



DEMYSTIFYING

hormone therapy



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INTRODUCTION

Modern hormone therapy (HT) has a complicated story; one that's left many women (and clinicians) understandably confused and, in some cases, afraid to even consider treatment.

For decades, estrogen and other hormones were promoted as a way to ease hot flashes, night sweats, sleep disruption, and vaginal symptoms, and even to support long-term health.

Then, early results from the Women's Health Initiative in 2002 triggered headlines about increased risks, prescriptions plummeted, and an entire generation of women missed out on nuanced, individualized conversations about hormone therapy.

In the years since, newer analyses and updated guidelines have painted a more balanced picture: for many women who start HT around the time of menopause, benefits can outweigh risks, especially for bothersome vasomotor symptoms, genitourinary syndrome of menopause, and bone protection.

At the same time, regulators have begun revising product labels and guidance to better reflect age, timing, dose, and route of therapy, moving away from one-size-fits-all fear toward informed, personalized decision-making.

This guide is designed to walk you through the history and today's more refined, evidence-based recommendations.



PART ONE

A BRIEF HISTORY

Hormone Therapy (HT or HRT) was widely used in the 1960s – 1990s

- The FDA initially approved HT for the treatment of hot flashes in the 1940s.
- Use of HT increased in the 1960s with the feminist movement ("feminine forever" concept).
- The FDA approved HT for the prevention of osteoporosis (weakening bones) in 1988.
- Several observational studies and meta-analyses in the 1980s/1990s suggested HT could be beneficial for the prevention of other diseases like heart disease, dementia, and all-cause mortality (death from any cause).
- In 1992, the American College of Physicians recommended HT for prevention of heart disease (note: HT is NOT currently recommended for the prevention of heart disease).

The FDA asked for more studies because there was still uncertainty around the benefit of HT on heart disease.

- This gave rise to the Women's Health Initiative (WHI) in 1998 which looked at things like heart disease, cancer, and osteoporosis in **post-menopausal** women (*average age in the trial was 63*).
- The first results from the trial published in 2002 **showed an increase in heart disease and breast cancer in one of the study groups** (with a reduction of fractures and a reduction in colorectal cancer).
- The negative results of the WHI received wide publicity, creating panic among many users and new guidance for doctors on prescribing HT.
- The message (which gained a lot of traction in the media) was that HT was associated with more risks than benefits for all women.
- HT prescribing declined rapidly (and remained low until very recently when prescribing began to increase slightly).

Since then, the design, conclusions and (mis)application to women not studied in the WHI trial have been extensively debated.

- Age of participants, type of HT, methods of analysis (and more) have been criticized.
- A reanalysis and stratification of the WHI and results from other new trials have suggested that there are several cases in which the benefits of HT outweigh the risks.
- In general, it is now agreed that the risks of HT vary depending on which type, the dosage, length of treatment, how it is administered, and the age when it is started.



PART TWO

CURRENT GUIDANCE

What do the experts say about the **BENEFITS** of hormone therapy?

- For healthy women who are younger than 60, and within 10 years of menopause onset, who do not have contraindications, the benefits of treating peri/menopause symptoms and preventing bone loss (osteoporosis) with HT outweigh the risks.
- HT is very effective for hot flashes and night sweats and can improve sleep quality, fatigue, mood, and quality of life.
- Some studies suggest that HT might be good for your heart if you start before age 60 or within 10 years of peri/menopause (it is not FDA- approved for cardio/heart protection).
- Combined HT also may reduce the risk of colon cancer.
- Systemic HT can improve peri/menopause-specific quality of life.
- HT may reduce the diagnosis of new-onset type 2 diabetes, (it is not FDA-approved for this indication).

What do the experts say about the RISKS of hormone therapy?

- Women who begin HT after age 60, or who begin HT more than 10 years after menopause onset, face greater risks including an increased risk of heart disease, stroke, venous thromboembolism (blockage), and dementia.
- Women with a uterus need to take estrogen plus progesterone to reduce the risk of endometrial cancer; the risk of breast cancer may increase if HT is taken for > 4 years.
- For women without a uterus who take only estrogen there is no increased risk of breast cancer for the first 7 years (may increase slightly if used for longer).
- HT does not further increase the risk of breast cancer in women with a family history.
- Women should not take oral and patch HT if they have: unexplained vaginal bleeding; liver disease, prior estrogen-sensitive cancer, prior heart disease, stroke, heart attack, or venous thromboembolism (blockage), or personal history or high risk of thromboembolic disease.
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The Bottom Line

- HT is the most effective treatments for the symptoms of peri/menopause (e.g., hot flashes and night sweats) and has been shown to prevent bone loss and fractures.
- Reanalysis of the study that ignited the controversy in addition to studies that have been conducted since WHI indicate that the benefits of HT outweigh the risks for many women.
- The risks of HT differ depending on type, dose, duration, route of administration, timing of initiation, and whether a progestogen is used.



PART ONE

QUESTIONS YOU CAN ASK YOUR DOCTOR

- Am I a good candidate for hormone replacement therapy?
- What are my risk factors for taking HT based on my health history?
- Do I have any health conditions that would make HT unsafe?
- What different types of HT are available (oral pills, patches, vaginal creams)?
- Which form of HT would be best suited for my needs and symptoms?
- Can I use a low-dose estrogen therapy if I only have vaginal symptoms?
- What are the potential benefits of HT for managing peri/menopause symptoms?
- What are the potential risks associated with HT, including increased risk of blood clots, breast cancer, or stroke?
- How can I minimize the risks of HT?
- What are the common side effects of HT?
- What should I do if I experience concerning side effects?
- How long should I plan to take HT?
- What are the steps to safely taper off HT when the time comes?
- Are there non-hormonal options available to manage my peri/menopause symptoms?
- What lifestyle changes can help alleviate peri/menopause symptoms?



THANK YOU!

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