

FORM: 43 - HORMONE USE INTERVIEW

Version: 2 - July 8, 1994

Description: Interviewer-administered with colored hormone chart; 12-page form; key-entered at Clinical Center (CC).

When used: Administered during screening (usually at Screening Visit [SV1]) on all Clinical Trial (CT) and Observational Study (OS) participants.

Purpose: To collect information about lifetime hormone use.

GENERAL INSTRUCTIONS

1. Affix the participant's barcode label to the front of the form.
2. Conduct interview in a private area without interruptions. Encourage the participant to feel free to offer her best guess or estimate when she is unsure of an exact answer.
3. Show the participant the color photos of hormone preparations and show card of reasons as indicated on the form. Each CC received 1-2 sets of the 2-page color photos of hormone preparations. Keep the color photos in plastic sheet protectors to extend the useful life of the photos.
4. Review the form for completeness.
5. File the form in the participant's file before sending the file to Data Entry.
6. Data Entry: Review the form for completeness and consistency. Return to interviewer with any problems noted. Key-enter the form when problems have been corrected. Detailed instructions for key-entering this form are found in *Vol. 5 - Data System, Appendix B.3. - Step-by-Step Task Instructions*. Initial the first page of the questionnaire after key-entry.
7. File the key-entered form in the participant's file.

Item Instructions

Date of interview	Date of interview.
Completed by	Standard 3-digit WHI staff ID.
Contact type	Mark appropriate oval or box. (See common data items.)
Visit type	Contact at which you conduct the interview. (See common data items.)
5.-13. Hormone questions	<p>For Questions 5 - 13, you are frequently instructed to leave items blank if the answer is "unknown." Always explain blank items with a note in the margin of the form.</p> <p>Begin with the statement, "Now I have some questions about the use of female hormone medications." Give the participant the Show Card listing reasons for taking estrogen or progesterone. Remind the participant that the first set of questions is about hormones used during or after menopause, <u>not</u> hormones used for birth control.</p>
5. Menopausal hormone use	<p>No/Yes. Hormone replacement therapy may be given for the relief of menopausal symptoms or for other reasons such as to prevent bone loss. Record whether the participant ever took estrogen, progesterone, testosterone, or any hormones for any of these reasons.</p> <p>Data Entry: Do not key-enter.</p>
5.1. Pill cream/suppository patch shot	<p>Mark the ovals or boxes to indicate "No" or "Yes" for each form in which these hormones were given. If "Yes" to any of the forms of hormones, ask Question 5.2.</p> <p>Data Entry: Do not key-enter.</p>
5.2. Take for \geq 3 months	<p>Mark "No" or "Yes" for each hormone form the participant took. If hormone pills were taken (for three or more months), complete 6.1. - 6.12. for each episode of use. If hormones were taken as vaginal cream or suppositories (for three or more months), complete 7.1. - 7.12. If hormones were taken as skin patches (for three or more months), complete 8.1. - 8.12. If hormones were taken as shots (for three or more months), complete 9.1. - 9.12.</p> <p>Data Entry: Do not key-enter.</p>
6.1.- 6.12. Hormone pills	<p>Use this chart to record information about use of estrogen, progesterone, or testosterone pills. Complete one line of the chart for <u>each</u> episode of pill usage. Any change in the type of estrogen, a change in dose of estrogen, or the addition of progesterone to an estrogen regimen should be entered as a "new" episode of pill use. Progesterone taken in conjunction with estrogen is recorded in 6.8. - 6.12. Progesterone taken alone is recorded in 6.1. - 6.7. and leave 6.8. - 6.12. blank.</p>

6.1. Name and code

Record the name of the pill taken.

Use the colored hormone photos to assist in identifying specific pills used.

The hormone photos contain pictures of different hormone preparations, including pills, creams, suppositories, and skin patches. The preparations included are meant to be a representative selection of preparations available in the past 20 years or so. Obviously, it was not feasible to make a totally inclusive list. We tried to include some of the more common preparations used.

If a product name is mentioned that is not on the list, probe for spelling and dose. If the woman has the pill bottle, ask if you can see it and copy the name and dose directly from the bottle. Leave blank if the woman can't remember the name. Make a note in the margin of the form explaining that the woman couldn't remember.

Data Entry: Key-enter name for uncoded hormones.

Code of hormone used. Hormone coding sheets beginning on page 9 below provide listings of female hormones by type (estrogen, progesterone, testosterone), and include in alphabetical order the brand, dose, and codes for pills, cream or suppositories, skin patches, and injections.

A unique code has been assigned to each different dosage of each different product. Note that for each product formulation with more than one dose there is a code for unknown dose. Also note that there are codes provided if the product name itself is unknown. They are:

497 = Unknown pill; estrogen pill, brand unknown

498 = Unknown pill; progesterone pill, brand unknown

499 = Estrogen or progesterone pill, unsure which one and brand unknown

001 = Any testosterone or androgen pill, brand known or unknown

There are also "Unknown Dosage" codes for pills reported in unknown dosages or dosages other than those listed. See the list of codes beginning on page 9. The list of codes can also be printed from WHILMA from Reports/Study-Wide/Hormone Types.

6.2. Frequency and unit of measure

Record the number of pills taken per day or week. Record what the participant actually took, not what was prescribed. If the woman doesn't know or can't remember, leave blank.

For example, if a woman used Premarin 0.3 mg, two pills a day, code as

02 per ₁ Day.

If a woman used Premarin 0.625 mg, one pill per day, this would code as

01 per ₁ Day.

If a woman used Premarin 0.9 mg, one pill a day for five days per week, code as

05 per ₂ Week.

The major indication (reason for prescription) for the use of hormone preparation. Since specific indications vary by physician-prescribing pattern, this is somewhat difficult. In general, we can say that the estrogen preparations are used predominantly for menopausal replacement therapy (menopausal symptoms such as hot flashes, night sweats, vaginal dryness), and to prevent osteoporosis or cardiovascular disease. Progestins are used predominantly for their antiestrogenic activity in women on menopausal estrogen therapy.

Record the specific reason stated by the woman, and record the appropriate code from the list below (also on the showcard). If a woman states more than one reason (e.g., for menopausal symptoms and to prevent osteoporosis) for using the hormone, ask her which was the main reason (e.g., "What was the reason for the doctor's visit that resulted in your prescription for hormones?").

6.3. Reason

Reasons for taking estrogen or progesterone include the following:

- 01 - Menopause-related symptoms
(hot flashes, sweating, vaginal dryness, bladder problems)
- 02 - Depression, anxiety, emotional distress
- 03 - Replacement therapy after hysterectomy or oophorectomy (ovaries removed)
- 04 - Osteoporosis (bone loss), to prevent osteoporosis or bone loss (or thinning)
- 05 - Cardiovascular disease, to prevent cardiovascular disease
- 06 - Irregular menstrual periods, to regulate periods
- 07 - Treatment of disease (specify): _____
- 08 - Prevention of disease (specify): _____
- 09 - Anti-estrogen effect in a woman using menopausal estrogens
- 98 - Other (specify): _____
- 99 - Does not know

If the participant mentions "7 - Treatment of disease" or "8 - Prevention of disease", specify the disease. If the participant mentions "98 - Other," specify the reason.

Data Entry: Key-enter the text if "7 - Treatment of disease," "8 - Prevention of disease," or "98 - Other" are marked.

6.4. Age start

Participant's age when she started taking this pill, recorded as 2-digit number. If unknown, leave blank.

6.5. Age stop

Participant's age when she stopped taking this pill. If she is still taking the pill, record her current age. If unknown, leave blank.

6.6. Duration of use

Record the total duration of use of the hormone pill in years and months. If unknown, leave blank.

6.7. Cycles

Mark only one code. If the pill was given in cycles, such as three weeks on and one week off, mark "7 - In cycles" and specify what the cycles were. If the pill was given on a schedule other than those listed, mark "8 - Other" and record the schedule on the line provided. If unknown, leave blank.

Data Entry: Key-enter text for "7 - In cycles" and "8 - Other."

- 6.8. Taking progesterone Determine if the woman took an estrogen pill and a progesterone pill in the same month(s). Use the colored hormone photos provided to help determine if reported pills are estrogen or progesterone preparations. If the woman doesn't know or can't remember if she took progesterone, answer "No." Indicate in the margin that she couldn't remember.
- The following information about schedule patterns may prove useful to you in probing.
- If no intact uterus, the approach is usually either:
- Continuous (every day) estrogen;
 - Continuous estrogen with progesterone given for 10-14 days; or
 - Estrogen for days 1-25 with progesterone for 10-14 days (started either day 14 or day 20).
- If intact uterus, the approach is usually either:
- Estrogen for days 1-20 or 25 with progesterone for 10-14 days (started on day 14); or
 - Estrogen for days 1-20 or 25 with progesterone for 10-14 days (started on day 20); or
 - Continuous estrogen with continuous progesterone.
- 6.9. Name Determine the name of the progesterone pill that the woman took at the same time as the estrogen pill. Use the colored hormone photos to assist her in identifying the particular progesterone pill. If unknown, leave blank.
- Data Entry: Key-enter the name for uncoded progesterone.
- Code Record the code for the pill. If unknown, use code 498.
- 6.10. Dose Record the dose for the pill. If unknown, leave blank.
- 6.11. Days took hormones (calendar) Circle the first and last "E" representing the days of the month that the woman took estrogen. Connect the first "E" to the second "E" with a line to indicate a time period in the month when the estrogen was taken. Repeat this procedure for the progesterone pills taken in the same month as the estrogen pills.
- Start day estrogen The day the participant started taking the estrogen. Record the number above the first circled E.
- End day estrogen The day the participant last took estrogen. Record the number above the last circled E.
- Total days E Total number of days participant took estrogen, including the first and the last days. Count and record.
- Start day progesterone The day the participant started taking progesterone in conjunction with estrogen. Record the number above the first circled P.
- End day progesterone The day the participant last took progesterone. Record the number above the last circled P.
- Total days P Total number of days the participant took progesterone, including the first and the last days. Count and record.
- Total days E+P Total number of days the participant took both estrogen and progesterone on the same day. Count and record. *Do not add the total days E to the total days P.* If the woman can't remember the days of the month that she took estrogen or progesterone, leave these items blank.

EXAMPLE:

1 2 3 4 5	6 7 8 9 10	11 12 13 14 15	16 17 18 19 20	21 22 23 24 25	26 27 28 29 30	First Day	Last Day	Total Days
E E E E E P P P P P	E E E E E P P P P P	E E E E E P P P P (P)	E E E E E P P P P P	E E E E E (E) P P P P P (P)	E E E E E P P P P P	<u>0</u> <u>1</u> E <u>1</u> <u>5</u> P	<u>2</u> <u>5</u> E <u>2</u> <u>5</u> P	<u>2</u> <u>5</u> E <u>1</u> <u>1</u> P <u>1</u> <u>1</u> E + P
E E E E E P P P P P	E E E E E P P P P P	E E E E E P P P (P) P	E E E E E P P P P P	E E E E E (E) P P P P P	E E E E E (P) P P P P	<u>0</u> <u>1</u> E <u>1</u> <u>4</u> P	<u>2</u> <u>5</u> E <u>2</u> <u>6</u> P	<u>2</u> <u>5</u> E <u>1</u> <u>3</u> P <u>1</u> <u>2</u> E + P

6.12. How often progesterone Determine how often the woman took the progesterone pill - every month, every other month, every three months, every few months, or other. If "8 - Other," write the specific interval on the line provided.

Data Entry: Key-enter the test for "8 - Other."

7.1.- Vaginal
7.12. cream/suppository Check 5.2. to verify if the woman ever used hormone vaginal cream or suppositories. If so, continue with 7.1. - 7.12. If the woman can't remember or doesn't know if she used hormone cream or suppository, then leave 7.1. - 7.12. blank.

7.1.- Vaginal
7.6. cream/suppository Refer to the specifications given in 6.1. - 6.7.

7.2. Frequency Number of times per day, week, month, or year that the woman used the cream/suppository.

7.6a. Amount used For creams, use the following amount codes:

- 5 - 1/4 applicator or less
- 1 - 1/4-1/2 applicator
- 2 - 1/2 to one full applicator
- 3 - 1-2 applicators full
- 4 - More than two applicators full
- 9 - Unknown amount

7.7. Cycles Mark only one code. If unknown, leave blank.

7.8. Taking progesterone No/Yes. Determine if the woman used an estrogen vaginal cream or suppository and progesterone in the same months. If the woman doesn't know or can't remember, answer "No."

7.9.- Estrogen and
7.12. progesterone use Refer to the directions for answering 6.9. - 6.12.

8.1.- 8.12.	Hormone skin patches	Check 5.3. to verify if the woman reported ever using hormone skin patches. If so, continue with 8.1. - 8.12.
8.1.- 8.6.	Hormone skin patches	Refer to the specifications given in 6.1. - 6.7. in completing this series of questions.
8.2.	Frequency of change	Record the number of times per week (or month) the woman changed the patch. If unknown, leave blank.
8.7.	Cycles	For 8.7., we are interested in how many weeks per month the woman used the skin patches. Typically, this will be every week (continuous), but some woman may use them for three weeks then not use them for one week (in cycles). Record how the patches were used on the line provided. If unknown, leave blank.
8.8.- 8.12.	Estrogen and progesterone use	Refer to directions for 6.8. - 6.12.
9.1.- 9.12.	Hormone shots	Refer back to 5.4. to determine if the woman ever received estrogen, progesterone, or testosterone injections. If so, continue with 9.1. - 9.12. Refer to directions for 6.1. - 6.12.
9.1.	Code	Code of hormone shot. If the participant does not know the type of hormone, use the codes for unknown shot: 492 - Combined Estrogen-Progesterone injection, brand unknown. 493 - Estrogen injection, brand unknown. 495 - Estrogen and progesterone injection, brand unknown.
9.2.- 9.6.	Frequency, age, years	For unknown frequency of injection, age, and years, please ask the participant to give her best estimate of these answers.
9.7.	Cycles	Note that in 9.7. we are asking for the <u>cycles</u> with which the shots were administered.
10.	Birth control pills	No/Yes. Question 10 asks about use of birth control pills (oral contraceptives). If "Yes," go on to questions 10.1. - 10.5. If unknown, answer "No." Data Entry: Do not key-enter for "No."
10.1.	Age started	Participant's age when she first took birth control pills. Leave blank if unknown.
10.2.	Age stopped	Participant's age when she last took birth control pills. Leave blank if unknown.
10.3.	Duration of use	The total <u>lifetime</u> duration of use. Ask the woman how many years and months between (age in 10.1.) and (age in 10.2.) she took birth control pills. Remind her to <u>exclude</u> any years and months between (age in 10.1.) and (age in 10.2.) when she did <u>not</u> take birth control pills (e.g., during pregnancy). If unknown, leave blank.
10.4.	Use before first pregnancy	Use of birth control pills before a first term pregnancy. A term pregnancy for this question is defined as the first pregnancy lasting six months or more, regardless of outcome (e.g., live birth, stillbirth). If unknown, leave blank.
10.5.	Duration of use before first pregnancy	Total duration of use of birth control pills <u>before</u> the first term pregnancy. If unknown, leave blank.
11.	DES (diethylstilbestrol)	No/Yes. If "Yes," go on to Questions 11.1. - 11.3. If unknown, answer "No." Data Entry: Do not key-enter for "No."
11.1.	Age started	Participant's age at first use of DES. Leave blank if unknown.
11.2.	Age stopped	Participant's age at last use of DES. Leave blank if unknown.
11.3.	Duration of use	Total duration of use in years and months. Leave blank if unknown.

12. Depo-provera (DMPA) Use of depo-provera (DMPA or depo-medroxyprogesterone acetate) shots for birth control or other reasons (e.g., treatment of endometriosis). If 12 = "Yes," go on to Questions 12.1. - 12.4. If unknown, answer "No."
Data Entry: Do not key-enter for "No."
- 12.1. Frequency The frequency with which the shots were administered. Leave blank if unknown.
- 12.2. Age started Participant's age at first use. Leave blank if unknown.
- 12.3. Age stopped Participant's age at last use. Leave blank if unknown.
- 12.4. Duration of use The total number of years and months she took DMPA shots. Leave blank if unknown.
13. Other hormones No/Yes. Use of any other female hormones that have not already been recorded.
Data Entry: Do not key-enter.
- 13.1. Name The name of the hormone.
Data Entry: Do not key-enter.
- 13.2. Reason The reason the participant took the hormone.
Data Entry: Do not key-enter.
- 13.3. Form of hormone The type of preparation (e.g., pill, vaginal cream/suppository, skin patch, shot, other). If "Other," specify.
Data Entry: Do not key-enter.

