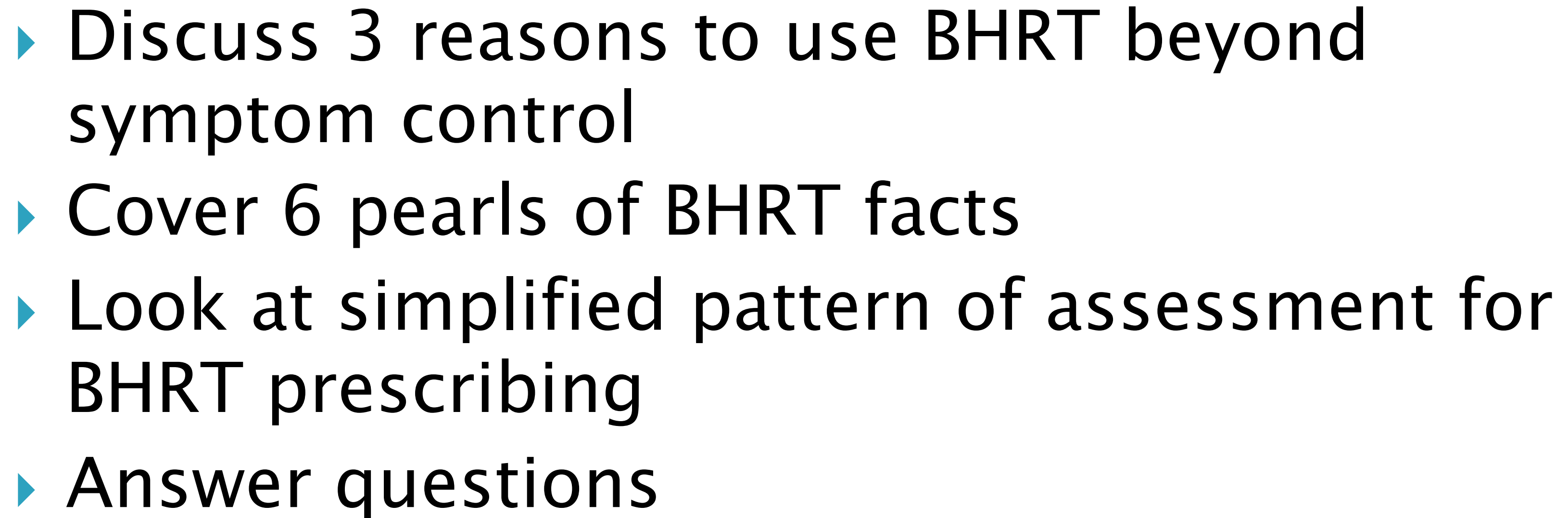
BHRT
Fact and Fiction

Vancouver
April 2014

True Balance Longevity Institute

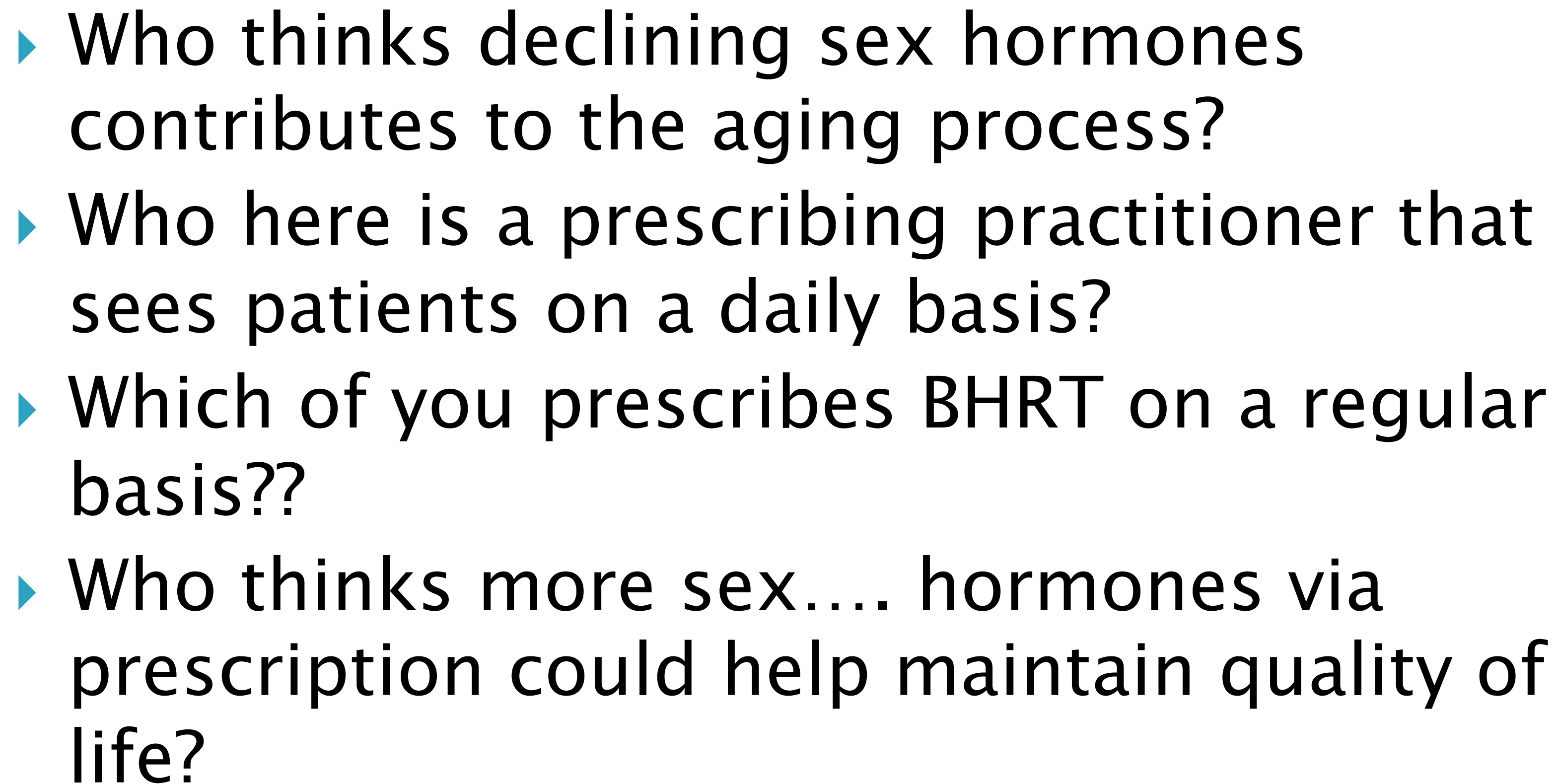
Objectives



Where Did BHRT Start With Me?

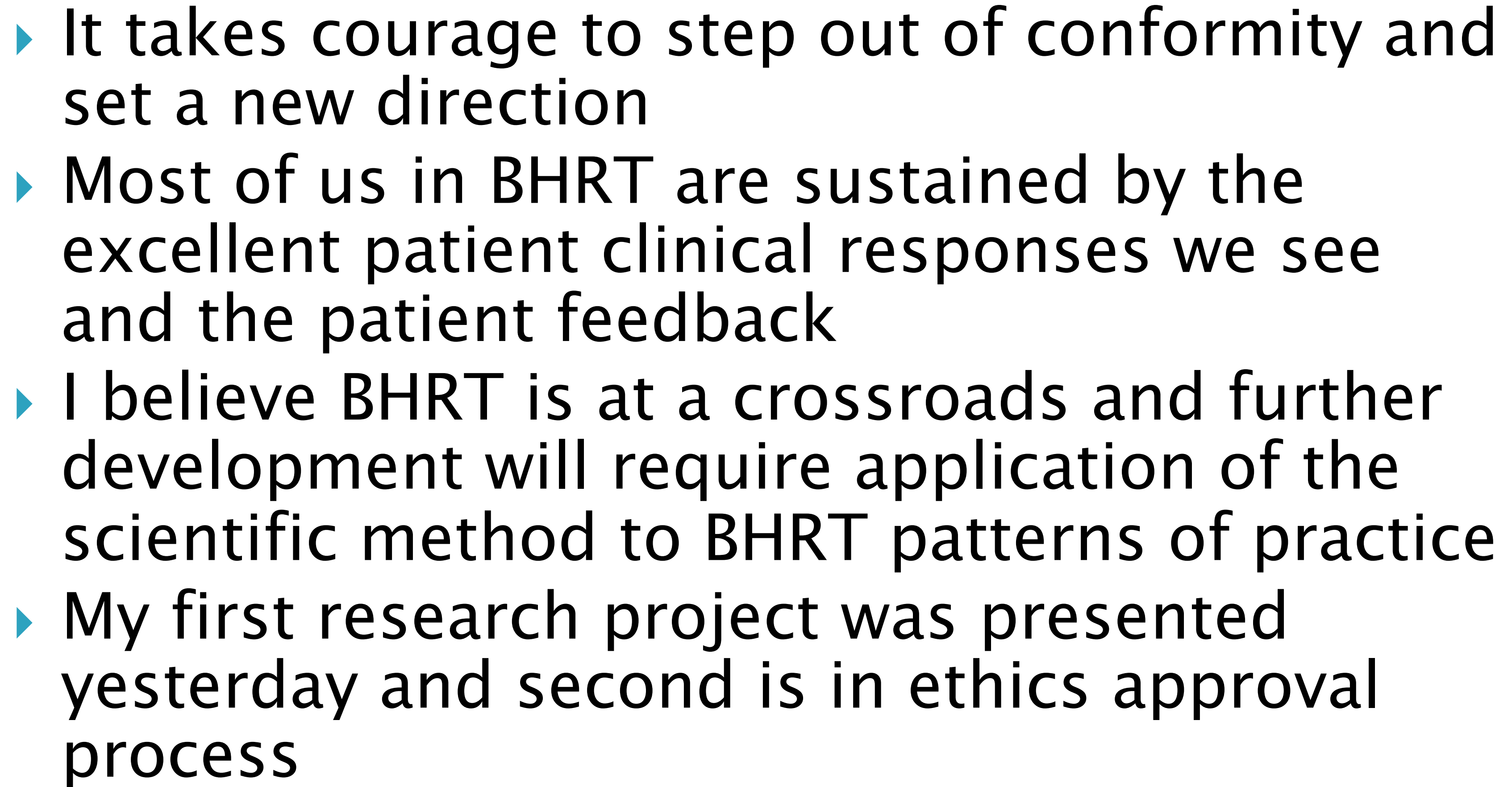
- Patient inquiry about bio-identical hormones
  - Wasn't I embarrassed about my lack of knowledge?
- BHRT conference in Denver
- American Academy of Anti-Aging
  - Board Certification in Functional and Regenerative Medicine
  - University of South Florida affiliation
- Private practice with 4000 BHRT visits last year

Patterns of Practice



- Who thinks declining sex hormones contributes to the aging process?
- Who here is a prescribing practitioner that sees patients on a daily basis?
- Which of you prescribes BHRT on a regular basis??
- Who thinks more sex…. hormones via prescription could help maintain quality of life?

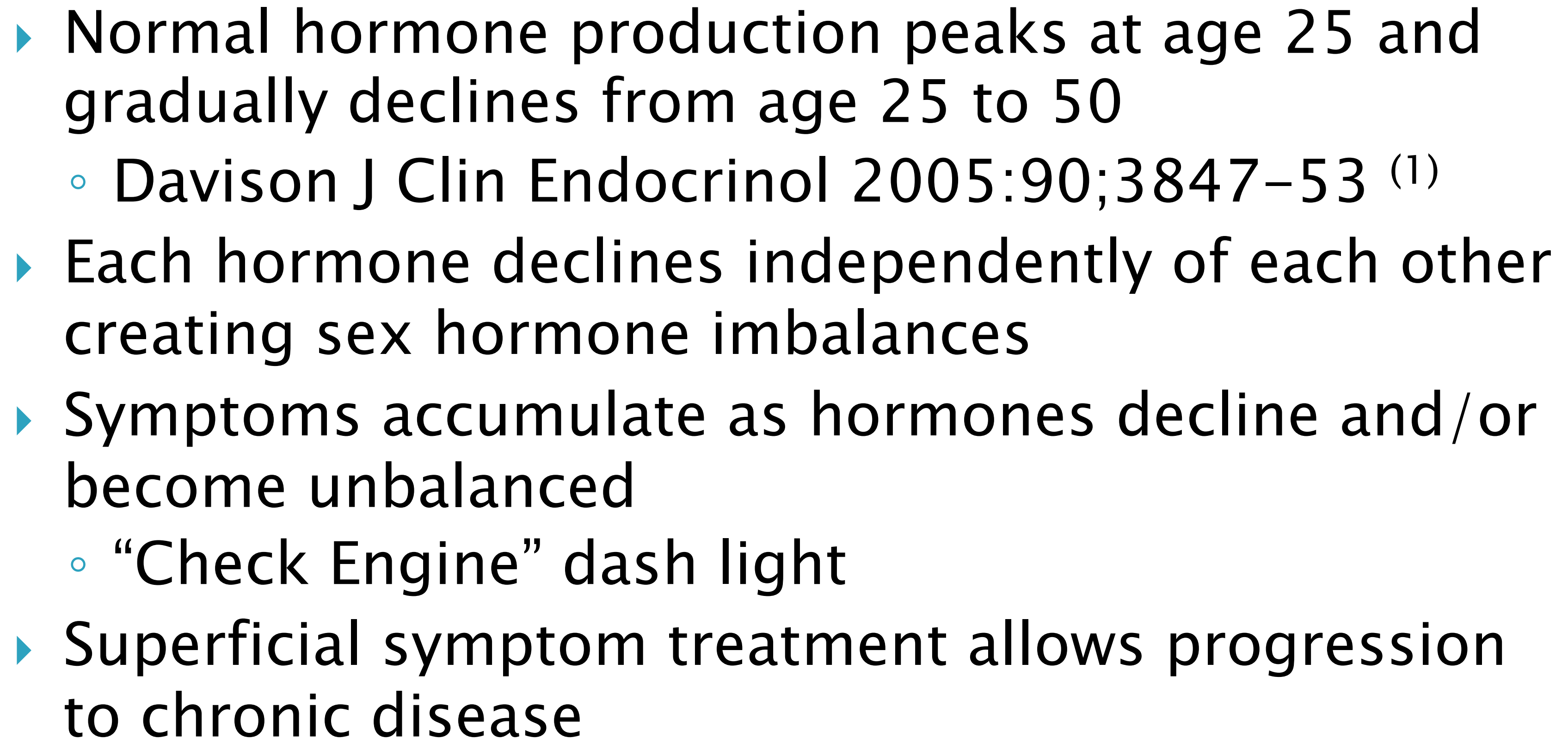
BHRT and Courage



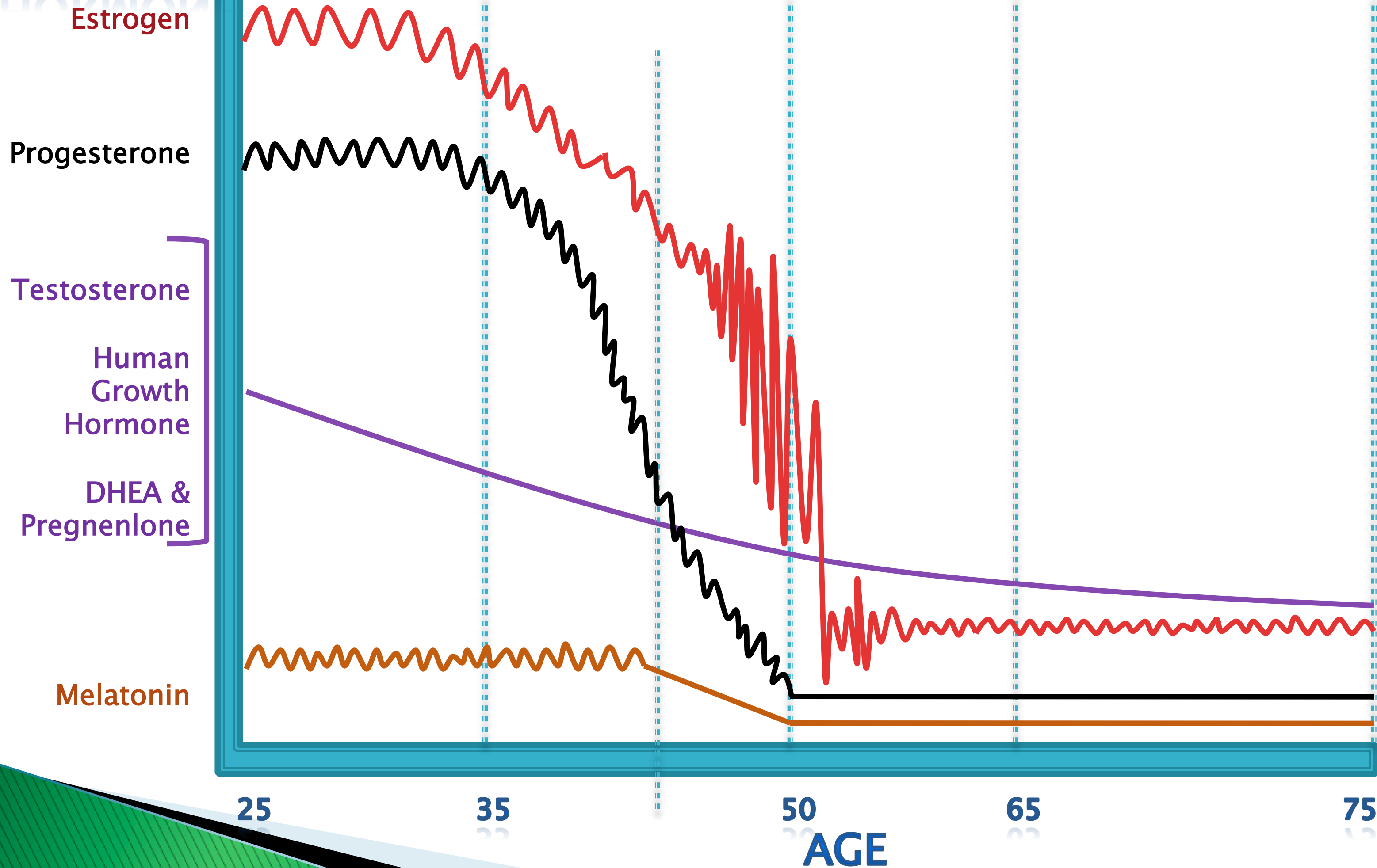
The "Other Side and Opinion"

- 'BHT is not a valid medical practice that is based on evidence-based medicine; rather it is the equivalent of treating patient's symptoms with sympathetic powders or potable gold' (Boothby)

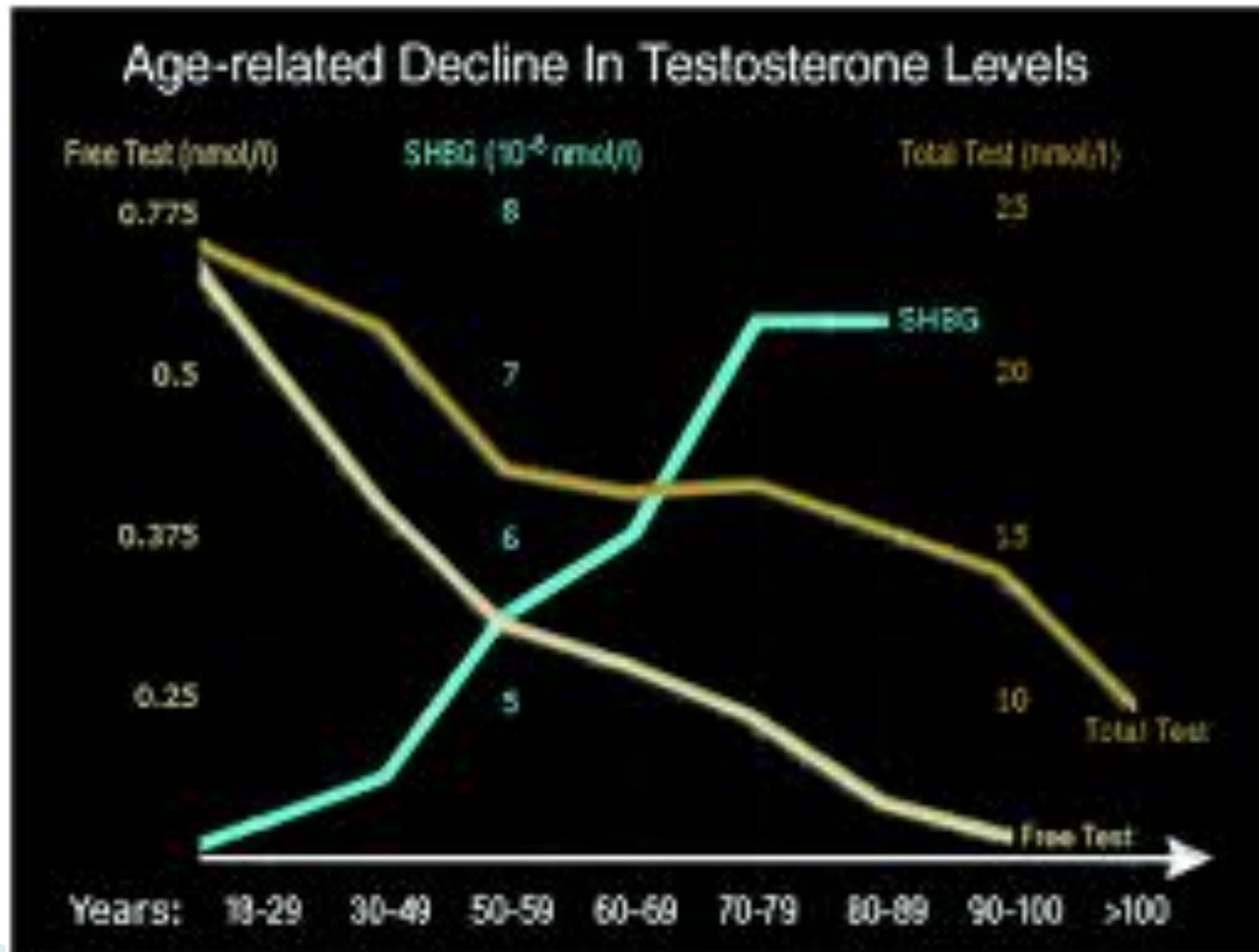
Why Is There a Problem?



Age Related Decline of Female Hormones

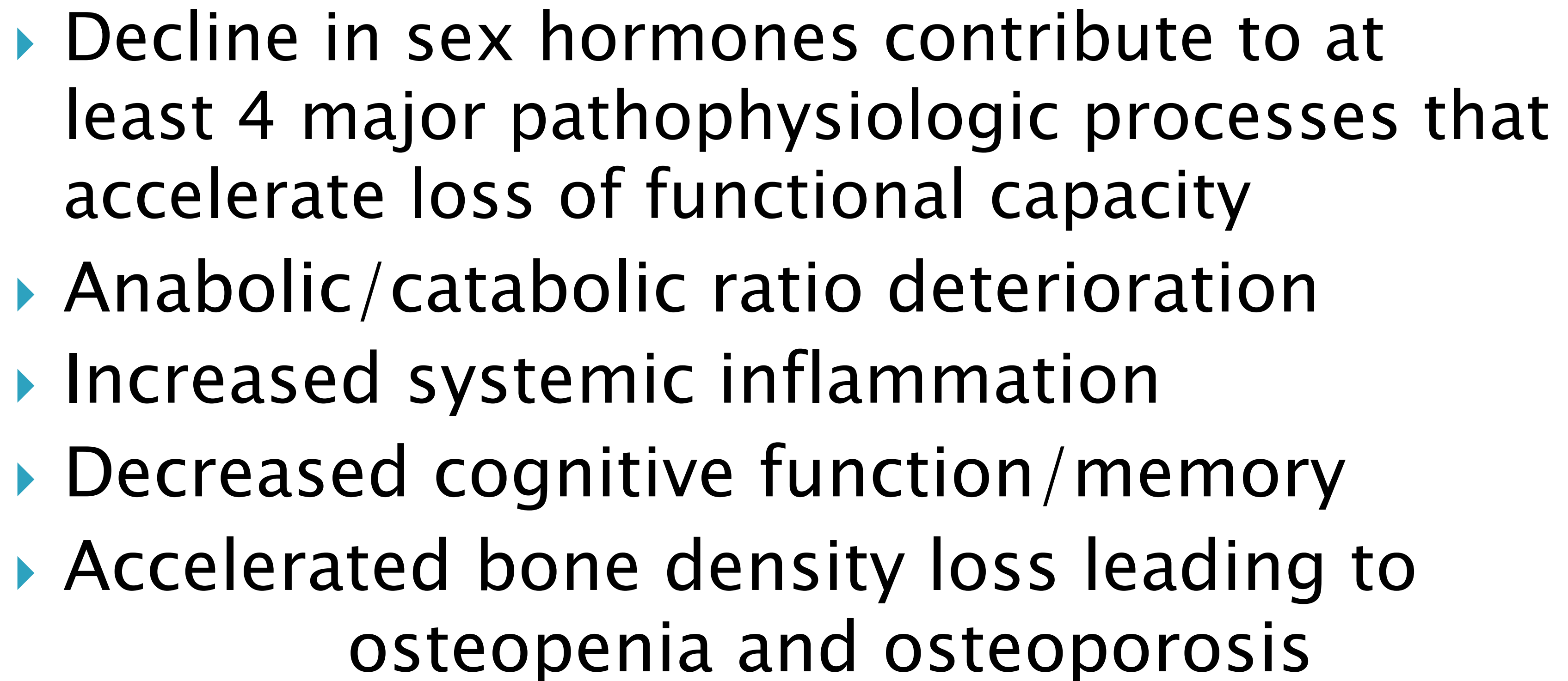


Men Too!



BHRT As A Health Promotion Strategy

Pearl 1: Hormone Decline and Resultant Diseases Are Treatable

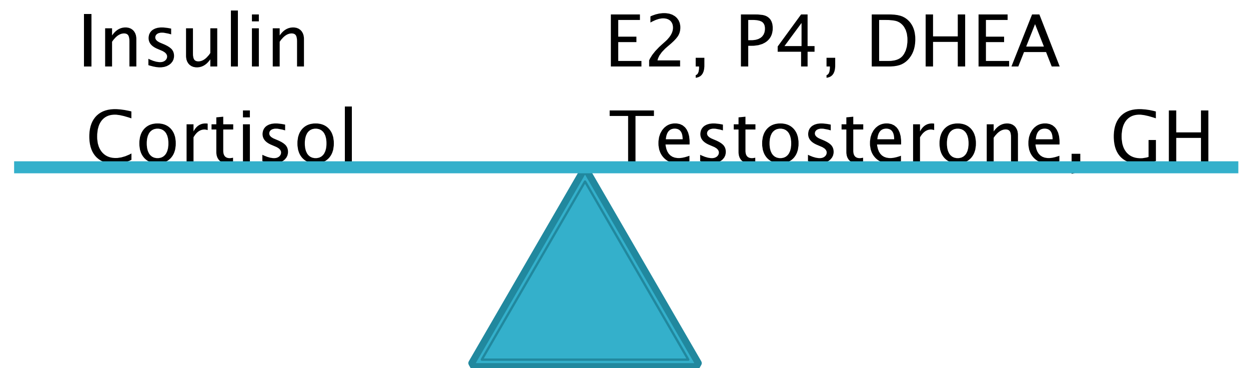


- Decline in sex hormones contribute to at least 4 major pathophysiologic processes that accelerate loss of functional capacity
- Anabolic/catabolic ratio deterioration
- Increased systemic inflammation
- Decreased cognitive function/memory
- Accelerated bone density loss leading to osteopenia and osteoporosis

The Anabolic/ Catabolic Ratio

- Critical to preservation of QOL as we age
- Catabolic hormones **'tear us down'** and increase as we age
  - **Insulin** **Cortisol**
- Anabolic hormones **'build us up'** and decline as we age
  - **Estrogen** **DHEA**
  - **Progesterone** **Testosterone**
  - **Growth Hormone**

The Anabolic / Catabolic Ratio

- We see the effects over time in 'sarcopenia' which is just an expression of a declining anabolic-catabolic ratio
- BHRT directly improves anabolic-catabolic ratio
- 

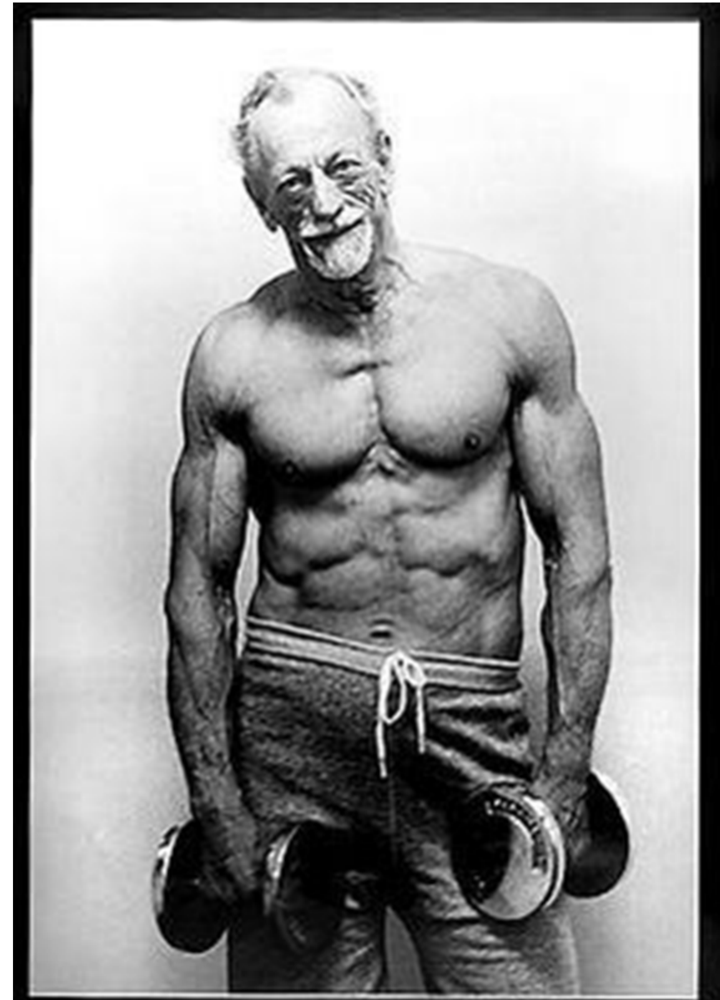
- What does sarcopenia look like?

Pearl 2: Your Anabolic/Catabolic Ratio is Predictive of Future Health

- All of you have an A/C ratio at present
  - What do you think yours is at this time?
- What it is in your 40's and beyond will determine quality of life in your 70's and perhaps overall longevity
- I believe diet, lifestyle and supplementation **alone** do not improve the A/C ratio in a meaningful way– you need hormones!
- You must pay attention to this as it is never too early or late to modify and the future might not be as bright as you think!

He Did Not Get Here Without Hormones!!

- Sarcopenia is **NOT** inevitable
- Sex hormones, exercise and diet can produce these kind of results
- We have to change the dialogue from talking about the inevitable– to what does the patient want and what are they going to put in!



Pearl 3 : Hormone Treatment Reduces Inflammation

- As we age our hormones decline and levels of inflammation increase
- Hormones reduce production of inflammatory cytokines
- Hormones are nature's anti-inflammatories
- Diseases of inflammation include
  - Heart disease
  - Cancer
  - Alzheimers
  - Hypertension
  - Diabetes
- 90% of chronic diseases are a direct result of inflammation

HRT Reduces Inflammation

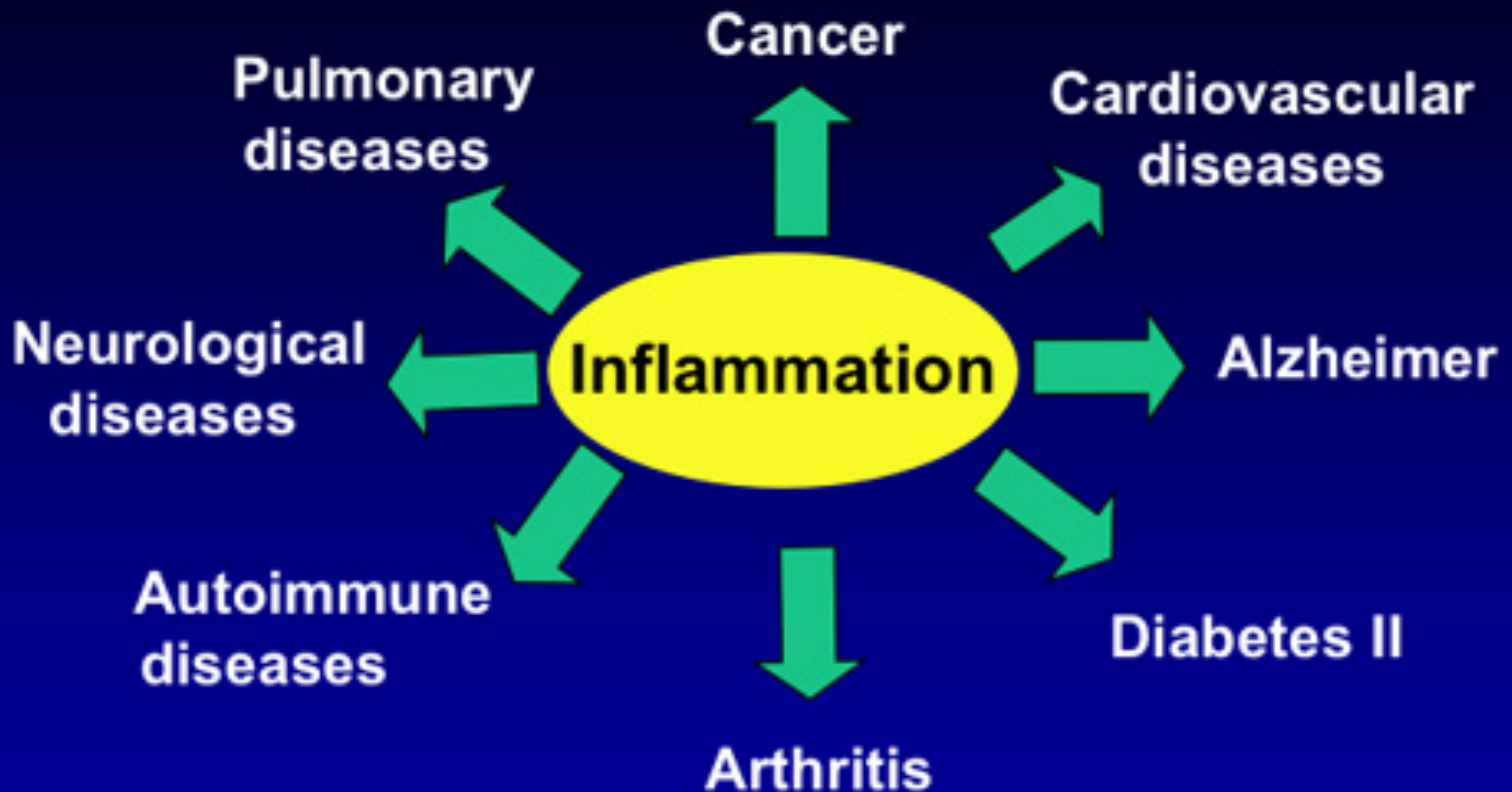
- Gynecologists have known this for years
  - NFKβ and IL-6 are cytokines that mediate inflammation and increase with age [2,3]
    - Harris Am J Med 1999:106;506-12
    - Brod,SA Inflammation res 2000:49;561-0
  - Estrogen and testosterone directly bind DNA promoter sites and prevent transcription of pro-inflammatory cytokines
    - Erschler Ann Rev Med 2000:51;245-70[4]

Estrogen and Inflammation

- Physiologic replacement doses of estrogen have been shown to reduce inflammatory cytokine response to endotoxin
- Estradiol patch with mean E2 level 374 pmol/l
  - High level– ? Dose response curve
- Standardized dose of endotoxin

	patch		no patch
IL-6	341±94	vs	936±620
IL-1	82±14	vs	133±24
TNFα	77±46	vs	214±87

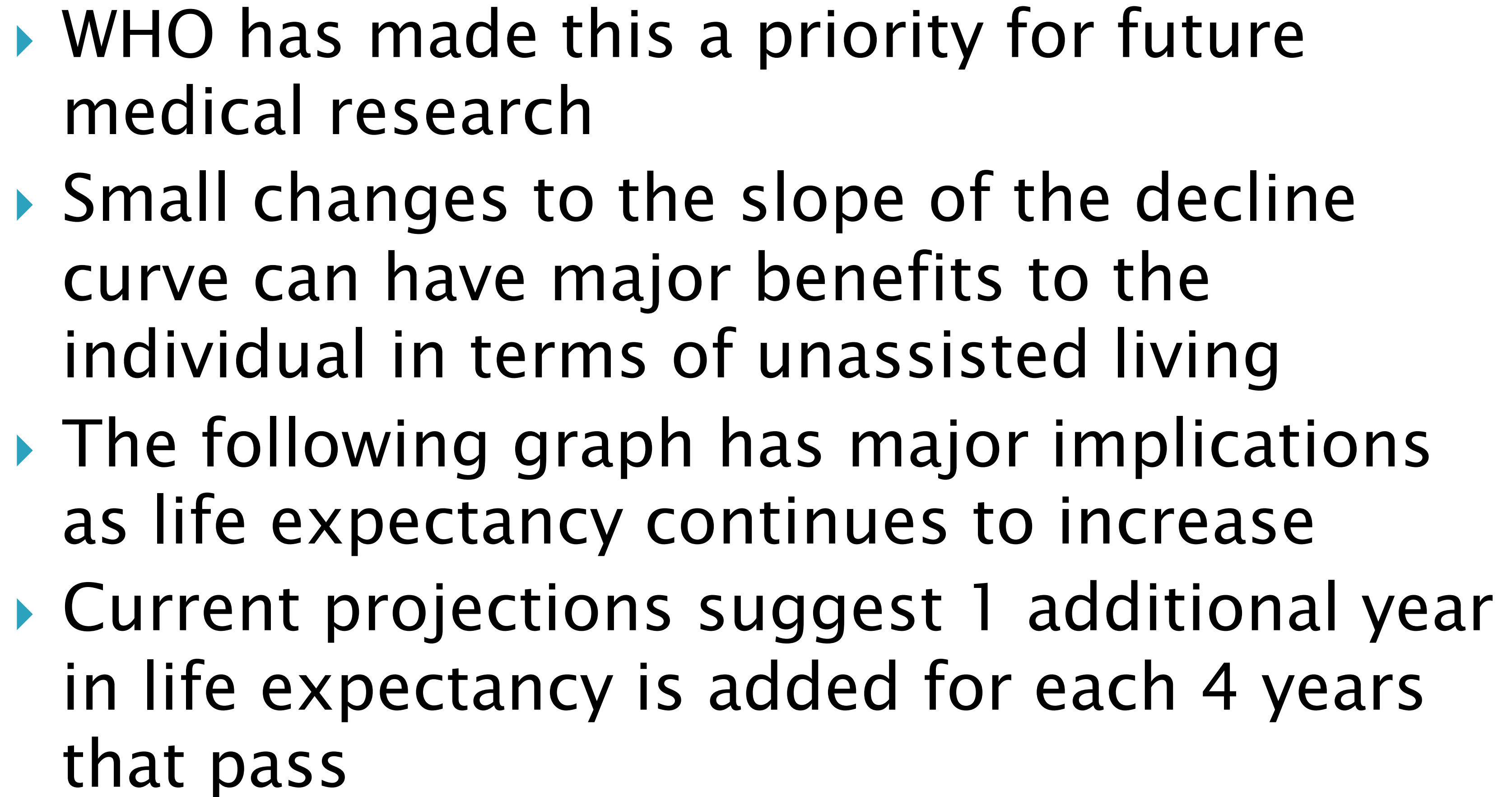
  - J Clin Endo Met 2001;86:2403-8 Puder et al[48]


Cancer
Pulmonary diseases
Cardiovascular diseases
Neurological diseases
Inflammation
Alzheimer
Autoimmune diseases
Diabetes II
Arthritis

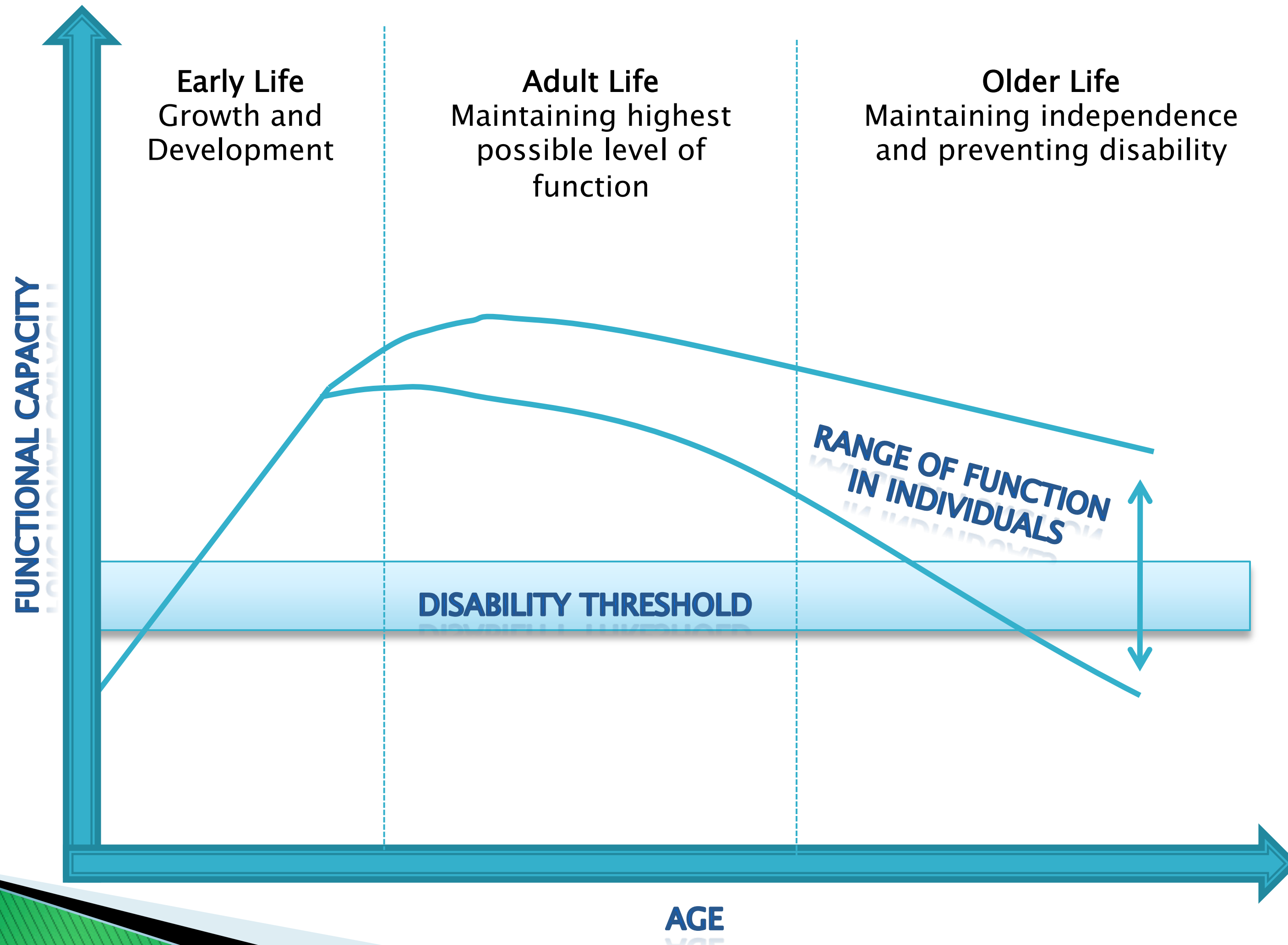
Pearl 4 : Hormones Have Beneficial Central Nervous System Effects

- We are aware of the potential psychiatric consequences due to hormonal shifts
  - Post-partum depression
  - Post-partum psychosis
  - Menopausal depression
- Will defer to your next speaker to elaborate

Functional Capacity



Maintaining Functional Capacity

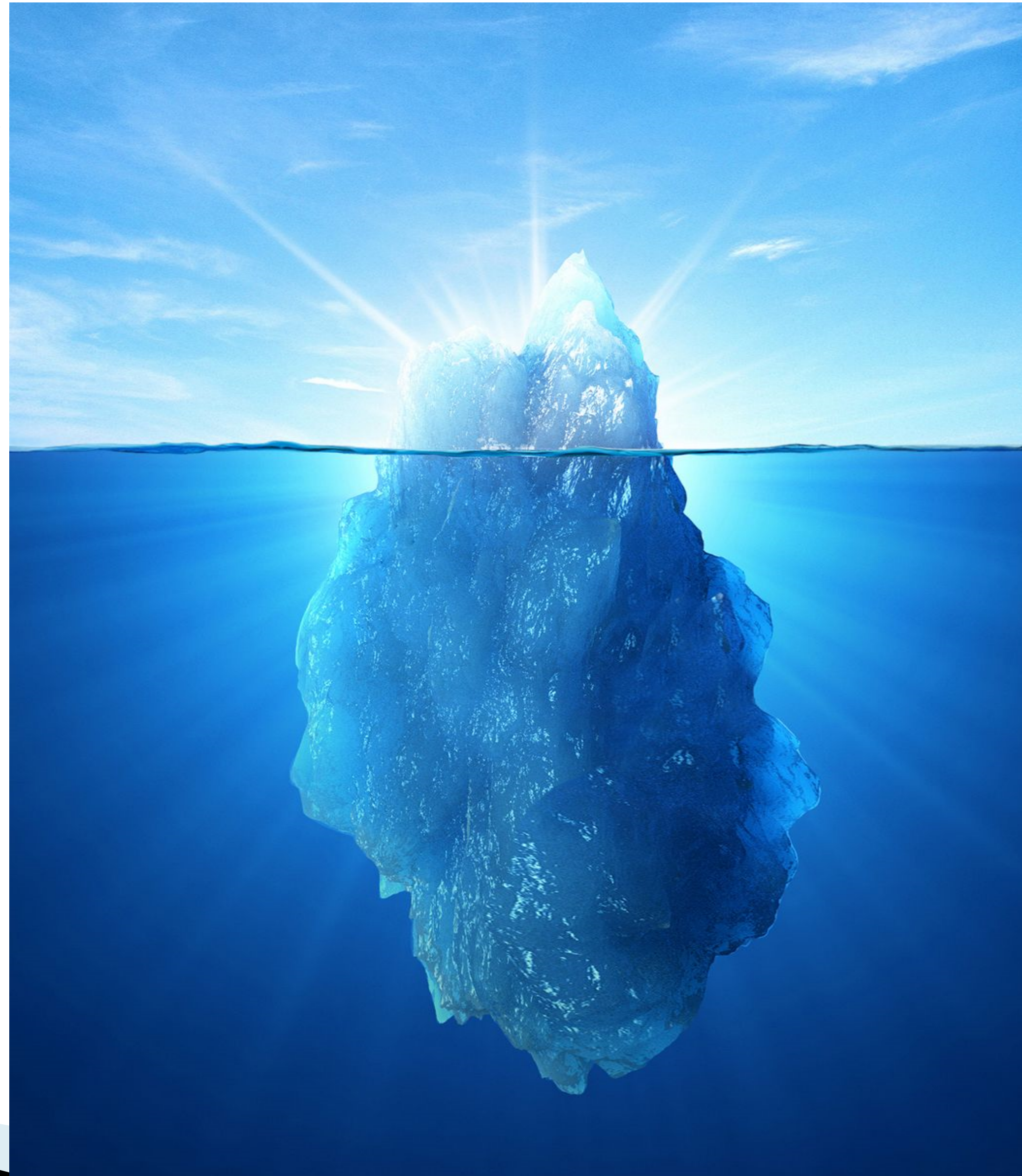


Non-Reproductive Sex Hormone Function

- We need to think of these hormones in a new fashion
  - Improve anabolic/catabolic ratio
  - Reduce inflammation
  - Neuroprotective/modulator function
- Patient symptoms attract them to BHRT practitioners
- Treatment addresses symptoms and also preserves and improves functional capacity

Hormone Symptoms

- Insomnia PMS
- Anxiety hot flashes
- Depression
- Low energy/fatigue
- Reduced sex drive



- Inflammation
- Sarcopenia
- Mental decline
- Osteoporosis

Hormones and Functional Capacity

- Evidence for HRT and longevity
  - Schairer et al Epidemiol 1997:8;59-65[5]
  - 23,000 Swedish women followed longitudinally
  - 23% decrease in all-cause mortality shown with HRT
- Numbers of animal studies showed reduced incidence of atherosclerotic heart disease and mortality
- Enter the Women's Health Initiative (WHI)

Pearl 5 : The Women's Health Initiative[29] Led to Fear of Hormones

- Large randomized, double blinded study of asymptomatic post-menopausal women age 50-70 started in 1991
- Continuous, combined Premarin (CEE) and Provera (MPA) vs placebo in women with a uterus
- Premarin (CEE) vs placebo in women with hysterectomy (remember the maxim of the day was no uterus-no progesterone)
- Measured heart disease, cancer, stroke and blood clots

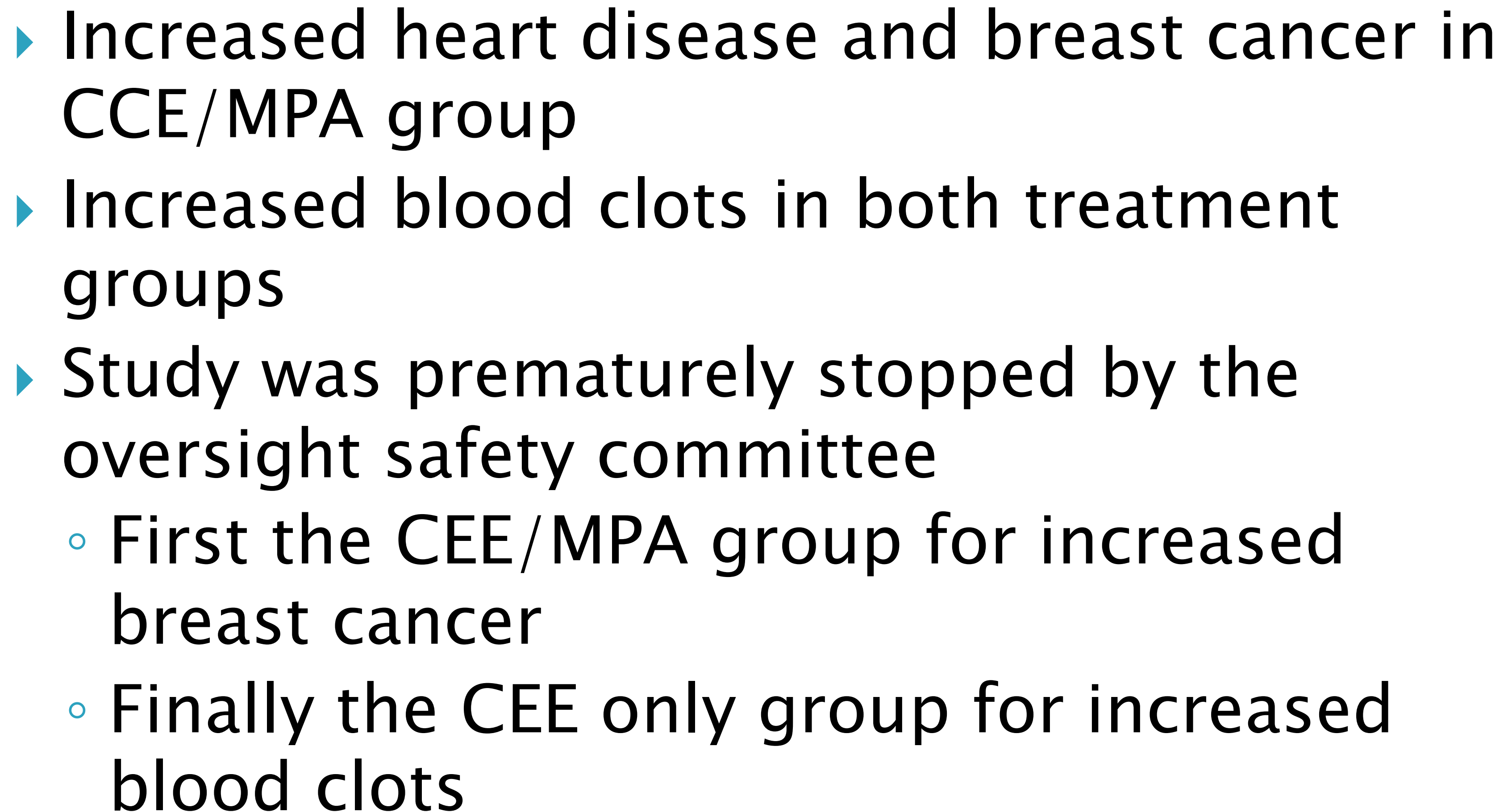
JAMA 2002:288;321-33 The WHI Steering Committee[29]

We Live In A Post- WHI Age

	CEE/MPA	CEE
Number	16,603	9,739
Mean age	63	63
CHD	1.29	.91
Breast cancer	1.26	.77
Stroke	1.41	1.39
Thromboembolism	2.13	1.34

Remember- No uterus-no progesterone!

Study Results



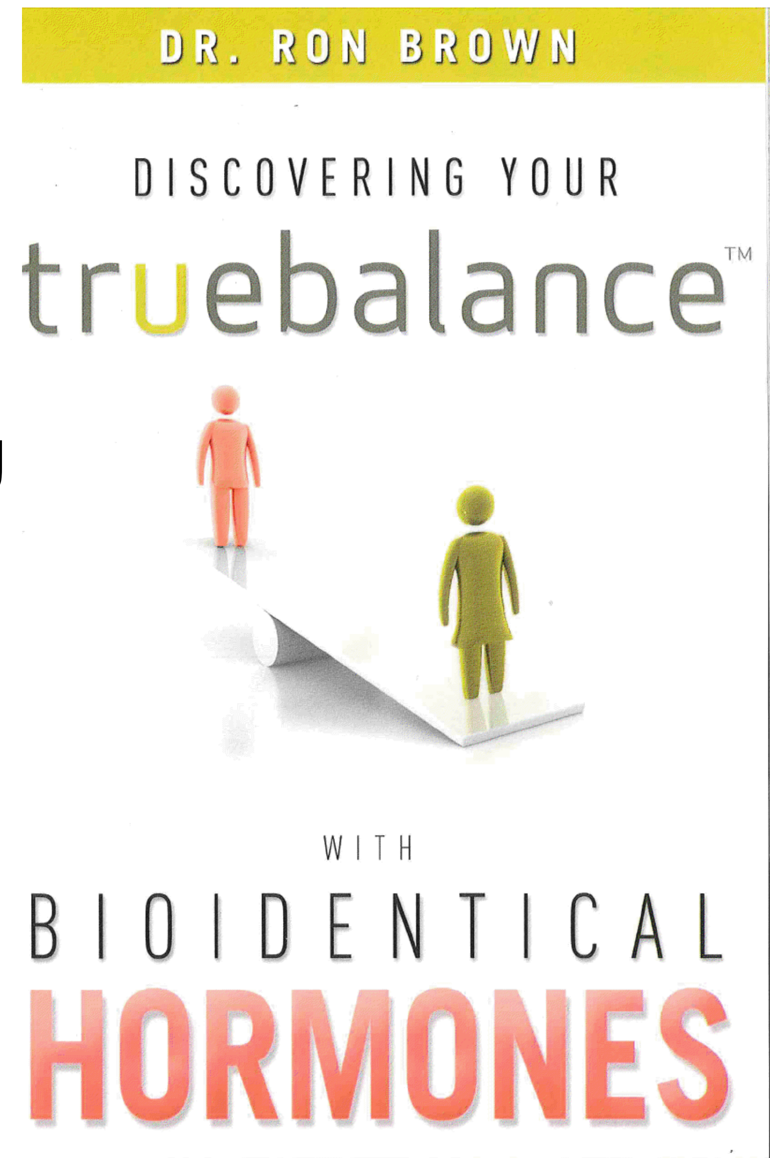
Bio-Identical Hormones

- Started and has grown as a patient grassroots movement and promoted by Suzanne Somers
- Much groundwork on treatment protocols has been done over the last 10 years
- Subject to criticism from ‘conventional’ medical experts often with good reason
- North American Menopause Society (NAMS) is one of the leaders in opposition to BHRT
  - Who here knows who NAMS is?
- Seems to be a real conflict of interest

Another Conflict of Interest??

How To Make the Message Medical

- I don’t agree with **some** of SS’s treatment recommendations
- Written for the average woman contemplating the BHRT decision
- This book is my attempt to bring supporting medical evidence into the decision



The Endocrine Society
Position Statement 2006

- Concerned about misleading and false information about benefits and risks with bio-identical hormone treatment
- Physicians should exercise caution when prescribing
- Much consideration should be given to **ANY** type of hormone therapy
- Claims of increased safety unsupported
- Compounding pharmacies not subject to FDA monitoring for dose, purity, safety and efficacy
  - **I agree completely with ALL the above statements!!!**

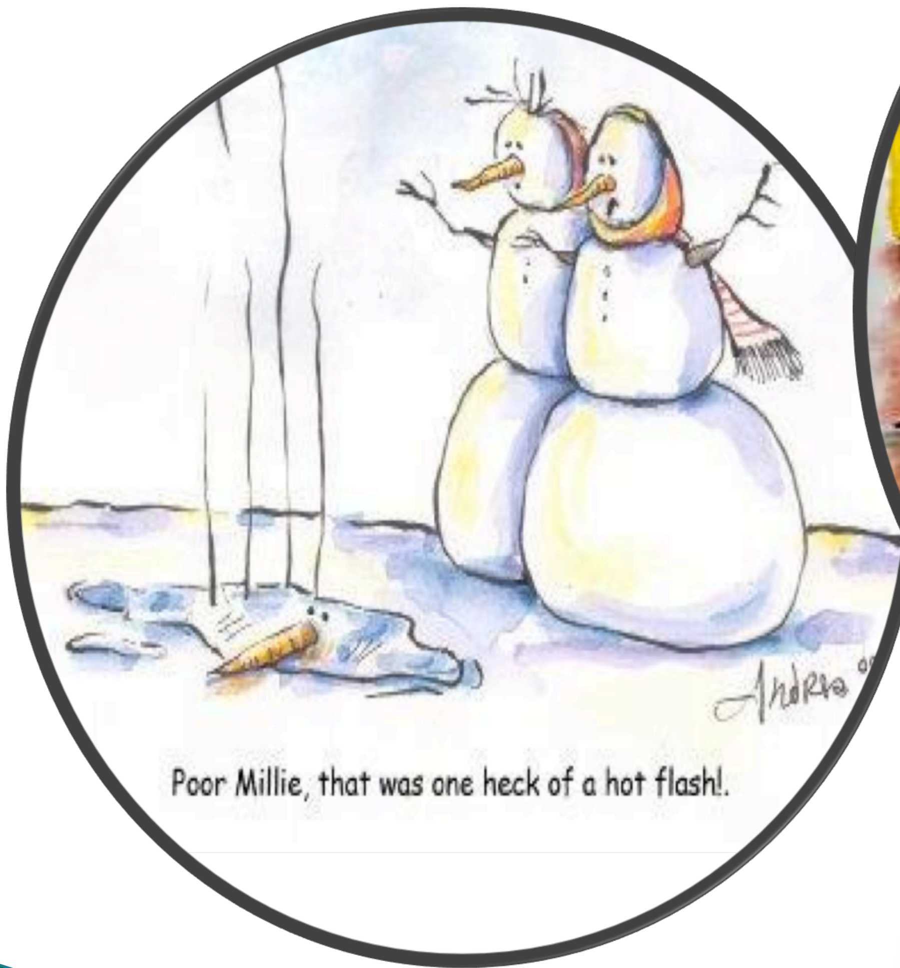
Pearl 6:Menopause–To Treat or not to Treat?

- WHI data does not support HRT treatment of asymptomatic women
- Symptomatic treatment is reasonable and should be based on most effective product via the safest route
- What did we REALLY learn from the WHI?
  - The important lessons were lost in the angst of a study that produced unexpected results

The REAL WHI Lessons

- MPA led to increased
  - Breast cancer
  - Heart disease
- Oral Premarin increased risk of blood clots and stroke
  - Not seen with transdermal estrogen
- Premarin reduced breast cancer risk which seems contradictory to promoter role that has been established for estrogen
  - What about estriol?

Menopause



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The poor girl is out of eggs.

Henopause

Treatment Decisions

- Serum hormone levels useful in patients not on HRT and are free!
  - Saliva useful but not free for me!
- Estradiol most important determinant to establish presence of estrogen sufficiency or deficiency– **always start here in your assessment of the patient**
- Detailed patient questionnaires very useful at start and during treatment
  - Questions very predictive of blood levels

Female Patient Questionnaire

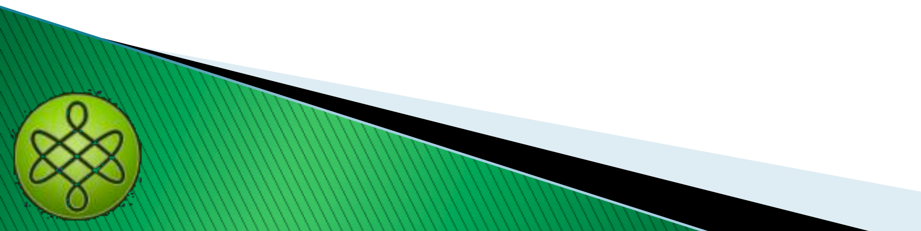
- All patients fill this out before treatment and at each follow-up visit
- Centers treatment decisions on how the patient feels
- Allows us to track improvement in well-being over time

Name:

Date:

Your Hormone Balance Inventory

		0 None	5 Slightly	10 Moderate	15 Severe	20 Extreme
PROGESTERONE						
	Difficulty Concentrating					
	Can't Sleep (Insomnia)					
	Depressed or Unhappy					
	Anxious					
	Headaches					
	Moodiness / Emotional Swings					
	Painful or Swollen Breasts					
	Weight Gain / Bloating					
	PMS					
ESTROGEN						
	Night Sweats					
	Difficulty Remembering Things					
	Hot Flashes					
	Vaginal Dryness					
	Dry Hair / Skin					
	Incontinence					
	Frequent Urinary Tract Infections					
	Inability to Reach Orgasm					
	Painful Intercourse					
TESTOSTERONE						
	Loss of Libido					
	Lack of desire to be intimate					
	Loss of motivation					
	Flat mood					
	Diminished well being					
GENERAL WELL BEING						
	Change to Bowel Motions	How many per day?				
	Change of weight	Increase			Decrease	
	Change to Stress Level	Yes / No (circle)	Current Stress Level:			



Patient Evaluation

- Complicated and time consuming to do well
- Average first visit 1 hour and recheck 45 minutes
- Wait a minute?
  - Fulltime OBGYN practice 60 hours/week
  - BHRT clinic with 4000 patient visits last year at 45 min/patient
- There are on average 2000 working hours per year
- If this conundrum intrigues you, come and talk to us at our booth

Estrogen Treatment

- **Estrogen ONLY used if deficiency is present**
- Lab work can be used to corroborate the clinical impression and symptom score
- Interventions target physiologic replacement and start with the safest product
- Risk-benefit calculations should be done at each stage of treatment
- Regular follow-up to document effectiveness of program is mandatory

Estrogens and Menopausal Rx

- Always start with assessment of estrogen status
- The patient is either replete or not
  - An estradiol level <100 pmol/l invariably leads to complaints associated with low estrogen
- If levels are above 150 pmol/l strong consideration should be given to other problems
  - Adrenal fatigue/stress
  - Thyroid dysfunction

Compounded Estrogens

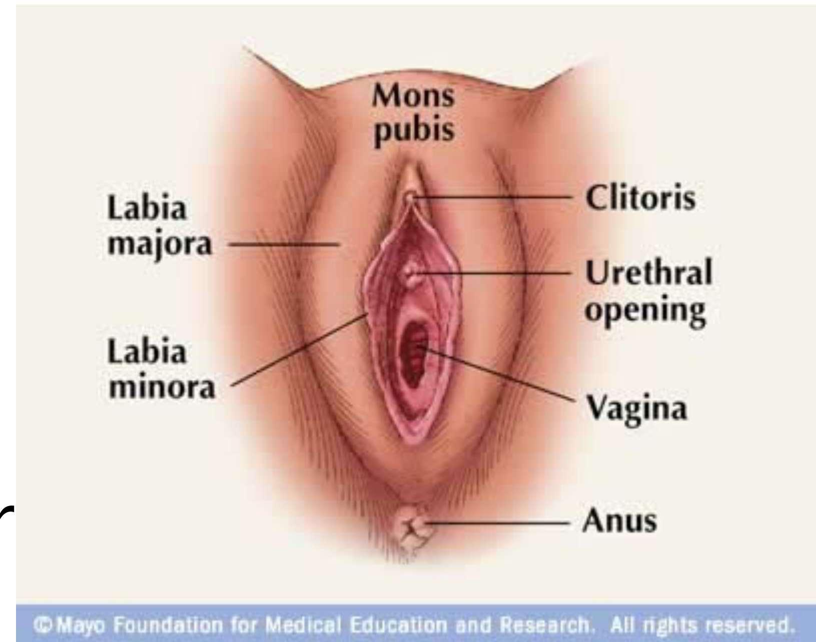
- Typically use a combination of estriol and estradiol- Biest
  - 80% estriol/20% estradiol most common for me
  - Typical start dose 1.25mg in .25cc HRT cream per vulva and can be combined with testosterone

Serum estradiol can be used to guide therapy

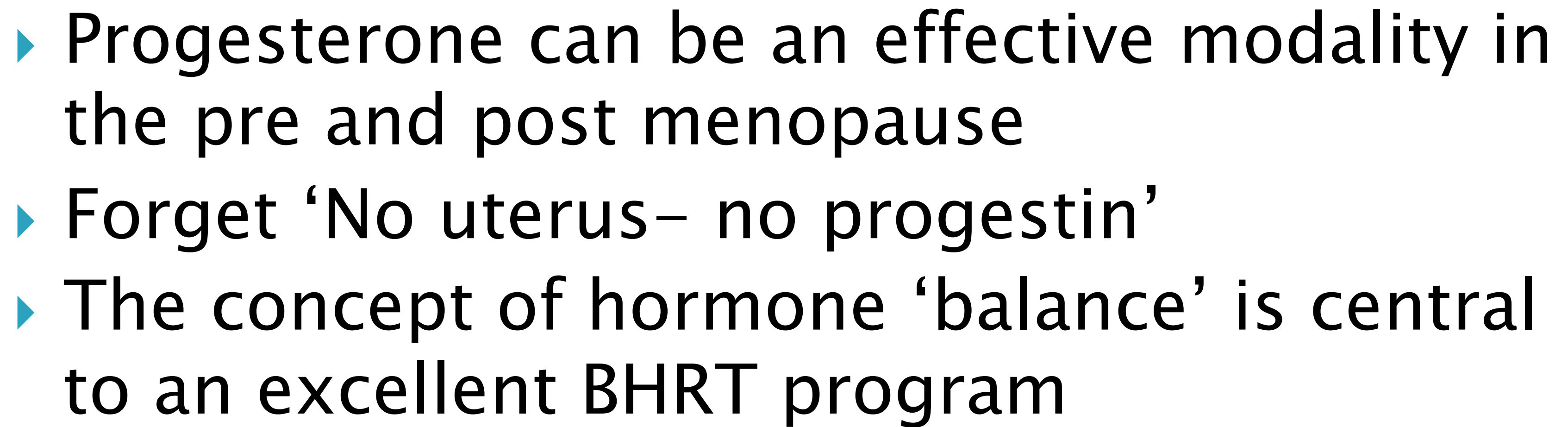
- 9-10 hour post-application serum level seems to be very representative of tissue levels
- Range of 150-200 pmol/l seems to be ideal target

Estrogen Application

- Biest is typically recommended for vulvar application
- More reliable serum levels achieved
- Better absorbed with lower doses needed
- Avoids darkening of hair at application site
- Occasional irritation can be addressed by compounder via hypoallergenic base



Progesterone Treatment



- Progesterone can be an effective modality in the pre and post menopause
- Forget ‘No uterus– no progestin’
- The concept of hormone ‘balance’ is central to an excellent BHRT program

Progesterone Decline

- Progesterone level production decline as women reach their late 30's
- Overall 50% decline from 20 to 40
  - And keeps falling from there!
- Related to the quality of ovarian follicles that are left at this time
- Poor quality follicles produce less progesterone from the corpus luteum
- Couple this with increased levels of estrogen and we see **Estrogen Dominance**

Estrogen Dominance

- Estrogen Excess
  - poor sleep/insomnia
  - agitation/anxiety
  - weight gain
  - tender breasts
  - headaches
  - mood swings
  - achy joints

Progesterone Deficiency
- poor sleep/insomnia
- agitation/anxiety
- weight gain
- tender breasts
- headaches
- mood swings
- fibrocystic breasts

Estrogen Dominance

- Estrogen Dominance can be seen at ALL levels of estrogen
  - Low/menopausal
  - Normal/pre-menopausal
  - High/PCOS
- This is why treatment decisions ALWAYS start with estrogen levels and symptoms
- Patient symptom questionnaire very useful to determine treatment priorities in women

Your Hormone Balance Inventory

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		None	Slightly	Moderate	Severe	Extreme
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TESTOSTERONE						
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	Lack of desire to be intimate					
	Loss of motivation					
	Flat mood					
	Diminished well being					
GENERAL WELL BEING						
	Change to Bowel Motions	How many per day?				
	Change of weight	Increase		Decrease		
	Change to Stress Level	Yes / No (circle)	Current Stress Level:			

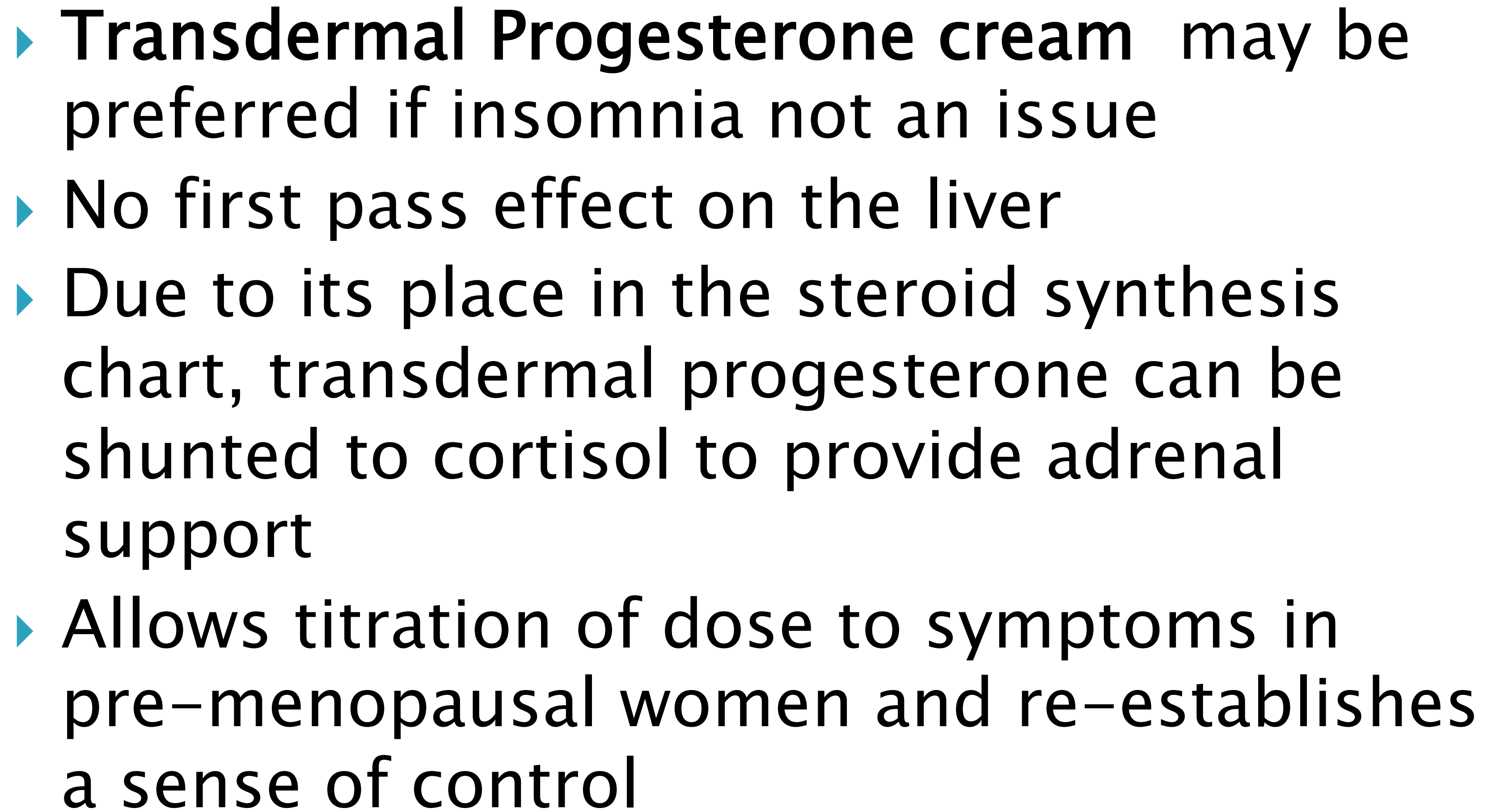
Progesterone

- **Relative** progesterone deficiency is endemic
- Symptom tipoffs
  - Poor sleep/insomnia
  - Anxiety/emotional lability
  - Tender breasts
- Progesterone treatment re-establishes balance with estrogen to improve symptoms

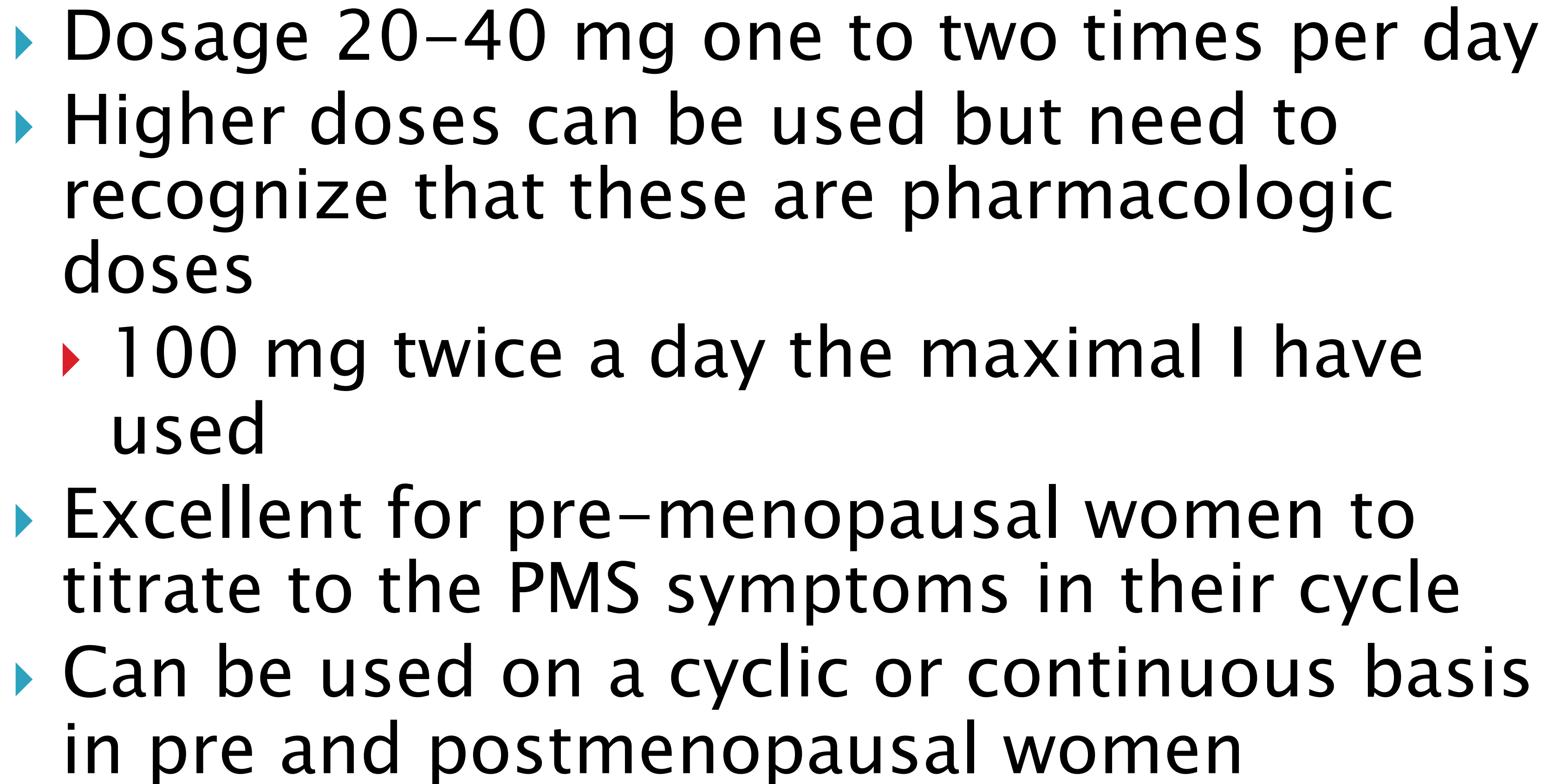
Oral Progesterone

- Its metabolite, 5-allo-pregnenolone, is sedating and improves sleep
  - **Prometrium** 100-200 mg 15 min before bedtime improves sleep (now in Safflower oil)
  - Can split dose vaginally for TD-like effect
- **Micronized Progesterone**
  - Compounded at doses from 50-300mg with addition of melatonin if required
  - Can be more cost effective than Prometrium- compounder dependant

Progesterone Cream



Progesterone Cream



Testosterone and Women

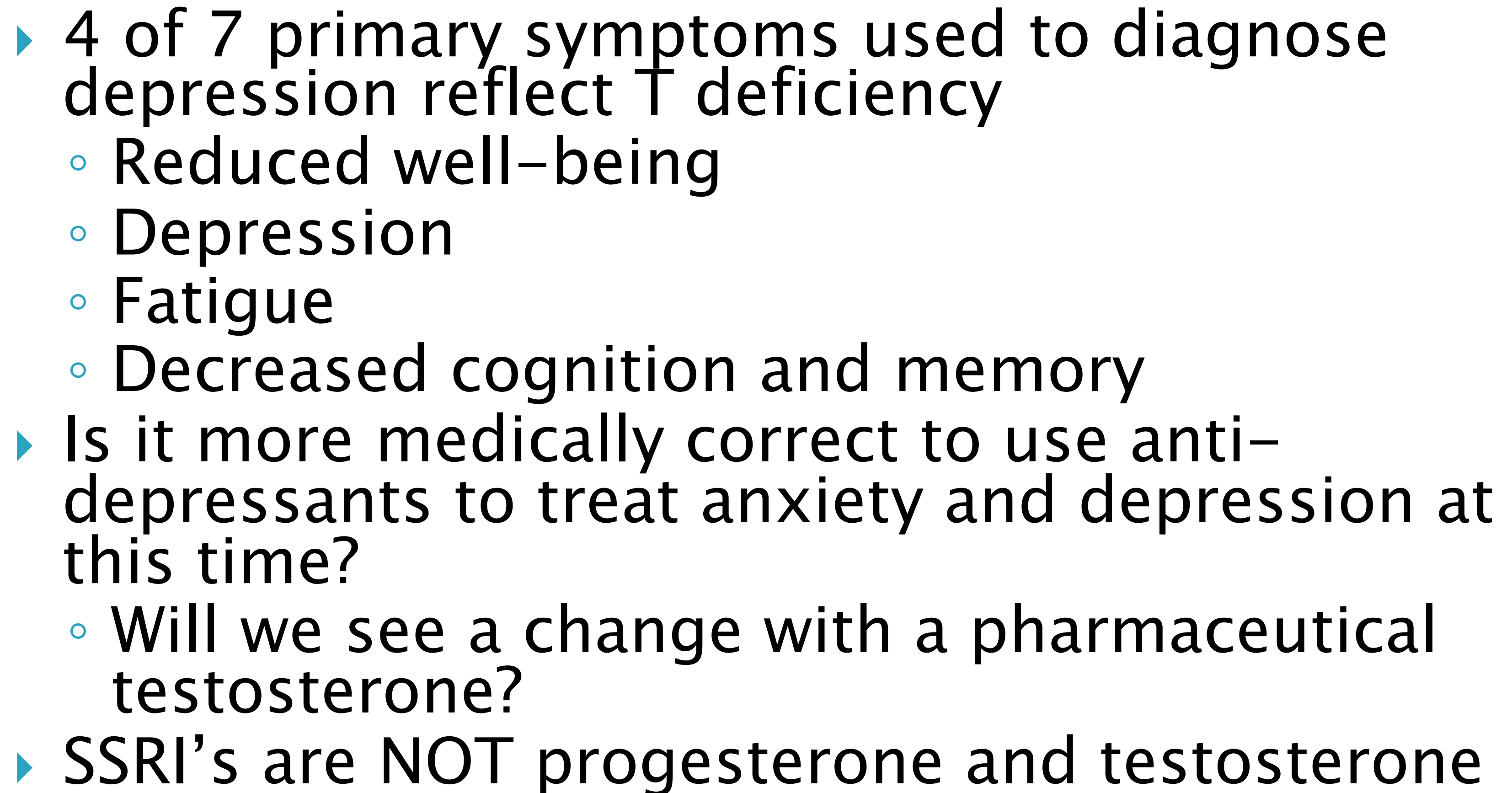
- Least understood and most controversial
- Gradual decline in testosterone production from age 25 to 50
  - 50% decline from age 20–40
  - 15% non-recoverable drop from each pregnancy
    - Natures family planning!
- Stable after the menopause

Minnie Pauz.....
I want the same bio-identical hormones as SHE'S got!
www.minniepauz.com

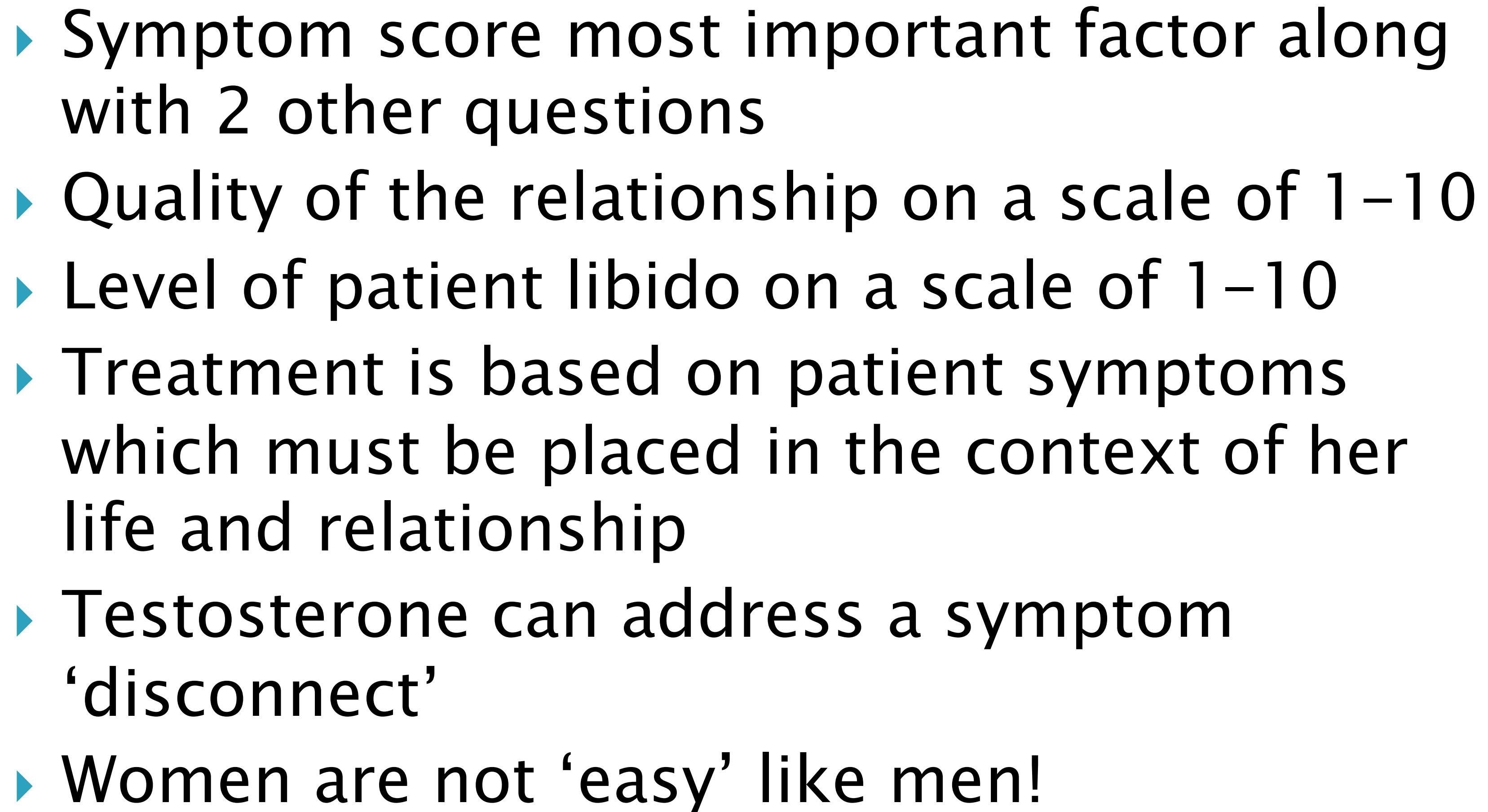
Testosterone Deficiency Princeton Consensus Statement

- Reduced sense of well-being and energy
- Dysphoric mood (depression)
- Persistent unexplained fatigue
- Decreased libido, sexual receptivity and pleasure(nipple and clitoral sensitivity)
- Vasomotor instability
- Changes in cognition and memory
- Bone loss and reduced muscle strength
  - Bachmann et al 2002 Fertil Steril 77(4)660-5 [30]

Testosterone



Testosterone Treatment in Women



truebalance™

Bio-Identical Intake Female

Note: Please read carefully and fill out as completely as possible. The information provided by this questionnaire will become part of your records at our clinic and is treated as confidential.

Name: ____________________ (First Last) **DOB:** __________ (Month/Day/Year) **Age:** ____ **Marital Status:** ____

Address: ______________________________ (Mailing Address, City, Province, Postal Code)

Phone Numbers: ( ) ________ Home ( ) ________ Cell ( ) ________ Business

Email: ____________________ **Personal Healthcare Number:** ____________

Would you like to receive newsletters, etc? ☐ YES ☐ NO

Family Physician: ____________________ **How did you hear of us?** ____________________

Chief Complaint: ______________________________

Medication	Strength/Dosage		Vitamins / Supplements	Quantity

Known Allergies:

Surgery/Medical History:

Family History:

Highlighted Sections are *FOR DOCTOR USE ONLY*

G___/P___ C-Sec/SVD Cycle: ____/____ LMP: ______ Flow ______ Pain: ______ Contraception: ______

Occupation ______________ Marital Status: ______ Relationship Quality: ______ (1-10) Libido: ______ (1-10)

Dyspareunia: Yes No Daily Bowel Motion: Yes N Sleep Quality: ______ (1-10)

Alcohol Use: Yes No Am't per week: ______ Smoker: Yes No Am't ______

Date of Last: Physical: Mammogram: Bone Density:

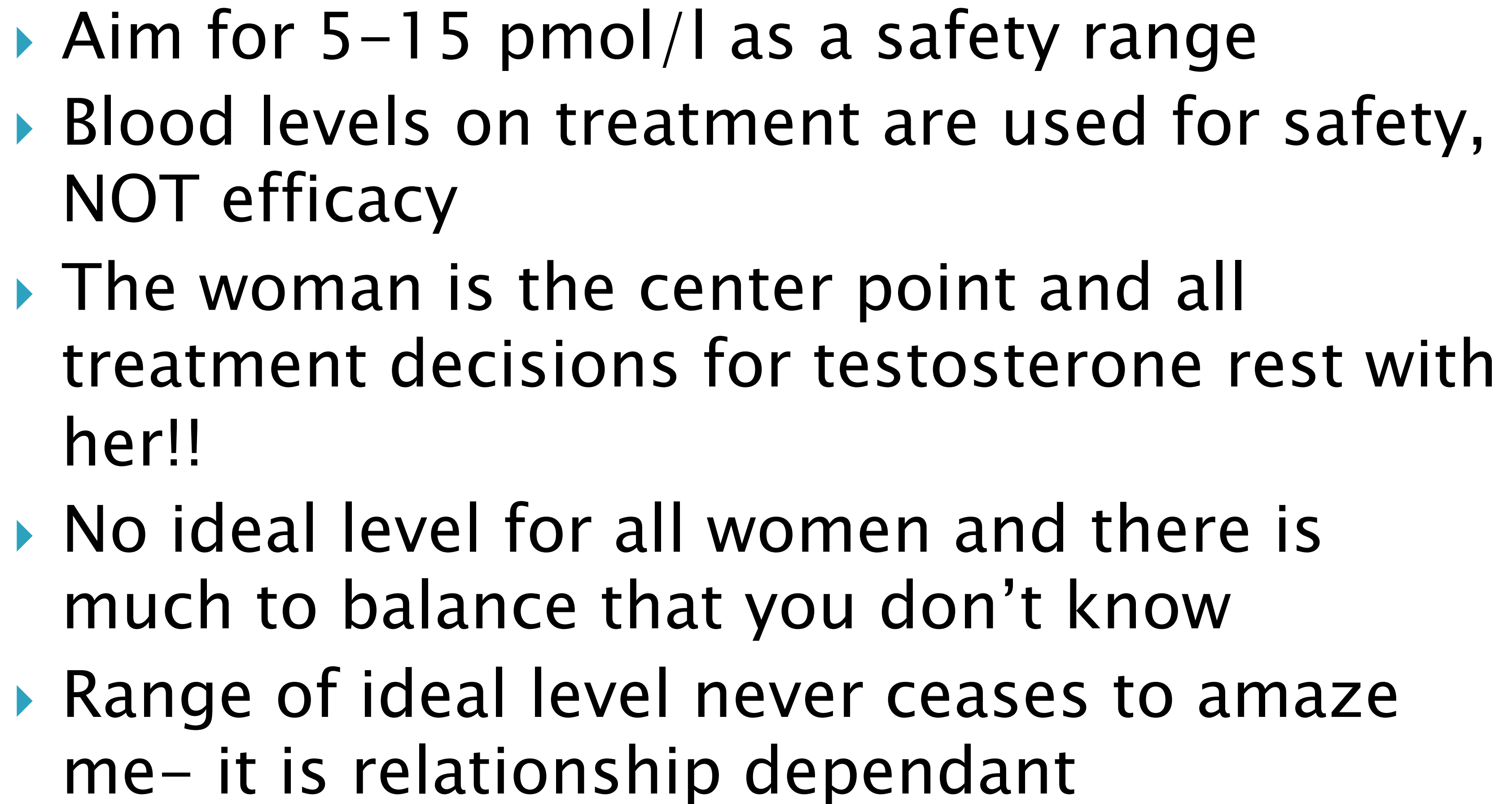
Height:		Waist Circ:		BP:		Weight:		Thermography:	
DVD watched:		Dispenser:		Diet Program:		Sleep			
Multivitamin:		Vitamin D:		Omega 3:		Mag		Sleep:	
Grey		Adr. Fatigue		4Pt Cortisol		IV		Toxicities:	

It's All a Matter of Balance

Testosterone and Women

- Testosterone is added to Biest cream or used alone and applied daily to the vulva
  - Typical start dose 1-1.5 mg in .25 cc HRT with or without Biest
- Blood levels establish **safety** of dosage
  - 9-10 hour post-application
- Woman determines dosage adjustment
  - Experienced benefits
  - Unwanted side effects
  - Relationship correlates

Testosterone Treatment in Women

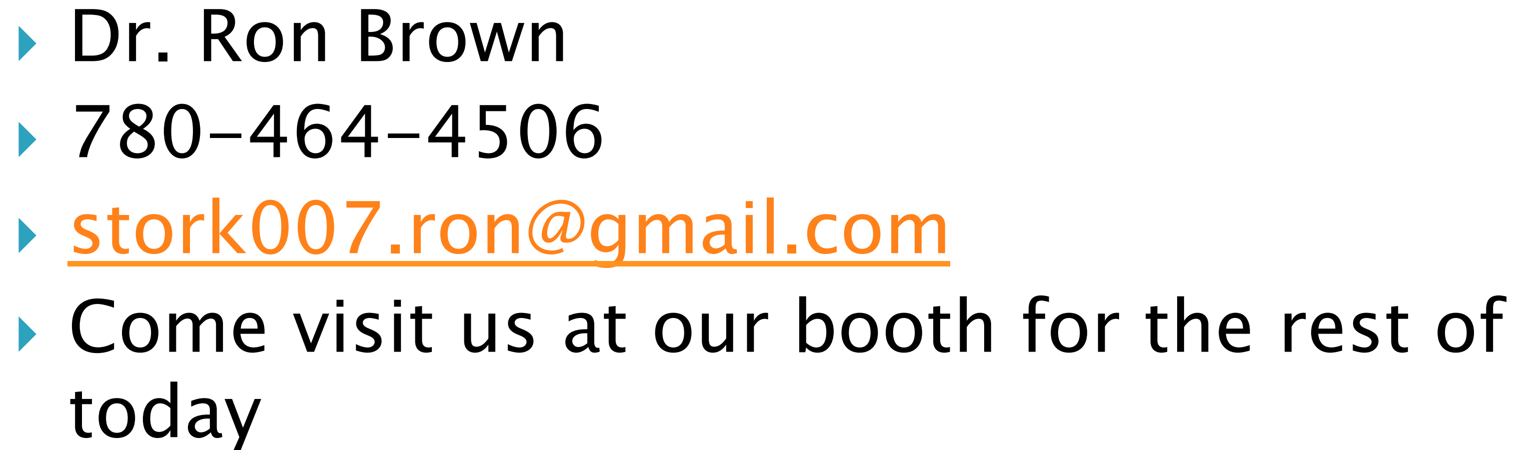


- Aim for 5-15 pmol/l as a safety range
- Blood levels on treatment are used for safety, NOT efficacy
- The woman is the center point and all treatment decisions for testosterone rest with her!!
- No ideal level for all women and there is much to balance that you don't know
- Range of ideal level never ceases to amaze me- it is relationship dependant

BHRT Conclusions

- BHRT works to improve quality of life
  - Symptomatic and physiologic
- BHRT needs literature support to move forward in meaningful way
- BHRT appears to reduce breast cancer and heart disease
- BHRT does not increase blood clot risk
- BHRT has to be patient centered and focused on the risk-reward ratio

BHRT and True Balance



Sometimes you just have to dive in!