

Objective

In the United States (U.S.), millions of prescriptions are filled annually for compounded bioidentical hormone therapy (cBHT). In the light of an increasing demand and supply for a personalized and natural approach to hormonal imbalance, the clinical utility of cBHT has been recently questioned. A nationwide survey research of clinical practices was conducted with the objective to provide current evidence-based data on the safety, effectiveness and use of compounded hormones for female patients.

Design

The survey research was developed using Google Forms, a versatile web-based survey instrument used to create online questionnaires with the purposes of standardized data collection. A bit.ly custom shortened web link was created and disseminated online to a purposive sample of physicians who commonly prescribe compounded hormones for female patients in the U.S. The online survey research was launched on December 7th, 2020 and closed on February 15th, 2021. The survey was organized in 5 sections and comprised a total of 12 brief questions, of which 5 questions were required. The majority of the survey questions were multiple-choice or check-boxes and only 3 were open-ended questions. The introduction of the survey stated the objective of the research and a confidentiality disclaimer. The first section was demographic and included a conditional question to ensure the eligibility of the respondents. The following section gathered data on the prescribing habits of U.S. physicians for female compounded hormones, namely the preferred route(s) of administration and the commonly prescribed hormones (2 questions). The third section addressed the physicians' evaluation of the efficacy of their prescribed hormones. Physicians were asked the methods used to evaluate efficacy and two examples were given in this openended question (symptom resolution and laboratory values). Three additional questions assessed the testing of laboratory values for hormone levels. The following section was one open-ended question regarding the safety evaluation of the prescribed hormones. The last section of the survey research was an invitation to enroll physicians in a retrospective and/or prospective study on compounded hormones for female patients (3 questions). The data collected was automatically stored online and entered into a spreadsheet for further analysis and interpretation.

Results

A total of 489 survey responses were submitted online, of which 434 met the eligibility criteria and were considered valid responses. This was a nationwide survey research including physicians' data across 44 U.S. States, mainly from Arizona, Texas and California. Topical and/or transdermal is the preferred route of administration of hormones, as stated by 78.1% physicians, followed by oral/sublingual/buccal (73.3%) and vaginal delivery (55.3%). Hormone pellets (implanted under the skin) are the least popular dosage form (35.5%). The top 3 most commonly prescribed hormones are, in descending order, progesterone, testosterone and Bi-Est (estradiol and estriol). Almost all physicians test laboratory values before initiating hormone therapy (Figure 1) and repeated testing is commonly performed at 3, 6 and 12 months. Close to 90% of physicians test hormones in serum (blood). Saliva and urine testing are also popular but to a much smaller extent (Figure 2). Almost all physicians evaluate the safety of their prescribed hormones, mainly using mammograms, follow-up laboratory values (hormones, CBC, CMP) and pelvic exams (pap smear, transvaginal ultrasound).

Compounded bioidentical hormones are currently prescribed to female patients across the U.S. Almost all physicians evaluate the efficacy and safety of the prescribed hormones on a regular and individual basis using recommended routine laboratory tests and OB/GYN exams.

Compounded Hormones for Female Patients: A Survey Assessment of Clinical Practices in the U.S.

PCCA, Professional Compounding Centers of America, Houston (TX)

Figure 1. *Survey question number 6: Do you test* laboratory values before initiating hormone therapy? Physicians' responses: Yes displayed in yellow colour (97%) and No displayed in black *colour (3%).*



*Corresponding author: mcarvalho@pccarx.com



Figure 2. Physicians' responses to survey question number 8: Which is your preferred testing for compounded hormones?

Poster digital version available at: https://www.pccarx.com/Science