What are Bio-Identical Hormones?

Although many bio-identical hormones are created in a lab, they have the exact same molecular structure as the hormones produced by the human body. In other words, they are chemically indistinguishable from one another. Because their chemical structures are identical, bio-identical hormones generate the same physiologic responses in the body as do the hormones already produced by the body. When making choices about hormone therapies, choosing bio-identical hormones makes good sense because they simply replace and replenish the balance your own hormones naturally provide. One well-known example of a bio-identical hormone therapy is the use of injectable human insulin in the treatment of diabetes.
• Same molecular structure as the hormones in the human body

• Replenish the balance your own hormones provide

Why BHRT?
With bio-identical hormone therapies, each individual's hormone deficiencies or excesses must be evaluated. In determining the optimal hormone therapy for an individual, a practitioner must take into consideration the interactions among the different hormones, as well as other potential effects of each hormone throughout the body. For example, bio-identical progesterone protects the uterus and, at the same time, has positive effects on mood, memory, and sleep.

• Unique prescription specified for each individual

• Potential effects throughout the body
Which Patients Do We Consider?

- Perimenopausal, symptomatic females
- Postmenopausal females
- Andropausal males
- Polycystic ovarian syndrome
- Urinary incontinence / vaginal atrophy in older females not taking HRT of any kind
- Transgendered patients

Which Hormones for BHRT?

- Most frequently used
  - Estrogen: Estradiol, Estriol
  - Progesterone
  - Testosterone
- Sometimes added
  - Pregnenolone
  - DHEA

Other Hormones to Consider

- Thyroid – porcine, levothyroxine, liothyronine
- Oxytocin
- HCG
- HGH
- Hydrocortisone
- Sermorelin
Pharmacy?

- BHRT prescriptions must be compounded, or mixed together into the desired format, in a Compounding Pharmacy

What is Compounding?
Compounding combines an ageless art with the latest medical knowledge and state-of-the-art technology, allowing specially trained professionals to prepare customized medications to meet each patient's specific needs. Compounding is fundamental to the profession of pharmacy and was a standard means of providing prescription medications before drugs began to be produced in mass quantities by pharmaceutical manufacturers.

- Care must be taken to find quality compounding pharmacies for your patients' needs.
- Visit the pharmacies and get to know the pharmacists and their policies for compounding.
- If it is a large pharmacy at a distance from you, ask for a representative to speak with you directly.
• MedQuest – PCAB Accredited, will ship throughout the country, computer/phone app for refills. All forms BHRT except pellets.
• Scottsdale Professional – Will ship throughout the country, reliable and accurate. All forms BHRT except pellets.
• VASCO Pharmacy – Will ship throughout the country. Wiley Protocol available plus all forms BHRT except pellets.
• Women’s International – Good price-point on creams and capsules, will ship throughout country. Insist on monthly renewals from PAs for BHRT prescriptions.
• Belmar Pharmacy – Will ship throughout the country. All forms of BHRT including pellets and BLA tablets
• Hallandale Pharmacy – specialty products such as sermorelin.
• College Pharmacy – specialty products including BHRT pellets and aesthetics.

Methods of Administration

• Topical—creams, gels, oils
• Sublingual/Buccal—troches, triturate tablets
• Vaginal—creams
• Subdermal—pellets
• Oral—capsules (never for testosterone)

Creams and Gels

• Creams and Gels are inexpensive.
• They are applied topically—typically to the inner thigh.
• BID administration is the most effective, however, for patient compliance, QD administration may be preferred.
Sublingual Buccal
• Troches are dosed QD.
• They are placed between the cheek and gum and take approximately 15 minutes to dissolve.
• Flavors and sweeteners may be added to make them more palatable.
• Triturate tablets are loosely packed, molded tablets which dissolve quickly.
• They are placed under the tongue and are dosed QD.

Vaginal Creams
• Vaginal Creams are applied at bedtime.
• If applied only twice a week, they will most likely remain a local application to the vaginal wall -- appropriate for atrophic vaginitis and/or urinary incontinence.
• If applied daily, this will become a systemic treatment.
• This may be an appropriate treatment for dryness and atrophic vaginitis in breast cancer patients, however, the patient should always consult their oncologist before using.
• Intercourse must be avoided after using.

Subdermal Pellets
• Fused pellet implants containing Estradiol or Testosterone.
• Inserted under local anesthesia into the upper buttocks.
• Pellets deliver consistent levels of hormone, taking effect within a week of insertion.
• Duration of action is approximately 3 months in women and 6 months in men.
• Higher levels of physical activity and stress can deplete the hormones, especially testosterone, more quickly.
How Do We Determine Which Method to Use?

- Creams work well for female patients new to BHRT – dosing can be flexible, least expensive.
- Troches or triturate tablets work well for male patients – once daily dosing, less worry about “sharing hormones” with a partner.
- Pellets work well for those who just don’t want to think about it or travel frequently.
- Vaginal Creams work well for older females wanting only local vaginal relief.

How Do We Determine the Dose?

- History and physical exam

- Discussion with patient about symptoms, their experience with hormone replacement therapy, and their beliefs about BHRT.

- Laboratory studies

History

- Do not consider BHRT if:
  - Personal History of DVT, PE, or clotting disorder
  - Personal History of active breast cancer
  - Personal History of prostate cancer
  - Elevated PSA with no urological consult
Physical Examination

• Do not consider BHRT if:
  – You find a breast mass, ovarian mass, abnormal pap, nodular prostate, or other serious concern, until after it has been investigated thoroughly.
  – You find evidence or cardiovascular disease which has not been investigated.
  – You get a feeling the patient is not being honest with you or will not be compliant.

Symptoms -- Female

• Fatigue
• Hot flashes
• Lack of mental clarity
• Forgetfulness
• Decreased or absent libido
• Weight gain
• Depression
• Moodiness
• Emotional lability
• Irritability
• Joint pains
• Insomnia
• Swelling / Edema
• Wrinkles
• Irregular menses
• Night sweats
• Palpitations

Symptoms -- Male

• Decreased or absent libido
• Disappearance of morning erections
• Weak or limp erections
• Decreased stamina
• Muscle weakness
• “Pear shape”
• Fatigue
• Disinterest in life
• Depression
• Decreased drive both at work and home
• Forgetfulness
• Irritability
• Wrinkles
ADAM Questionnaire

Do you have a decrease in libido (sex drive)?
Are your erections less strong?
Do you have a lack of energy?
Do you have a decrease in strength and/or endurance?
Have you lost height?
Have you noticed a decreased "enjoyment of life?"

ADAM, continued

Are you sad and/or grumpy?
Have you noticed a recent deterioration in your ability to play sports?
Are you falling asleep after dinner?
Has there been a recent deterioration in your work performance?

If you answered “yes” to either of the first two questions, OR if you answered, “yes” to three other questions, you have androgen deficiency (low testosterone).

Laboratory Testing -- Females

<table>
<thead>
<tr>
<th>Test</th>
<th>Unit</th>
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</thead>
<tbody>
<tr>
<td>CBC with differential</td>
<td>Progestrone</td>
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<tr>
<td>CMP</td>
<td>Pregnenolone</td>
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<tr>
<td>HgBA1C</td>
<td>SHBG</td>
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<tr>
<td>Lipid panel</td>
<td>DHEA-S</td>
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<tr>
<td>HsCRP</td>
<td>Cortisol, fasting</td>
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<tr>
<td>FSH</td>
<td>D-25-hydroxy</td>
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<tr>
<td>Estrone</td>
<td>TSH</td>
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<tr>
<td>Estradiol</td>
<td>Free T3</td>
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<tr>
<td>Estriol</td>
<td>Free T4</td>
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<tr>
<td>Total Testosterone</td>
<td>Reverse T3</td>
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</table>
### Laboratory Testing -- Males

<table>
<thead>
<tr>
<th>Test</th>
<th>Description</th>
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</thead>
<tbody>
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<td>CBC with differential</td>
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<tr>
<td>CMP</td>
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<td>HsCRP</td>
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<tr>
<td>LH</td>
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<tr>
<td>Total Testosterone</td>
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<td>Free Testosterone</td>
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<tr>
<td>PSA</td>
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<td>Progesterone</td>
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<td>DHEA-S</td>
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<td>Free T4</td>
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<tr>
<td>Reverse T3</td>
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</tr>
</tbody>
</table>

### Laboratory Testing

**Serum, Saliva, Urine??**

- Use whatever modality you are most comfortable in interpreting.
- Take into consideration cost to patient. Insurance will usually cover serum testing if you code it properly.
- There are less-expensive, cash-pay lab services available, such as Cooperative Lab Services, [http://www.professionalco-op.com/](http://www.professionalco-op.com/)

### The Prescription

- Each prescription becomes as unique as the patient, depending on age, lifestyle, co-morbidities, medications, results, personal concerns.
- You can start with a basic prescription and then recheck pertinent labs and the patient’s experience at 6 weeks, and again at 3 months.
What Are Good Starting Doses?

Postmenopausal Women, healthy, up to five years past menopause, no cardiovascular disease, daily dosing:
- Estradiol 0.5mg
- Testosterone 1mg
- Progesterone 100mg (cervix intact)
- Progesterone 25mg (no cervix)
- DHEA, Pregnenolone dependant upon lab results

What Are Good Starting Doses?

Andropausal Men, healthy, normal PSA and DRE, no cardiovascular disease, daily dosing:
- Testosterone 50mg
- DHEA, Pregnenolone dependant upon lab results

What Are Good Starting Doses?

Postmenopausal Women, wanting only relief from vaginal dryness/atrophy:
- Estriol 1mg/gm Vaginal Cream, inserted vaginally QHS x 2 weeks, then twice weekly thereafter.
Perimenopausal Women

Much will depend on the laboratory results and patient complaints.
- A daily dose of Estradiol and Progesterone may stop menses altogether.
- Progesterone only or Testosterone only may be appropriate.
- A cycling dosing, such as the Wiley Protocol® may be appropriate.

The Wiley Protocol®

Dosing of BHRT (or biomimetic) to mimic the natural wavelike rhythms of the hormone blood levels in a normal menstrual cycle in a healthy young woman.

The Wiley Protocol®

Creams are compounded in Wiley-certified compounding pharmacies only.
Calendars are supplied following either a Lunar Cycle or a Personal Cycle.
Estrogen (green) and Progesterone (purple) creams are applied BID to the upper outer arm or inner thigh region.
Testosterone is also available for Women. A calendar is provided for dosing to accompany the Estradiol and Progesterone dosing schedule.

The Wiley Protocol® is also available for Men. Testosterone and DHEA creams in syringes are supplied. Calendars follow a “Sun Cycle” and can be coordinated with their partner’s calendar.

Who is appropriate for the Wiley Protocol?
- Perimenopausal women
- Young women with polycystic ovarian syndrome
- Recently postmenopausal women who wish to continue to cycle
- Andropausal men
- Transgendered patients
The Wiley Protocol®

• For more information on the Wiley Protocol go to: www.thewileyprotocol.com
• Attend one of her Back to Earth weekend conferences to really understand how to work with this Protocol.
• Expect to acquire new patients who are very interested in this method of BHRT.
• Read *Sex, Lies, and Menopause* by T.S.Wiley for more insight.

But what about the WHI results?

• WHI results are based on a study using Premarin® (conjugated equine estrogen) and Provera® (progestin), not BHRT.
• Premarin® contains ten estrogens not found in the human body.
• The increased risk of breast cancer was attributed to Provera® and not the estrogen.
• The only harm found in the estrogen only arm of the study was increased risk of stroke found in older women who started HRT after age 65. This was not seen in women starting before age 60.

Benefits of BHRT

• Elimination of symptoms of menopause/andropause
• Maintenance of normal bone density
• Improved energy levels
• Improved mental clarity and attention span
• Lowered lipid levels
• Improved skin turgor → fewer wrinkles
• Improved strength and stamina
• Improved libido
• Improved mental outlook and joy of life
Before you write a prescription for BHRT…

• Don’t consider this a complete course on BHRT—take some courses. Good sources are Age Management Medicine Group, www.agemed.org, and Worldlink Medical, www.worldlinkmedical.com/.
• Don’t believe everything you read on the Internet.
• Don’t believe everything you were taught in PA school.
• Listen to your patients.
• Test and retest your patients to get things right.
• Enjoy your work, and your patients.

References to Ponder

“Fear of breast cancer is the strongest factor limiting postmenopausal hormone use. The most powerful study to date definitively demonstrated that estrogen does not cause an increased risk for cancer. The increased risk was associated only with taking the progestin (Provera®) and not estrogen.”
JAMA 2004;291(24);2947-2958

“Bone density is rapidly lost when HRT is stopped. HRT should be continued indefinitely.”
JAMA 2002 August;Vol.288No.7;880-887

References to Ponder

“In the final analysis of the estrogen only arm of the WHI, there was no increased risk of breast cancer or heart disease. There was 35% decrease in hip fractures, 35% decrease in diabetes and a 60% decrease in urinary sepsis. This leads to a significant decrease in all causes of mortality.”
J Gen Internal Medicine 2004;19(7);791-804

“The largest study to date, the Nurses’ Health Study, demonstrated a 100% decrease in heart disease and cancer for estrogen users. It is never too late to initiate estrogen therapy to arrest the progression of osteoporosis and hip fractures.”
Female Patient 2004 Oct;Vol29;35-44
“There are now over 60 studies demonstrating that estrogen can be safely given to women after treatment for breast cancer. Most studies show a decrease in breast cancer in women on estrogen compared with controls.”
Female Patient 2004 Oct;Vol29;40-46

“Natural estradiol and progesterone are safe and show no increase in breast cancer or heart disease; however the synthetic hormones do increase risk of heart disease and cancer.”
Breast Cancer Res Treat 1997 Fe27;60-175

“Loss of testosterone causes loss of libido, energy, strength, sexual function, memory, cognition, muscle and bone. Testosterone replacement, as far as quality of life is concerned, is tremendous.”
Medical Crossfire 2001 Jan;Vol.3No.1:17-18

“Low testosterone levels are associated with an increased risk of diabetes, hear disease, and carotid atherosclerosis.”
Diabetes Care 2003 June;Vol.36,No.6:20-30

“Testosterone levels have nothing to do with causing cancer.”
Cancer 1999, July 15;88(2):312-5

“Testosterone administration in the highest dosage resulted in increased sexual activity, pleasure, and orgasm in women. There was an increase in sexual fantasies, masturbation, and frequency of sex. There was an improvement of well-being and mood.”
New England Journal of Medicine 2000;343;683-88

“Testosterone protects against Alzheimer’s dementia, type II diabetes, obesity, depression, osteoporosis, muscle wasting, cognitive decline, loss of libido, erectile dysfunction, and cardiovascular disease. The prevalence of prostate cancer in men with low testosterone levels is substantial in comparison with high testosterone levels. Lower testosterone levels increase risk of prostate cancer and cancer severity.
New England J of Med 2004; 350;482-92
Thank you!