED)
- Intracavernosal Injections (ICI)
- Intra-urethral suppositories
- Low-intensity Shock Wave Therapy (LiSWT)
- Penile Implant


Injections


Penile Implants

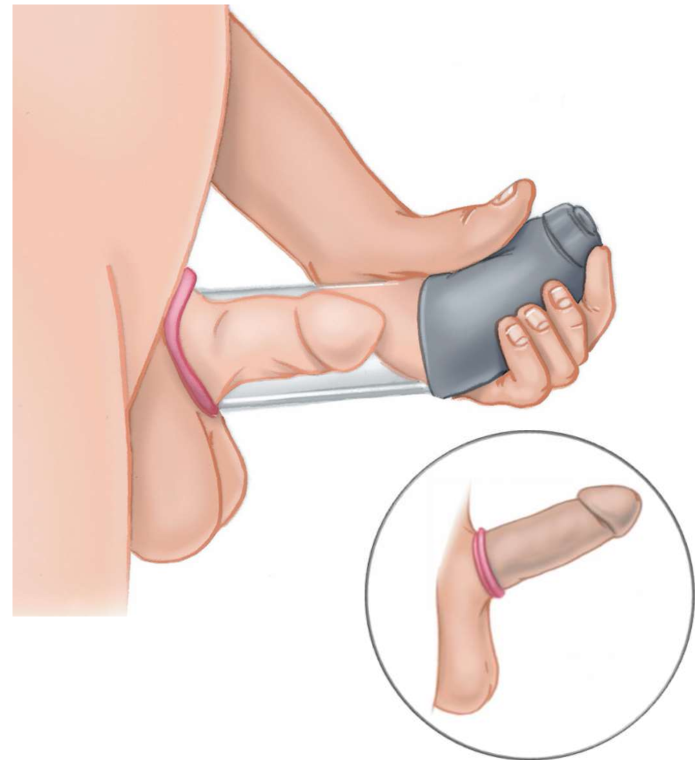

Vacuum Erection Devices


Urethral Suppositories

Boston Scientific Educational Material – EDCure.org

# Vacuum erection device (VED)

- Externally applied device mechanically affects penile blood engorgement
- Cylinder/pump placed over penis creates closed chamber, pump slowly creates vacuum, drawing blood into corpora cavernosa
- Constrictive elastic ring then placed at base of penis to restrict blood flow out of penis



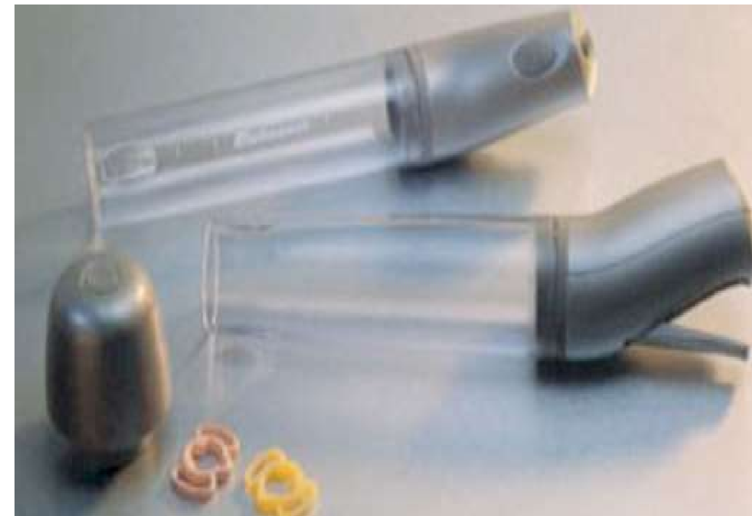
# Vacuum erection device (VED)

**Product characteristics**

- Non-invasive
- Drug-free
- Cost-effective

**Concerns**

- Erection is not warm to the touch; different color
- Bruising
- Discomfort or numbness
- Blocked ejaculation
- Limits spontaneity



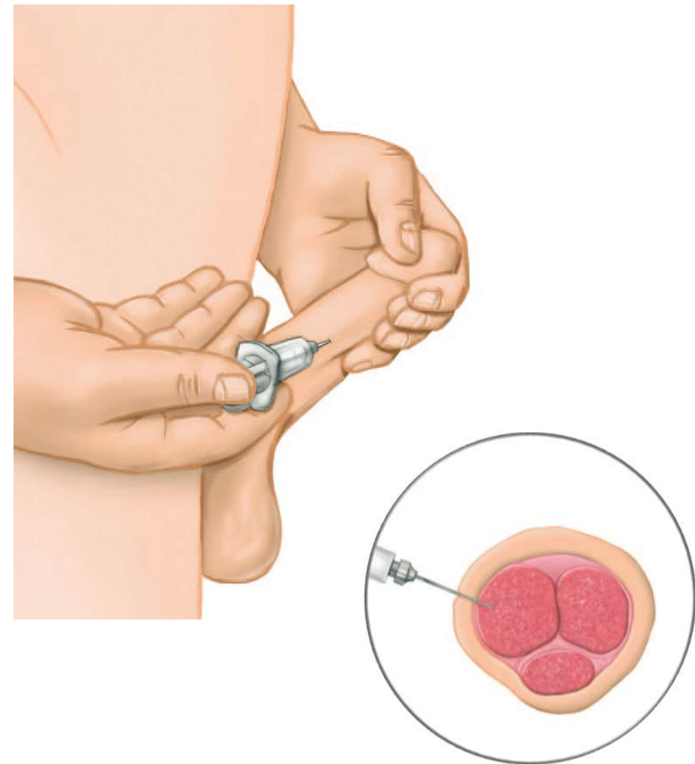
# Intracavernous injection therapy

**Product Characteristics**

- Trimix most widely used combination
  - Alprostadil, papaverine, phentolamine
- Injected directly into corpora cavernosa
- Onset of erection within 5–20 minutes

**Concerns**

- Penile pain
- Prolonged erection/priapism
- Penile fibrosis
- Injection site hematoma
- Interferes with spontaneity



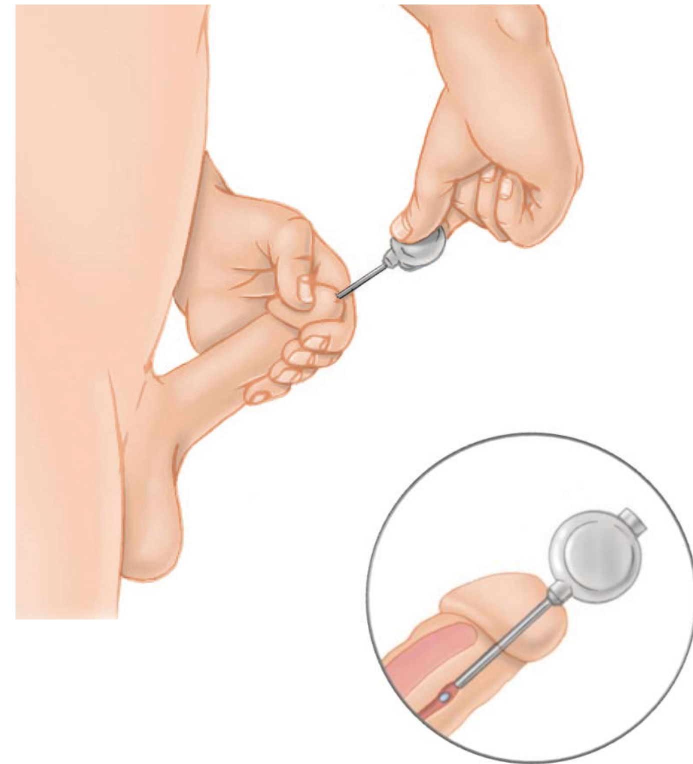
# Urethral suppository

**Product characteristics**

- No needles or injections
- Alprostadil vasodilatory effects increase blood flow
- Erection within 5–10 minutes
- Must be refrigerated, may limit spontaneity

**Concerns**

- May cause pain: penis, urethra or testes
- Urethral pain or burning
- Hypotension/dizziness
- Recommend condom use with oral sex
- Costly, often not covered



# Low Intensity Shock Wave Therapy (LiSWT)

- Acoustic waves transferred to target tissues causing mechanical stress, potentially increasing angiogenesis and stem cell stimulus
- LiSWT has potential benefit for mild to moderate vasculogenic ED
- Unclear treatment effect duration[3]
- Low-risk, non-invasive
- Not covered by insurance, can be $$$

[1]Kalyvianakis et al 2022
[2]Fojecki et al 2017
[3]Kitrey et al 2018

# Penile implants

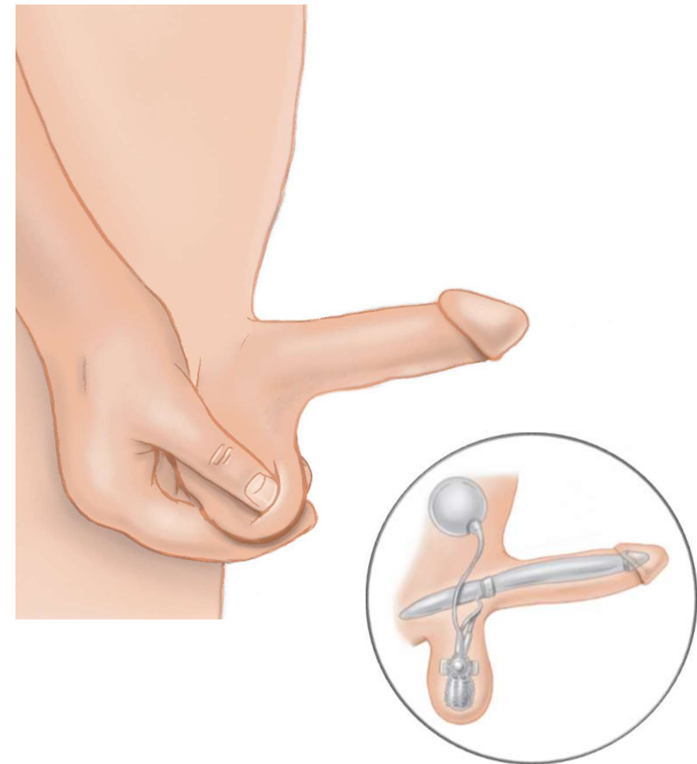
**Product Characteristics**

- In clinical use since the 1970s
- Device entirely contained within the body
- To operate, squeeze and release the pump in the scrotum to achieve an erection

**Concerns**

Most common side effects/complications:[54]

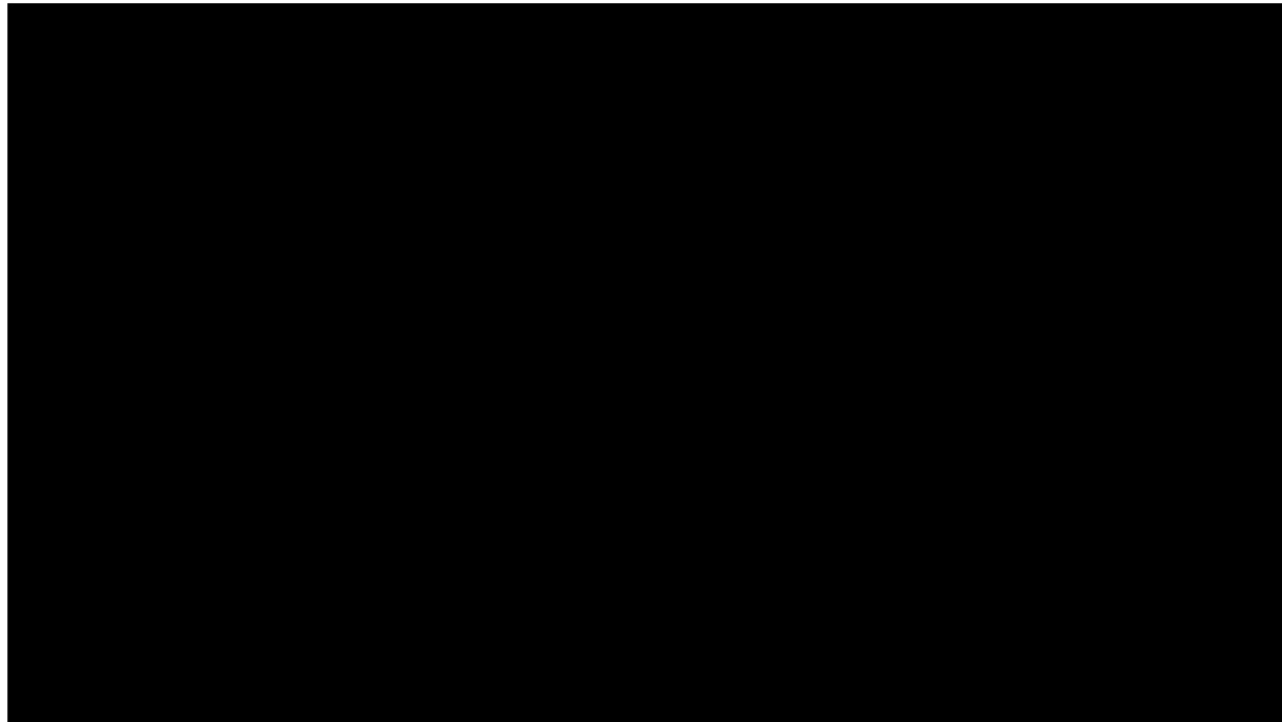
- Pain associated with healing
- Mechanical malfunction, including auto-inflation
- Infection
- Repeat surgery



OPTIONAL SLIDE

# How an Inflatable Penile Prosthesis works

- Squeeze the pump located in the scrotum
- Fluid moves into the cylinders to create an erection
- Deflate the device by pressing the deflate button on the pump
- Fluid moves from cylinders back into the reservoir
- The penis then returns to a soft, flaccid and natural-looking state



Boston Scientific Educational Video – EDCure.org

# Features of a penile implant

- Designed as a permanent solution to ED
- Allows for spontaneity
- Once activated, an erection can be maintained for as long as desired
- Entirely contained inside the body
- Designed to feel natural during intercourse
- Does not interfere with ejaculation, orgasm or urination[55]
- Implants have been in use for more than 40 years[56]
- Nearly 500,000 patients have been treated with a Boston Scientific penile implant[57]

# Penile implant satisfaction

## Penile implants have been well-received by patients and partners

In one study of 200 patients and 120 partners, both men and their partners found the penile prosthesis to be satisfying[58]

**92%**

**of patients** reported sexual activity with the implant to be excellent or satisfactory

**96%**

**of partners** reported sexual activity with the implant to be excellent or satisfactory

**98%**

**of patients** reported their erections to be excellent or satisfactory

# Peyronie's Disease

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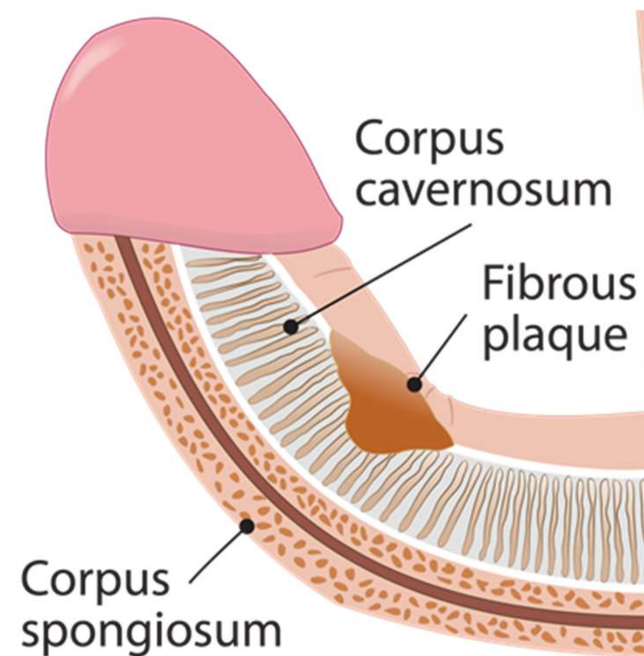
# What is Peyronie's Disease

Development of fibrous scar tissue inside the penis that causes curved, painful erections

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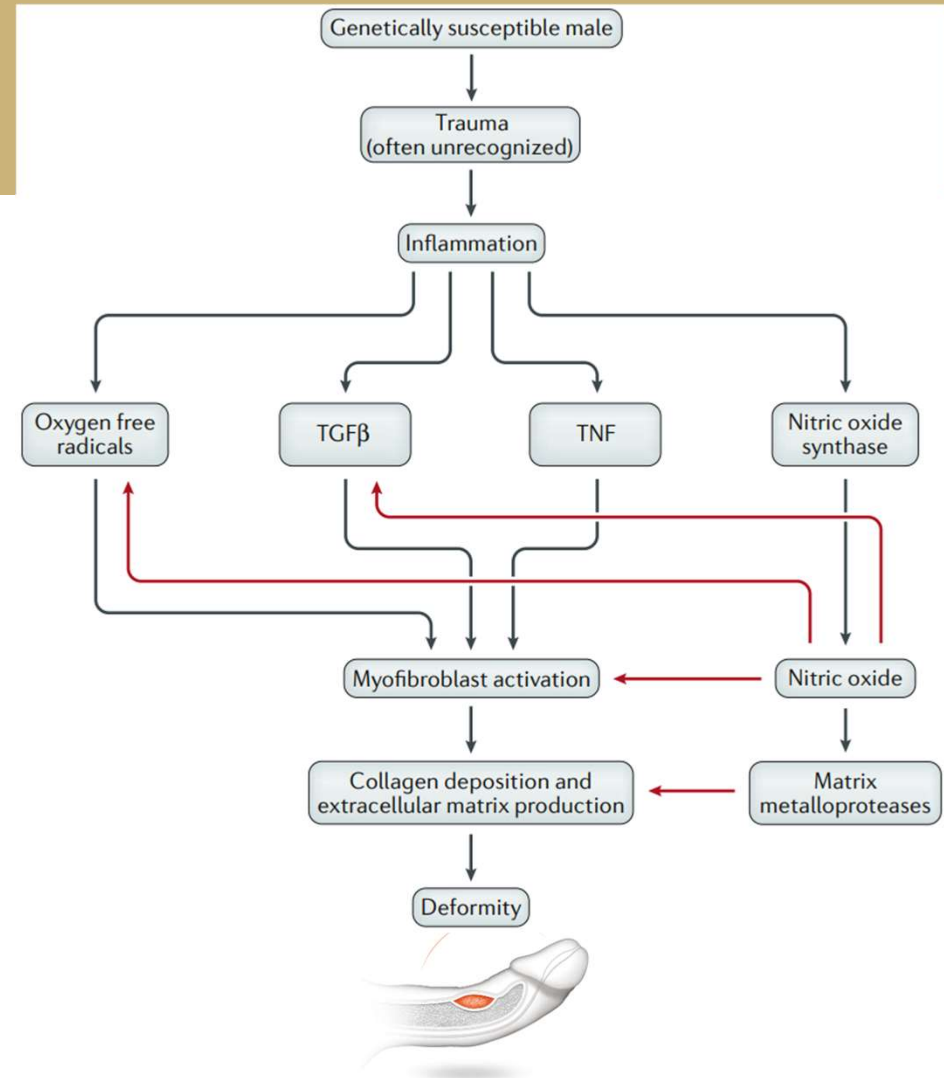
# Peyronie's Disease – History

- Francois Gigot de la Peyronie
- First Surgeon to Louis XV in 1736
- Dissertation: *On Impaired Ejaculation. Dissertation on Some Obstacles to the Natural Ejaculation of Semen*

# Peyronie's Disease

- Connective tissue disorder of the tunica albuginea
- Two phases:

| **Acute Phase** | **Chronic Phase** |
| --- | --- |
| - First 6-18 months | -Pain resolves |
| - Painful | -Curve persists |

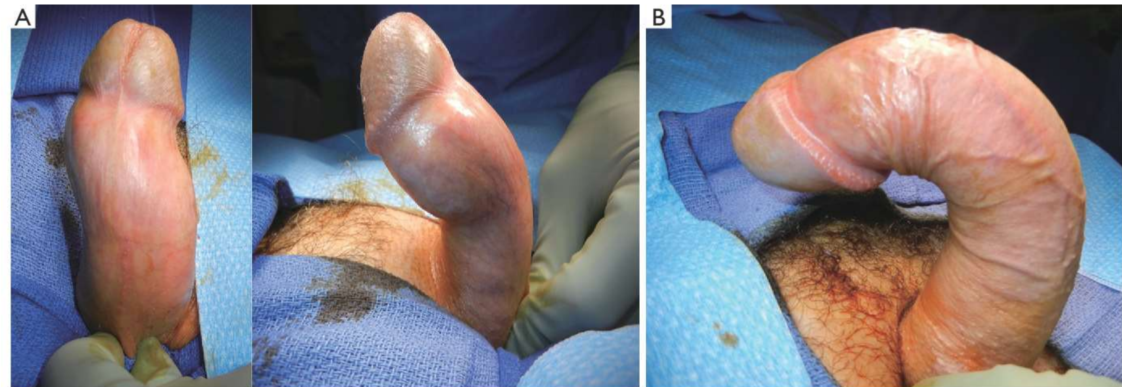



Tsambarlis, Levine et al 2019 Nat Rev Urol

OPTIONAL SLIDE

# Peyronie's Disease - Impact

- Inability to have sexual intercourse
- Difficulty achieving or maintaining an erection
- Anxiety or stress about sexual abilities or appearance of the penis
- **Psychological stress to patient and partner**




Wayne et al 2018 *Translational Anrol and Urol*

# Peyronie's Disease - Epidemiology

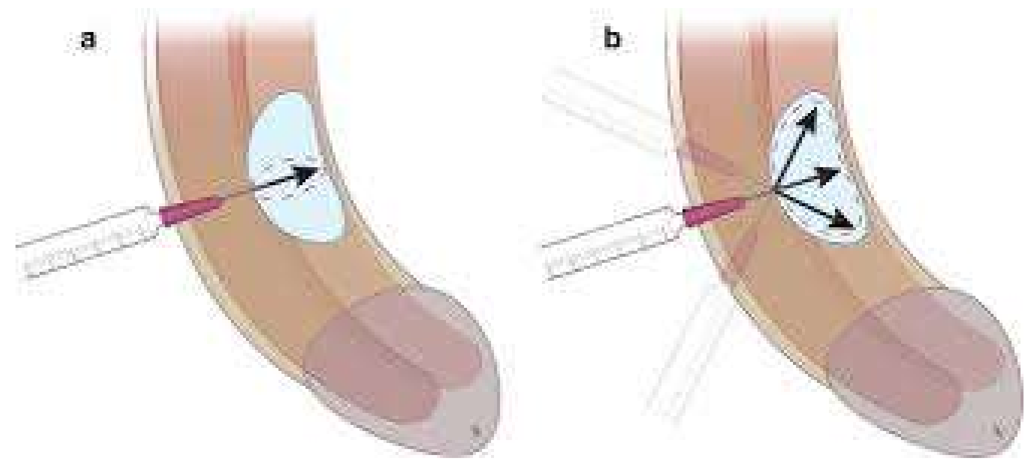
- Estimated prevalence: ~10%
- Average age of onset: 45-55 yrs
- Associated with Dupuytren's contracture and plantar fasciitis
- Often carries significant psychological burden

Stuntz et al 2016 PLoS One

# Treatment options for Peyronie's disease

Medication:

- **XIAFLEX™ injections** – series of 8 separate injections of collagenase enzyme into the fibrous plaque




"Fan" injection technique - Mills et al WJU 2019

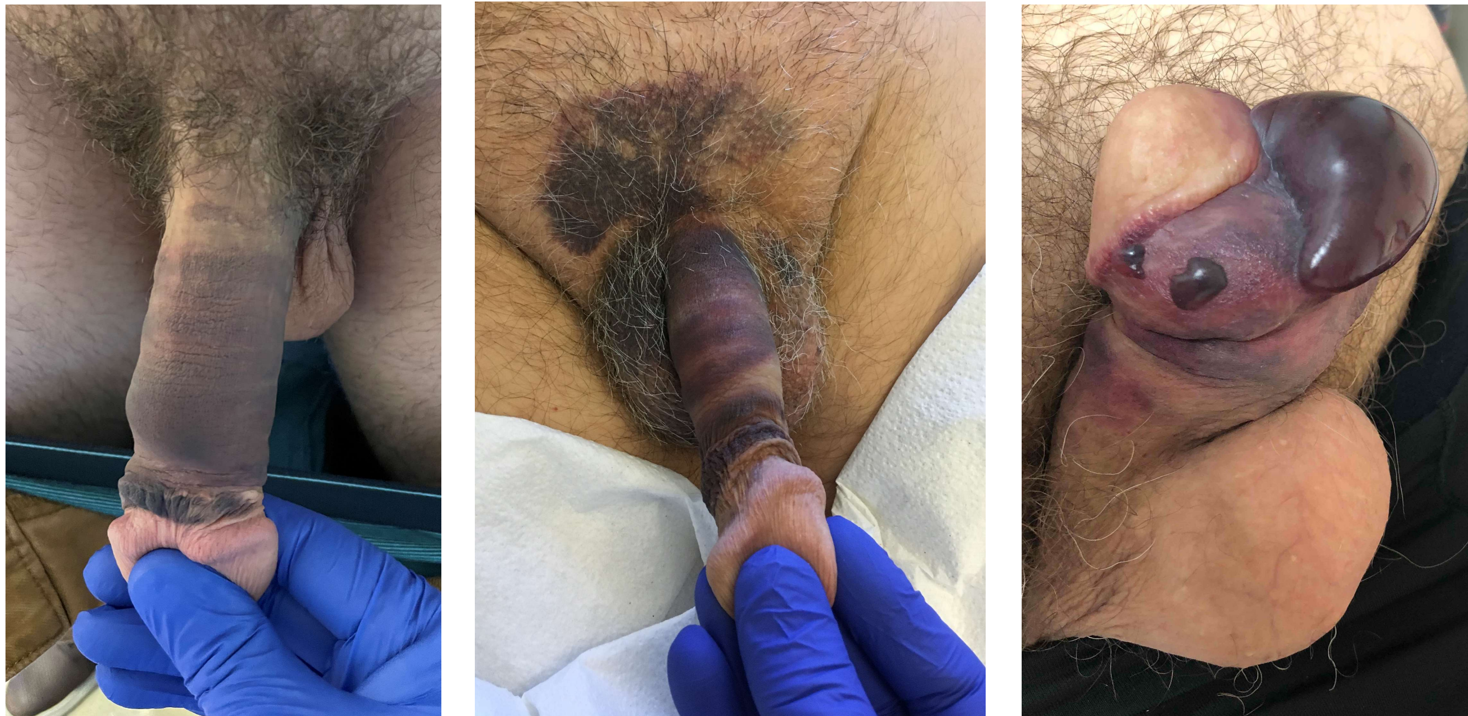
# Treatment options for Peyronie's disease

**XIAFLEX**

- Only FDA-approved, non-surgical treatment for Peyronie's Disease
- Mixture of Type I and II collagenases
- Expected Improvement?
  - → ~35% improvement in penile curvature

[1]IMPRESS Trial Gelbard et al 2013 J Urol

# Adverse Effects – Xiaflex Hematomas

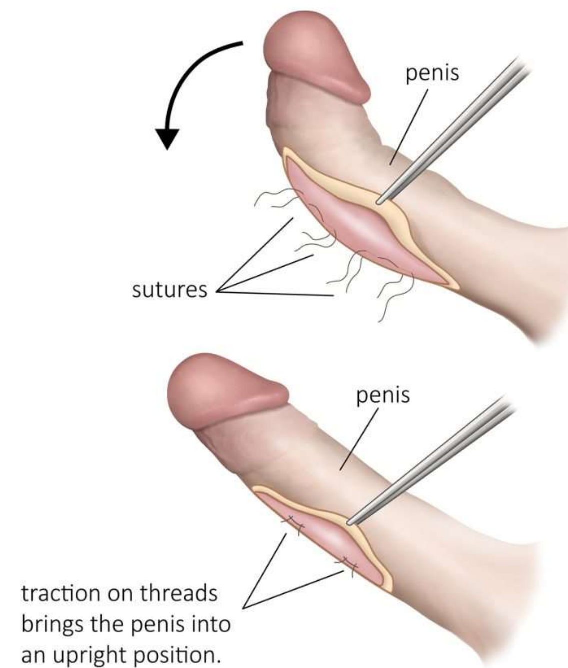


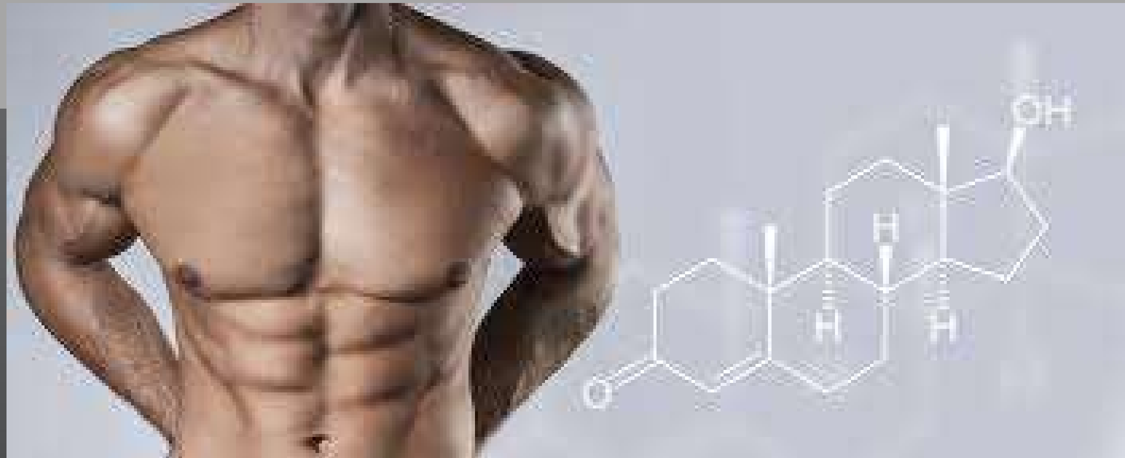
"Fan" injection technique has lowered risk to ~5%

# Treatment options for Peyronie's disease

Surgical Treatments for Peyronie's Disease:

- **Penile Plication**
- **Plaque Excision and Grafting (PEG)**
- **Penile Implants** – for patients with BOTH ED and PD





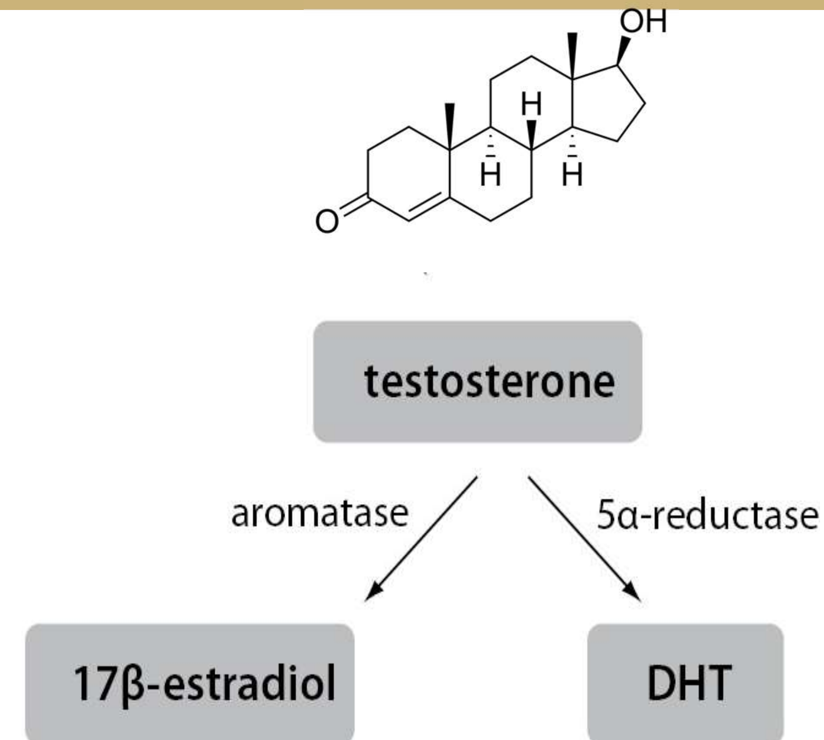

# Hypogonadism / Testosterone Deficiency: Recent Updates

# Testosterone - Review

- Quintessential male hormone
  - Secreted by testes
  - Half life in plasma = 12 minutes
  - Predominant circulating androgen

- **Men > 40yrs: T levels decline at 1-2% per year[2]**

- **Normal range: 300-1,000 ng/dl**




[1]Basaria et al 2008
[2]Bremner et al 1983

# Evaluation of Testosterone Deficiency

Signs and symptoms along with a total testosterone < 300 ng/dL (AUA)

Sexual

- **Diminished libido**
- Decreased spontaneous erections
- **Erectile dysfunction (ED)**
- Diminished response to PDE5i (sildenafil/tadalafil)

Non-Sexual / Psychological

- **Diminished energy**/vitality/well being
- Fatigue
- Depressed mood
- Irritability
- Decreased cognition
- Reduced motivation
- **Decreased bone mass**

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# Controversy Surrounding TRT

- Majority of retrospective studies showed that LOW testosterone associated with increased CV risk
- However, 4 articles in early 2010s suggested potential increased CV risk of TRT
  - *Basaria et al NEJM 2010, Finkle et al PLoS One 2014, Vigen et al JAMA 2013, Xu et al BMC 2013*
- 2015 – FDA Label Change
  - **Black Box Warning**: Studies have been inconclusive for determining risk of MACE and patients should be informed of this possible risk
- 2015 – FDA guidance to start RCT to better evaluate – TRAVERSE trial genesis

# TRAVERSE TRIAL

The NEW ENGLAND JOURNAL of MEDICINE
ESTABLISHED IN 1812 JULY 13, 2023 VOL. 389 NO. 2

## Cardiovascular Safety of Testosterone-Replacement Therapy

A.M. Lincoff, S. Bhasin, P. Flevaris, L.M. Mitchell, S. Basaria, W.E. Boden, G.R. Cunningham, C.B. Granger, M. Khera, I.M. Thompson, Jr., Q. Wang, K. Wolski, D. Davey, V. Kalahasti, N. Khan, M.G. Miller, M.C. Snabes, A. Chan, E. Dubcenco, X. Li, T. Yi, B. Huang, K.M. Pencina, T.G. Travison, and S.E. Nissen, for the TRAVERSE Study Investigators*

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- Inclusion: men ages 45-80 yrs with CV disease or CV risk factors, 2018-2023
- T<300 ng/dl and hypogonadal symptoms
- 6000 patients randomized to testosterone gel or placebo – double blinded
- 5 year follow up
- Largest RTC ever of men receiving testosterone therapy
- Findings:

→ **CV safety: no significant difference in major CV events**

→ **Prostate safety: no significant difference in prostate cancer incidence**

## Testosterone Take Home Points

- Testosterone Deficiency is common and treatable
- Testosterone Deficiency = T < 300 + symptoms
- Exogeneous testosterone therapy does impair sperm production
- Testosterone Replacement Therapy now with proven CV and prostate safety

# Updates in Prostate Cancer Screening

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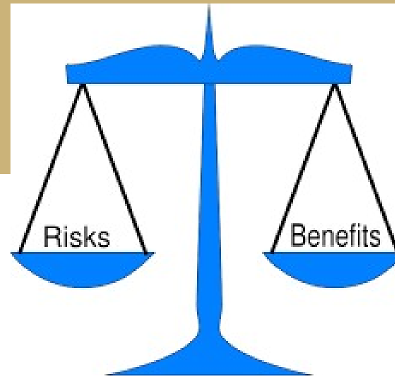
# Prostate Cancer Overview

- Prostate cancer is common
  - #1 solid organ cancer in men
  - #2 cause of cancer-related mortality in men
- Lifetime risk of PCa = 17%
- Risk of dying from PCa = 2.6%
- Prostate cancer is treatable if diagnosed early

| SEER Stage | 5-year Relative Survival Rate |
|---|---|
| Localized | Nearly 100% |
| Regional | Nearly 100% |
| Distant | 30% |
| All SEER stages combined | 98% |

American Cancer Society statistics

# PSA Screening




### Risks

- False Positive
- Overdetection
- Overtreatment
- Anxiety/psychological stress
- Cost
- Risk of biopsy (sepsis)

### Benefits

- Much higher treatment success rates if caught early
  - 5 year survival:
    - ~100% if detected early
    - ~30% if detected with distant metastasis
- RCTs show decreased prostate cancer mortality by ~30%

# PSA Screening Timeline

- **2012**: USPSTF recommended against PSA screening
- Subsequent rise in number of metastatic prostate cancer cases and prostate cancer deaths
  - 2011 – 4% with metastatic disease
  - 2019 – 8% with metastatic disease
- **2018**: USPSTF reversed decision: men aged 55-59 should make an individualized decision about PSA-based screening

Nyame et al 2020 JNCI Cancer Spectr

# PSA Screening: Current Recommendations

* Use Shared Decision Making

* Offer screening starting ages **45-50 years**

* For men at increased risk of PCa, start offering screening at ages **40-45 years**
  - Black ancestry
  - Known germline mutations (BRCA1 & 2)
  - Strong family history of prostate cancer

* Offer regular screening every 2-4 years for men ages **50-69 years**

* Clinicians may personalize the re-screening interval based on:
  - Patient preference, age, PSA, prostate cancer risk, life expectancy, general health

Wei et al 2023 *J Urol* AUA/SUO Guideline

# What to do when PSA returns elevated?

- Repeat test and refer to Urology
- Refer for any elevated PSA or rise in PSA >0.5 ng/ml/year

**Age-Based Cutoffs for Normal PSA Values**

| Age | Upper limit ng/mL* |
|---|---|
| <40 | 2.0 |
| 40-49 | 2.5 |
| 50-59 | 3.5 |
| 60-69 | 4.5 |
| 70-79 | 6.5 |
| ≥80 | 7.2 |

Mayo Clinic

# Men's Health Take Home Points

- Men represent an undertreated and at-risk population within American health care
- ED is common, treatable, and harbinger of greater cardiovascular disease and mortality
- Peyronie's disease is psychologically devastating condition with different treatment options
- Testosterone Updates: new Level I data proves cardiovascular safety of testosterone therapy
- Prostate Cancer Screening: offer PSA surveillance ages 45-69 yrs for average risk men

# Thank You

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