Estimation of Compounded Menopausal Hormone Therapy Use in the USA Following the WHI

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INTRODUCTION

- Prior to the publication of the Women's Health Initiative (WHI) in 2001, approximately 17.9 million women were taking FDA approved MHT totaling $3.9 billion in sales (112 million units). [1,2]
- The use of FDA approved MHT decreased significantly after the publication of the WHI; how ever the increased use of compounded non-FDA approved MHT has gone largely unrecognized.
  - o Quantification of compounded prescriptions is not reliably captured as there is no database for compounded products - in contrast to FDA approved prescriptions.

OBJECTIVES

- To quantify usage of non-FDA approved compounded MHT in the US following the publication of the WHI

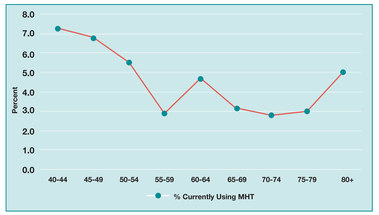
METHODS

- Three separate data sources were utilized to quantify the total use of both FDA approved MHT and non-FDA approved compounded MHT in US women ≥ 40 years of age:
  1. A 2014 internet survey conducted by Rose Research (Rose) surveyed a cross section of female consumers across the US. Respondents included 17,825 women ≥ 40 years queried to determine the incidence of current, and past use of MHT.
  2. Source Healthcare Analytics Prescription Data from 1998 through 2013
  3. 2012 US Consensus Data
- The number of women taking non-FDA approved compounded MHT was estimated using a 4 step process.

Step 1 Use of total MHT (Compounded MHT and FDA approved MHT) extrapolated from the Rose Survey and the US Census Bureau Data
Step 2 Calculation of annual prescriptions of MHT – Total (Compounded and FDA approved)
Step 3 Estimation of annual compounded MHT prescriptions
Step 4 Estimated number of US women using compounded MHT

RESULTS

Total MHT usage (Compounded and FDA approved) by age group from the Rose Survey



Rose Survey

- Overall, 5% (883/17,825) of women ≥ 40 years reported current use of MHT
- 13% (2369/17,825) reported having taken MHT previously
- Current use of MHT was greatest in the 40-49 age ranges
- Current users reported taking on average 1.7 MHT products

STEP 1 Use of Total MHT (Compounded MHT and FDA approved MHT) Extrapolated from the Rose Survey and the US Census Bureau Data

Current MHT use by age.

Age Range, y	US Women, No. (US Census)	Current MHT Use by Age, %	Current Users, No.
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	NA	3,744,183

- To estimate the number of US women currently using MHT, the percentage of current MHT use in the Rose survey was determined for each 5-year age span between 40 and 79 years and for the group of women 80 years and older.
- These rates were then applied to the same age ranges of women per 2012 estimates from the US Census Bureau
  - o Based on these calculations, approximately 3.7 million US women ≥ 40 may use MHT annually

Step 2. Calculation of Annual Prescriptions of MHT – Total (Compounded and FDA approved)

- To estimate the number of annual total prescriptions of MHT, the number of women using MHT obtained from the Rose and US census data were multiplied by the average number of MHT products used per month times an estimated duration of use of 9-12 months to yield an annual prescription number of total MHT.
- This calculation yielded a total of 57-75 million annual prescriptions.

Approximate number of total MHT annual prescriptions.

Step 3. Estimation of Annual Compounded MHT Prescriptions

- There were 36 million annual prescriptions filled for FDA-approved MHT in 2012 based on Source Healthcare Analytics prescription data
- Subtracting the 36 million prescriptions for FDA-approved MHT from the estimated 57-75 million total prescriptions of MHT filled annually suggests that 21 – 39 million prescriptions for compounded MHT may be filled annually.

Approximate number of annual prescriptions of compounded MHT.

STEP 4 Estimated that 1-2.5 million US women are using compounded MHT annually

- To derive the number of US women ≥ 40 yearslikely using compounded MHT, the extrapolated number of compounded MHT prescriptions filled annually was divided by the average number of MHT products used in the Rose Survey (1.7) by the average use of 9-12 months.

Approximate number of US women using compounded HT.

Approximately 1-2 billion dollars were spent on compounded MHT last year

- The average price reported to be paid out-of-pocket for compounded MHT was $49 per month per the Rose Survey.
  - o Multiplying the number of compounded MHT prescriptions filled annually by the average $49 price per month suggests that approximately 1 to 2 billion dollars were spent on compounded MHT last year in the US.

LIMITATIONS

- Although the sample for the survery is representative of the US population of adult women, generalizability of the data to the population at large may be limited.
- Women received an incentive only if they completed the survey, which may have influenced how they answered screening questions.
- Known limitations of self-reported questionnaires have been reported to introduce a potential for recall bias.
- It is not clear to what extent women interpreted terms such as bioidentical, natural, individualized, or even compounded to mean compounded MHT.

SUMMARY AND CONCLUSIONS

- FDA approved MHT has declined from 17.9 million users prior to WHI to approximately 3.7 million users in 2013.
- During this same time, the compounded MHT market has grown from almost a negible amount to approximately 2.5 million women (approximately 2% of US women).
  - o Representing almost 40% of the overall MHT usage in the US
- Understanding the breadth of use of compounded MHT is important in assessing the magnitude of potential safety and efficacy issues that may be associated with compounds that are not regulated under Good Clinical Practice (GCP).

References

1. *Trends in Hormone Replacement Therapy Drugs Utilization and Expenditures for Adult Women 2001-2008 (Medical Expenditure Panel Survey – Statistical Brief #347: Agency for Healthcare Research & Quality).*
2. *Source Healthcare Analytics Prescription Data 6.*

Disclosures

The Rose Research Survey was funded by TherapeuticsMD.
G.C. consults to pharmaceutical companies including but not limited to TherapeuticsMD. B.B., M.K. and S.M. are employees of TherapeuticsMD.

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