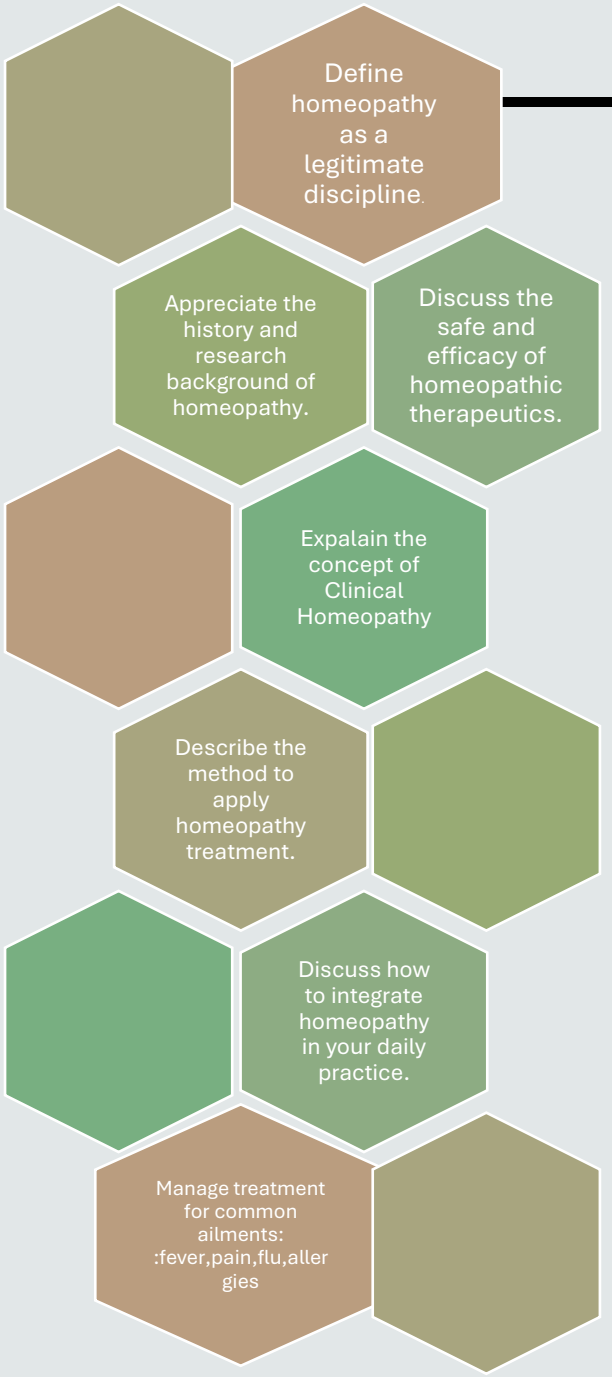
HOMEOPATHY:A SIMPLE VIEW

BY: LCDA VIRNA MARTINEZ COLÓN

Disclosure

I have NO relevant financial relationship (s) with ineligible companies to disclose”

OBJECTIVES


Define homeopathy as a legitimate discipline.
Appreciate the history and research background of homeopathy.
Discuss the safe and efficacy of homeopathic therapeutics.
Expalain the concept of Clinical Homeopathy
Describe the method to apply homeopathy treatment.
Discuss how to integrate homeopathy in your daily practice.
Manage treatment for common ailments: :fever,pain,flu,allergies

DEFINITION

Homeopathy consists in giving the patient a medicine made from a substance from an animal, plant or mineral origin that has been

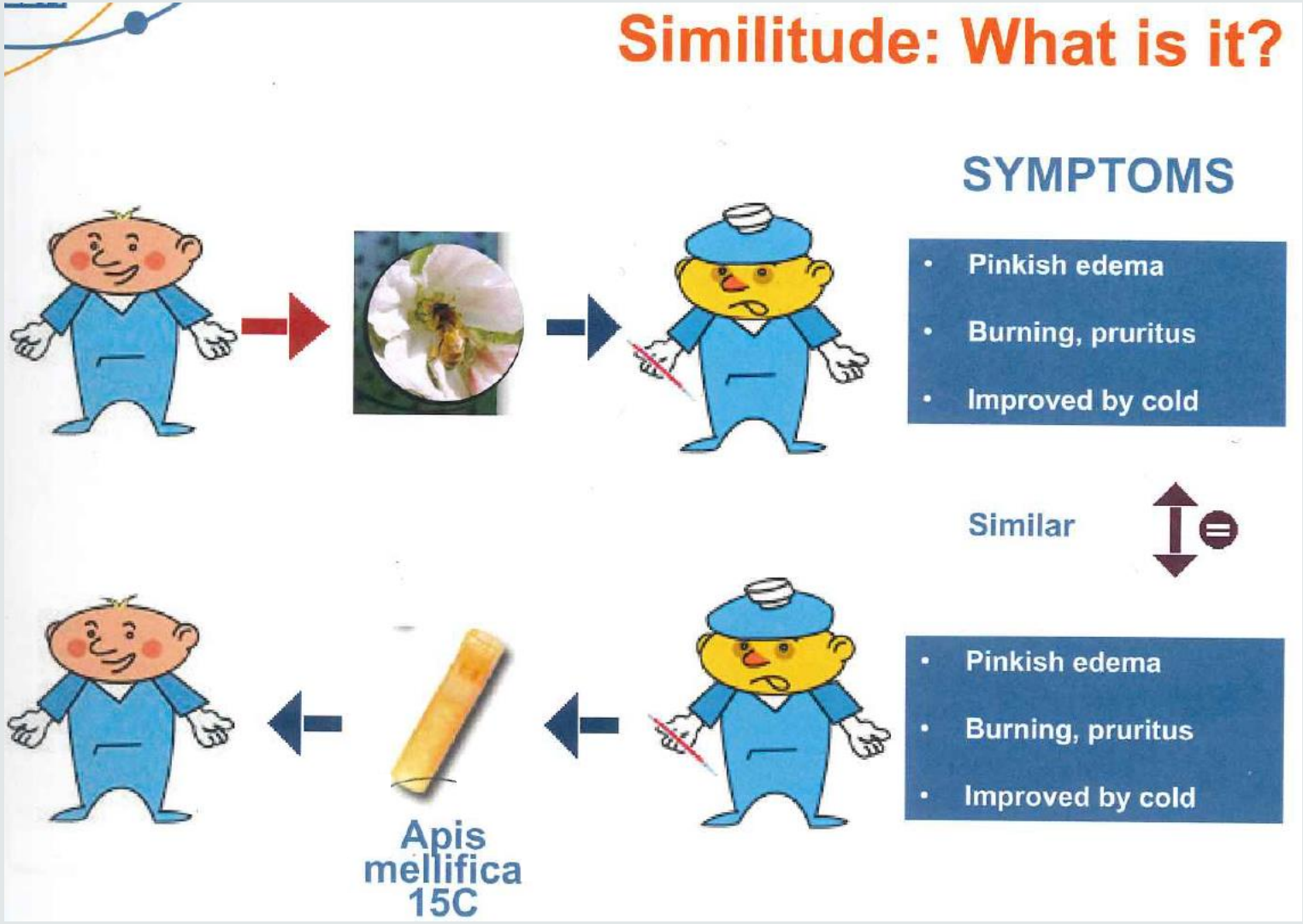
diluted and potentiated.

Its use is based on the principle of similitude: The substance triggers the same clinical picture in healthy patients than the one presented by the sick patient.

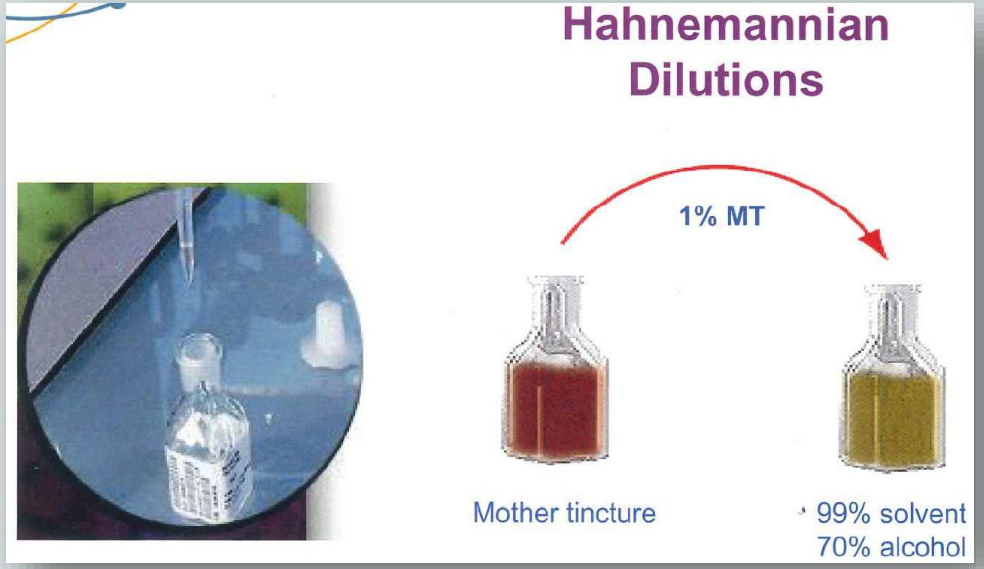
The homeopathic medicine is defined by the Latin name of the substance and its level of dilution

Example :Apis mellifica 15c

Similitude: What is it?

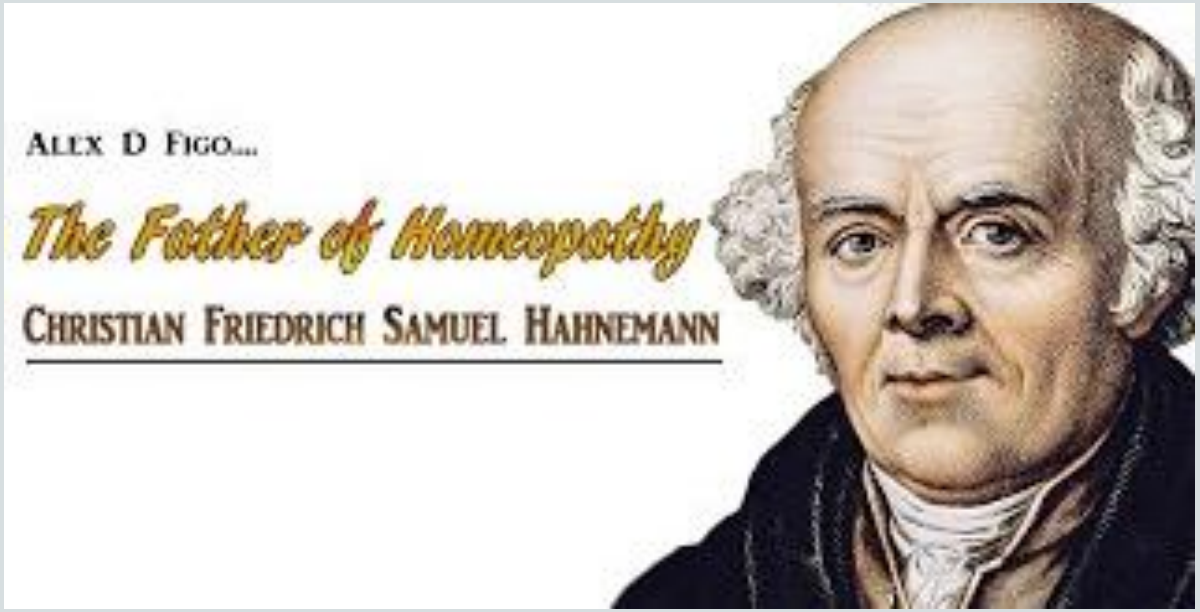


Dilution Methods



- Manufacturing homeopathic medicines is a rigorous process
- Both are complicated and long time procedures.

HISTORY



The founder

Christian Samuel Hahnemann (1755-1843)

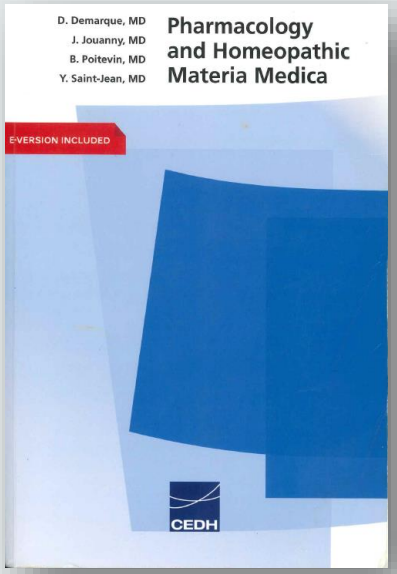
Hahnemann was the inventor of homeopathy, the art of curing ills with water. With a trial in himself Hahnemann drew the conclusion that quinine is able to cure malaria, because it could cause the same symptoms as malaria on healthy people. This is the basic principle oy homeopathy ,Similia similibus (with the help of the same)

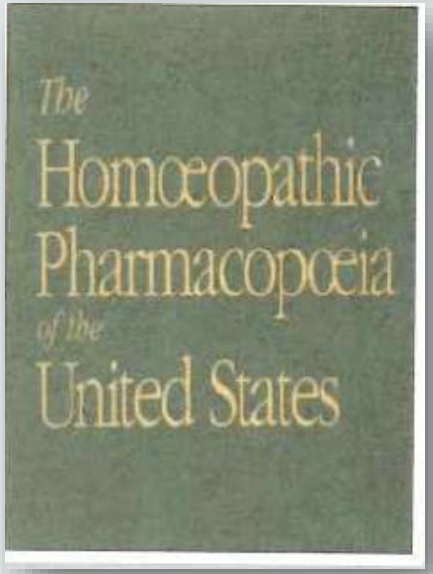
1805 -27 drugs himself

1807-likes are cured by likes

1832-homeopathic hospital in Leipzig

Safety and Efficacy





FDA-1938

The FDA regulates the manufacturing and distribution of homeopathic medicines.

Most of them are available OTC.

The official compendium is the Homeopathic Pharmacopeia of the United States (HPUS), referenced in the USP, and recognized by the FDA.

Other reference is Pharmacology and Homeopathic Materia Medica.

HOMEOPATHIC MEDICINES

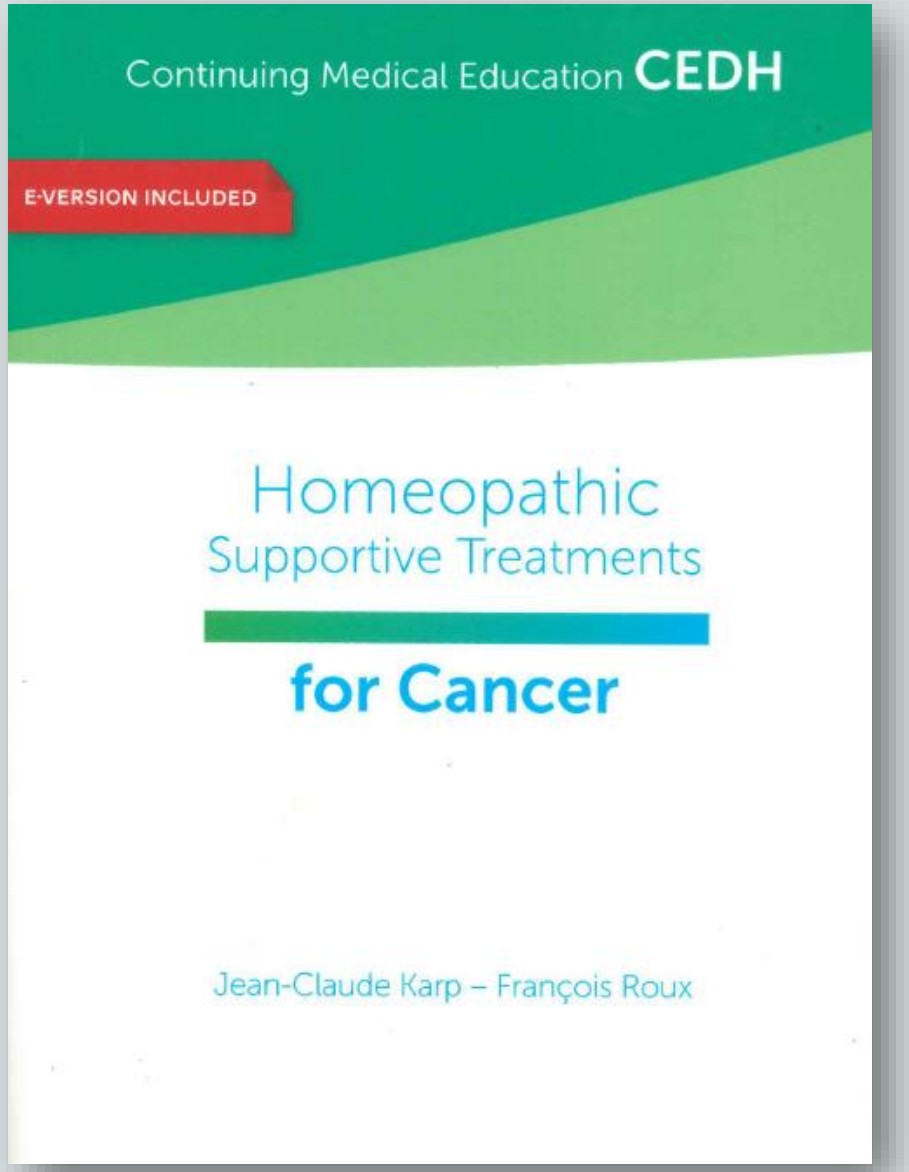
Homeopathic medicines can be given:

Alone as first line of treatment.

In association with other homeopathic medicines.

In association with allopathic medicines.

In addition to other therapeutics.



Clinical concepts

The 5 key notions of clinical homeopathy

- Etiology
- Targets
- Individual Reaction of the Patient
- Sensitive Type
- Chronic Reactional Mode

Etiology-a cause responsible for the clinical picture. “following what?

Targets-what are they?

IRP-sensations, aggravation, improvement, concomitant to the pathology

CRM-recurrent pathology

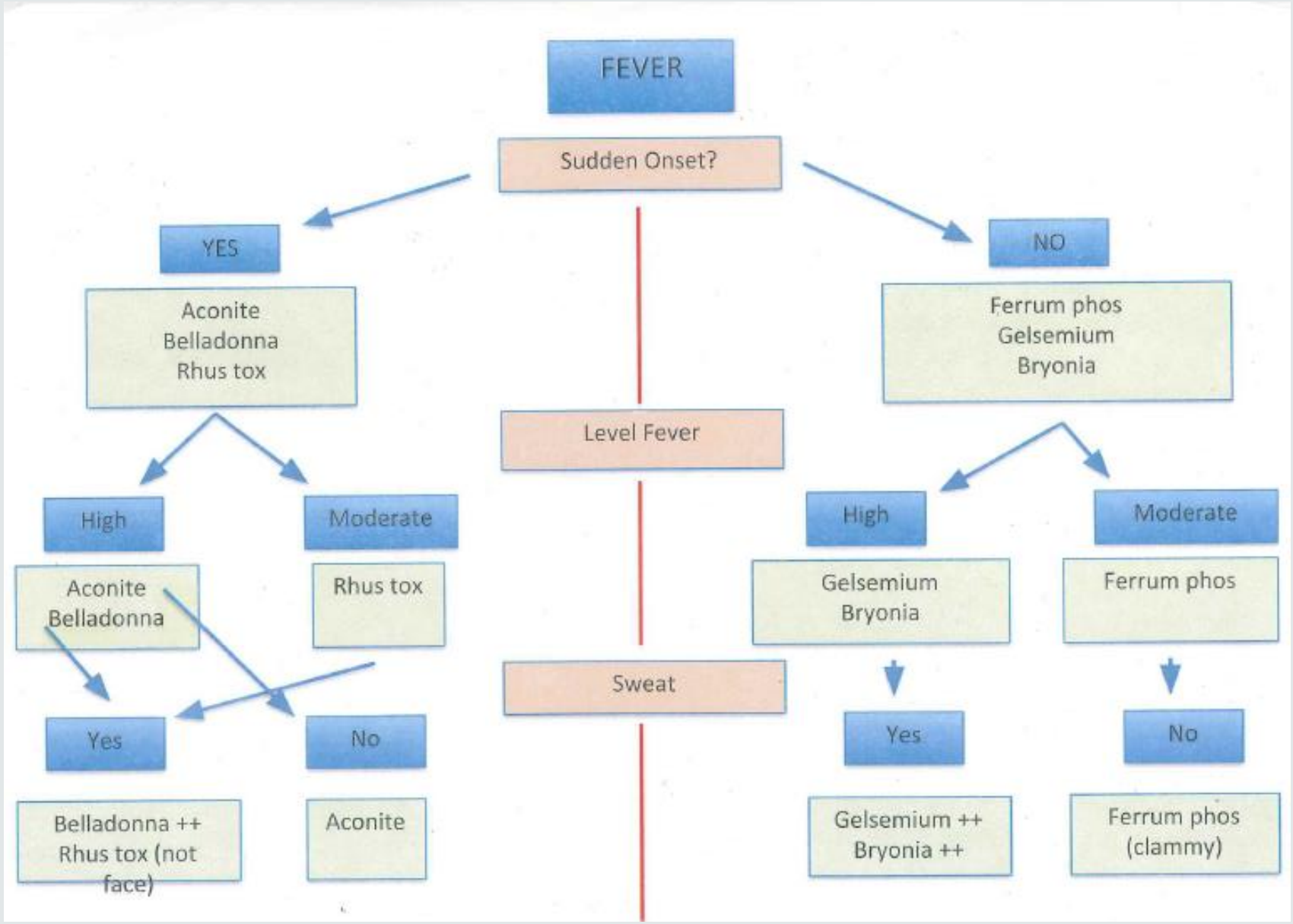
CONSULTATION

What brings you here today?

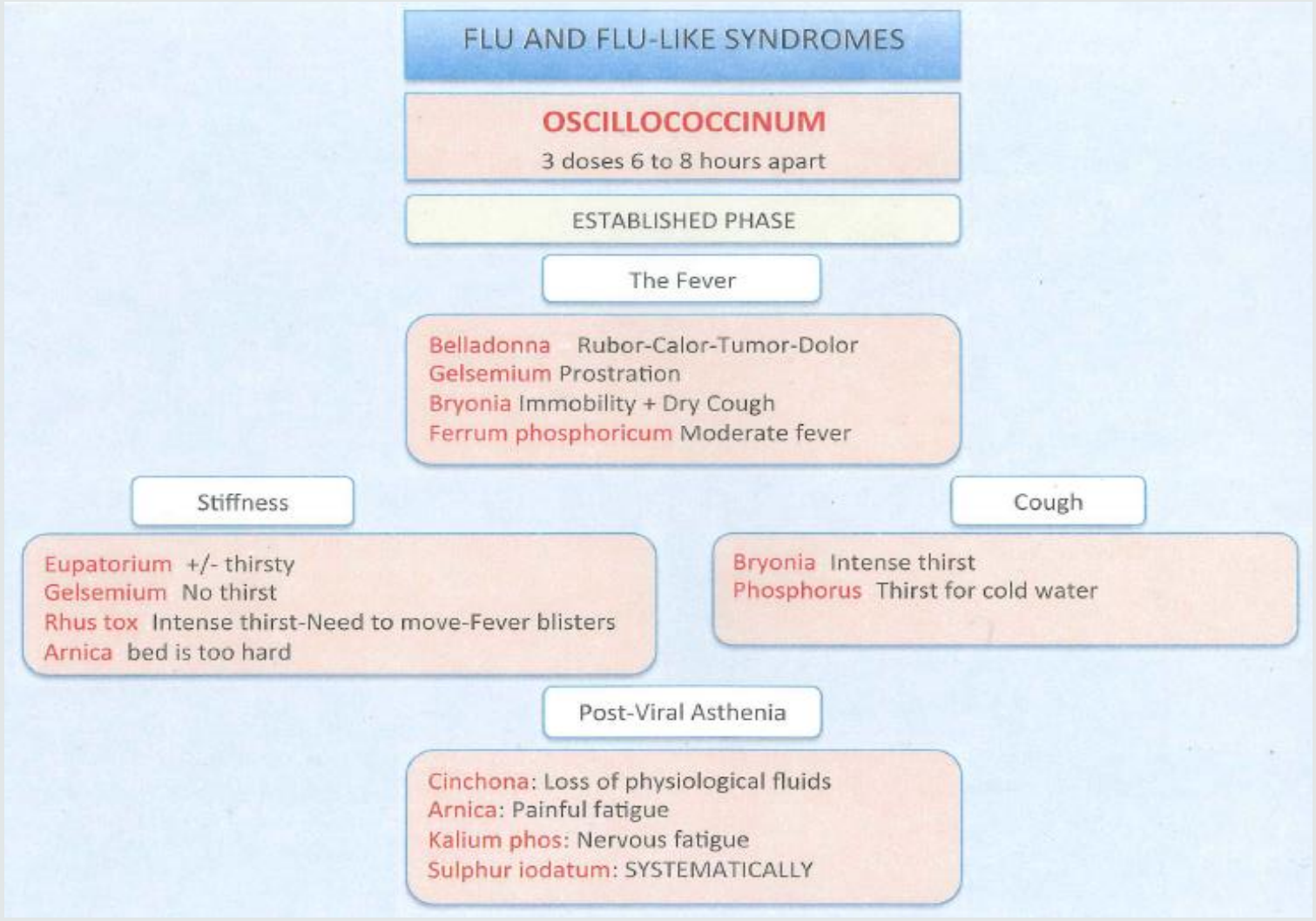
- *REASON FOR CONSULTING*
- *ETIOLOGY*
- *FAMILY HISTORY*
- *PERSONAL HISTORY*
- *INTERVIEW*
- *EXAMINATION*

BASIC MEDICINES

Fever


FEVER
Sudden Onset?
YES
Aconite
Belladonna
Rhus tox
NO
Ferrum phos
Gelsemium
Bryonia
Level Fever
High
Moderate
Aconite
Belladonna
Rhus tox
High
Moderate
Gelsemium
Bryonia
Ferrum phos
Sweat
Yes
No
Yes
No
Belladonna ++
Rhus tox (not face)
Aconite
Gelsemium ++
Bryonia ++
Ferrum phos
(clammy)

Flu and Flu-Like Syndromes



Everyday Trauma

In every case

As soon as the trauma occurs

Arnica 9 C

→ 5 pellets every hour for 6 hours /
then 5 pellets 3 times a day until symptoms disappear.

Ligament or tendon trauma

Tendons and ligaments	Stiffness	Edema
Ruta graveolens 6 C	**Rhus tox 9 C**	**Apis mellifica 15 C**

→ 5 pellets of each every hour for 6 hours /
then 3 times a day for two weeks.

Muscle fatigue or muscle trauma

In cases of muscle contracture or cramping

Muscle contracture	Cramping
Magnesia phosphorica 15 C	**Cuprum metallicum 15 C**

→ 5 pellets 3 times a day until symptoms disappear.

Muscle injury

A basketball player suffers muscle injury after crashing into the backboard. He is in considerable pain and a hematoma is starting to appear.

Arnica 9 C → 5 pellets every 15 minutes for 2 hours.

Sprain

A young man visits the doctor complaining of a sprained ankle sustained the previous day while playing tennis. The emergency x-ray does not show any visible damage. On examination, the ankle appears swollen with evidence of a small hematoma; this is accompanied by localised pain in the ligament.

Arnica 9 C **Ruta graveolens 6 C** **Rhus tox 9 C**

LEDUM PALUSTRE 9 C → while the ankle is immobilised

→ Take 5 pellets of each 3 times a day for two weeks.

Muscle contusion

A football player visits the doctor complaining of persistent pain in the thigh. Muscle contusion had been diagnosed. An x-ray reveals a persistent small intramuscular hematoma.

Arnica 9 C

→ 5 pellets 3 times a day.

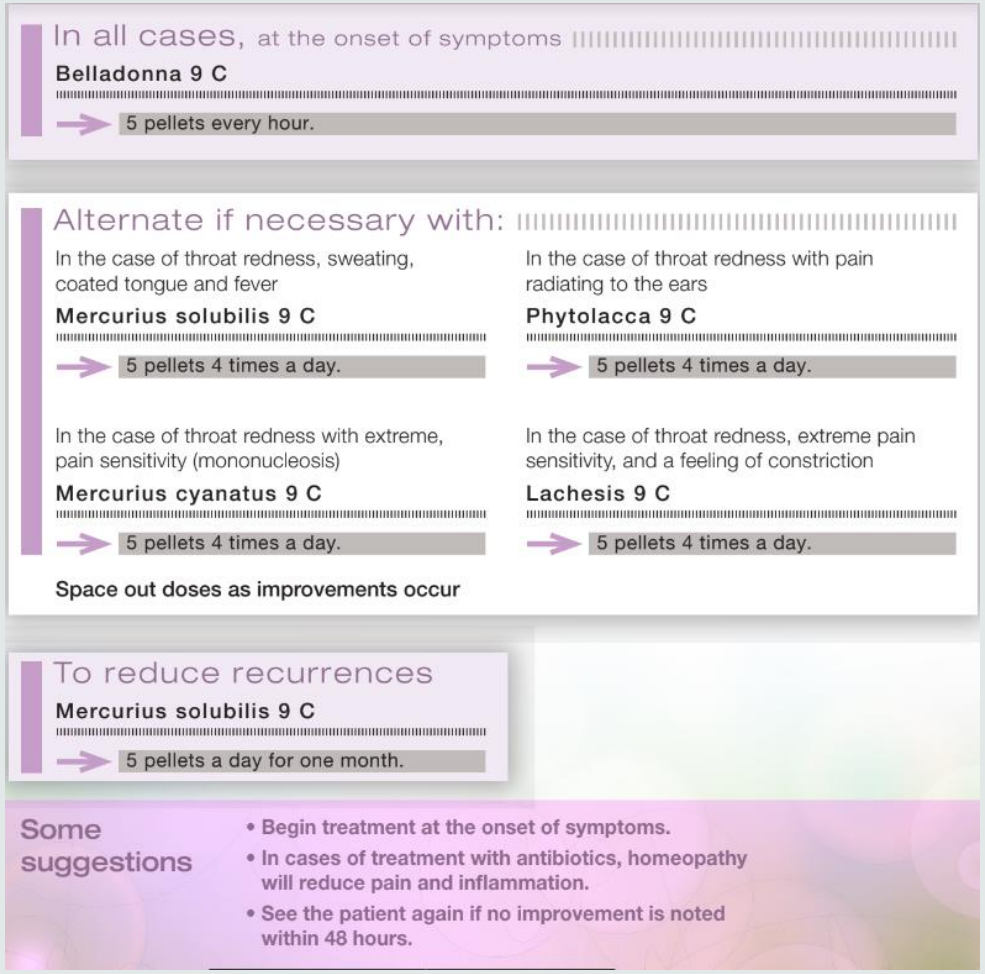
Muscle contracture

A young marathon runner complains of contracture of the calves during training.

Arnica 9 C **Magnesia phosphorica 15 C**

→ 5 pellets 3 times a day.

Sore Throat



A 20-year-old woman has had, for the last 24 hours, a sore throat when swallowing. When examined, her throat is red. She has a fever of 101°F, swollen lymph nodes, furry tongue and bad breath. The streptotest is positive.

Prescription

Amoxicillin	Belladonna 9 C	Mercurius solubilis 9 C
1 g morning and evening for 6 days.	5 pellets every hour.	5 pellets 4 times a day.

A 14-year-old boy visits the doctor complaining of sore throat. He is suffering from exhaustion, and has redness of the throat, which is covered in places with a greyish-white discharge (false membranes). He has difficulty swallowing and widespread enlargement of the lymph nodes, with a fever of 103°F. The rest of the examination is normal and the streptotest is negative. He is diagnosed with mononucleosis. An assessment (FBC and mononucleosis serology test) is ordered for confirmation. Pending the results:

Prescription

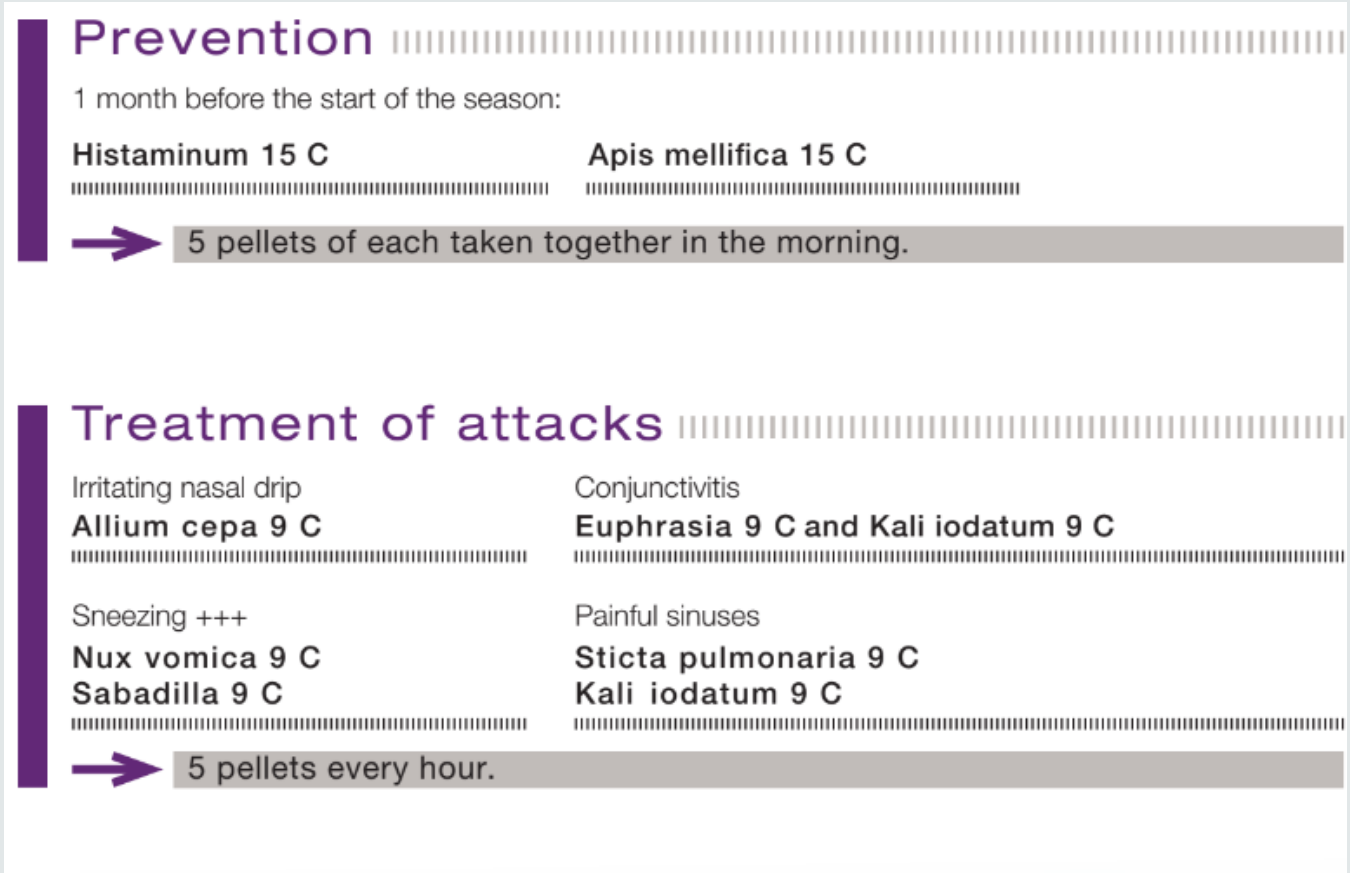
Belladonna 9 C	Mercurius cyanatus 9 C
5 pellets every hour.	5 pellets 4 times a day.

A 40-year-old man visits the doctor complaining of a painful throat and has a fever of 100°F. His throat is red, with pain radiating to the ears when he swallows. The streptotest is negative. He has been experiencing frequent similar episodes 4 to 6 times a year.

Prescription

Belladonna 9 C Phytolacca 9 C	Phytolacca 9 C
5 pellets alternately every hour.	5 pellets a day for one month. to reduce recurrence pending administration of customised preventive treatment.

Seasonal Respiratory Allergies



Joint Pains

Sensations of stiffness, numbness, improvement by slow movement, change in position, or heat:

Rhus tox 15 C

→ 5 pellets morning and evening.

Muscular pain, improvement by rest:

Arnica montana 9 C

→ 5 pellets 3 times a day, increase the intake to 6 times a day in case of painful flares.

Joint swelling with prickly, burning pains and improvement by cold. *Examples: Hydrarthrosis, arthritis...*

Apis mellifica 15 C

→ 5 pellets 3 times a day, increase the intake to 6 times a day in case of painful flares.

Joint swelling with prickly, stabbing pains in fixed places, worsened by movement. *Examples: hydrarthrosis, rheumatic arthritises...*

Bryonia 6 C

→ 5 pellets 3 times a day, increase the intake to 6 times a day in case of painful flares.

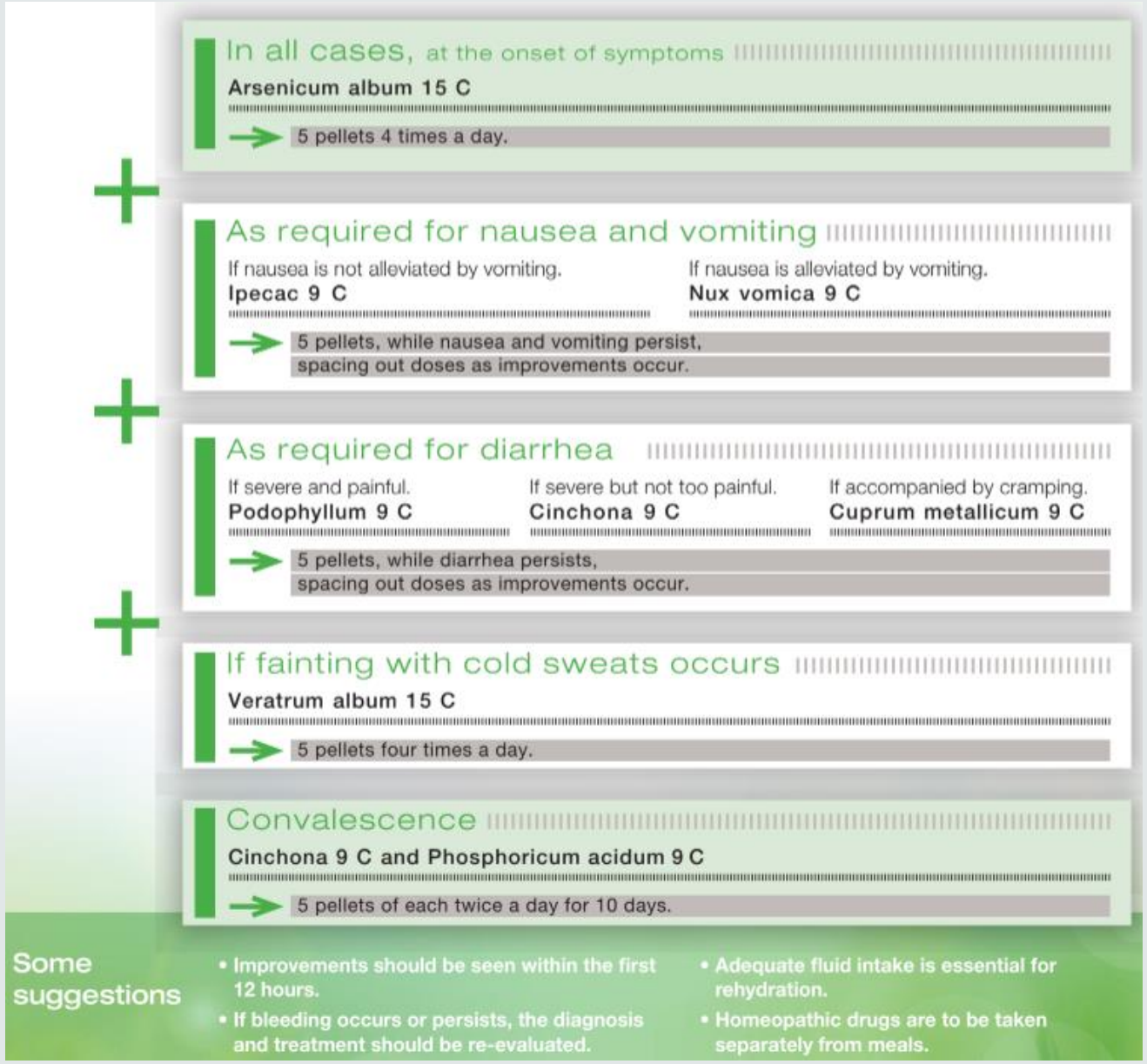
\+

In case of inflammatory rheumatism

Sulphur iodatum 9 C

→ 5 pellets each day
during the period of inflammation (8 to 15 days).

Acute Gastroenteritis



Homeopathy and Pharmacy

New opportunity to help patients

Alternative to traditional treatment

Education

Different approach

Business opportunity

Conclusion

Homeopathy is an alternative medicine that can be used to help patient without causing any type harm. It’s being proven that homeopathy has improve patient’s conditions with less amount than conventional medicine. As mentioned, before it can be used in many areas of the medicine starting from a simple flu to a more severe condition like vitiligo. With this we can conclude that, this might be the best choice for those patients that want another type of treatment that is less invasive that conventional medicine.

References

1. Demarque, D., Jouanny, J., Poitevin, B., & Saint-Jean, Y. (2005). *Pharmacologie et matière médicale homéopathique*. CEDH.

2. Busser, M., Chefdeville, F., & Cousin, J. (2005). *Mémento homéopathique: du symptôme à la matière médicale.* CEDH.

Bioidentical Hormone Replacement Therapy

Dr. Mariela Vázquez, PharmD, ABAAHP
2023 CFPR Annual Meeting

Disclosure of Conflict of Interest

I have no actual or potential relevant financial relationships with ineligible companies to disclose.

At the end of the activity pharmacists should be able to:

1. Describe bioidentical hormone replacement therapy (BHRT).
2. Discuss efficacy, safety, and place in therapy of hormone replacement therapy (HRT).
3. Value the role of the pharmacist as educator and provider of care in hormone replacement therapy

At the end of the activity pharmacy technicians should be able to:

1. Describe bioidentical hormone replacement therapy (BHRT).

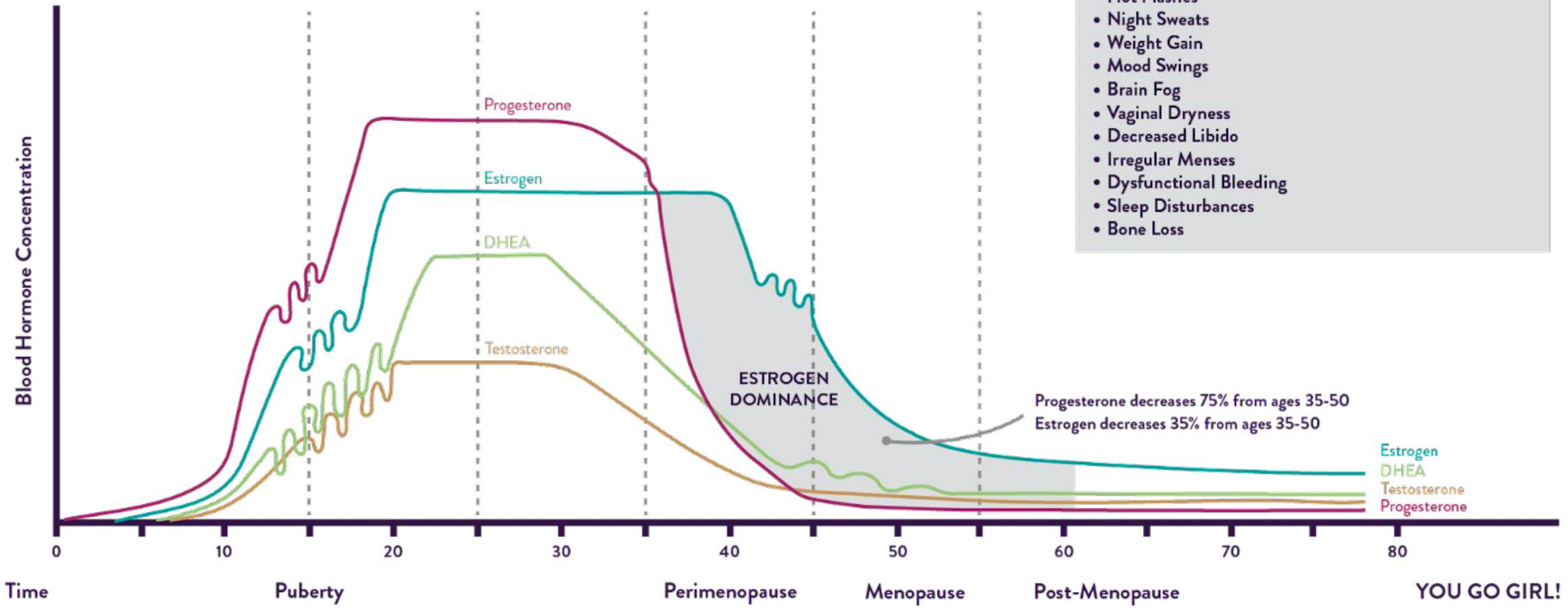
2. Identify efficacy, safety, and place in therapy of hormone replacement therapy (HRT).

3. Value the supporting role of the pharmacy technician in Non-traditional treatments

Pre-Test: True or False

1. All women with menopause symptoms should be treated with hormone replacement therapy.
2. Bioidentical hormones are substances that have the same chemical and molecular structure as hormones that are produced in the human body.
3. Hormone pellets can be compounded in any pharmacy as long as USP 795 requirements are met.

The Hormone Fix Timeline



SYMPTOMS OF ESTROGEN DOMINANCE

- PMS
- Hot Flashes
- Night Sweats
- Weight Gain
- Mood Swings
- Brain Fog
- Vaginal Dryness
- Decreased Libido
- Irregular Menses
- Dysfunctional Bleeding
- Sleep Disturbances
- Bone Loss

WHAT'S HAPPENING TO MY HORMONES? -Dr. Anna Cabeca

Numbers in Menopause

51

Average age for menopause

60M

women with menopause in the US

4Y

Average length of perimenopause

5%

Women who experiment menopause at 40-45 y/o

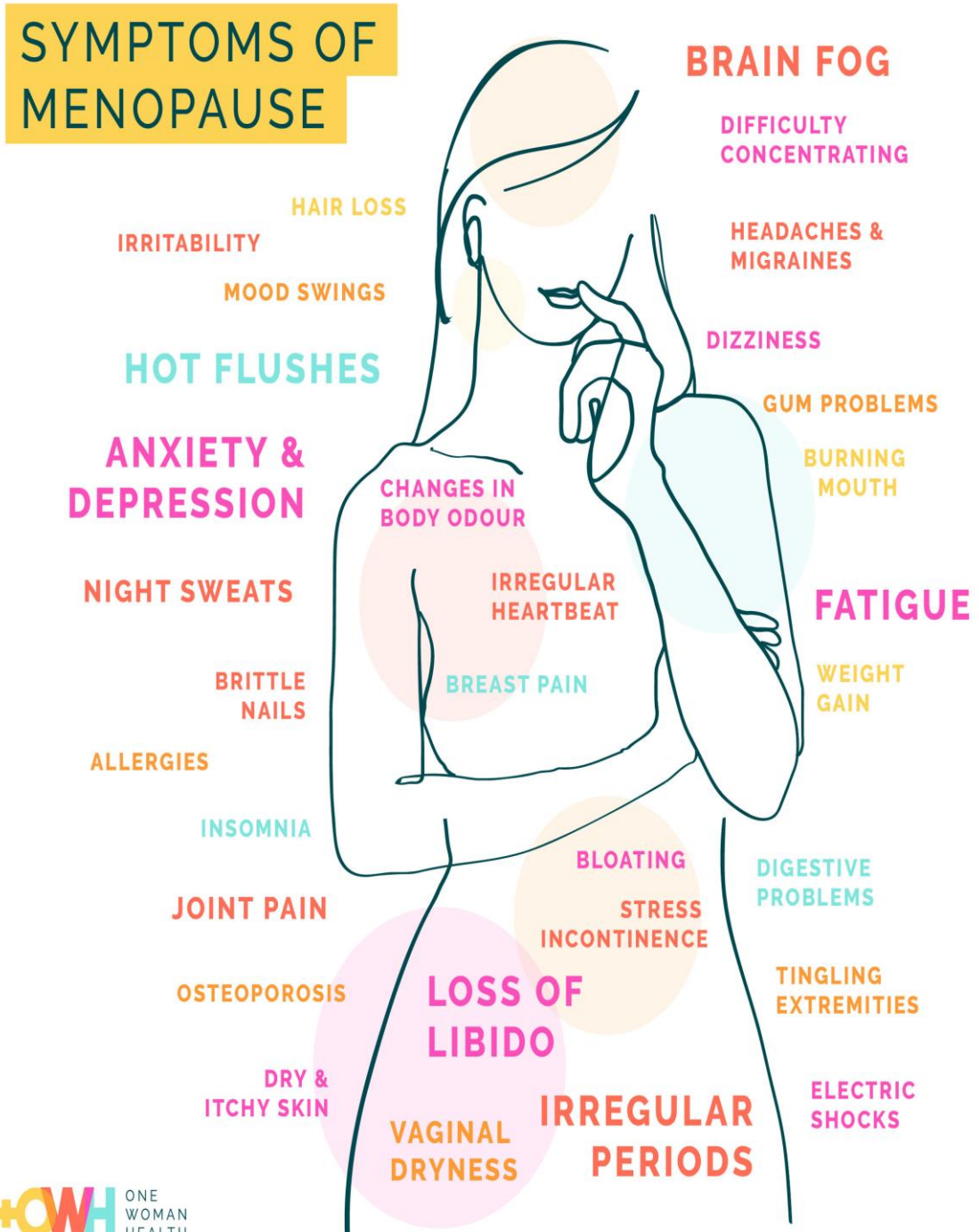
12

Months without a period

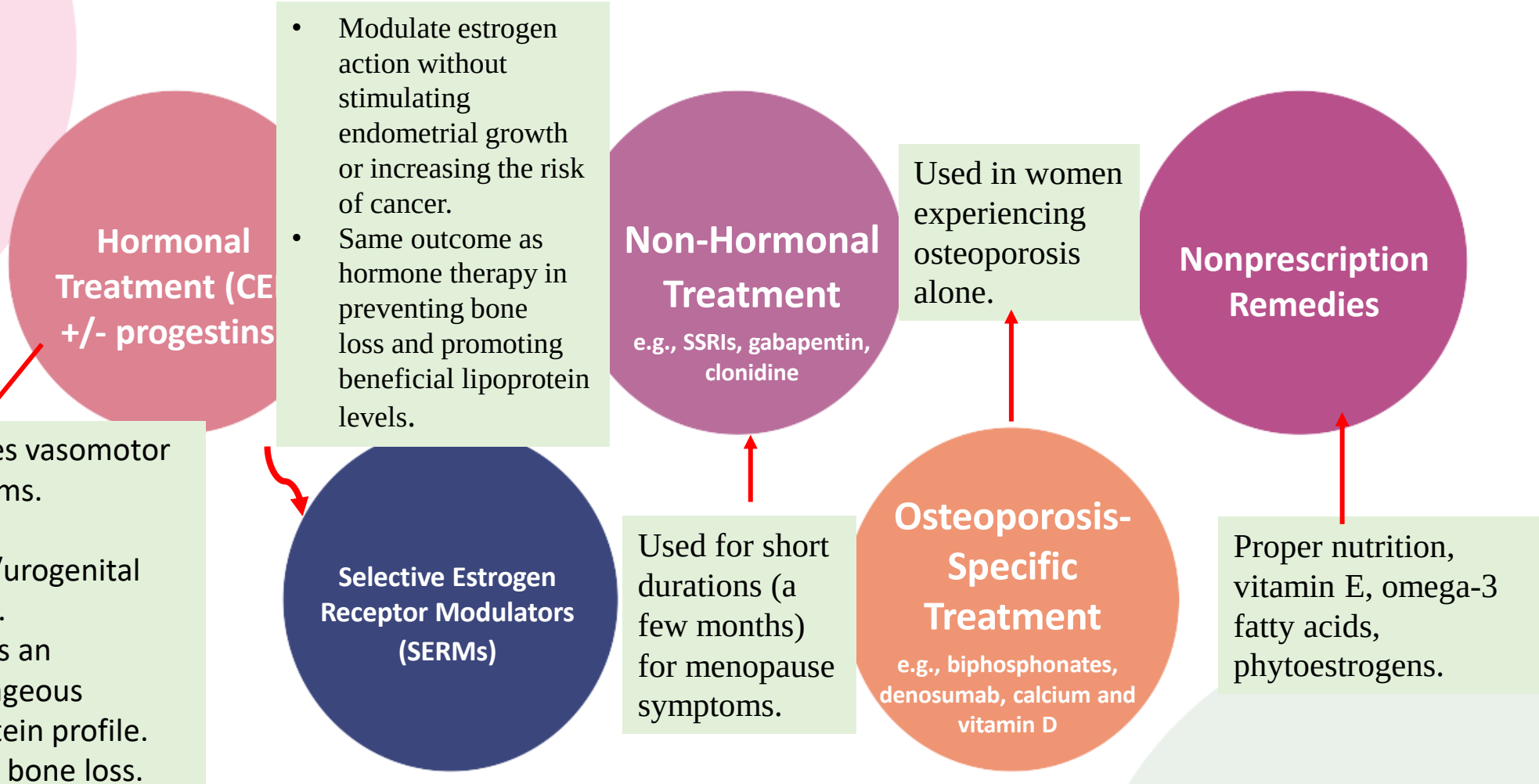
1M

Women who experiment menopause for the 1st time each year in US

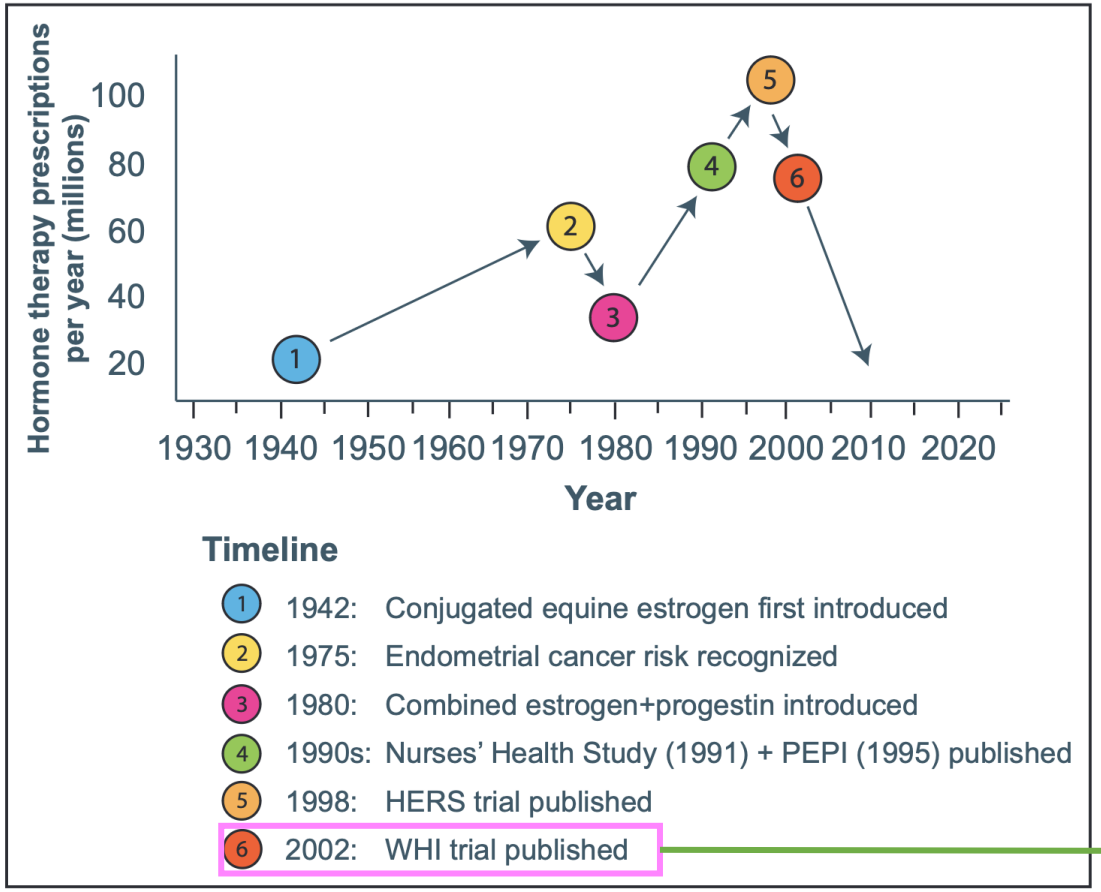
Most women experience vasomotor symptoms, but menopause can affect many areas, including urogenital and cardiovascular symptoms.



Traditional menopause management revolve around minimizing disruptive symptoms and preventing long-term complications



Hormone Therapy Use in the US: Timeline



After WHI was stopped, HRT prescriptions decreased by 70%-80%

Menopause, Stroke, Heart Disease, and Breast Cancer: The Women's Health Initiative Study

- Large, parallel, NIH-sponsored, randomized, placebo controlled trial aimed to evaluate the long-term risks and benefits of HRT in the prevention of chronic diseses
- 27,347 women participated in the hormone study
- The Hormone Study had two main comparisons
  - Women with intact uterus: combined HRT (conjugated equine estrogens (CEE, 0.625 mg) plus Medroxyprogesterone Acetate (MPA, 2.5 mg) vs placebo (n=16,608)
  - Post-hysterectomy: conjugated equine estrogens (0.625 mg) vs placebo (n=10,739)
- Primary outcome: Coronary heart disease (CHD) events (nonfatal myocardial infarction and CHD death)
- Primary safety outcome: Invasive breast cancer
- Both studies were supposed to run from 1993-2005, but were stopped early because of the increased risk observed in the active groups
  - CEE + MPA: Stopped in 2002 because of an increased risk of breast cancer and cardiovascular events compared to placebo
  - CEE alone stopped in 2004 because of an increased risk of stroke, DVT, and PE with no benefit in CHD compared to placebo

Inclusion criteria:

- Postmenopausal status
- 50-79 y/o
- Intact uterus for the CEE + MPA trial and hysterectomy for the CEE trial
- Good general health
- Willingness to participate

Women's Health Initiative

Los Angeles Times- July 10, 2002

LUIS SINCO / Los Angeles Times

...e leads protesters, irate over police ...an Jackson, at Inglewood City Hall.

Risks of Hormone Therapy Stop Study

Medicine: Large clinical trial finds more cases of breast cancer and cardiovascular disease after long-term use of post-menopause drugs.

By ROSIE MESTEL
TIMES STAFF WRITER

Three years ahe... scientists have halted a critical clin... the effects of ho... ment therapy on menopause because ... significant increase ... breast cancer, heart ... clots and strokes.

The trial, which trac... women taking either the estrogen and progestin ... cebo for five years, was ... an end after a review ... made it clear that the ... hormone regimen outw... benefits.

The findings are to be ... in the Journal of the ...

said Dr. Howard Judd, chairman of obstetrics and gynecology at Olive View-UCLA Medical Center and a principal investigator at one of the three study sites in the Los Angeles area. "The results should have profound effects on hormone replacement—or if they don't, they should."

Many women may still opt to ...

achieved with other drugs and life-style changes that do not confer the same risks as hormone replacement therapy, the researchers said.

"You're hard pressed to say 'take estrogen to prevent colorectal cancer' if you see someone's more likely to develop breast cancer, have a heart attack, a stroke or clot in the lungs or the legs," sai...

...port Offers Beating

... a copy of which was shared with The Times on Tuesday. "He didn't respond and continued to stare at me."

But a family member said Dono... van Jackson suffers from a speech ...

2002 HEADLINES

News > Health

MHT-breast cancer link: Women told to discuss menopause hormone therapy with GP after study reveals higher risk

Hormone replacement therapy could have been responsible for around one million breast cancers in western countries, says University of Oxford research

FINANCIAL REVIEW

...enopause ...rug scare ... hits women

600,000 women warned to stop combined HRT medication

Hormone alert for cance...

True degree of therapy risk lost in the clamour of commentato...

People claims that statistics have been skewed, HRT issues more than a small possibility of breast cancer, writes John Kaldor.

Expert panel backs HRT cancer warning

John Kerr
Helen Tobler

AUSTRALIAN women have been warned to limit their use of hormone replacement therapy to prevent heart disease and stroke to no more than three years, after an expert committee last night backed US concerns over the long-term safety of HRT.

Latest guidelines

- Limit HRT therapy to no more than three years
- Review its use in the treatment of osteoporosis
- Remains an appropriate short-term treatment for symptoms of menopause

'There can be risks with stopping medication suddenly without supervision'

HRT linked to cancer and stroke: doctors demand drug restrictions

Deborah Smith
Science Writer

The NSW Cancer Council has called for a common form of hormone replacement therapy to be restricted to short-term use after a new study linked it to breast cancer.

United States doctors have abruptly halted a major clinical trial of combined oestrogen and progestin use by healthy post-menopausal women because the harm from the drugs was found to be significantly greater than the benefits.

Along with a 26 per cent increase in breast cancer, the study showed the hormone combination also led to an increase in heart disease, stroke and blood clots.

The Cancer Council's chief executive, Andrew Penman, said the increased risk of breast cancer could occur after three years of combined HRT use. "This is much earlier than previously thought and our concern is that some women have been using the treatment for over 10 years."

Dr Penman said the council would recommend to the Pharmaceutical Benefits Advisory Committee that

HORMONE THERAPY

THE RISKS
41% increase in strokes; 29% increase in heart attacks; doubling of venous blood clots; 26% increase in breast cancer.

THE BENEFITS
37% cut in colorectal cancer; one-third reduction in hip fractures; 24% reduction in all fractures.
Source: Journal of the American Medical Association

combined HRT be restricted to symptomatic relief of menopausal symptoms, and not be taken for more than two years.

However, the president-elect of the Australasian Menopause Society, Susan Davis, cautioned against a "knee-jerk reaction" by doctors and women. "I don't think this changes anything for women who are peri-menopausal and aged around 50, or who have used any form of HRT for less than five years."

The American trial, part of the Women's Health Initiative run by the US National Institutes of Health, was due to be completed in 2005 but was stopped after the women were followed for an average of 5.2 years. It involved 16,600 women aged 50 to 79.

The results were published yesterday by the Journal of the American Medical Association. Although the risks overall outweighed the benefits, only a small number of individual women – about 2.5 per cent – had problems.

Compared with women taking a placebo, for every 10,000 women taking combined HRT eight more would get breast cancer, seven more would have heart attacks, eight more would have stroke, and 18 more would have blood clots, in a year.

But six fewer would get colorectal cancer and five fewer would have hip fractures, the researchers said. They stressed, however, that the new study did not apply to women without a uterus taking oestrogen-only preparations.

The Cancer Council says an estimated 600,000 Australian women aged 45 to 64 use some form of HRT. Concerned women should see their doctors or call the Cancer Helpline on 131 120.

More needed to settle HRT scare

The hormone replacement therapy scare inspired last month by US researchers is having predictable results. Australia's biggest supplier of the oestrogen-progestin combination has reported a 30 per cent decline in sales since Americas doctors cut short a long-term study of 16,000 HRT users to warn the world that the therapy increased the risks of breast cancer, heart disease, stroke and blood clots, particularly among women who took the therapy for five years or more. A Melbourne specialist went further, claiming two-thirds of his patients had quit HRT. These outcomes will suit, if not fully satisfy, doctors who embraced the US warnings. What has not been answered is whether doctors too quickly ruled out HRT for women trying to prevent or minimise the debilitating symptoms of menopause, including sweats, sleeplessness, hot flushes and deterioration in bone density.

For the defenders of HRT, the American report prompted understandable panic among its users. This might have been avoided, or at least lessened, had the researchers not highlighted their findings with a simplistic, misleading and, arguably, mischievous set of statistics. The ensuing furore left little room, for instance, to counter arguments such as women being twice as likely to develop breast cancer if they took two alcoholic drinks a day, instead of HRT. The American report said an HRT user's breast cancer risk, for example, jumped 26 per cent (with similarly alarming rises in the risks of other side effects). To women who know little about statistical interpretation, this might (and probably did) suggest their odds of developing breast cancer would increase by 26 chances in 100. In fact, the odds grew by 0.08 per cent. In Australia, where 600,000 women used HRT pre-scare, this would mean 1200 extra cases a year of life-threatening heart attacks, strokes, breast cancer and pulmonary embolism. Conversely, abandoning HRT would lead to 6660 extra cases a year of bowel cancer and hip fractures because the therapy limits these risks. No-one suggests these numbers are insignificant. But the preliminary reports about the drop-out rate from HRT provide no assurance that women are making informed choices about this important decision. Indeed, they are accompanied by anecdotal evidence of scared women quitting HRT on little more than their own poor understanding of poorly presented statistical results. They deserve better than that. They deserve a clear lead from those best placed in the medical and scientific world to warn, advise and reassure.

BBC NEWS WORLD EDITION

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Wednesday, 10 July, 2002, 11:29 GMT 12:29 UK

HRT linked to breast cancer

The study examined estrogen and progestin

Women who take hormone replacement therapy may be at increased risk of breast cancer, heart disease and stroke, a study suggests.

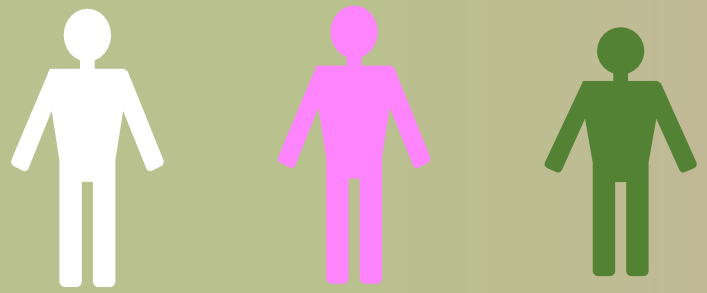
Early results from a major clinical trial in the US indicate that long term use of one type of HRT can seriously damage women's health.

The findings have caused such concern that authorities in the US have ordered researchers to end ...

Although inclusion criteria of WHI was 50-79 years of age, most participants were > 60 y/o

CEE + MPA

Mean Age was 63.2 years



33% 50-59 years

45% 60-69 years

22% 70-79 years

Approximately 37% had used HT for an average duration of 5.4 years at the time of enrollment.

CEE alone

Mean Age was 63.6 years

28% 50-59 years

50% 60-69 years

22% 70-79 years

Approximately 48% had used HT for an average duration of 7.2 years at the time of enrollment.

Should we apply the results of the WHI study to all patients?

- Outcomes resulting from postmenopausal hormone therapy trials may be affected by multiple factors, including:
  - The specific estrogen or progestogen agent used
    - Oral conjugated equine estrogen (CEE):
      - Synthetic estrogen preparation containing estrone sulfate, equilin sulfate, and 17α-dihydroequilin sulfate.
      - Oral administration → hepatic metabolism
        - Pro-inflammatory
      - Estradiol vs Estrone
    - Medroxyprogesterone acetate (MPA)→ Synthetic progesterone
      - Unfavorable safety profile compared with bioidentical progesterone formulations
  - Duration of therapy
    - Many patients had used HRT for several years before starting WHI
  - Characteristics of the group of women treated
  - Mean age in WHI was 63 years, but approximately 70% were over 60 years
    - Average age for menopause is 51 y/o
    - Most observational studies prior to WHI showed benefits in younger, symptomatic patients closer to their age of menopause.

In the total population of the WHI trial, CEE + MPA was associated with an increased risk of CVE and CEE with a trend of an increased risk

	CEE + MPA Arm					CEE-Only Arm				
	No. of Events (annualized %)					No. of Events (annualized %)				
	CEE + MPA, n = 8506	Placebo, n = 8102	Difference/ 10 000 PY	HR (95% CI)	*P* Value	CEE, n = 5310	Placebo, n = 5429	Difference/ 10 000 PY	HR (95% CI)	*P* Value
Intervention										
CHD	196 (0.41)	159 (0.35)	6	1.18 (0.95-1.45)	0.13	204 (0.55)	222 (0.58)	−3	0.94 (0.78-1.14)	0.53
Total MI	168 (0.35)	129 (0.29)	6	1.24 (0.98-1.56)	0.07	164 (0.44)	173 (0.45)	−1	0.97 (0.79-1.21)	0.81
CABG or PCI	198 (0.42)	200 (0.45)	−3	0.95 (0.78-1.16)	0.64	249 (0.68)	255 (0.67)	0	1.00 (0.83-1.19)	0.96
All CV events	786 (1.70)	663 (1.52)	19	1.13 (1.02-1.25)	0.02	877 (2.51)	813 (2.24)	27	1.11 (1.01-1.22)	0.03
CV deaths	79 (0.16)	70 (0.15)	1	1.05 (0.76-1.45)	0.77	109 (0.29)	112 (0.29)	0	1.00 (0.77-1.31)	0.98
All-cause mortality	250 (0.52)	238 (0.53)	−1	0.97 (0.81-1.16)	0.76	301 (0.80)	299 (0.77)	3	1.03 (0.88-1.21)	0.68

The age-stratified data from the WHI supports that the risks associated with HRT are related to the time of initiation since menopause

Risks are low in women < 10 years from menopause and age < 60 years, and higher for older women further from menopause.

	CEE + MPA Arm					CEE-Only Arm				
	No. of Events (annualized %)					No. of Events, (annualized %)				
	CEE + MPA, n = 8506	Placebo, n = 8102	Difference/ 10 000 PY	HR (95% CI)	*P* Value	CEE, n = 5310	Placebo, n = 5429	Difference/ 10 000 PY	HR (95% CI)	*P* Value
Intervention										
CHD					0.81					0.08
50–59 y	38 (0.23)	27 (0.17)	5	1.34 (0.82-2.19)		21 (0.17)	35 (0.28)	−11	0.60 (0.35-1.04)	
60–69 y	79 (0.37)	73 (0.37)	0	1.01 (0.73-1.39)		100 (0.61)	108 (0.63)	−3	0.95 (0.72-1.24)	
70–79 y	79 (0.82)	59 (0.63)	19	1.31 (0.93-1.84)		83 (0.97)	79 (0.90)	7	1.09 (0.80-1.49)	
Total MI					0.55					0.02
50–59 y	32 (0.19)	23 (0.15)	4	1.32 (0.77-2.25)		17 (0.14)	31 (0.25)	−11	0.55 (0.31-1.00)	
60–69 y	70 (0.33)	62 (0.31)	2	1.05 (0.74-1.47)		76 (0.46)	82 (0.48)	−2	0.95 (0.69-1.30)	
70–79 y	66 (0.69)	44 (0.47)	21	1.46 (1.00-2.15)		71 (0.83)	60 (0.69)	14	1.24 (0.88-1.75)	
CABG or PCI					0.67					0.06
50–59 y	34 (0.20)	32 (0.20)	0	1.03 (0.63-1.68)		29 (0.24)	51 (0.41)	−17	0.56 (0.35-0.88)	
60–69 y	92 (0.43)	103 (0.52)	−9	0.85 (0.64-1.13)		129 (0.79)	116 (0.69)	11	1.13 (0.88-1.46)	
70–79 y	72 (0.75)	65 (0.70)	5	1.08 (0.77-1.51)		91 (1.07)	88 (1.02)	5	1.07 (0.79-1.43)	
All-cause mortality					0.20					0.04
50–59 y	35 (0.21)	48 (0.31)	−10	0.67 (0.43-1.04)		35 (0.29)	50 (0.40)	−11	0.70 (0.46-1.09)	
60–69 y	111 (0.51)	94 (0.47)	5	1.07 (0.81-1.41)		130 (0.78)	134 (0.77)	0	1.01 (0.79-1.29)	
70–79 y	104 (1.06)	96 (1.02)	4	1.03 (0.78-1.36)		136 (1.55)	115 (1.29)	26	1.21 (0.95-1.56)	
Extended follow-up										
CHD					0.99					0.12
50–59 y	93 (0.26)	69 (0.21)	5	1.27 (0.93-1.74)		42 (0.21)	64 (0.32)	−11	0.65 (0.44-0.96)	
60–69 y	201 (0.44)	199 (0.46)	−2	0.97 (0.79-1.18)		183 (0.67)	188 (0.67)	0	1.00 (0.82-1.23)	
70–79 y	193 (0.98)	162 (0.84)	14	1.17 (0.95-1.44)		138 (1.03)	141 (1.03)	0	1.01 (0.80-1.28)	
Total MI					0.46					0.007
50–59 y	75 (0.21)	57 (0.17)	4	1.25 (0.88-1.76)		35 (0.17)	58 (0.29)	−11	0.60 (0.39-0.91)	
60–69 y	165 (0.36)	158 (0.36)	0	0.99 (0.8-1.24)		140 (0.52)	139 (0.49)	2	1.03 (0.82-1.31)	
70–79 y	149 (0.76)	109 (0.57)	19	1.34 (1.05-1.72)		110 (0.82)	91 (0.67)	16	1.25 (0.95-1.65)	
CABG or PCI					0.34					0.40
50–59 y	102 (0.29)	96 (0.29)	0	1.01 (0.76-1.34)		71 (0.36)	83 (0.42)	−6	0.83 (0.60-1.14)	
60–69 y	246 (0.54)	244 (0.57)	−3	0.98 (0.82-1.18)		212 (0.80)	192 (0.69)	10	1.12 (0.92-1.37)	
70–79 y	158 (0.81)	131 (0.69)	12	1.18 (0.94-1.49)		122 (0.93)	121 (0.90)	2	1.03 (0.80-1.33)	
All-cause mortality					0.23					0.10
50–59 y	141 (0.39)	149 (0.44)	−5	0.88 (0.70-1.11)		90 (0.45)	115 (0.56)	−12	0.78 (0.59-1.03)	
60–69 y	452 (0.97)	429 (0.97)	−1	0.99 (0.87-1.13)		301 (1.08)	308 (1.07)	1	1.02 (0.87-1.19)	
70–79 y	418 (2.07)	388 (1.97)	9	1.04 (0.91-1.20)		313 (2.26)	302 (2.15)	11	1.06 (0.90-1.24)	

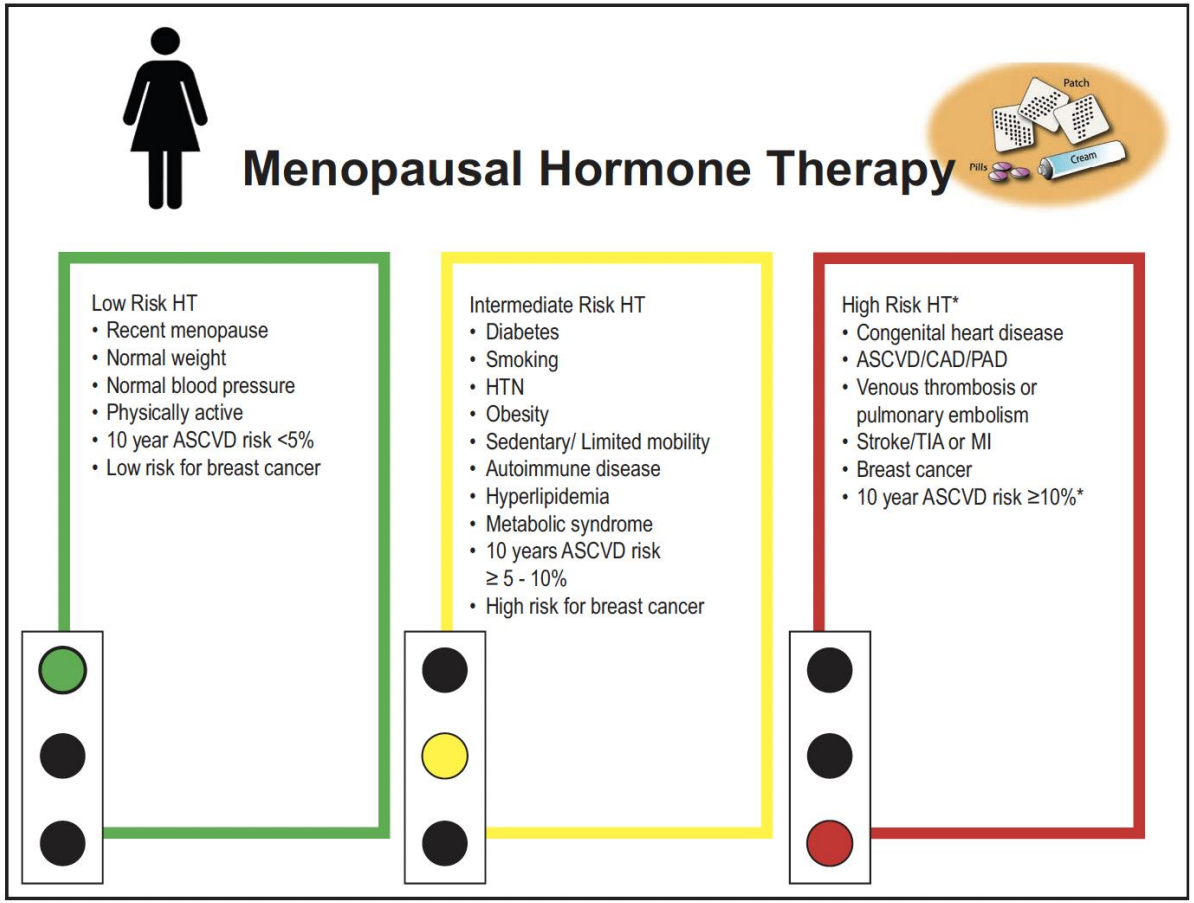
Additional evidence confirms the “time of initiation” theory

Study	Population	Results
KEEPS Trial 4-year randomized, placebo-controlled, double-blind prospective trial aimed to evaluate the effects of hormone therapy o progression of atherosclerosis as measured by carotid intima-media thickness (CIMT) and coronary arterial calcification (CAC). 4 years	727 healthy women 42-58 years (mean age, 52 years) who were within 3 years of menopause onset. • Oral CEE (lower dose than WHI) + cyclical micronized progesterone • Transdermal estradiol + cyclical micronized progesterone • Placebo	• Neutral effects on atherosclerosis progression as measured by CAC or CIMT • No effect in BP • Oral CEE (but not transdermal estradiol) was associated with a fovorable change in lipid profile (increase in HDL, decrease in LDL). Also an increase in TGs. • Improvements in vasomotor symptoms, sexual function, mood, and bone density with both estrogen formulations. • Both formulations similarly maintained bone mineral density compared to placebo at the wrist, hip, and spine in a subset of participants at one site who had undergone dual-energy X-ray absorpti-ometry throughout the study • No differences un adverse events, including breast cancer, MI, TIA, stroke, or VTE.
ELITE Trial was a randomized, double-blind, placebo-controlled trial that evaluated the effects of oral hormone therapy on subclinical atherosclerosis by measuring CIMT every 6 months and cardiac computed tomography	643 healthy women early in menopause (< 6 years past menopause) vs late in menopause ($\geq$ 10 years past menopause), who didn’t have CVD at baseline. • Oral estradiol (1 mg/d 17 B-estradiol) +/- cyclical vaginal progesterone gel (in women with uterus) • Placebo	• Effectsin CIMT differed between the early and late post-menopausal groups (P=0.007 for the interaction) after a median of 5 years. • Women $\geq$ 10 years past menopause: The rate of progression of atherosclerosis by CIMT in the estrogen group was similar to placebo (0.0100 and 0.0088 mm per year, respectively; p=0.29). • Women < 6 yers post menopause: mean CIMT progression was slower for women in HRT than placebo (0.0044 mm/y vs 0.0078 mm/y; P=0.008).

Most professional associations recommend HRT for the management of symptomatic menopausal women who are younger and for the shortest time possible.

Aspect of treatment	American College of Obstetricians and Gynecologists[10]	North American Menopause Society[13]	American Association of Clinical Endocrinology and American College of Endocrinology[11]	Endocrine Society[12]
Principal indication	Menopause symptoms	Menopause symptoms	Menopause symptoms	Menopause symptoms
Prevention of coronary heart disease	Not recommended	Not recommended	Not recommended	Not recommended
Special considerations	None	Consideration of age and time from menopause onset	Consideration of age, time from menopause onset, and risk of cardiovascular disease, with lipid profile, smoking history	Consideration of age, time from menopause onset, and baseline risks of cardiovascular disease and breast cancer
Dose and route of administration	Lowest effective dose	Appropriate dose to manage symptoms with consideration of route	Lowest effective dose	Shared decision-making to determine formulation, dose, and route
Duration of use	Shortest period based on risk-benefit analysis, with recommendation against routine discontinuation in patient ≥65 y of age	May be extended for persistent vasomotor symptoms, prevention of bone loss, or quality of life after attempt at stopping; reassess benefits and risks regularly	Recommended for ≤5 y with reduction of dose if continuing	Shortest total duration consistent with the treatment goals and evolving risk assessment of the individual woman

According to the American College of Cardiology, the decision to use HRT should be based on the patient's individual risk of Major Adverse Cardiovascular Events (MACE) from therapy



All women, independent of risk category, are candidates for low-dose vaginal estrogen therapy for genitourinary symptoms of menopause.

Bioidentical Hormone Replacement Therapy (BHRT)

- “Bioidentical” hormones → substances that have exactly the same chemical and molecular structure as hormones that are produced in the human body.
  - BHRT vs traditional HRT
    - Functional medicine
  - Any hormone can be made to be “bioidentical”
  - Term has also been used to describe compounded formulations containing estrogens, progesterone, and testosterone (cBHRT).

BHRT vs Synthetic Hormone Products

- Contrary to bioidentical hormones, synthetic hormones are not chemically identical to the hormones that are naturally produced by the human body.
- To be physiologically active, synthetic hormones are converted in the body into a usable form.
  - E.g., Premarin and Provera
- Although there are FDA-approved bioidentical hormone products, most FDA-approved formulations are synthetic.

Bioidentical Hormone Replacement Therapy

Commercially available FDA aproved products

- Manufactured under strict standards, and their effects are subjected to scientific scrutiny for FDA approval.
- Dose and formulation cannot be individualized.
- Generally more expensive.

Route	Product
Oral	Estradiol tablets Estradiol/progesterone capsule Progesterone capsule
Vaginal	Estradiol Vaginal Cream Estradiol Vaginal Ring Estradiol Vaginal Insert
Topical	Estradiol Patch Estradiol Gel Estradiol Spray
Injection	Estradiol injection

Compounded BHRT

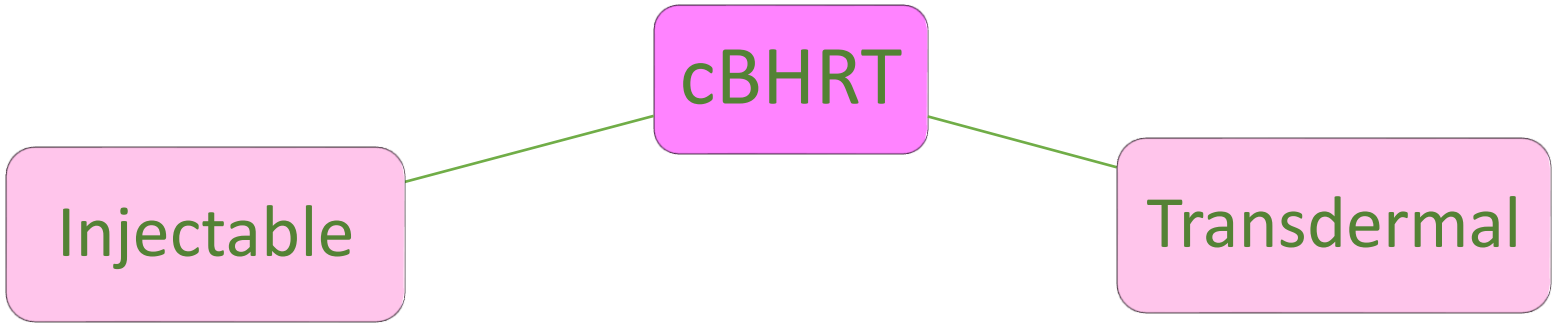
- Compounded Bioidentical Hormones are specifically compounded to meet the individual needs of a patient.
- Compounding pharmacies should meet USP quality standards
  - Non-Sterile Preparations: USP 795
  - Hazardous Drugs: USP 800
  - Sterile Preparations: USP 797
- May offer improved safety, efficacy, and tolerability because of the individualization of the formulas, the source of the hormones, and the routes of delivery.

Route	Product
Oral	Progesterone capsules
Vaginal	Estradiol 0.1mg/g, 0.5 mg/g Estriol 1mg/g, 3mg/g DHEA vaginal cream Progesterone vaginal suppositories
Topical	Estriol/Estradiol (Biest 80/20, 70/30, 50/50) Progesterone cream 50 mg Testosterone topical cream or gel
Injection	Pellets

BHRT can be compounded in many different formulations and routes of administration, making it possible to individualize the product to meet the patient's unique needs

Dosage Form	Hormones									
	Estradiol		Estriol		Progesterone		Testosterone		DHEA	
	Preparation									
	C	M	C	M	C	M	C	M	C	M
Capsule	✓	✓	✓		✓	✓	✓		✓	
Capsule SR					✓					
Cream	✓	✓	✓		✓		✓		✓	
Enema					✓					
Film/Patch		✓						✓		
Gel	✓	✓	✓		✓	✓	✓	✓	✓	
Injection	✓					✓				
Insert/Ring	✓	✓				✓			✓	✓
Lotion							✓			
Lozenge	✓				✓		✓			
Oil					✓					
Ointment	✓		✓				✓			
Pellet	✓				✓		✓	✓		
Solution	✓				✓		✓	✓	✓	
Spray		✓			✓		✓			
Suppository	✓				✓				✓	
Suspension					✓					
Tablet	✓	✓			✓					
Total	11	7	4	0	13	4	9	4	6	1

Compounded Bioidentical Hormone Replacement Therapy



Administration	Under de skin (a simple surgical procedure)	Topical (arms, abdomen, buttocks, thighs) or vaginal application. Available as creams, gels, sprays, patches.
Duration of Action	3-4 months (in some patients the effects can last up to 6 months)	12-24 hours
Adverse effects	Risk of infection or allergic reaction at the injection site. Some patients develop skin bumps or nodules. Hormone imbalance side effects, such as spotting.	Skin-related adverse effects (in addition to hormone imbalance side effects, such as spotting)
Dose Adjustments	Once inserted, the dose can't be changed	Dose can be modified easily based on response and tolerability
USP quality Standards	USP 797 and USP 800	USP 795 and USP 800
Tests used to monitor hormone levels	Blood tests	Salivary tests
Risk of transference	No	Yes
Dose delivery	Delivers a controlled and steady dose throughout time	Absorbed through the skin and into the bloodstream, providing a more immediate and adjustable hormone delivery
Cost	$$$	$$

Compounding Medications... why?

Medications are compounded to meet the unique needs of patients, including vulnerable populations such as seniors and children.

1. **Customization**

   Tailor medications to meet the unique needs of individual patients.

2. **Dose Adjustments**

   Adjust the dosage strength of medications to match the precise requirements of a patient.

3. **Combination Products**

   Compounded formulations can combine multiple active ingredients into a single medication, simplifying the therapy.

4. **Alternative Dosage Forms**

   Medications can be compounded in various forms such as creams, gels, troches, sprays, or suppositories, offering flexibility.

5. **Allergen Avoidance**

   Compounded formulations can be prepared without certain allergens for patients who have sensitivities or allergies to these components.

6. **Pediatric and Geriatric Considerations**

   Compounding allows for dosage adjustments and the creation of suitable dosage forms for these specific patient groups.

USP Quality Standards

USP develops standards for compounding nonsterile medications to help ensure the patient's benefit and reduce risks such as contamination, infection, or incorrect dosing.

USP Chapter 795

- Provides standards for quality for non-sterile preparations.
- Help define what constitutes good compounding practices and provide general information to enhance the compounder's ability in the compounding facility to extemporaneously compound preparations that are of acceptable strength, quality, and purity.

USP Chapter 800

- Provides standards for the safe handling of hazardous drugs to minimize the risk of exposure to healthcare personnel, patients, and the environment.

USP Chapter 797

- Provides guidelines and standards for compounding pharmacies that prepare sterile medications.
- Addresses the compounding of injectable medications, intravenous solutions, and other sterile preparations intended to be administered directly into the bloodstream or body tissues.

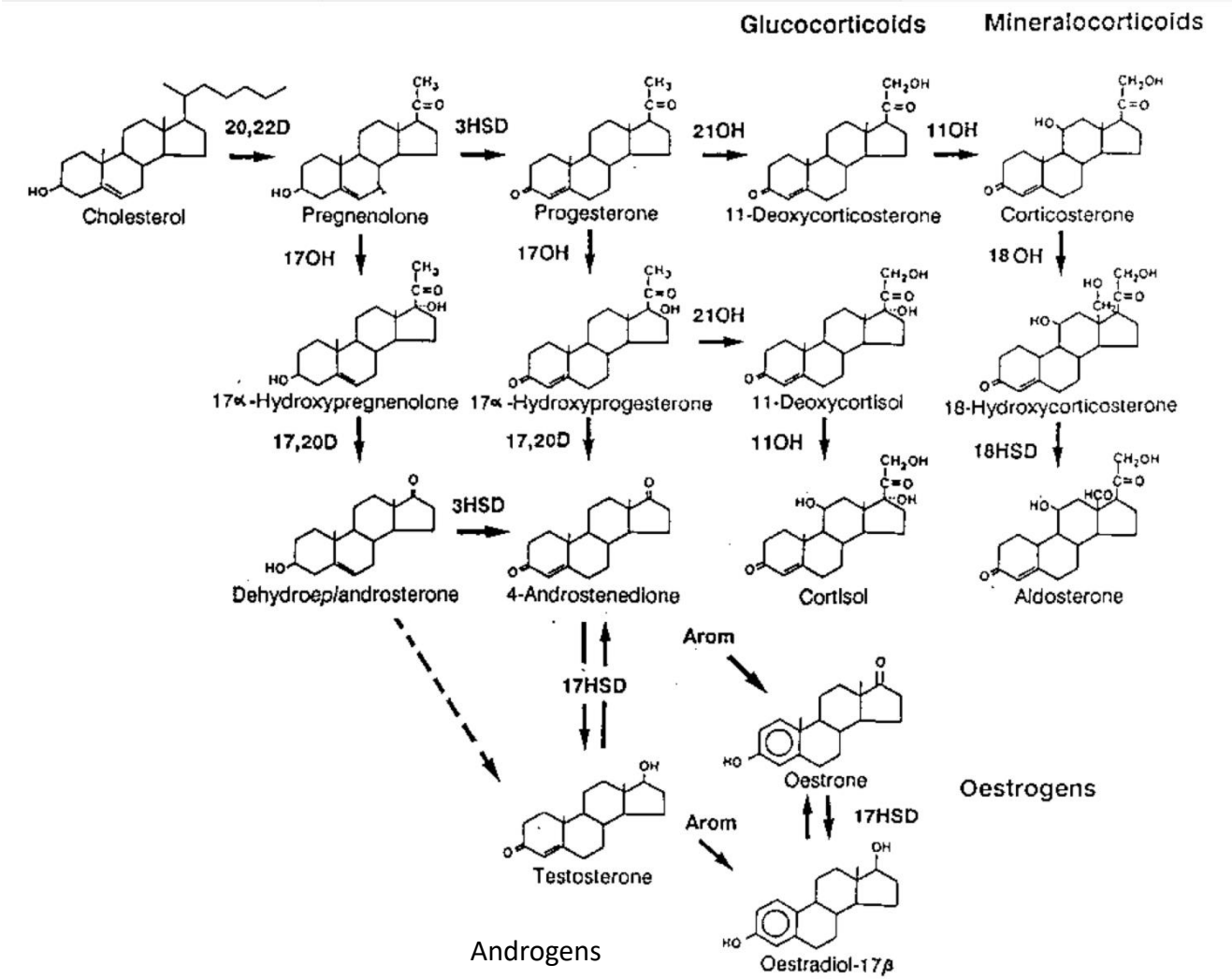
Compounding ≠ Manufacturing

Non-sterile compounding is the process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug or bulk drug substance to create a non-sterile preparation (solutions, suspensions, ointments, creams, powders, suppositories, capsules, and tablets)

Compounded BHRT: Estrogen

- Predominant female sex hormone produced in the ovaries.
- Levels increase during puberty and diminish with age, achieving their lowest levels after menopause
- Symptoms associated with low estrogen levels in women may include:
  - Hot flashes, mood changes, vaginal dryness and atrophy, decreased libido, fatigue, sleep disturbances, bone loss, and urinary incontinence.
- Oral estrogen is pro-inflammatory
  - Should be avoided whenever possible.
- Transdermal administration has anti-inflammatory effects and provides adequate symptom relief with a favorable safety profile.

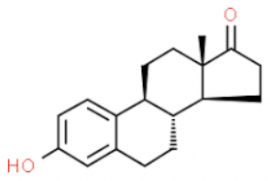
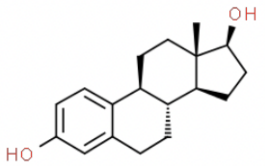
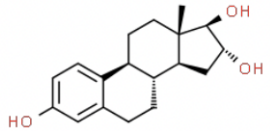
The hormone metabolism pathway determines its effects in the body



There are three main types of estrogen: estriol, estradiol, and estrone

Estrogen products are available in several routes of administration:

- Oral administration (capsules and tablets)
- Topical administration (creams, gels, patches, ointment)
- Intravaginal administration (suppositories, vaginal creams, vaginal rings)
- Intradermal pellets

	Structure[1,2,3]	Function	Availability for compounded preparations	Uses in topical preparations
Estrone (E1)		- Transformed to Estradiol by a 17-beta hydroxy steroid dehydrogenase - Elevated relative to estradiol during menopause	Y (capsules, gels, creams)	- Hot flashes: topical estrone applied to the skin provides localized estrogenic effects and help alleviate hot flashes. - Vaginal dryness - Skin health
Estradiol (E2)		- The strongest estrogen in the body responsible for the beneficial effects on the brain and heart.	Y (capsules, creams, gels, injections, lozenges, rings, ointments, pellets, solutions, suppositories, tablets)	- Menopausal symptom relief such as hot flashes, night sweats, mood swings, and vaginal dryness. - Vaginal health (atrophy. Dryness, itching, discomfort, and pain during the intercourse) - Skin health: improve skin quality, reduce wrinkles, and enhance overall skin appearance.
Estriol (E3)		- Weak estrogen that has been shown to have anti-cancer properties by antagonizing the effects of estrogen in the breast tissue.	Y (capsules, gels, ointments, creams, patches, pellets)	- Vaginal symptoms: Estriol has preferential affinity for estrogen receptors in the vaginal tissue, allowing for targeted treatment of specific menopausal symptoms (vaginal dryness, itching, elasticity, and pH balance). - Urinary symptoms- topical preparations can support the tissues of the lower urinary tract.

[1] CSID:5660, http://www.chemspider.com/Chemical-Structure.5660.html (accessed 20:01, May 22, 2023)
[2] CSID:5554, http://www.chemspider.com/Chemical-Structure.5554.html (accessed 19:59, May 22, 2023)
[3] CSID:5553, http://www.chemspider.com/Chemical-Structure.5553.html (accessed 14:58, May 22, 2023)

Estrogen Vaginal Cream

Vaginal Cream		
Estradiol	0.1 mg/g, 0.5 mg/gm, other as prescribed	Recommended for women with moderate to severe menopause symptoms, as well as proven estrogen deficiency.
Estriol	1 mg/g, 3 mg/g. other as prescribed	Recommended in women with mild symptoms, women sensitive to estrogen effects, and as maintenance therapy after effective estradiol treatment.
Sig. Measure prescribed dose with the provided applicator and insert intravaginal.		

Clinical Pearls: Estrogen Vaginal Cream

Product:
- Estradiol 0.1 mg/g, 0.5 mg/g
- Estriol 1 mg/g, 3 mg/g

Uses: Manage vaginal symptoms associated with menopause, such as dryness, itching, burning, pain during intercourse, and urinary incontinence. Estriol also balances vaginal pH, reducing the risk of recurrent urinary tract infections.

Patient counseling points:
- Use at bedtime.
- Wash your hands before and after using.

Precautions:
- History of breast cancer- Estradiol products
- Do not use in pregnant or lactating women- Not enough evidence or safety data
- Potential side effects may include vaginal irritation or discharge.

Estrogen Topical Cream

Topical Creams		
Biest 80/20, 70/30, 50/50. The ratio is based on the quantity (in mg) of each component in the final product.	Estriol/Estradiol combination available as a final concentration 0.5 mg/g, 1 mg/g, 1.5 mg/g, 2 mg/g, or as prescribed	Perimenopausal or menopausal women with mild to moderate symptoms may use Biest 80/20 or Biest 70/30. Women with more severe symptoms can use Biest 50/50
Sig. Apply once a day. Massage into inner thighs, buttocks or lower abdomen or apply to inner forearm and rub arms together.		

Clinical Pearls: Estrogen Topical Cream

Product: Biest 80/20, 70/30, 50/50

Uses: To balance hormones and provide temporary relief of menopause symptoms such as hot flashes, anti-inflammatory effect, cardio and neuroprotection.

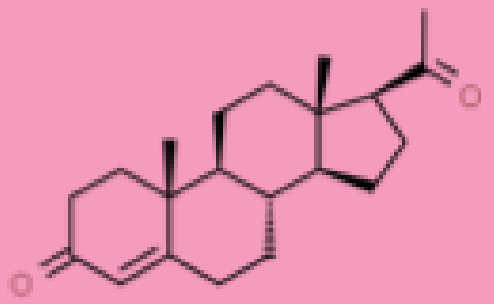
Patient counseling points:

- It is not recommended to apply in the breasts or neck
- Wash your hands before and after use
- Avoid swimming, bathing, or showering for at least 2 hours after administering. Avoid exercising or sweating for at least 2 hours after administering to improve absorption.
- To avoid transferring the product to another person or pet, avoid physical contact with the area in which the product was applied for at least 2 hours

Precautions:

- Avoid in women with a history of breast cancer
- Do not use in pregnant or lactating women- not enough evidence or safety data
- Potential side effects may include skin irritation. Monitor patients for high levels of estrogen, such as irritability, mood swings, acne, breast tenderness, swelling, and vaginal bleeding, among others.

Progesterone



- Levels of progesterone are the first to become deficient during menopause.
- Progesterone balances the effects of estrogen.
- When levels are too low relative to estrogen levels:
  - A woman may experience symptoms of estrogen dominance such as breast tenderness, poor sleep, menorrhagia, anxiety, agitation, bloating, fluid retention, headaches, mood swings, and sleep disturbances.
  - The endometrium becomes thicker, increasing the risk of endometrial cancer.
- Additional beneficial effects of progesterone include protection against breast cancer, reducing fluid retention, regulating blood sugar levels, support in maintaining low LDL-C levels, and has anxiolytic and sedative effects by interacting with GABA-receptors.
- In healthy women 65 years of age or younger, oral progesterone administration is recommended because of its cardiovascular and neurological protective effects. In women over 65 years of age, as well as in younger women with cardiovascular or neurological diseases, transdermal administration (with estrogen) may be recommended

Although more studies are needed, bioidentical progesterone has been suggested to have a more favourable effect than synthetic progestins

Synthetic progestins, such as MPA and progestins used in oral contraceptives are associated to a wide array of side effects in women, including water retention, bloating, weight gain, mood changes, menstrual irregularities, gastrointestinal effects, fatigue, and breast tenderness.

Although more studies are needed to fully understand the potential difference, bioidentical progesterone has been suggested to have a more favorable cardiovascular risk and breast cancer risk profile compared to certain progestins, as well as better patient tolerance.

Progesterone Compounded Preparations

Topical Cream	
Progesterone cream 50 mg	Recommended for the management of symptoms of vaginal atrophy and dyspareunia (painful sexual intercourse).
Sig. Insert a full applicator intravaginally once daily before bedtime.	

Oral capsules	
Progesterone oral capsule 25 mg, 50 mg, 100 mg, 150 mg, 200 mg, other	Healthy women < 65 y/o: recommended for CV or neurologic protection Women >65 y/o or with CV or neurologic disease: Transdermal progesterone is preferred to manage symptoms of low levels.
Sig. Take one capsule by mouth daily before bedtime	

Vaginal Suppositories	
Progesterone vaginal supp 25 mg, 50 mg, 100 mg, 150 mg, 200 mg, other	Used in Assisted Reproductive Technologies (ART), support pregnancy in women with threatened miscarriage, and to induce withdrawal bleeding in women with regular menstrual cycles.
Sig. Insert a suppository intravaginally daily.	

Clinical Pearls

Product: Progesterone topical cream, oral capsules, and vaginal suppositories

Patient counseling points:

Topical Cream:

- Apply on the neck, chest, breasts, belly, inner arms, or inner thighs.
- Wash your hands before and after use
- Avoid swimming, bathing, or showering for at least 2 hours after administering. Avoid exercising or sweating for at least 2 hours after administering to improve absorption.
- To avoid transferring the product to another person or pet, avoid physical contact with the area in which the product was applied for at least 2 hours

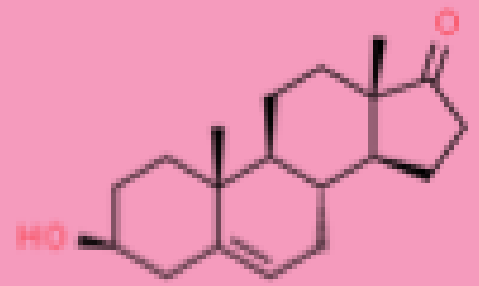
Oral capsule:

- Take as directed before bedtime

Precautions:

- Potential side effects of topical administration may include skin irritation. Oral administration can cause breast tenderness, mood changes, bloating, headache, and nausea.
- Vaginal suppositories can cause vaginal irritation, itching, or redness. This is usually temporary and resolves on its own. Additional side effects include vaginal discharge, headache, and breast tenderness.
- Use cautiously in individuals with a history of certain health conditions, such as liver or kidney disease, blood clots, or hormone-sensitive cancers.

DHEA (**Dehydroepiandrosterone**)



- Precursor of sex hormones in both women and men.
- Levels decrease with age to as much as 90% by 70 years of age.
- Supplementing women with DHEA is done primarily to increase testosterone levels to a youthful range without having to provide testosterone supplementation.
- DHEA supplementation benefits include Improved cognitive function, bone density, immune system response, energy, and well-being.
    - Topical DHEA supplementation can help improve symptoms related to androgen deficiency, such as low libido, painful sexual intercourse, and vaginal atrophy.
    - Intravaginal administration of DHEA may effectively manage menopausal vulvovaginal atrophy and dyspareunia.

Vaginal Cream	
DHEA 3 mg	Recommended in the management of vulvo-vaginal atrophy and dyspareunia.
Sig. Measure prescribed dose with the provided applicator and insert intravaginal.	

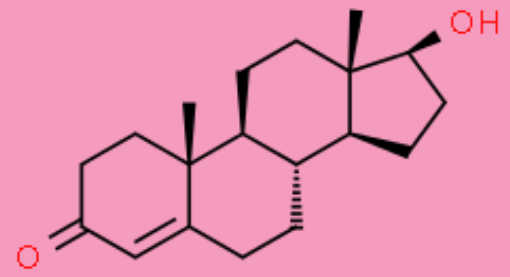
Clinical Pearls

Product: DHEA vaginal cream

Uses: to address symptoms of vaginal atrophy and dyspareunia (painful sexual intercourse).

Counseling Points and Precautions:
- Do not use in pregnant or lactating women
- Potential side effects include vaginal irritation, itching, or redness

Testosterone



- Potent androgen that plays an important role in the development of male sexual characteristics in men, and in the sexual health of both men and women.
- Women only have approximately 10% of male circulating testosterone → adequate levels are needed for strength, nipple and clitoral sensitivity, body composition, bone density, and overall well-being.
- Testosterone replacement therapy in women with testosterone deficiency may result in increased bone density, muscle strengthening, abdominal fat burn, and improved quality of life, as well as increased sexual desire, arousal, orgasm frequency, and satisfaction in women premenopausal and postmenopausal with sexual desire/arousal problems.
- Management;
  - DHEA may increase testosterone levels in women with borderline low testosterone levels or experiencing mild symptoms.
  - Practitioners may recommend bioidentical testosterone transdermal treatment in patients who continue experiencing symptoms despite treatment with DHEA and in women with laboratory-confirmed sub-optimal testosterone levels.

- Barret, B., Jurow, A., Hart, K., & Rothenberg, A. (2019). *Hormonal BioIdentity Keeping your Patient Happy, healthy and Sexually Active* (p. 271). Barrowberg Press.
- Nathorst-böös, J., Flöter, A., Jarkander-Rolff, M., Carlström, K., & Schoultz, B.V. (2006). Treatment with percutanous testosterone gel in postmenopausal women with decreased libido--effects on sexuality and psychological general well-being. *Maturitas, 53 1*, 11-8 .
- Davis, S.R., & Wåhlin-Jacobsen, S. (2015). Testosterone in women--the clinical significance. *The lancet. Diabetes & endocrinology, 3 12*, 980-92 .
- Rahrovan, S., Fanian, F., Mehryan, P., Humbert, P., & Firooz, A. (2018). Male versus female skin: What dermatologists and cosmeticians should know. *International Journal of Women's Dermatology, 4*, 122 - 130.

Testosterone Cream or Gel

Topical Cream or Gel	
Testosterone Cream 0.5 mg, 1 mg, 1.5 mg, 1.5 mg	Used in women to increase libido and improve sexual satisfaction. Also recommended to increase muscle mass, abdominal fat burn, to manage vulvar lichens sclerosus, and as part of osteoporosis treatment.
Testosterone Gel 25 mg/g, 50 mg/g, 75 mg/g, 100 mg/g, other as prescribed	Used in men for the management of hypogonadism (low testosterone levels), age-related testosterone decline, conditions where there is muscle wasting (e.g., chronic illnesses or HIV), or to improve bone health as part of osteoporosis treatment.
Sig. Measure the prescribed dose and apply to a hairless area in the inner thighs, upper buttocks, or lower abdomen (below the belly button) daily in the morning or as prescribed. Men can also apply testosterone gel in the shoulders and the foot instep.	

Symptoms of high testosterone levels in women include:
- Oily skin
- Scalp hair loss
- Acne
- Unwanted body hair
- Clitoral enlargement
- Increased libido

Clinical Pearls

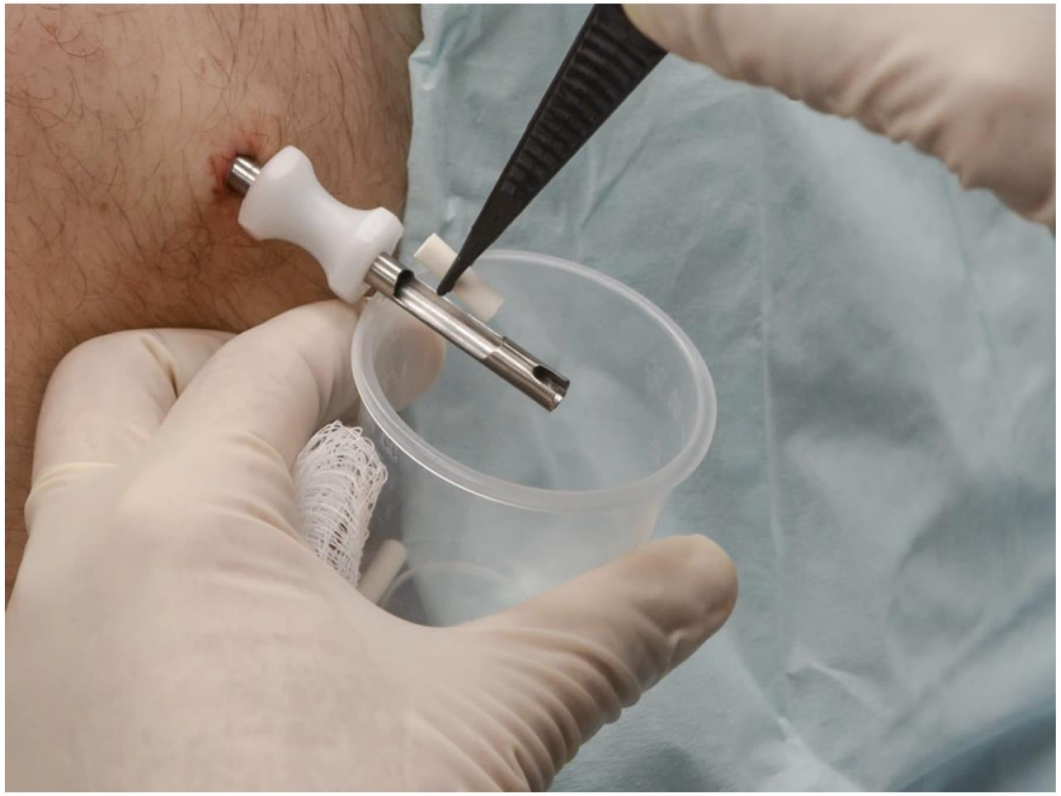
Product: Testosterone Cream and Gel

Patient counseling points:
- Wash your hands before and after use.
- Apply to a clean, dry, healthy, and intact skin.
- Avoid swimming, bathing, or showering for at least 2-4 hours after administering.
- Avoid exercising or sweating for at least 2-4 hours after administering to improve absorption.
- To avoid transferring the product to another person or pet, avoid physical contact with the area in which the product was applied for at least 2 hours

Precautions:
- Do not use in pregnant or lactating women.
- Contraindicated in breast and prostate cancer
- Potential side effects may include vaginal irritation and discharge.
- Potential for secondary exposure to testosterone- avoid contact with unwashed or unclothed application sites.

HRT Pellets

- Estrogen and testosterone
- Minor surgical procedure



Clinical Pearls

Product: Hormone Replacement Therapy Pellets

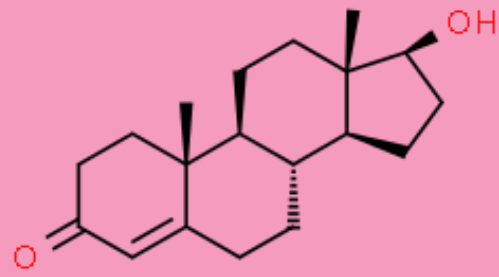
Patient counseling points:

- Appropriate care of the incision area post-administration.
- Monitor and notify any new symptom that may be related to high hormone levels.
- Visit your prescriber every three to four months for re-evaluation and follow-up

Precautions:

- A small percentage of women may experience a procedure-related issue, such as infection, bleeding under the skin, or transient discomfort.
- Once administered, the dose cannot be altered.

And what about men?



- Testosterone levels decline after 30 years old.
- Testosterone deficiency may include:
  - Increased dysfunction of the CV system
    - Increased MI's and CVA's
  - Increased cognitive dysfunction
  - Fatigue, tiredness, irritability, dysphoria, and sexual dysfunction.
- Testosterone can be replaced in topical gel or cream, intramuscular injection, and injectable pellets.
- Adverse effects can include gynecomastia, acne, fluid retention, possible decrease in testicular size, and decreased sperm count.

How is BHRT monitored? Saliva vs. Blood Hormone Level Tests

Characteristic	Saliva	Serum
Products measured	Transdermal	Pellets and oral
Hormones	Estradiol, Estrone, Estriol, DHEA, Testosterone, Progesterone, Cortisol	Estradiol, Estrone, Estriol, DHEA, Testosterone, Progesterone, Cortisol
Pro's	• Steroids in saliva are free forms of hormones, whereas steroids in serum are bound to proteins and inactive. • Free steroids diffuse into saliva and into target tissues. • Convenient and less stressful- collected at home and mailed to labs. • Used for follow-up to evaluate efficacy and safety.	• Point of reference for hormone levels. • Used to initiate therapy.
Con's	• Not completely understood. • Easily contaminated by food, bacteria, etc.	• Measures circulating bound and unbound hormone levels. • More expensive than salivary testing.

Compounding Pharmacists are crucial in the process of preparing customized medications tailored to meet the specific needs of individual patients

- Formulation expertise:
  - Extensive knowledge of pharmaceutical ingredients, dosage forms, and compounding techniques.
- Problem-Solving and Innovation:
  - Compounding pharmacists are problem-solvers who can address medication challenges and find suitable solutions. They have the ability to overcome formulation obstacles and find alternatives for patients with unique medication needs or preferences.
- Adherence to Quality Standards:
  - Compounding pharmacists adhere to stringent quality standards and follow guidelines set forth by regulatory bodies, such as USP. They ensure the integrity, safety, and potency of compounded medications through appropriate ingredient sourcing, proper compounding techniques, and quality assurance processes.
- Patient education and counseling
- Collaborative care
- Continuous learning → Compounding pharmacists stay updated with the latest compounding techniques, regulations, and advancements in pharmaceutical science

Pharmacy technicians play a crucial role in supporting the operations of a pharmacy and ensuring the safe and efficient delivery of medications and healthcare services

- Formulation
- Medication dispensing
- Prescription processing
- Medication inventory management
- Prescription filling
- Billing and insurance
- Medication safety
- Administrative tasks

Post-Test: True or False

1. All women with menopause symptoms should be treated with hormone replacement therapy. **False**
2. Bioidentical hormones are substances that have the same chemical and molecular structure as hormones that are produced in the human body. **True**
3. Hormone pellets can be compounded in any pharmacy as long as USP 795 requirements are met. **False**

References

- Peacock K, Ketvertis KM. Menopause. [Updated 2022 Aug 11]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan. Available from: https://www.ncbi.nlm.nih.gov/books/NBK507826
- Leslie Cho et al, Rethinking Menopausal Hormone Therapy: For Whom, What, When, and How Long?, Circulation (2023). DOI: 10.1161/CIRCULATIONAHA.122.061559
- Chester, RC, Kling, JM, Manson, JE. What the Women's Health Initiative has taught us about menopausal hormone therapy. *Clin Cardiol*. 2018;41:248–253. https://doi.org/10.1002/clc.22891
- Prentice, R.L., & Anderson, G.L. (2008). The women's health initiative: lessons learned. *Annual review of public health, 29*, 131-50 .
- Hays, J., Hunt, J.R., Hubbell, F.A., Anderson, G.L., Limacher, M.C., Allen, C., & Rossouw, J.E. (2003). The Women's Health Initiative recruitment methods and results. *Annals of epidemiology, 13 9 Suppl*, S18-77.
- Miller, V.M., Taylor, H.S., Naftolin, F., Manson, J.E., Gleason, C.E., Brinton, E.A., Kling, J.M., Cedars, M.I., Dowling, N.M., Kantarci, K., & Harman, S.M. (2020). Lessons from KEEPS: the Kronos Early Estrogen Prevention Study. *Climacteric, 24*, 139 - 145.
- Modis HN, Mack WJ, Henderson VW, et al. Vascular effects of early versus late postmenopausal treatment with estradiol. *N. Engl. J. Med.* 2016; 374: 1221-1231
- Cho, L., Kaunitz, A.M., Faubion, S.S., Hayes, S.N., Lau, E.S., Pristera, N., Scott, N., Shifren, J.L., Shufelt, C.L., Stuenkel, C.A., & Lindley, K.J. (2023). Rethinking Menopausal Hormone Therapy: For Whom, What, When, and How Long? *Circulation, 147*, 597 - 610.
- Endocrine Society Position Statement. Compounded Bioidentical Hormone Therapy. September 2019. https://www.endocrine.org/-/media/endocrine/files/advocacy/position-statement/position_statement_compound_biomedical_hormone_therapy.pdf. Accessed April 26, 2023.

References

- Jackson, L., Parker, R.M., & Mattison, D.R. (2020). The Clinical Utility of Compounded Bioidentical Hormone Therapy.
- United States Pharmacopeia Quality Standards. Available at: https://www.usp.org/compounding
- B., Jurow, A., Hart, K., & Rothenberg, A. (2019). *Hormonal BioIdentity Keeping your Patient Happy, healthy and Sexually Active*. Barrowberg Press.
- Steroid Hormone Metabolism. Available at: https://www.gfmer.ch/Books/Reproductive_health/Steroid_hormone_metabolism_Fig2.htm
- Stevenson JC, Rozenberg S, Maffei S, Egarter C, Stute P, Römer T. Progestogens as a component of menopausal hormone therapy: the right molecule makes the difference. Drugs Context. 2020 Dec 2;9:2020-10-1. doi: 10.7573/dic.2020-10-1. PMID: 33312219; PMCID: PMC7716720.
- S. Scheffers, S. Armstrong, AEP. Cantineau, C. Farquhar, V. Jordan Dehydroepiandrosterone for women in the peri- or postmenopausal phase. Cochrane Database of Systematic Reviews 2015, Issue 1. Art. No.: CD011066. DOI: https://doi.org/10.1002/14651858.CD011066.pub2
- Labrie, F., Archer, D.F., Koltun, W.D., Vachon, A., Young, D., Frenette, L., Portman, D.J., Montesino, M., Côté, I., Parent, J., Lavoie, L., BSc, A.B., Martel, C., Vaillancourt, M., Balser, J., & Moyneur, É. (2015). Efficacy of intravaginal dehydroepiandrosterone (DHEA) on moderate to severe dyspareunia and vaginal dryness, symptoms of vulvovaginal atrophy, and of the genitourinary syndrome of menopause. *Menopause, 25*, 1339–1353.
- Barton, D.L., Shuster, L.T., Dockter, T., Atherton, P.J., Thielen, J.M., Birrell, S.N., Sood, R., Griffin, P.C., Terstriep, S.A., Mattar, B.I., Lafky, J.M., & Loprinzi, C.L. (2018). Systemic and local effects of vaginal dehydroepiandrosterone (DHEA): NCCTG N10C1 (Alliance). *Supportive Care in Cancer, 26*, 1335-1343.

References

- Nathorst-böös, J., Flöter, A., Jarkander-Rolff, M., Carlström, K., & Schoultz, B.V. (2006). Treatment with percutanous testosterone gel in postmenopausal women with decreased libido--effects on sexuality and psychological general well-being. *Maturitas, 53 1*, 11-8 .
- Davis, S.R., & Wåhlin-Jacobsen, S. (2015). Testosterone in women--the clinical significance. *The lancet. Diabetes & endocrinology, 3 12*, 980-92 .
- Rahrovan, S., Fanian, F., Mehryan, P., Humbert, P., & Firooz, A. (2018). Male versus female skin: What dermatologists and cosmeticians should know. *International Journal of Women's Dermatology, 4*, 122 - 130.


Any
Questions