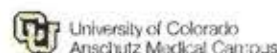


Women's Use and Knowledge of Custom-Compounded Bioidentical Hormones



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Introduction

Custom-compounded "bioidentical" hormone therapy (CBHT) is widely advertised as an alternative to conventional FDA-approved prescription hormone therapy for menopausal symptoms (MHT). FDA approval is not required for CBHT, and high-quality clinical trials to establish the safety and effectiveness of these compounded drugs have not been conducted.

There is a dearth of information on the extent of CBHT use in the United States and on patient awareness of the distinctions between CBHT and FDA-approved forms of MHT. Two Internet surveys were conducted to elicit information about US women's use and knowledge of MHT—including CBHT—and their menopausal experience. Data were extrapolated to estimate the extent of CBHT use in the United States.

Objectives

- Quantify use of CBHT by menopausal women in the United States
- Explore women's knowledge of CBHT vs FDA-approved MHT

Methods

- Both Harris Interactive and Rose Research fielded an Internet survey using representative samples drawn from proprietary nonprobability opt-in panels
- Women were asked about menopausal symptoms, MHT use, and knowledge of CBHT
- Eligibility:
 - Harris—women aged 45 to 60 years with current or prior menopausal symptoms
 - Rose—women aged ≥40 years with current or prior MHT use
- Completers were eligible women who answered 100% of survey questions
- To estimate trends in CBHT use, Rose survey findings were extrapolated to the US population using Census data¹ and Source Healthcare Analytics PHAST 2.0 prescription data (Symphony Health, Horsham, PA). For a more detailed description of the estimations, see poster (P-79) presented at this meeting.²

Results

- Most completers in Rose and Harris were white, had some post-secondary education/vocational training, and had healthcare coverage
- Extrapolating data from the Rose survey to the US Census and PHAST 2.0 data suggests an estimated 1 million to 2.5 million women aged 40 years and older fill 21 million to 39 million prescriptions for CHT annually
- Women lacked knowledge of CBHT:
 - Three-quarters (76%) of Harris completers did not know whether "bioidentical hormone therapies compounded at a specialty pharmacy" were FDA-approved, and 10% believed they were FDA-approved
 - More than one-quarter (27%) of the 1771 ever-users in Rose asked about CBHT did not know whether their HT had been personalized or compounded

FIGURE 1. Survey Recruitment and Eligibility Information

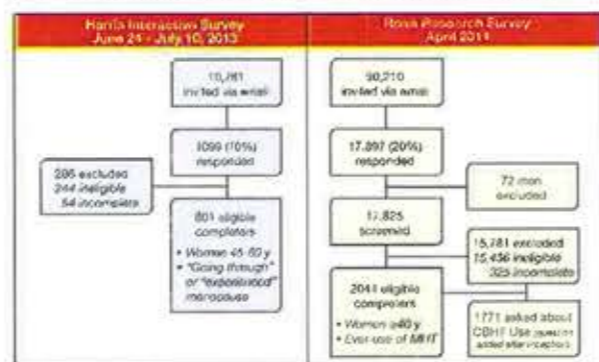


TABLE 1. Characteristics of the Survey Cohorts

Demographic	Harris, No. (%)	Rose, No. (%)
Completers	801	2044
Mean age	53	—
Age group (Harris/Rose)		
40-44	—	278 (14)
45-50/45-49	208 (26)	286 (14)
51-55/50-54	312 (39)	307 (15)
56-60/55-59	280 (35)	287 (14)
60-69	—	431 (21)
70-79	—	270 (13)
≥80	—	185 (9)
Race/ethnicity		
White	641 (80)	1726 (84)
Black	72 (9)	136 (7)
Hispanic	72 (9)	99 (5)
Other	16 (2)	83 (4)
Highest level of education		
≤High school degree	264 (33)	418 (20)
Vocational/some college	NA	579 (29)
Associate's/bachelor's	449 (56)	716 (35)
Some graduate school	NA	99 (5)
Household income, \$		
<25,000	128 (16)	305 (15)
25,000-49,999	168 (21)	599 (29)
50,000-99,000	264 (33)	678 (33)
≥100,000	216 (27)	335 (16)
No answer	—	126 (6)
Healthcare coverage		
PPO/HMO	489 (61)	792 (39)
Traditional insurance	56 (7)	239 (12)
Medicare/Medicaid	88 (11)	752 (37)
Other/unknown	56 (7)	165 (8)
No coverage	104 (13)	96 (5)
Prior hysterectomy	160 (20)	927 (45)
Menopausal status		
Postmenopausal ^a	600 (75)	1594 (78)
Perimenopausal	200 (25)	259 (12) ^b
Nonmenopausal	—	301 (15)

^aWomen indicated they had gone through menopause >1 year ago. ^bFor the Rose survey, up to 110 women in the postmenopausal group may overlap with the perimenopausal group.

TABLE 2. Current MHT Use in Rose Survey Extrapolated to 2012 US Census Data

Age Range, y ^a	No. of US Women ^b	Current MHT Use by Age, % ^c	No. of Current MHT Users in US
40-44	10,569,227	7	739,846
45-49	10,962,854	7	767,400
50-54	11,499,014	5	574,951
55-59	10,704,108	3	321,123
60-64	9,279,200	5	463,960
65-69	7,370,497	3	221,115
70-74	5,412,023	3	162,361
75-79	4,198,131	3	125,944
≥80	7,349,650	5	367,483
Total	77,344,704	—	3,744,183

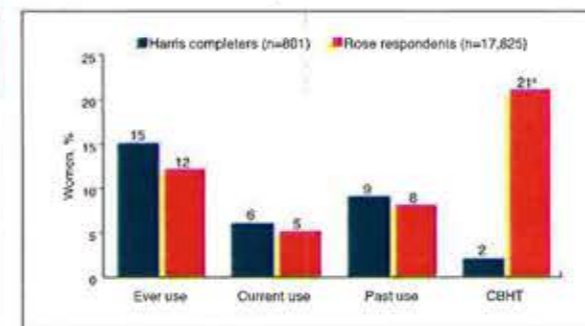
MHT, menopausal hormone therapy. ^aAge brackets used in the Rose survey. ^bCurrent MHT use per Rose survey.

TABLE 3. Derivation of Estimated Amount and Cost of CBHT Use in the United States

Variable (annual)	Source/Calculation	Outcome
Current MHT users in US	See Table 2	3.7 million
MHT prescriptions	Current MHT users × mean number of products used per month in Rose × est. months of use per year	57-75 million
FDA-approved MHT prescriptions	PHAST 2.0 database (2012)	36 million
CBHT prescriptions	MHT prescriptions - FDA-approved prescriptions (57-75M - 36M)	21-39 million
Spending on CBHT	CBHT prescriptions × monthly cost of MHT per Rose (21-39M × \$49)	\$1-2 billion
US women using CBHT	CBHT prescriptions ÷ mean number of products used per month ÷ est. months of use per year (21-39M ÷ 1.7 ÷ 9-12 mo)	1-2.5 million
Proportion of MHT prescriptions for CBHT	CBHT prescriptions ÷ MHT prescriptions (21-39M ÷ 57-75M)	28%-68%

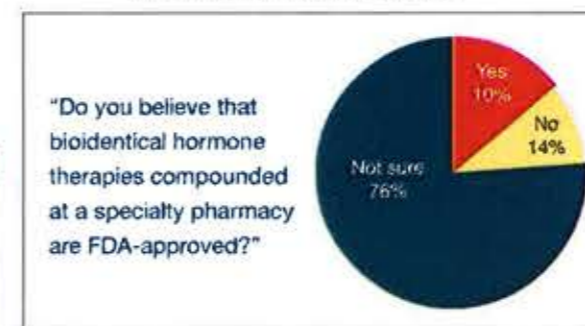
CBHT, compounded bioidentical hormone therapy; FDA, US Food and Drug Administration; MHT, menopausal hormone therapy.

FIGURE 2. Rates of MHT Use in the Harris and Rose Surveys



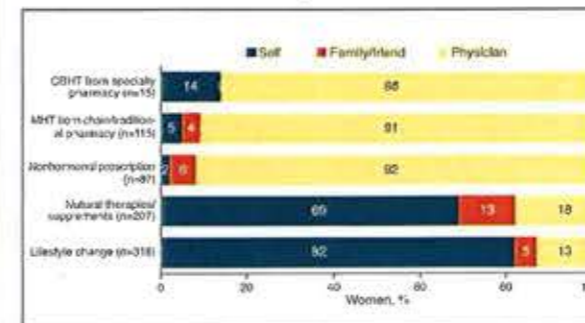
^aQuestion on CBHT was added after survey inception (n=1771). CBHT, compounded bioidentical hormone therapy; MHT, menopausal hormone therapy.

FIGURE 3. Harris Completers' Knowledge of Whether CBHT is FDA-Approved



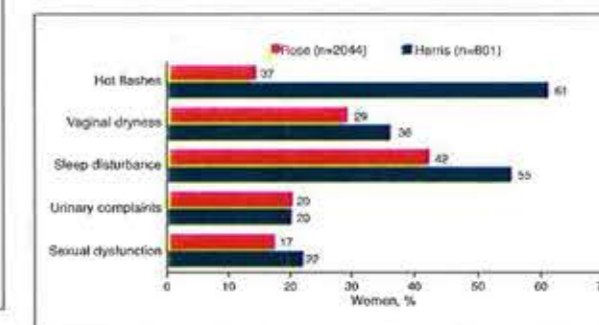
CBHT, compounded bioidentical hormone therapy; FDA, US Food and Drug Administration; MHT, menopausal hormone therapy.

FIGURE 4. Source of Treatment Recommendation in the Harris Survey



CBHT, compounded bioidentical hormone therapy; MHT, menopausal hormone therapy.

FIGURE 5. Self-Reported Moderate to Severe Menopausal Symptoms Ever Experienced by Harris and Rose Completers



CBHT, compounded bioidentical hormone therapy; MHT, menopausal hormone therapy.

Conclusions

- A large proportion of the US market for MHT consists of CBHT prescriptions
- An estimated 1 million to 2.5 million US women currently use CBHT
- Physicians strongly influence women's choice of treatment for menopausal symptoms
- Most Harris completers (86%) were unaware that CBHT is not FDA-approved
- More than one-quarter of Rose completers (27%) did not know whether their HT was personalized or compounded
- This knowledge gap presents an opportunity for providers to educate patients on the different levels of evidence for the efficacy, safety, and quality of FDA-approved MHT vs CBHT

References

- US Census Bureau. Annual estimates of the resident population by single year of age and sex for the United States: April 1, 2010 to July 1, 2012. http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2012_PEPSYASEXN&prodType=table. Accessed June 15, 2014.
- Constantine G, et al. Estimation of compounded menopausal hormone therapy use in the USA following the WHI. Poster (P-79) presented at the 25th Annual Meeting of The North American Menopause Society, October 15-18, 2014, Washington DC.

Acknowledgments

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