Bio-identical hormones – What are the concerns?

http://womenshealth.med.monash.edu.au

The prescribing and dispensing of compounded hormonal products is rife across Australia and appears to be increasing exponentially. This is becoming a significant public health issue for Australians, an issue on which the FDA and the US Endocrine Society have been quite vocal.

Prescribers and manufacturers of compounded 'bio-identical' hormones claim that these products are identical to hormones made by the body and that these 'all-natural' pills, creams, lozenges (troches), lotions, and gels are without the risks of therapies approved by the Australian Therapeutic Goods Administration (TGA) for the management of menopause, thyroid disease and other hormonal conditions.

Specific concerns are

1. **The potential serious public health risk and the potential for harm from the prescription of hormones in doses and combinations for which**
   a. pharmacokinetic data are lacking
   b. no evidence for efficacy
   c. safety data are lacking

A clinical example is concern that there may be inadequate endometrial protection for non hysterectomised women using combination compounded oestrogen progesterone therapy – three endometrial cancers have been reported in NSW in relation to 'bioidentical' hormone use.

2. **No accounting for purity and dose accuracy**
3. **The lack of consumer information pertaining to these products at the time they are dispensed-consumers are not warned of risks.**
4. **The compounding pharmacies acting as pharmaceutical companies** but are not being governed by the regulations that govern the pharmaceutical industry. Because they are 'dispensing' on prescription they are able to skirt around the laws that would normally apply to the production of controlled substances such as testosterone and oestrogens.
5. **The promotion of substances NOT approved for use in Australia** such as DHEA, melatonin and pregnenalone for which there is no evidence to support use.
6. **The misinformation being disseminated to the community**
   a. **that 'natural menopausal hormone therapy' is safer than** approved pharmaceuticals and will do no harm. There is no evidence for this in that several approved product are equally 'natural' and there is no evidence that compounded sex steroid therapy is more or less safe than other therapies
   b. **that doses are custom-formulated on the basis of salivary hormone levels**–because of the complexity of sex steroid metabolism and the intra-individual variation across menopause treatment can only be titrated on clinical endpoint. The validity of salivary tests for sex steroids has not been established.
7. **The increasing use of porcine/beef thyroid extract,** often prescribed to euthyroid individuals with diagnosis and management based on urine hormone metabolites.
8. **The use of low dose glucocorticosteroid therapy for the management** of 'adrenal fatigue' which over time may cause adrenal suppression in individuals who had no such condition and put individuals at serious risk.

Changes that are needed include:

1. Requirement that patients are informed that compounded hormones are not TGA approved
2. Inclusion of uniform information for patients, such as warnings and precautions, in packaging of compounded hormone products
3. Mandatory reporting by hormone compounders and prescribers of adverse events.

Considering the increasing use of these compounded hormones in the community strategies to protect the community from harm are urgently required.

MONASH University
Medicine, Nursing and Health Sciences