"IN THE LATEST REPORT FROM THE WHI, THE DATA CONTRADICT THE CONCLUSIONS"
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Enigmatic inconsistencies between WHI data and conclusions

The issue of the inconsistencies between the Women's Health Initiative (WHI) data and conclusions is enigmatic because the integrity and judgment of researchers has in the past and should remain above reproach.

For those of us in the private sector of obstetrics and gynecology, the feeling that there must be information that intentionally or unintentionally has been omitted from our view remains the most comfortable and convenient explanation for the discrepancies.

The vindication of observational studies predating WHI by the reanalysis of WHI data seems to be continually suppressed in the literature, and the unreasoning exclusion of the critical issue of timing in the initiation and continued administration of estrogen therapy (ET) and hormone therapy (HT) is inexplicable. One is repeatedly tempted to consider some underlying agenda.

Elimination of sampling by Wyeth, and now exclusion from drug formularies with the attendant exorbitant increases in cost have, in addition to the absence of a defense by researchers or manufacturers, discouraged continuing use of this valuable medication, even among those in whom the safety and benefits of Premarin and Prempro have been established over years of experience and scores of studies.

It is much like the children's story, "The Emperor's New Clothes." It seems incredible that so many knowledgeable authorities seem unable to recognize a 60% reduction in coronary artery plaque in recently menopausal women (ages 50–59 years) after 5.2 years of HT, which underscores the importance of patient selection and timing of administration.[1] Wyeth's explanation, when I inquired, was that this involved "off-label" use, although the data are from reanalysis of WHI data. I would think that a 60% reduction of arterial plaque deserves front-page coverage.

When articles about the discontinuation of WHI began to appear in 2001, stated reasons included the overwhelming predominance of new breast cancer cases in estrogen-administered subjects, but no one seems to appreciate the 47% decrease in breast cancer mortality discovered in the reanalysis, due to the chronologically earlier appearance of disease at earlier clinical stages. In my practice, we are finding in situ disease in HT and ET patients after 4 to 5 years of use.

Consequently, I am appreciative of Dr. Thacker's mention of the Sarrel data[2] and her expansion into the "so often" overlooked issues. I think that it's overdue—integrity must be restored to the interpretation of NIH's $780,000,000 expenditure of taxpayer dollars. After all, WHI was to be the statistically unimpeachable clarification of estrogen and hormone replacement.

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References
1. Manson JE, Allison MA, Rossouw JE, et al; WHI and WHI-CACS Investigators. Estrogen therapy and coronary-artery calcification. N Engl J Med. 2007;356(25):2591–2602.
2. Sarrel PM, Njike VY, Vinante V, Katz DL. The mortality toll of estrogen avoidance: an analysis of excess deaths among hysterectomized women aged 50 to 59. Am J Pub Health. 2013;103(9):1583–1588.

Exaggerated or intentionally fabricated data?

Thank you for publishing Dr. Holly Thacker's commentary regarding the travesty that was and is WHI. I enthusiastically support her admonition to "look at the totality of the data on menopausal HT, evaluate our patients individually, treat those who are truly hormonally deficient and suffering, and counsel them that many of the harms linked to HT have been exaggerated."

My only disagreement is Dr. Thacker's choice of the word "exaggerated" when describing the harms linked to HT. I would have chosen instead the words "intentionally fabricated." How? By taking data out of context, by releasing data selectively, by withholding data—all for the purpose of achieving and then protecting their frighteningly negative and destructive initial conclusions.

I wish it were the case that an independent commission might right these wrongs. Unfortunately, that cannot happen in today's intellectual context. The fundamental error that made WHI's multitude of errors possible was the notion that we can dispense with the difficult work of considering "the totality of the data" by placing our faith in "statistical significance" derived from a single "randomized controlled trial." That fundamental error is too deeply entrenched, too highly remunerative, and too propitiously useful to those seeking a world concordant with their fantasies.

Reality demands that we account for every fact and will in time put an end to this deadly conceit.

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