

# Bio-Identical Hormones: Do they really work?

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Assure Wellness Group  
Chesapeake, VA

# Speaker Information



Bio: James Cannon, DHA, MBA, PA-C, DFAAPA of Chesapeake, Va., is a practicing PA working in hospital medicine and psychiatry (inpatient/outpatient) in addition to serving as a managing partner/clinician for a bio-identical hormone practice. He is a past chairman of the board of the NCCPA, where he has served for 8 years as a director at large, secretary, and treasurer.

James completed his PA training and Masters of Science from the Arizona School of Health Sciences/A. T. Still University. He has also earned a Masters of Business Administration and a doctorate in health care administration and policy. He is a certified PA with a Certificate of Added Qualification in Psychiatry in addition to advanced training and certification in age management from the American Board of Anti-Aging Health Practitioners (A4M).

In addition to publishing his dissertation, he has authored numerous articles in medical journals and books. James works with numerous professional groups, including the American Academy of Physician Assistants and Association of PAs in Psychiatry. He also serves on the Board of Trustees of A.T. Still University the founding school of osteopathy as the only non-physician/dentist director. James and his wife reside in Chesapeake, VA with two dogs while his daughter attends the University of Texas, in Arlington, studying pre-law.

## DISCLOSURE:

No disclosures or conflicts to report

# Disclosures

- Biote (BHRT) practice owner ([www.biotemedical.com](http://www.biotemedical.com))
- BHRT patient 10 years
- Shire advisory board
- Psychiatric congress steering committee

# Objectives

- Understand the basics of Bio-identical Hormone Replacement Therapies (BHRT)
- Understand the indications and contraindications for BHRT
- Understand the most common methods for treating BHRT
- Be able to describe the clinical picture of a successfully treated BHRT patient

# What would a medicine be worth?

- Increased bone density
- Lowered the risk of breast cancer
- Relieved anxiety and depression
- Increased libido and sexual performance
- Increased muscle mass
- Decreased fatty tissue
- Heart protective, coronary vasodilator
- Brain protective, restored memory
- Does not increase the risk of strokes
- Does not adversely affect the liver

Like This ?



Or Like This?



# What are Hormones?

- Chemicals made by the glands that act to control certain actions of cells and organs
- They are the messengers & work in a Lock & Key Fashion





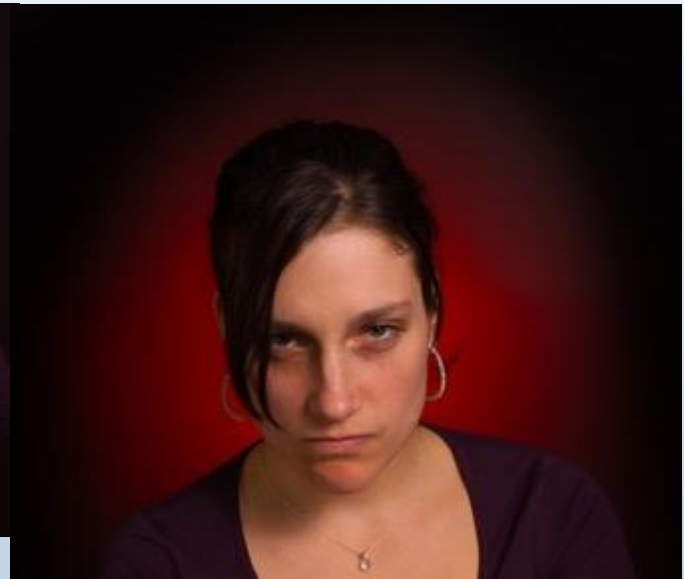
# Case 1 – Bob

- 48 y/o male professional
- Weights 222 lbs with 28 BMI
- Afternoon crash at 3pm
- General decline ins sense of “wellbeing”
- Rarely working out/exercising
- Non existent libido

## Case 2 - Mary

- 52 y/o female G2P2
- Menopause for 2 years
- Significant vaso-motor complaints with major life impact
- Poor sleep hygiene
- Labile mood prescribed SSRI
- Painful intercourse

# Hormone Havoc!



# How are these symptoms usually addressed?

- **Self-treated: energy drinks, B12, alcohol, “uppers”, weight loss meds, etc...**
- **Many doctors treat classically...**
  - **Fibromyalgia → pain meds → drowsiness/addiction**
  - **Depression → antidepressants → sexual dysfunction**
  - **Insomnia → sleeping pills → worsening sleep apnea or daytime sleepiness**
  - **Erectile dysfunction → from Medication side-effects?? (BP meds, diabetes meds, etc...) → Viagra, Cialis, etc...**
  - **Many more...**

# The Health/Wealth Connection

What Your clinician doesn't know!



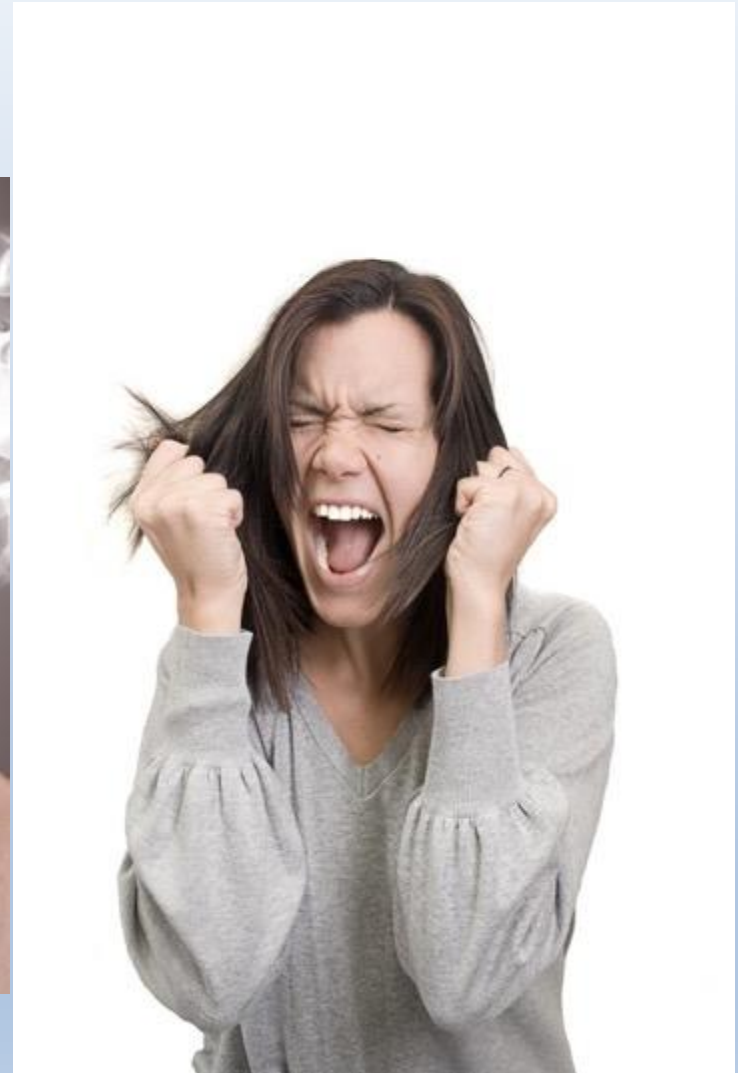
# Why talk about hormones?

## How will this help me?

***Hormone balance*** gives you the ability to be FULLY present and productive each and every day, creating wealth and abundance in all aspects of life:

- *Financially*
- *Emotionally*
- *Physically*
- *Spiritually*

# ***How do you *FEEL*?***



# HRT Facts

- Every day 3,500 women enter into menopause
- Symptoms of menopause can begin up to 15 years earlier
- Male Hypogonadism is present in 39% of males over 45 years old (2006 HIM Study)
- Men lose up to 3% testosterone production per year after age 35



# Facts about Andropause

- AKA male menopause or “Manopause”
- 20% of males over 50 have low testosterone
- Low testosterone common in men with diabetes, high BP, sleep apnea & other chronic disease
- Low testosterone linked to early heart disease
- Underdiagnosed

# BHRT Basics

- Similar vs. identical (“bio” & “human”)
- Synthetic vs. natural
- Quality
- Cost
- Efficacy

# What You Need To Know

- 1) Not all hormone therapies are created equal
- 2) Hormone replacement therapy is not a “one-size-fits-all” approach
- 3) You need an expert !

# Estrogen has 400 functions in your body:

- Control hot flashes
- Maintain bone density
- Helps maintain memory
- Reduces risk of colon cancer
- Maintains collagen in your skin
- Increases serotonin and dopamine
- Smoking and Stress decrease your estrogen



# ***TESTOSTERONE: THE BRAIN HORMONE***

Besides providing major symptom relief, it protects the BONES, BRAIN, BREASTS, HEART, JOINTS, and *RELATIONSHIPS!!!*

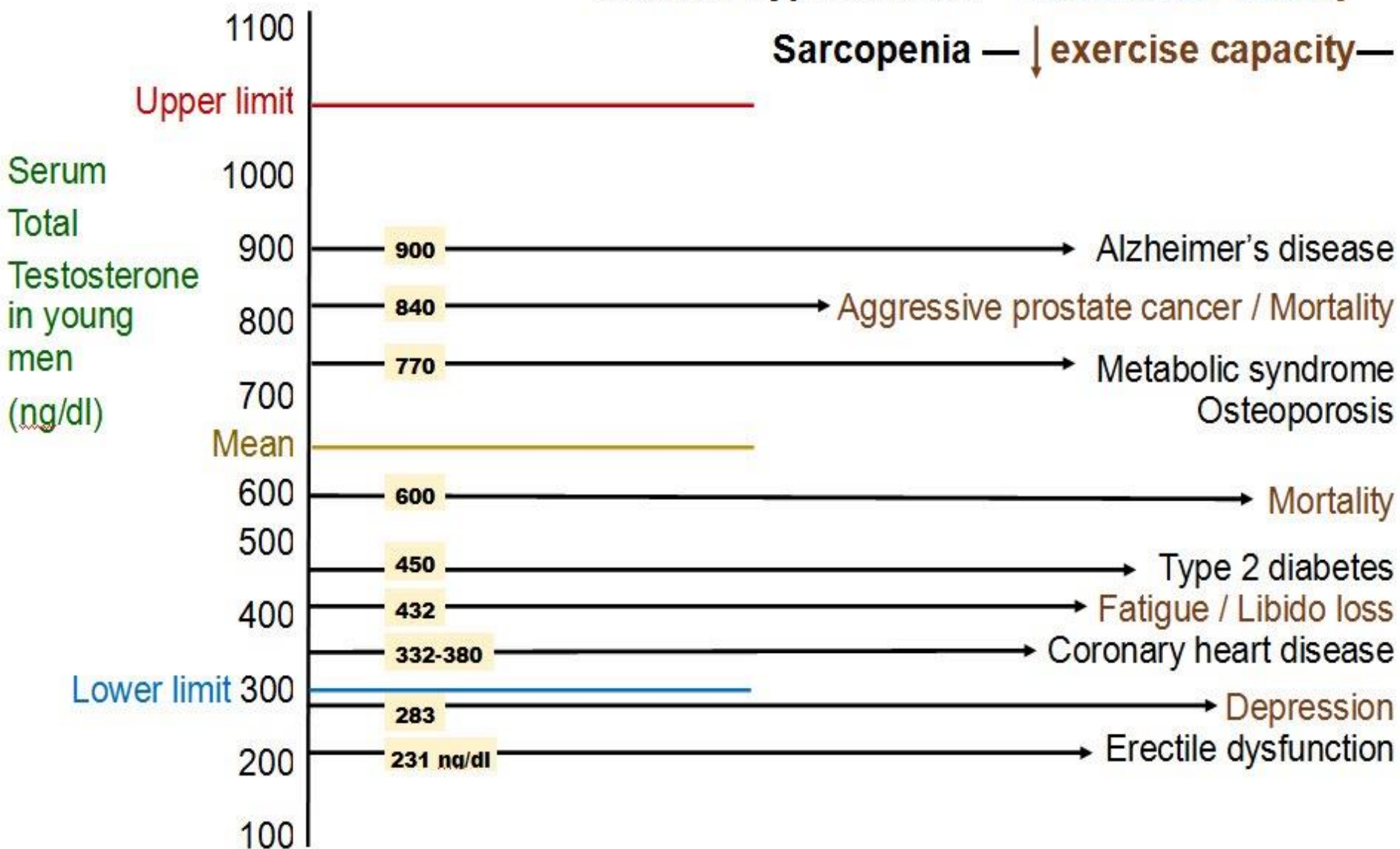
- Men age 30-70 will lose 1- 3% of total testosterone production per year
- Women age 20-40 lose 50% of their testosterone production
- (YES women make and NEED testosterone!)

# Testosterone Thresholds below = > ↑ disease, mortality

Dyslipidemia — Atherosclerosis, Arterial Stiffness —

Arterial Hypertension — Abdominal obesity —

Sarcopenia — ↓ exercise capacity —



# Male and/or Female Symptoms

- Tired
- Mood swings
- Tension
- Lack of sleep
- Memory loss
- Decreased sex drive
- Depression
- Hot flashes
- Night sweats
- Weight gain
- Joint pain
- Migraine/severe headache
- Fatigue 3-4 o'clock hit a wall??
- Loss of erectile ability



***Sounding Familiar?***

# Standardized Screen

- Men
  - Andropause Scale
  - BHRT scale
- Women
  - Menopause scale
  - BHRT scale



# HRT Methods

- **Synthetic**

- Pills
- Patches
- Injectables

- **Bio-identical**

- Pills
- Patches
- Creams/Gels
- Pellets

# Contraindications

- Men
  - Prostate cancer?
  - BPH?
  - Erythrocytosis?
  - Coronary Artery Disease?

# Contraindications

- Women
  - Breast cancer?
  - Coronary Artery Disease?



If the shoe were on the other hoof

# Conventional HRT

## Women's Health Initiative Trial

- 41% increase in stroke
- 29% increase in heart attacks
- 26% increase in breast cancer
- Twice the rate of blood clots
- 76% Increase in Alzheimer's Dementia



**Note:**

*After this trial many women were left with NO alternative for hormone balance and symptom relief.*

*Sadly, there have been safe, alternative methods available for years.*

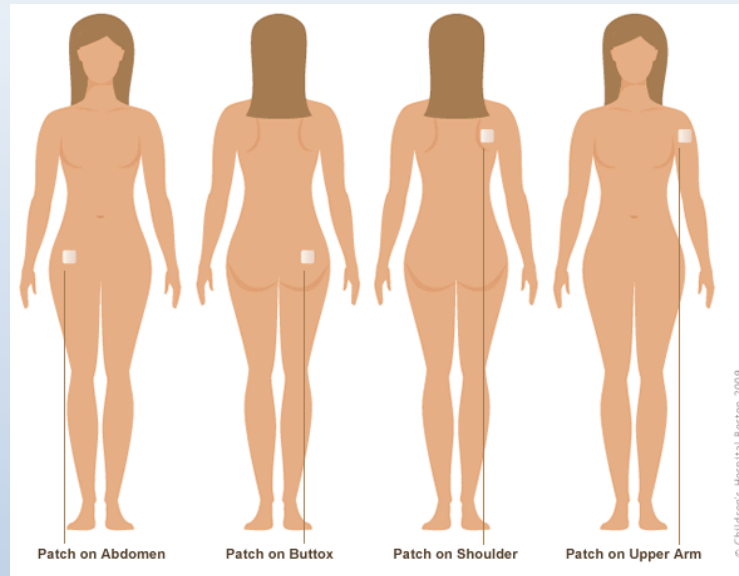
# Pills

- Peaks and valleys
- First pass metabolism “Sludge” through the liver
- Breast stimulators
- Take something everyday
- Vaginal bleeding
- Blood clots
- Headaches

# Potential and Unnecessary Effects of Oral Estrogen Therapy

- Breast tenderness
- Increased risk of endometrial cancer and breast cancer
- Vaginal bleeding
- Headaches
- Nausea and vomiting
- Fluid retention
- Blood clots
- Leg cramps
- Gallstones

# Patches



- Estradiol levels better than pills, but not as good as pellets
- Adhesive problem
- Need to be changed throughout the week

- Some weight gain, but less fluid retention than being on synthetic or horse estrogen  
45% of people do not absorb hormone through the skin

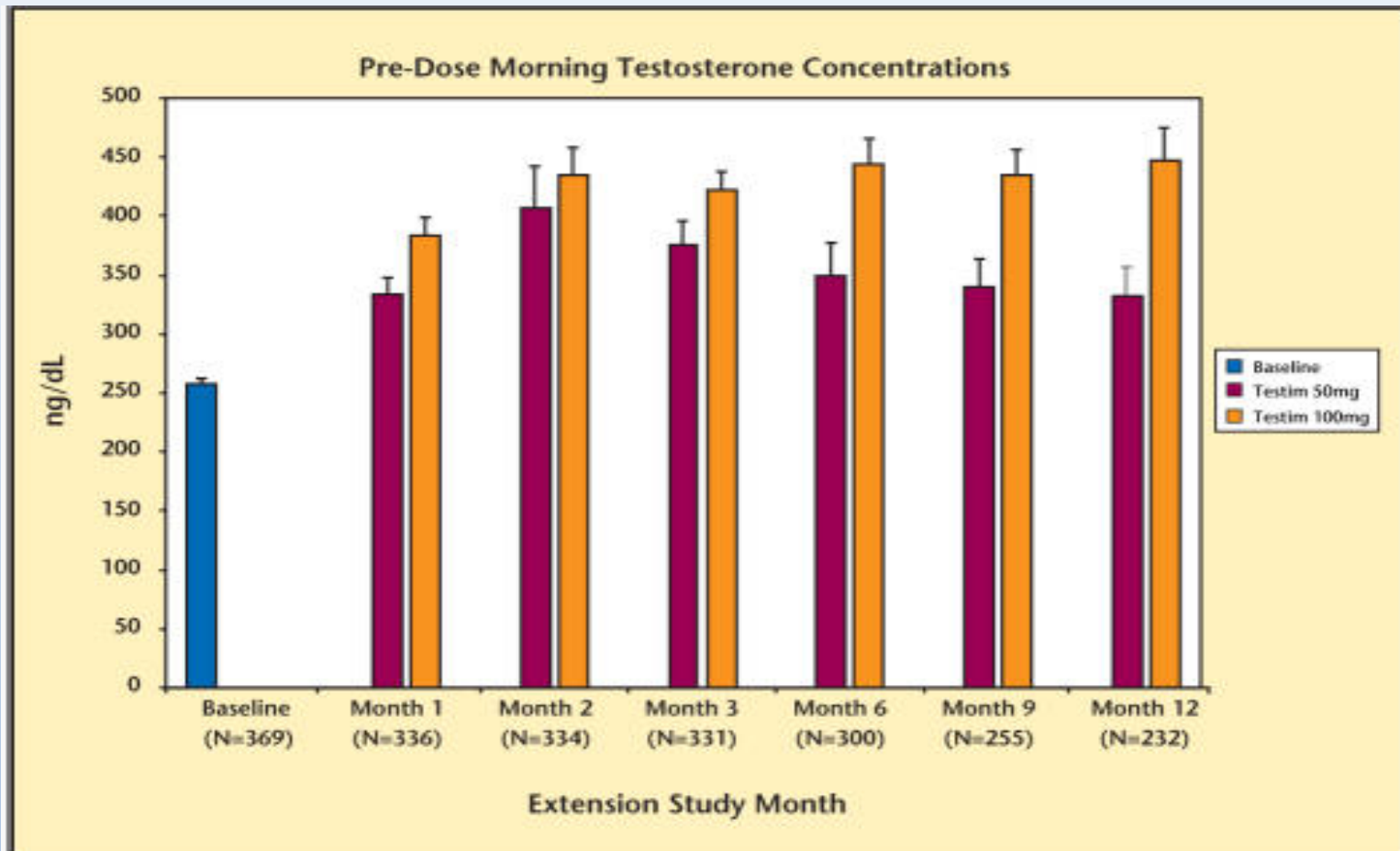


# Creams/Gels

- Did you apply enough?
- Have to remember to rub it in daily
- Short half-life; may need twice daily dosing
- Applied topically onto the skin
  - How long do I have to wait to get dressed?
- Can transfer to others (babies and pets)
- Most important Estriol (as in the product BiEst) does not have bone, heart, and brain protection



# TESTIM 1%



# Injectable Testosterone

- Uneven absorption
- Significant “roller coaster” effect
- Synthetic hormone
- Significant adverse effects:
  - Liver toxicity, CAD, Prostate Cancer and many others
- Anabolic steroids (17- $\alpha$ -alkyl) cannot be aromatized and therefore are very dangerous. Many studies prove this.
- Elevate LDL, decreases HDL
- ALWAYS Wears off before the time for next shot...  
*makes guys really cranky....*



# Pellets

- Keeps the estradiol to estrone ratio at 2:1
- Biologically identical
- Natural yam/soy derived compounds
- Constantly available to the body
- Absorbed directly, not taken orally
- Steady state of hormones - No roller coaster effect
- Minimal weight gain, if any
- Safe and hassle Free
- Individualized dosing
- Lasts longer than other treatments



# Pellets (con't)

No perfect therapy including pellets

- Requires a procedure
- Requires inventory or pre-planning for pellets
- Men = extrusion, some discomfort, higher occurrence of localized reaction (3-5%)
- Women = rare occurrence of complication

# History of Pellets

- Developed in 1939 for women who had radical hysterectomies
- Widely used in Europe and Australia

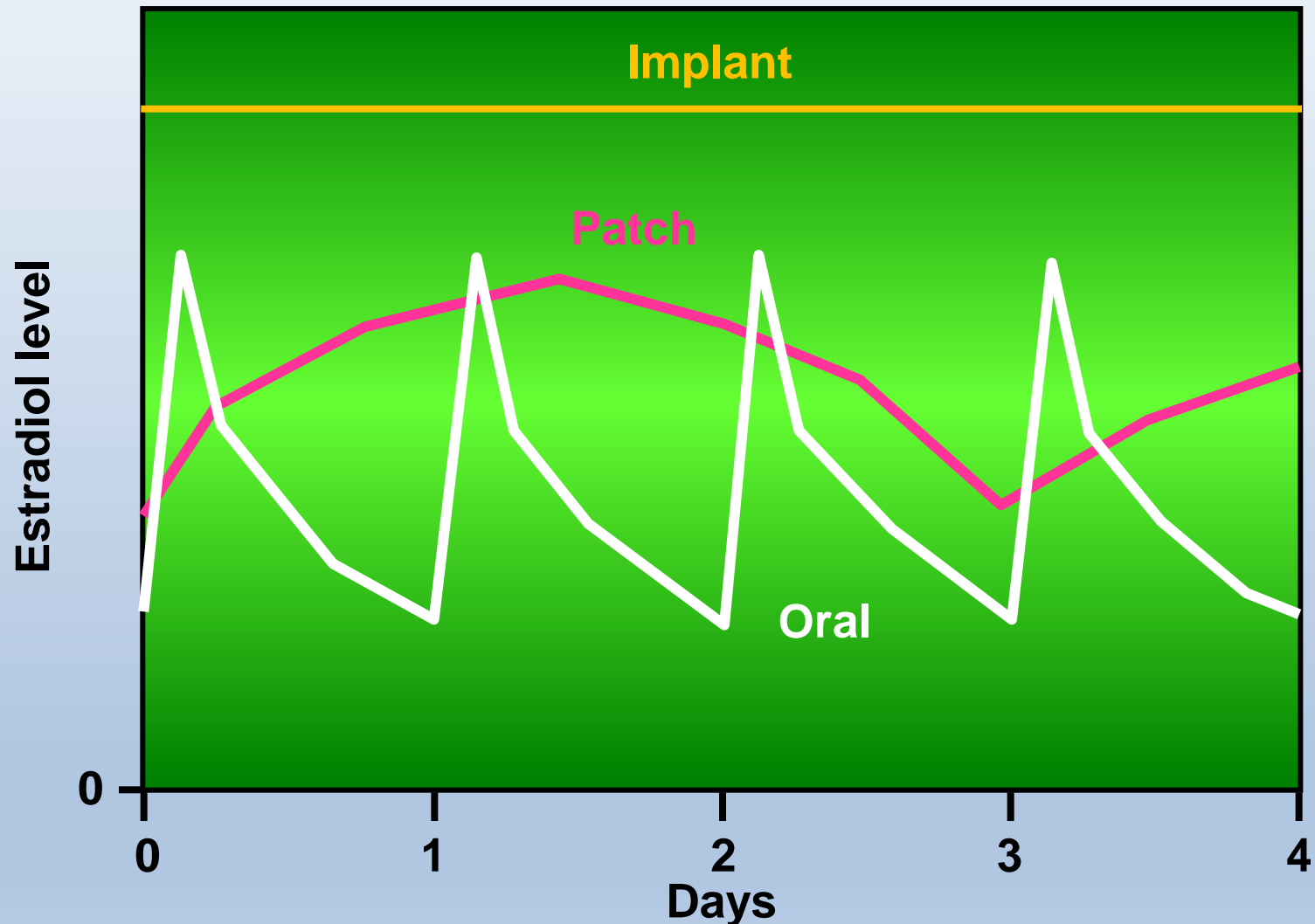


# How does pellet therapy work?

- Help your body return to normal hormonal balance and physiological state
- Based on:
  - Delivering the right kind of hormone (bio-identical)
  - In the right amounts (individualized dosing)
  - Using the right delivery system (pellets placed SubQ)



# Estradiol Levels Pills, Patches vs. Pellets



Smith R/ Studd, J WW *Brit Jour Hosp Med*, 1993, Vol 49, No 11



# Compounding Pharmacies

- FDA approved ???
- PCAA
- Insurance acceptance
- Cost vs. co-pay
- Quality and consistency

# Pellet Studies



- No increase in thrombotic (blood clots) activity with pellet therapy
- Reduces cardiovascular risk compared to oral therapy
- Does not increase the risk of breast cancer incidence

**Roger NJ Smith/John WW Studd et al**

**Recent Advances in Hormone Replacement Therapy, British Journal of Hospital Medicine, 1993**

# Medical Studies

## Osteoporosis:

1. Testosterone the bone builder
2. Demonstrated the four fold increase in bone density over oral estrogen and 2.5 times greater than patches

- 8.3% per year for pellet therapy
- 3.5% per year for patches
- 1-2% per year for oral estrogen



**Studd (1990) AM, Journal OB/GYN**

# Nurses Health Study

- 121,700 nurses
- Conjugated Estrogens increase risk of breast cancer

RR 1.32 (1.14-1.54)

- Estrogen plus Testosterone **no increase risk of breast cancer**

RR 1.64 ( 0.53-5.00)

**Colditz NEJM 1995**

# Archives of Internal Medicine

## ORIGINAL INVESTIGATION

### Combined Estrogen and Testosterone Use and Risk of Breast Cancer in Postmenopausal Women

Fulla M. Tamimi, ScD; Susan E. Hankinson, ScD; Wendy Y. Chen, MD;  
Bernard Rosner, PhD; Graham A. Colditz, MD, DrPH

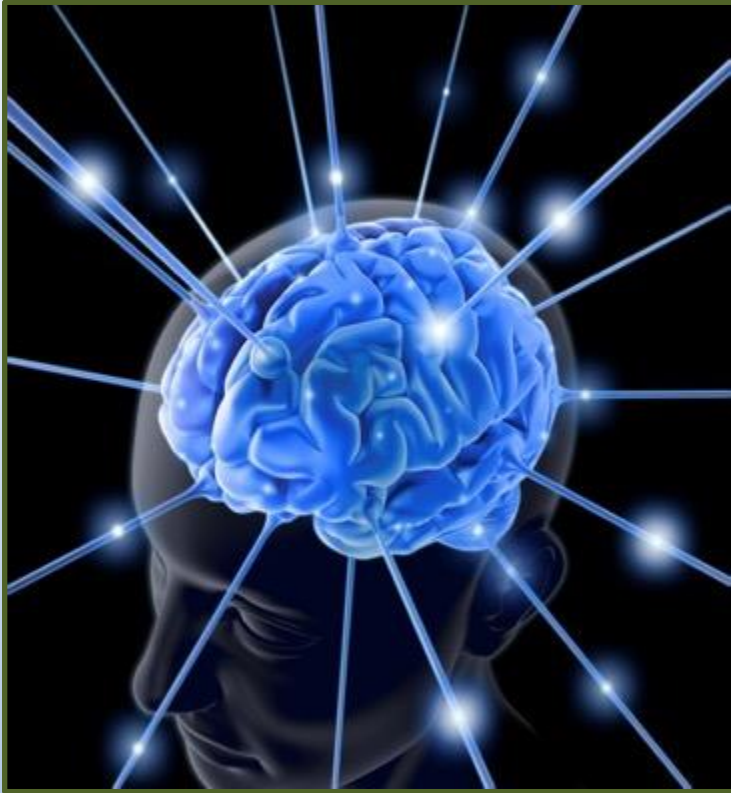
- Oral, synthetic, chemical methyl testosterone increased the risk of breast cancer
  - Estratest, Estratest HS, Syntest and Syntest DS
- Non-oral, testosterone prevents the stimulation of breast tissue and lowers the risk of breast cancer

# Breast Cancer Studies

*There are hundreds of studies, the take home is this:*

- Testosterone delivered by pellet implants does not increase risk of breast cancer unlike oral, synthetic methyl-testosterone
- Testosterone implants have shown less stimulation of breast tissue
- Treatment with testosterone and estradiol implants does not increase the risk of breast cancer, even in breast cancer survivors

# Alzheimer's Disease



- Women get Alzheimer's disease 8:1 over men
- Women on testosterone are 50% less likely to develop Alzheimer's disease
- Men with low testosterone are 3x more likely to develop Alzheimer's disease

1 in 7 premenopausal  
women die of  
**HEART DISEASE.**

For postmenopausal  
women that number RISES  
TO 1 IN 3.



# Arthritis: Hormones Could Ease Pain

- 10% of men and 18% of women >60 Y.O. have osteoarthritis
- By 2020 OA will be 4<sup>th</sup> leading cause of disability
- Condrogenic progenitor cells are present in arthritic tissue
- Both estrogen and testosterone can stimulate these cells

**Arthritis and Rheumatism, April 2010**

# Prostate Studies

- High levels of circulating testosterone are not associated with increased Prostate Cancer Risk: A Pooled Prospective Study. *Par Stattan et al; International Journal of Cancer, 418-424 (2004)*
- Blood levels of androgens are not related to the risk of developing prostate cancer. *Z. Chustecka; Journal of the National Cancer Institute, Feb 6, 2008*
- After one year of testosterone replacement therapy (TRT), men with Prostatic Intraepithelial Neoplasia (PIN) do not have a greater increase in PSA or a significantly increased occurrence of prostate cancer compared to men without PIN. These results indicate that TRT is not contraindicated in men with PIN. *E. Rhoden, A. Morgentaler; Journal of Urology, Vol. 179, 2348- 2351, Dec 2003*  
*Testosterone Replacement Therapy in Hypogonadal Men at High Risk for Prostatic Cancer: Results of One Year of Treatment in Men With Prostatic Intraepithelial Neoplasia (PIN)*

# BHRT Work up

- Medical history
- Lab testing
- Physical exam/depression screen
- Make BHRT choice
- Initiate treatment
- Monitor treatment
- Adjust dose

# Female Labs

- FSH
- TSH, Total T4, Free T3, TPO
- Estradiol
- Total testosterone
- Vitamin D
- B-12
- CMP
- Lipid panel & progesterone (optional)

# Male Labs

- CBC
- PSA
- TSH, Total T4, Free T3, TPO
- Total & free testosterone
- Estradiol
- Vitamin D
- CMP
- Lipid panel (optional)

# Hormone Imbalance

- Symptoms overlap
- Can occur in men and women at any age
- **GET TESTED**
- Low normal may not be **optimal** for health
- Many labs do not have ‘age specific ranges’
- Guideline and ranges change
  - New ranges for TSH (thyroid) & PSA

# Positive Effects of Bio-Identical Testosterone

- Enhanced erectile ability
- Prostate protection
- Enhanced libido
- Cardiovascular protection
- Increased bone strength
- Increased muscle strength
- Cognitive clarity
- Lower cholesterol
- Increased energy and vitality
- Feeling of overall well-being
- Reducing body fat
- Depression relief

# Bob Labs - PreTx

- CBC        normal
- PSA        1.0
- TT         320
- FreeT      7 (5-23)
- E2         24



# Case 1 – Bob

- Treated with BHRT
- At 6 months 195 lbs and 25 BMI
- Improved body composition
- Working out 3-4 times a week
- Improved libido
- Feels like a new man

# Bob Labs – Post Tx

- CBC        normal
- PSA        1.0
- TT         1050
- FreeT     22 (5-23)
- E2         30

No more blue pill, increased libido, no more afternoon crash, & significant change in body composition.

# Mary Labs - PreTx

- FSH 88
- E2 2
- TT 23

## Case 2 - Mary

- Treated with BHRT
- At 90 days no VMS, sleeping improved, libido improved
- At 120 days off SSRI mood normalized and remains in remission today
- Lost 6 pounds
- Improved outlook

# Mary Labs – Post Tx

- FSH        22
- E2         35
- TT         133

# What Patients are Saying

- Increased energy levels
- Restored interest in life
- Increased sexual drive
- Consistency in moods
- Relief from anxiety and depression
- Increased mental clarity
- Decreased body fat
- Greater capacity for getting the body in shape

# PTSD and TBI Study

- 360 veterans
- Mixed TBI and PTSD positive findings
- Lifetime treatment for participant
- Results pending publication

# What would a medicine be worth?

- Increased bone density
- Lowered the risk of breast cancer
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- Increased libido and sexual performance
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# Contact Information

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