

Date of interview : \_\_\_/\_\_\_/\_\_\_

## CORTICOSTEROID EFFECTS PHONE QUESTIONNAIRE

All Patients : initial interview

May I please speak with Mr./Ms. \_\_\_\_\_? (Do not write patient's name on questionnaire!) If patient is not available, record date & time call was placed, and try again later.

Attempted calls : date \_\_\_/\_\_\_/\_\_\_ time : \_\_\_\_\_  
 date \_\_\_/\_\_\_/\_\_\_ time : \_\_\_\_\_  
 date \_\_\_/\_\_\_/\_\_\_ time : \_\_\_\_\_ .

Hello, Mr./Ms. \_\_\_\_\_. My name is \_\_\_\_\_ and I am calling from \_\_\_\_\_. Recently, you received some information regarding a study being conducted at the Medical College of Virginia. Is that correct?

*If patient did not receive such information, verify the name and address of the person to whom you are talking. Explain to the patient that he/she will receive the letter in a few days and thank him/her for his/her time. End interview.*

I'd like to ask you a few questions. This interview should last about 15 minutes. All the information we collect today will not have your name on it and will be completely confidential. Would you be willing to participate?

*If no, thank patient for his/her time. End interview.*

*If yes :*

Is now a good time for me to interview you?

*If no, reschedule and call back.*

*If yes :*

Good! Thank you for agreeing to participate. After our talk today, I would like to send you some information in the mail, and then if you'll let me, I'd like to call you again in six months to see how things are going and if there are any changes in your health.

Today, I am calling to see what you know about some of the side effects of your medicines, and to help you learn more about ways of preventing these side effects. Recently, I have talked to your doctor/pharmacist and I understand that you are taking a corticosteroid medication. Is that correct?

*If no, verify information. End interview.*

*If yes :*

1. [Ctsd, 1-9] What is the name of the corticosteroid you are currently taking?

- |                |                 |                |                   |
|----------------|-----------------|----------------|-------------------|
| (1) prednisone | (2) medrol      | (3) orasone    | (4) dexamethasone |
| (5) deltasone  | (6) other _____ | (7) don't know | (9) none          |

*Note : If the corticosteroid being taken by the patient is something other than prednisone, insert the correct name in place of “prednisone” throughout the questionnaire. Also, for our study, we’ll use only patients currently taking prednisone, medrol, deltasone, orasone or dexamethasone*

**2. [Nwdse/mg/d, 8 or mg/d]** What is your current dose? *If the patient is currently taking less than 5 mg/d, they are not eligible for participation in the study. The required dose criterion was part of the eligibility checklist during chart review.*

- (1) 5-9 mg/d                      (2) 10-14 mg/d                      (3) 15-19 mg/d                      (4) 20-29 mg/d  
 (5) 30-39 mg/d                      (6) 40-49 mg/d                      (7) <sup>≥</sup> 50 mg/d                      (8) **don't know**  
 (9) \_\_\_\_\_dose/mg/day

*Questions #3 and #4 build to #5. The total mg of corticosteroid taken over the past 4 weeks is the important information, and is to be entered in the database. **Enter dose as mg/d for both nwdse & mnthdse in database.***

3. Do you take the same dose every day?    yes                      no                      don't know

4. If not, what dose do you take on the different days? \_\_\_\_\_mg/d    don't know

**5. [Mnthdse/mg/d, 8 or mg/d]** Think about the past four weeks. Please tell me what dose of \_\_\_\_\_prednisone\_\_\_\_\_ you were taking for each week.

- Week 1 \_\_\_\_\_mg/d.  
 Week 2 \_\_\_\_\_mg/d.                      **Mean dose** \_\_\_\_\_mg/day  
 Week 3 \_\_\_\_\_mg/d.  
 Week 4 \_\_\_\_\_mg/d.

*(The interviewer may have to calculate this separately. Just get a month's history of the medication and then calculate.)*

Cumulative dose for the past 4 weeks :

- (1) <50 mg    (2) 50-99 mg    (3) 100-299 mg    (4) 300-499 mg    (5) 500-999 mg    (6) 1000-1500 mg  
 (7) >1500 mg    (8) **don't know**    (9) \_\_\_\_\_monthly dose in mg/day

**6. [Uslngh, 1-6]** How long would you estimate you have been using \_\_\_\_\_prednisone\_\_\_\_\_?

**Since (date or exact # of years/months)** \_\_\_\_\_

- (1) <1 year    (2) 1-2 years    (3) 3-5 years    (4) 5-10 years    (5) >10 years    (6) don't know

**7. [Dx, 1-17]** What is the health problem for which you are taking the medicine?

- (1) asthma    (2) chronic obstructive pulmonary disease (COPD)  
 (3) rheumatoid arthritis (RA)                      (4) multiple sclerosis (MS)  
 (5) arthritis, other or unknown type                      (6) systemic lupus erythematosus (SLE)  
 (7) polymyositis    (8) dermatomyositis  
 (9) transplant    (10) cancer  
 (11) polymyalgia rheumatica                      (12) vasculitis  
 (13) sarcoid    (14) Crohn's disease  
 (15) ulcerative colitis  
 (16) don't know  
 (17) [Dxothr] other \_\_\_\_\_

*Note: If the response here is **CANCER**, then this person is not eligible for the intervention because prednisone treatment*

is temporary in cancer patients and the risk would not apply to them. Thank them for their time.

8. Are there any other illnesses or health problems you have?

[Hlthprob1] - [Hlthprob10]. For the interview, just check off or write in the ones mentioned. Then enter in to the database the names. Use periods for no or missing responses.

<u>Respiratory</u>	<u>Cardiovascular</u>	<u>Genito-urinary</u>	<u>Gastrointestinal</u>
<input type="checkbox"/> COPD	<input type="checkbox"/> angina	<input type="checkbox"/> kidney infection	<input type="checkbox"/> ulcerative colitis
<input type="checkbox"/> asthma	<input type="checkbox"/> CHF	<input type="checkbox"/> renal insufficiency	<input type="checkbox"/> Crohn's disease
	<input type="checkbox"/> hypertension	<input type="checkbox"/> kidney stone	<input type="checkbox"/> gastritis
	<input type="checkbox"/> myocardial infarction		<input type="checkbox"/> peptic ulcer
	<input type="checkbox"/> peripheral vascular disease		<input type="checkbox"/> hepatitis
			<input type="checkbox"/> jaundice
<u>Rheumatic diseases</u>	<u>Neurological</u>	<u>Endocrine/Metabolic</u>	<u>Neoplastic</u>
<input type="checkbox"/> lupus (SLE)	<input type="checkbox"/> convulsions (seizures)	<input type="checkbox"/> diabetes	<input type="checkbox"/> cancer
<input type="checkbox"/> temporal arthritis	<input type="checkbox"/> stroke	<input type="checkbox"/> hyperthyroidism	(May not be active so can
<input type="checkbox"/> polymyalgia rheumatica		<input type="checkbox"/> hypothyroidism	finish questionnaire)
<input type="checkbox"/> vasculitis		<input type="checkbox"/> hyperlipidemia	
<u>Immunological</u>	<u>Dermatological</u>	<u>Other</u>	
<input type="checkbox"/> immune deficiency	<input type="checkbox"/> psoriasis	_____	
<input type="checkbox"/> allergy		_____	
		_____	
		_____	
<input type="checkbox"/> <u>NO</u>			

Some of the next questions I am going to ask you are general information about yourself and some relate more specifically to prednisone, what you know about it, and why you take it. If you have questions at any point during our talk, please don't hesitate to stop me and ask.

9. [Speclty, 1-10] What type of doctor prescribed prednisone?

1. Family physician
2. Internal Medicine (internist)
3. Allergy specialist (allergist)
4. Specialist in treating diseases of the stomach, liver, and bowels (gastroenterologist)
5. Kidney specialist (nephrologist)
6. Lung specialist (pulmonary)
7. Arthritis specialist (rheumatologist)
8. Specialist in treating diseases of the brain and nerves (neurologist)
9. Eye specialist (ophthalmologist)
10. Don't know (then get first and last name of doctor and address to verify \_\_\_\_\_)

If more than one doctor has told the patient to use a corticosteroid, then ask which one changes the prescription. That one should be the primary doctor in this case.

10. What other medications are you currently taking? (Attempt to get brand names here by asking person to get bottles and read to you)

- 1. medicine [Mds1] \_\_\_\_\_
- 2. medicine [Mds2] \_\_\_\_\_
- 3. medicine [Mds3] \_\_\_\_\_
- 4. medicine [Mds4] \_\_\_\_\_
- 5. medicine [Mds5] \_\_\_\_\_
- 6. medicine [Mds6] \_\_\_\_\_
- 7. medicine [Mds7] \_\_\_\_\_
- 8. medicine [Mds8] \_\_\_\_\_
- 9. medicine [Mds9] \_\_\_\_\_
- 10. medicine [Mds10] \_\_\_\_\_

11. Just to be sure, are you taking any of the following?

estrogen [Estrgn, 1-3]	(1) Yes	(2) No	(3) Don't know
calcium [Ca, 1-3]	(1) Yes	(2) No	(3) Don't know
bisphosphonates [Bsphs, 1-3]	(1) Yes	(2) No	(3) Don't know
Vitamin D [VtD, 1-3]	(1) Yes	(2) No	(3) Don't know
calcitonin [Clcit, 1-3]	(1) Yes	(2) No	(3) Don't know
fluoride [Flrd, 1-3]	(1) Yes	(2) No	(3) Don't know
vitamin pill [Vit, 1-3]	(1) Yes	(2) No	(3) Don't know

If the patient is currently taking a vitamin, what is the name of it? [Vitnme] \_\_\_\_\_

\*\* Ask patient to get bottle, what is the brand name? \*\*

Circle one : (in the database, enter "9" if no medicine is being taken)

- [Estrmd, 1-4] estrogen medicine : (1) premarin, (2) estralert, (3) estrone, (4) other \_\_\_\_\_
- [Bismd, 1-2] bisphosphonates : (1) didronel (etidronate), (2) fosamax (alendronate)
- [Calcitmd, 1-3] calcitonin : (1) miacalcin, (2) calamor, (3) calcimax
- [Camd, 1-3] calcium sources : (1) Oscal, (2) Tums, (3) Citracal, (4) vitamin (type \_\_\_\_\_), (5) Other \_\_\_\_\_ [Calname]

If the patient is currently taking calcium what is the name of it? \_\_\_\_\_

\*\* Ask patient to get bottle, what is the brand name? \*\*

If the patient is currently taking calcium, how much calcium per day is he or she taking? \_\_\_\_\_ mg  
 or mg/tab \_\_\_\_\_  
 or # of tablets \_\_\_\_\_

[TypeCa, 1-5] Type of calcium: (1) carbonate, (2) gluconate, (3) lactate, (4) acetate, (5) other \_\_\_\_\_

- [Cadse, 1-99] (1) < 200 mg/d (2) 200-499 mg/d (3) 500-999 mg/d  
 (4) 1000-1499 mg/d (5) 1500-1999 mg/d (6) 2000-3000 mg/d  
 (7) > 3000 mg/d (8) don't know (9) none

12. [PstBMdmeds& typ, 1-3] Have you taken any of these medicines in the **past**?

(1)yes (2)no (3)don't know

13. [Se, 1-3] Do you remember what you were told about possible side effects of prednisone ?

(1) yes (2) no (3) don't know

*Do not read the list to the patient, just mark appropriately if the patient states that he or she knows about the symptom.*

- \_\_\_ 1. Mood changes [Mood, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 2. Difficulty sleeping [Slp, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 3. Weight gain [Wtgn, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 4. Acne or blemishes [Acne, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 5. High blood pressure [Htn, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 6. High blood sugar (diabetes) [Dibetes, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 7. Osteoporosis [Osteo, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 8. Easy bruising of the skin [Brusng, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 9. Cataracts [Ctrct, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 10. Glaucoma (increased pressure in the eye) [Glacma, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 11. Gastritis (upset stomach, acid stomach, ulcers) [Gstrits, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 12. Muscle weakness [Msclwek , 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 13. other [othse1, 2-3] \_\_\_\_\_ yes (2) no (3) don't know
- \_\_\_ 14. other [othse2, 2-3] \_\_\_\_\_ yes (2) no (3) don't know
- \_\_\_ 15. other [othse3, 2-3] \_\_\_\_\_ yes (2) no (3) don't know

13. [Septlst, 1-3]What side effects are you aware of or have you experienced since you began taking prednisone? *Do not read the list to the patient, just mark appropriately if the patient states that he or she knows about the symptom.*

(1) yes (2) no (3) don't know

- \_\_\_ 1. Mood changes [Moodx, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 2. Difficulty sleeping [Slpx, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 3. Weight gain [Wtgnx, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 4. Acne or blemishes [Acnex, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 5. High blood pressure [Htnx, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 6. High blood sugar (diabetes) [Dibetsx, -1-3] (1) yes (2) no (3) don't know
- \_\_\_ 7. Osteoporosis [Osteox, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 8. Easy bruising of the skin [Brsngx, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 9. Cataracts [Ctrctx, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 10. Glaucoma (increased pressure in the eye) [Glcmax, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 11. Gastritis (upset stomach, acid stomach, ulcers) [Gstirsx, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 12. Muscle weakness [Msclwekx, 1-3] (1) yes (2) no (3) don't know
- \_\_\_ 13. other [othrse, 2-3] \_\_\_\_\_ yes (2) no (3) don't know
- \_\_\_ 14. other [othrse2, 2-3] \_\_\_\_\_ yes (2) no (3) don't know
- \_\_\_ 15. other [othrse3, 2-3] \_\_\_\_\_ yes (2) no (3) don't know

*For options #12-13, enter the names into databases if other side effects are mentioned. Otherwise, enter "(2) no".*

14. [Wkbns, 1-3] Has anyone ever mentioned or talked with you about the possibility that long term prednisone use can lead to weaker bones, a condition called osteoporosis?

(1) Yes (2) No (3) Don't know

15. **[Bntst, 1-3]** Are you aware that there is a test that can measure how strong your bones are?  
 This test is called Densitometry or Bone Mineral Density.  
 (1) Yes (2) No (3) Don't know

If no, then go to #17.

16. **[Tstrn, 1-4]** Have you ever had this test?  
 (1) Yes (2) No (3) Don't know (4) patient says 'yes', but it seems doubtful to interviewer

If yes, when was it done **[tstdt]**     \_\_\_ / \_\_\_ / \_\_\_  
 Where was it done? **[tstlc]**     \_\_\_\_\_   
 Who ordered it? **[tstdc]**     \_\_\_\_\_   
 What kind of doctor is he/she? **[tstdc]**     \_\_\_\_\_   
 What was the result? **[tstrslt]**     \_\_\_\_\_   
 (1) Normal\_\_\_ OK\_\_\_or High\_\_\_ (2) Lo\_\_\_Osteoporosis\_\_\_ (3) Don't know\_\_\_ (4) Osteopenia\_\_\_  
 Did you receive any shots during the test? **[tstsht, 1-3]**  
 (1) Yes (2) No (3) Don't know

17. **[Bmdmed, 1-3]** Do you know of any medications or vitamins that will keep your bones strong during prednisone treatment?  
 (1) Yes (2) No (3) Don't know

If yes, then which ones? (A 'b' preceding the field name indicates that the patient knew about the medication and its beneficial effects on bone strength.)

estrogen <b>[Bestrgn, 1-3]</b>	(1) Yes	(2) No	(3)don't know
calcium <b>[Bca, 1-3]</b>	(1) Yes	(2) No	(3)don't know
bisphosphonates <b>[Bbsphs, 1-3]</b>	(1) Yes	(2) No	(3)don't know
Vitamin D <b>[Bvtd, 1-3]</b>	(1) Yes	(2) No	(3)don't know
calcitonin <b>[Bclcit, 1-3]</b>	(1) Yes	(2) No	(3)don't know
fluoride <b>[Bflrd, 1-3]</b>	(1) Yes	(2) No	(3)don't know
vitamin pill <b>[Bvtmn, 1-3]</b>	(1) Yes	(2) No	(3)don't know
<b>other [Bothr]</b>	_____		

Check # 11 for similar answers

20. **[Bonesave, 1-3]** Do you know about things you can do besides taking medicines that might protect your bone strength?  
 (1) Yes (2) No (3) Don't know

If no, go to question #22.

21. **[Bnsv 1-5, 1-3]** What sorts of things can protect your bone strength?  
 More than one answer may be given. (1) Yes (2) No (3) Don't know  
 (1) exercise (2) diet (3) no smoking  
 (4) no alcohol  
 (5) other **[Bnsvothr]** \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Finally, I would like to ask some information about you. We would like to be able to put together a profile of the types of people we talk to. You can choose not to answer any question that you don't want to answer.

First, verify the address as printed in (PATIENT.WB2) (QuattroPro). For the sake of confidentiality, do not write the address on this sheet.

22. **[Brthyr, 01-99]** In what year were you born? Enter the last two digits of the birth year.

1 9 \_\_\_ \_\_\_ (99) don't know

23. **[Sex, 1-3]** Sex (silent) : (1) male (2) female (3) don't know

24. **[Hse, 1-4]** How would you describe where you presently live?

(1) urban (2) suburban (3) rural (4) don't know

25. **[Rce, 1-7]** Are you? :

\_\_\_ (1) African American

\_\_\_ (2) Asian American

\_\_\_ (3) Hispanic

\_\_\_ (4) Native American

\_\_\_ (5) Caucasian (white)

\_\_\_ (6) other \_\_\_\_\_ (Please specify)

\_\_\_ (7) don't know

26. **[Edu, 1-8]** What is the grade you completed in school?

(1) never entered high school

(2) not a high school graduate

(3) high school graduate

(4) some college, but did not graduate; 2 year college or technical school

(5) college graduate

(6) some education after college

(7) professional

(8) don't know

27. **[Insrnce, 1-3]** Do you have health insurance? (1) yes (2) no (3) don't know

If so, go to #28.

**28. [Insrntyp1&2, 1-8]** What type is it? (*Circle the response given. More than one may be circled.*)

- (1) *Medicaid*                      (2) *Medicare*                      (3) *HMO*  
(4) *Blue Cross / Blue Shield*    (5) *Commercial*                      (6) *other* : \_\_\_\_\_  
(7) *don't know*                      (8) *Uninsured*

[HMO is the abbreviation for Health Maintenance Organization. An HMO is a company similar to an insurance company except they are more in control of your health care. You have one doctor, called your primary care doctor, who you go to see for all your problems. That doctor then decides whether or not you need to see a specialist. Sometimes the HMO makes you choose your primary care doctor from their list.]

**29. [Incme, 1-7]** What is your household income level? (Read all categories first)

- (1) *< \$20,000*    (2) *\$20,000-50,000*    (3) *\$51,000-75,000*    (4) *> \$75,000*  
(5) *don't know*    (6) *disability*                      (7) *decline*

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Mr./Ms. \_\_\_\_\_, thank you very much for your time. We would like to send you a pamphlet about the possible side effects of prednisone. May we do that for you? *Yes/No.*

*If yes, verify address.*

Also, may I call you again in six months to see if this has been helpful? *Yes/No.*

Thank you again for your time. Good-bye.

*End of interview.*