

The Women's Health Initiative: Hormone Therapy Trials

JoAnn E. Manson, MD, DrPH
WHI Investigator (PI of Boston site)
Chief, Division of Preventive Medicine
Brigham and Women's Hospital
Professor of Medicine and the
Michael and Lee Bell Professor of Women's Health
Harvard Medical School

WHI Webinar
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INSIDE HARKEN AND HALLIBURTON • THE OLDEST SKULL

Newsweek

July 22, 2002

newsweek.msnbc.com

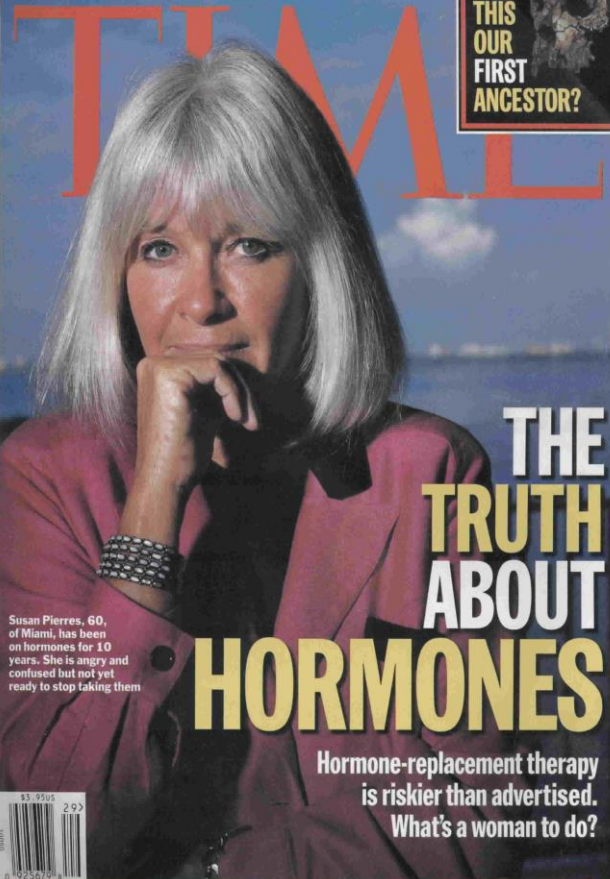
A New Study
Raises Fears
About the Risks
For Millions
Of Women.
Here's What
You Should Do

Beyond Hormone Therapy

JULY 22, 2002

WALL STREET: LOSING SAVINGS—AND TRUST

IS
THIS
OUR
FIRST
ANCESTOR?



Susan Pierres, 60,
of Miami, has been
on hormones for 10
years. She is angry and
confused but not yet
ready to stop taking them

THE TRUTH ABOUT HORMONES

Hormone-replacement therapy
is riskier than advertised.
What's a woman to do?



www.time.com AOL Keyword: TIME

MARTHA'S HARD TIME • KERRY'S VP HUNT

U.S. News & WORLD REPORT

MARCH 15, 2004

www.usnews.com

THE MENOPAUSE MAZE

WHAT WOMEN NEED TO KNOW NOW
NEW RISKS AND REWARDS OF TREATMENT
HOW MEN ARE AFFECTED



019

Women's Health Initiative (WHI), Ages 50-79

Hormone Program Design

**Women who had
prior hysterectomy
at start of study**

**YES
N= 10,739**

**Conjugated equine
estrogens (CEE) 0.625 mg/d
Placebo**

Hysterectomy

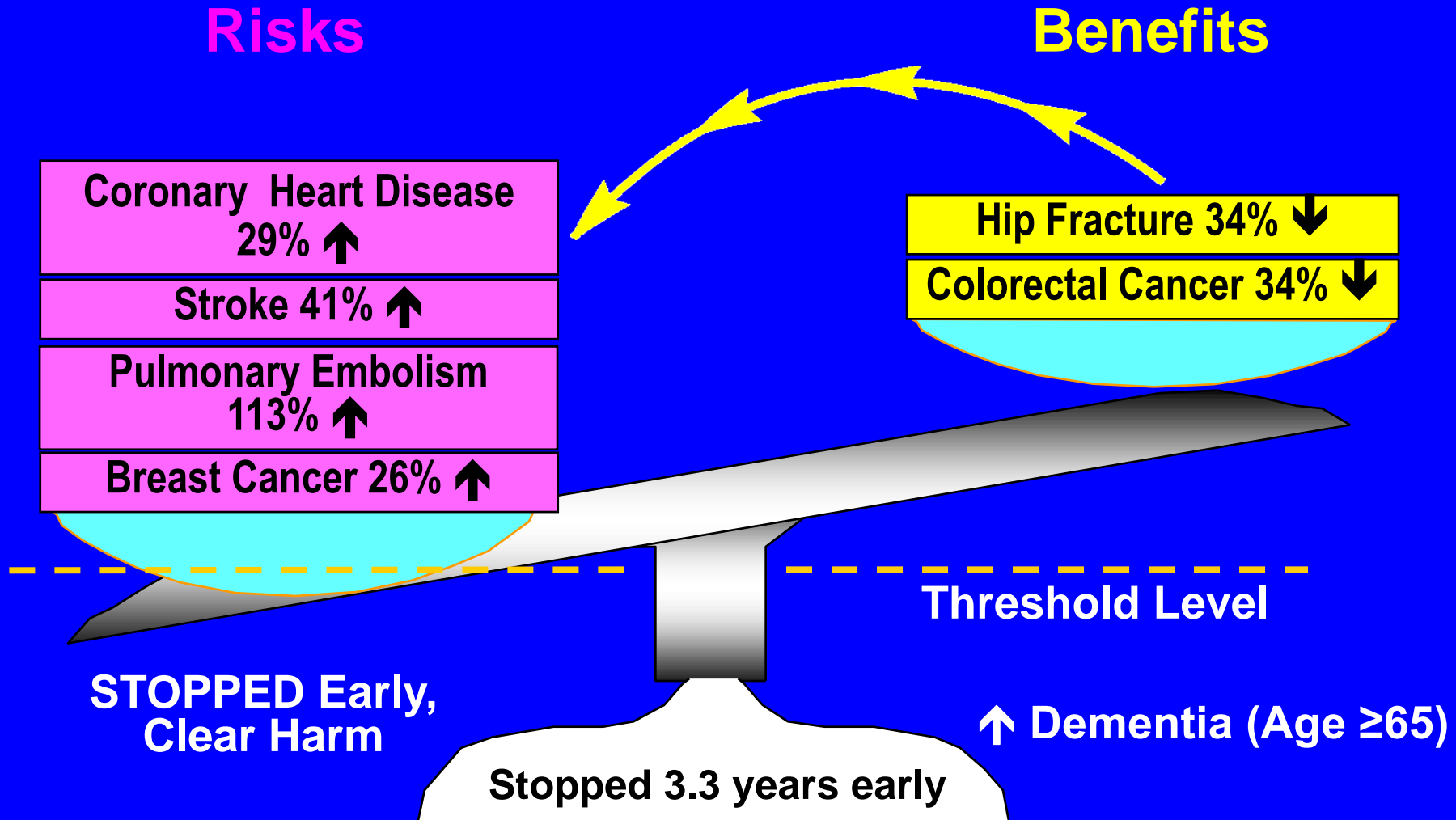
**Women who had
an intact uterus at
start of study**

**NO
N= 16,608**

**CEE 0.625 mg/d +
medroxyprogesterone
acetate (MPA) 2.5 mg/d
Placebo**

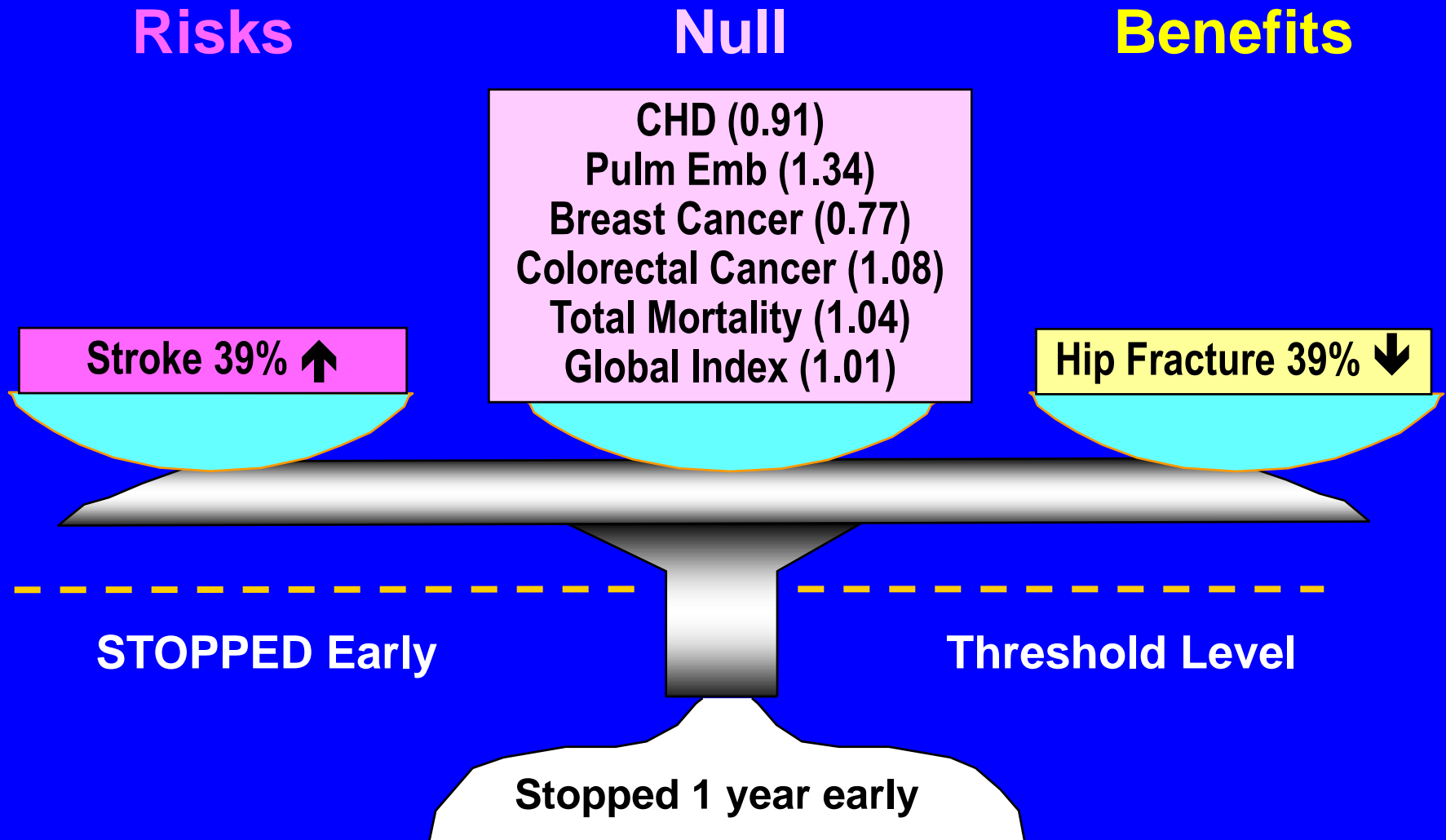
WHI Estrogen+Progestin Trial Findings, July 2002

(N=16,608; mean age 63 yrs; mean follow-up 5.2 yrs)

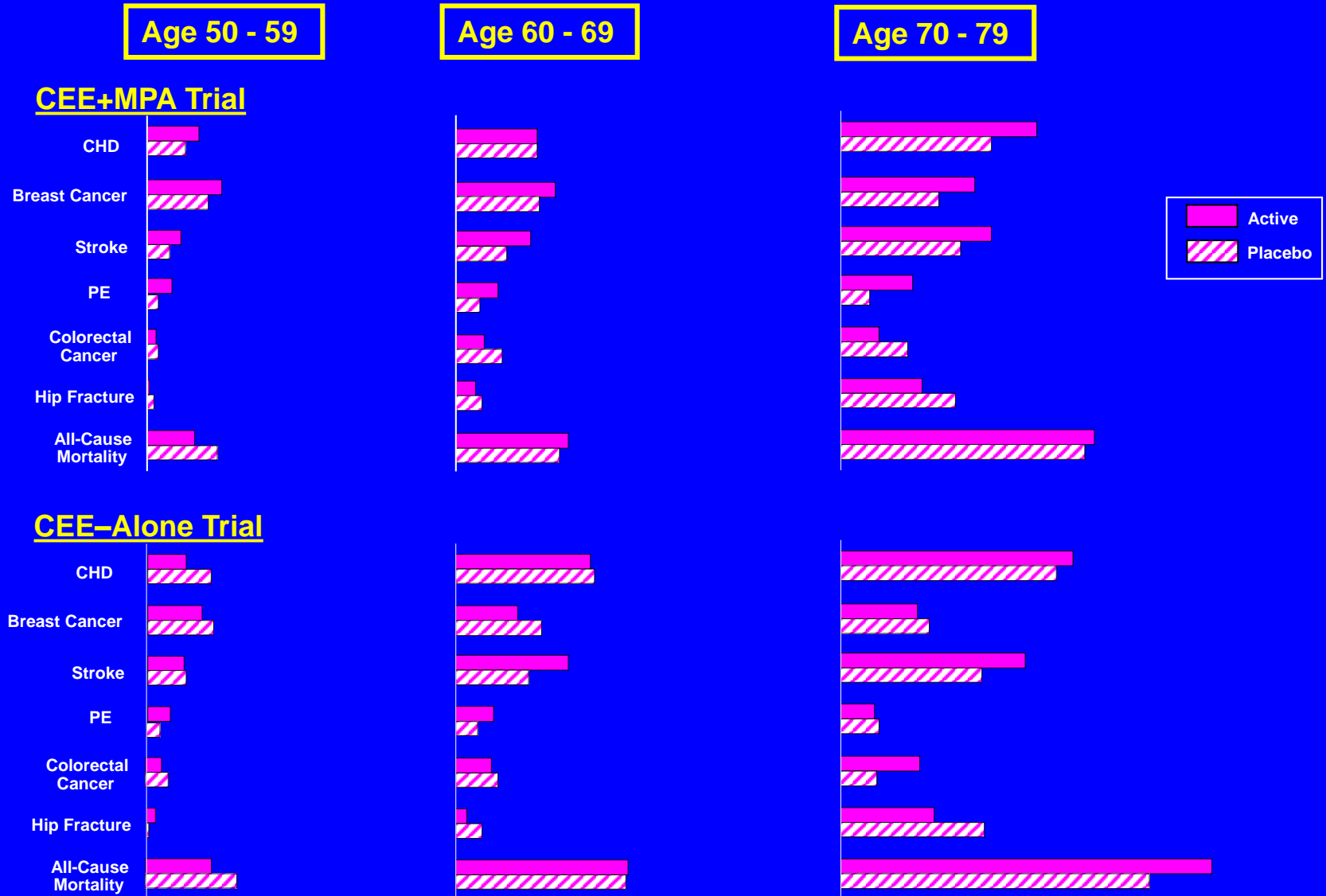


WHI Estrogen-Alone and Health Outcomes

(N=10,739; mean age 63.6 yrs; mean follow-up 6.8 yrs)



WHI Hormone Therapy Trials: Absolute Risks (cases per 10,000 person-years) for Outcomes in the Estrogen-Progestin and Estrogen-Alone Trials, by Age Group



WHI HT Trials: Summary of Results for Primary and Other Major Endpoints by Study Phase

Major Endpoints	Intervention		Post-Intervention	
	CEE+MPA	CEE	CEE+MPA	CEE
CHD	0	0	0	0
Breast cancer	↑	↓	↑	↓
Stroke	↑	↑	0	0
PE	↑	0	0	0
Colorectal cancer	↓	0	0	0
Endometrial cancer	0	NA	↓	NA
Hip fracture	↓	↓	0	0
All-cause mortality	0	0	0	0
Global index	↑	0	0	0

Source: Manson, Chlebowski, Stefanick, et al. *JAMA* 2013;310:1358-68.

Estrogen+Progestin Therapy and Risk of Heart Attack in WHI: Results According to Time Since Menopause

**Time since
Menopause Onset**

HR

<10 yrs

Neutral

10-19 yrs

Slightly ↑

≥20 yrs

2x ↑

P, interaction = 0.01

WHI Estrogen-Alone Trial: Results for Heart Attack by Age Group

<u>Age Group</u>	<u>Risk</u>
50-59	↓
60-69	↔
70-79	↑

P, interaction = 0.02[†]

Absolute Risks (Cases per 1000 Women Over 5 Years) by Age in the WHI HT Trials

	<u>E+P Trial</u>			<u>E-Alone Trial</u>		
	<u>50-59</u>	<u>60-69</u>	<u>70-79</u>	<u>50-59</u>	<u>60-69</u>	<u>70-79</u>
Total mortality	-5	+2	+2	-6	0	+13
Global Index†	+6	+11	+19	-10	-1	+25

†Global index is a composite outcome of CHD, stroke, pulm embolism, breast cancer, colorectal cancer, endometrial cancer, hip fracture, and mortality.

Conclusions

- **Current evidence does not support the use of HT for the prevention of cardiovascular disease or other chronic diseases (due to increased risk of venous blood clots and stroke/breast CA [E+P] in all age groups).**
 - **A personalized approach to decision making is recommended for women with menopausal symptoms.**
 - **The best candidates for systemic HT are recently menopausal and symptomatic women in generally good health (low absolute risks and greater quality-of-life benefits).**
 - **Additional studies of different HT formulations, doses, routes of delivery, and of non-hormonal options are needed.**
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Thanks to the Participants, Investigators, and Staff of WHI and other Research Studies



Thank you!