



Identifying Candidates for Pellet Hormone Replacement Therapy

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Long term Outcomes of HRT

- The “All cause mortality” provides an important summary measure
- Represents the net effect of hormone therapy on life threatening outcomes



Menopausal Hormone Therapy and Long term All cause and Cause specific Mortality JAMA ;318(10):927.938



WHI Initial Findings (5-6 yrs. into study)

Outcomes	CEE-MPA	CEE alone
CVD	Increased risk heart attack 29%	No difference
Invasive breast Ca	Increased risk 26%	Uncertain
Stroke	Increased risk 41%	Increased 39%
Colorectal cancer	Reduced risk 37%	No difference
DVT / PE	Increased risk blood clots 2X	Increased risk 33%
Hip / vertebral fractures	Decreased 33%	Reduced 39%
Global index	Increased risk	No significant change

Menopausal Hormone Therapy and Long term All cause and Cause specific Mortality JAMA ;318(10):927.938



WHI Findings – 18 years later

Outcomes	Analysis
CVD	No difference in younger; increased in women whom therapy initiated 10 yrs. post menopause with oral meds due to impact on atheromatous plaques
Invasive breast Ca	Increased risk 26% with CEE/MPA; Significant reduction in breast cancer risk over time. No increase in breast cancer related deaths
Stroke	Increased 3.8/10,000 women years 30% risk; nullified by low dose oral or transdermal.
Colorectal cancer	Reduced risk 37% in combination, and no difference in estrogen alone
DVT / PE	30/100,000; Oral meds is issue
Hip / vertebral fractures	Decreased 33%
Global index All cause mortality	No impact but overall , lower in 50-59yo by 31%

Menopausal Hormone Therapy and Long term All cause and Cause specific Mortality
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Womens' Health Initiative

Bottom Line:

- Less ALL CAUSE MORTALITY
- Less cardiovascular deaths
- Less cancer related deaths

- Hormones can be safely used in younger symptomatic women
- With preference for NON-oral formulations

Menopausal Hormone Therapy and Long term All cause and Cause specific Mortality
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Cardiovascular Statistics FEMALE

**Number one cause of death in women:
HEART DISEASE**

Premenopausal 1 in 7

Postmenopausal woman
RISES TO 1 in 3



CDC, (2017) Leading cause of death. *Health, United States*. <https://www.cdc.gov/nchs/data/hus/2017/019.pdf>

TD a Major Medical Condition

Testosterone Deficiency (TD) low levels of testosterone

- May predict increased risk diabetes, metabolic syndrome
- Contributes to decreased bone density
- Associated with all cause CV mortality
- Negatively impacts health and QOL

Morgentaler, A, Zitsman, M., et al. (2016) Fundamental concepts regarding testosterone deficiency and treatment: International Expert Consensus Resolutions. Mayo Clin Proc, July:91(7):881-896



No Restriction on Testosterone Therapy

- Treatment not limited to men with known underlying etiology
- Classical hypogonadism accounts for small fraction of men with TD
- TD occurs frequently with other than classical symptoms
- Recommended to treat signs and symptoms of TD related to common conditions

Morgentaler, A, Zitsman, M., et al. (2016) Fundamental concepts regarding testosterone deficiency and treatment: International Expert Consensus Resolutions. Mayo Clin Proc, July;91(7):881-896



TD is a Global Public Health Concern

- Prevalence rates 2-38% in studies
- Variation explained by difference in operative definition TD, and biochemical threshold
- US study estimates an additional \$190-\$525 Billion in health care expenditures in next 20 years due to TD

Morgentaler, A, Zitsman, M., et al. (2016) Fundamental concepts regarding testosterone deficiency and treatment: International Expert Consensus Resolutions. Mayo Clin Proc, July:91(7):881-896

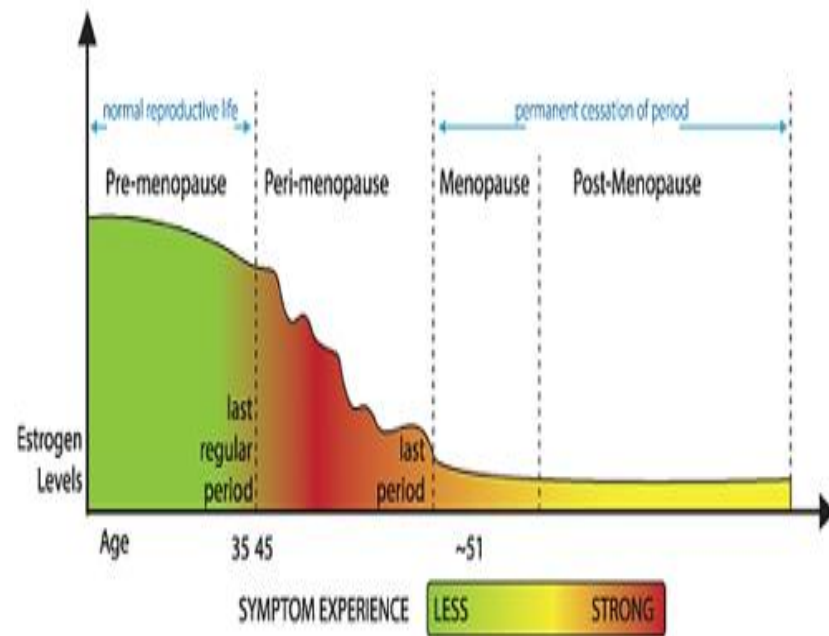


Candidates for BHRT



Optimal Candidates Females

- **No prior use of HRT**
- Women 30-40
 - Fatigue, Stress, Weight gain
 - Mood disorder Depression, Anxiety
 - HSDD Low sexual drive
 - Premenopausal Mid to late 40s
 - Symptomatic Peri-menopausal women



Optimal Candidates Females



... of women say their symptoms interfere with their lives; 12% say they interfere “a great deal” or are debilitating.

The most common symptoms of menopause for women:



Hot flashes



Night sweats



Vaginal dryness



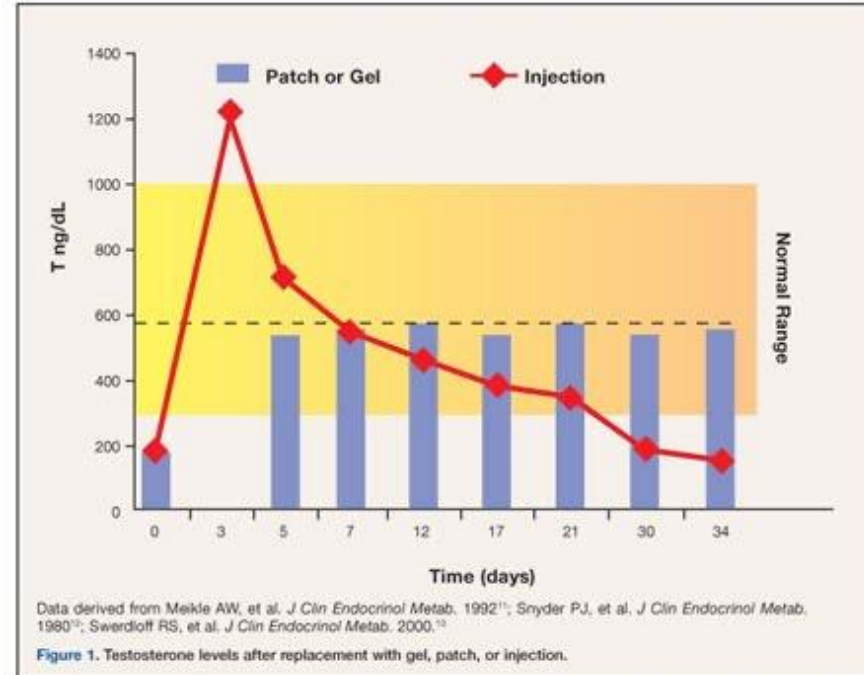
... say they've never discussed menopause with a health provider.



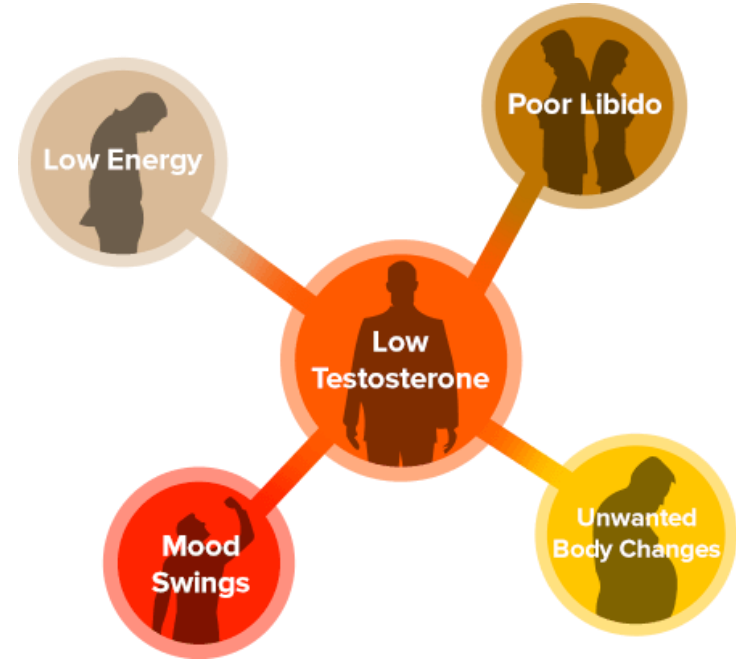
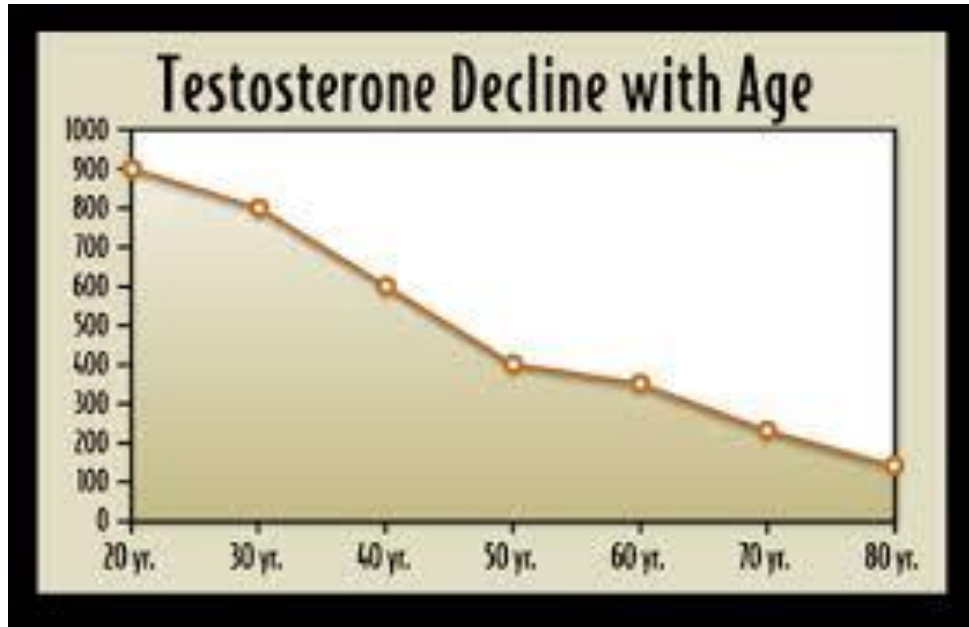
Only 1 in 5 women received a referral to a menopause specialist.

Suboptimal results with prior use of HRT

- Poor response to fluctuating hormone levels
- Persistent symptoms despite adequate levels
- Current therapy is inconvenient
- Non-Compliance
- Seeking customized titration



Optimal Candidates Males



Prevalence (%) of chronic conditions/diseases between men with deficiency (<300 ng/dL [10.4 nmol/L])) versus those with normal TT.

Prevalence (%)	Age 20–39.9 years		Age 40–59.9		Age ≥ 60 years	
	Normal TT (≥300 ng/dL)	TT Deficiency (<300 ng/dL)	Normal TT (≥300 ng/dL)	TT Deficiency (<300 ng/dL)	Normal TT (≥300 ng/dL)	TT Deficiency (<300 ng/dL)
	<i>n</i> = 669	<i>n</i> = 195	<i>n</i> = 490	<i>n</i> = 276	<i>n</i> = 501	<i>n</i> = 268
Obesity (BMI >30)	22.8	55.7*	30.0	48.0*	25.8	45.9*
Abdominal Obesity (WC >102 cm)	21.5	57.1*	37.1	59.5*	42.9	64.9*
Diabetes	3.1	7.7*	15.9	26.5*	27.9	41.8*
Arthritis	3.6	4.1	18.2	18.1	36.3	44.4*
Cardiovascular Disease	0.3	2.1*	5.5	2.9	15.2	20.2*
Stroke	0.2	0.1	2.9	1.5	10.2	7.8
Pulmonary Disease	0.0	1.0	2.0	1.8	3.8	7.5*
Hypertension	18.4	38.5*	49.6	50.7	73.0	80.0*
Clinical Depression	5.5	11.5*	8.7	8.0	6.2	6.7
Low HDL-Cholesterol	20.2	42.1*	25.1	39.1*	20.2	35.1*
Hypertriglyceridemia	17.9	48.0*	33.6	50.1*	20.4	32.2*
Multimorbidity	13.5	36.4*	42.9	49.3	61.5	75.0*



Cardiovascular Statistics MALE

Heart disease is also the leading cause of death for men

- **1 in every 4 male deaths.**



CDC, (2017) Leading cause of death. *Health, United States*. <https://www.cdc.gov/nchs/data/hus/2017/019.pdf>



Conclusion Identifying Candidates



THANK YOU FOR YOUR ATTENTION

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