



HARVARD SCHOOL OF PUBLIC HEALTH

Health Professionals Follow-Up Study

January 2016

Dear Colleague,

Thank you for your longstanding participation in the Health Professionals Follow-Up Study. As you know, we are studying the determinants of long-term survival from prostate cancer. Through this study, we are gaining valuable insight about how diet and other factors can improve prognosis. **Please note that we have all of your original diagnosis information. The purpose of this mailing, as we do every couple of years, is to obtain new follow-up information regarding your prostate cancer. Even if nothing has changed, that information is still important to our study.**

We would greatly appreciate it if you could complete the enclosed questionnaire regarding your prostate cancer and return it to us in the envelope provided. We realize this is a lengthy questionnaire; please fill out whatever you can. Your participation is completely voluntary, and if you do not wish to participate in this study on prostate cancer survival, you will still be a valuable member of the Health Professionals Follow-Up Study. By participating, you will be making a key contribution to our understanding of prostate cancer, which may ultimately lead to strategies geared at prevention or cure. Please do not hesitate to call me or Dr. Edward Giovannucci at 617-384-8663 if you have any questions about the study.

Sincerely Yours,

Walter Willett

Walter Willett, MD, DrPH
Professor of Nutrition and Epidemiology
Harvard School of Public Health



PLEASE USE AN ORDINARY NO. 2 PENCIL TO ANSWER ALL QUESTIONS.

Fill in the appropriate response circles completely, or write the requested information in the boxes provided. The form is designed to be read by optical-scanning equipment, so it is important that you make **NO STRAY MARKS** and keep any write-in responses within the spaces provided. Should you need to change a response, erase the incorrect mark completely. If you have comments, please write them on a separate piece of paper.

Please fill in the circles completely; do not mark this way:

EXAMPLE

15. Please read the *entire* list below of medications and treatments for prostate cancer and prostate cancer symptoms. Mark all of the treatments you have had SINCE JANUARY 2014 and provide the dates as best you can (if you cannot remember the month, include just the year).

Treatment/medication since January 2014 only	Start date or procedure date	End date or...	...Currently doing/taking?
1. <input type="radio"/> No new treatment since January 2014	N/A	N/A	N/A
2. <input type="radio"/> No treatment ever / continued active surveillance	N/A	N/A	N/A
Procedures	month/year	month/year	
3. <input checked="" type="radio"/> Radical prostatectomy	01/2014	N/A	
If radical prostatectomy, which type?	N/A	N/A	
<input type="radio"/> laparoscopic	N/A	N/A	
<input checked="" type="radio"/> robotic	N/A	N/A	
<input type="radio"/> open / retropubic	N/A	N/A	
<input type="radio"/> open / perineal	N/A	N/A	
<input type="radio"/> don't know type	N/A	N/A	
4. <input checked="" type="radio"/> Radiation to the pelvis (external beam, proton beam, cyberknife, etc.)	02/2014		<input checked="" type="radio"/>
5. <input type="radio"/> Brachytherapy/seeds		N/A	<input type="radio"/>
6. <input type="radio"/> Orchiectomy		N/A	<input type="radio"/>
7. <input type="radio"/> Cryosurgery/cryoablation		N/A	<input type="radio"/>
8. <input type="radio"/> High intensity focused ultrasound		N/A	<input type="radio"/>

The research team has great respect for your continued study participation, and therefore would like to remind you of several important points, as is standard practice in research. We do so in recognition of the fact that consent is an ongoing process rather than a one-time agreement. Please do not hesitate to contact us if you have any questions regarding this information.

- a. You are participating in a research study that focuses on how to decrease the risk of prostate cancer in men. Participation involves the completion of questionnaires.
- b. Your participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.
- c. There is a small risk of breach of confidentiality; however we have taken many steps to minimize this risk.
- d. Samples are sometimes shared with entities outside of Harvard as part of research collaborations; in such cases we use a separate ID number to ensure confidentiality.
- e. You will not receive monetary compensation for participating.
- f. There are no direct benefits to you from study participation.
- g. If you wish to speak with someone not directly involved in this research study about your rights as a research participant, please contact the Harvard School of Public Health's Office for Human Research Administration at 617-432-2143 (local calls) or 866-606-0573 (long distance calls), or at: ohra@hsph.harvard.edu.
- h. If you have any questions regarding the study itself, please call the study research coordinator at 617-384-8663.

THANK YOU FOR PREVIOUSLY PROVIDING VALUABLE INFORMATION RELATED TO YOUR PROSTATE CANCER.
PLEASE NOTE THAT WE HAVE ALL OF YOUR ORIGINAL DIAGNOSIS INFORMATION.
WE NOW SEEK TO UPDATE YOUR INFORMATION.

URINARY AND BOWEL FUNCTION

This section is about your urinary and bowel habits. Please consider your function over THE LAST 4 WEEKS ONLY.

1. Over the PAST 4 WEEKS, how often have you leaked urine? (Please select only one)

- Rarely or never
- About once a week
- About once a day
- More than once a week
- More than once a day

2. Which of the following best describes your urinary control DURING THE LAST 4 WEEKS? (Please select only one)

- Total control
- Occasional dribbling
- Frequent dribbling
- No urinary control whatsoever

3. How many pads or adult diapers per day did you usually use to control leakage DURING THE LAST 4 WEEKS? (Please select only one)

- None
- 1 pad per day
- 2 pads per day
- 3 or more pads per day

4. How big a problem, if any, has each of the following been for you DURING THE LAST 4 WEEKS?

	No problem	Very small problem	Small problem	Moderate problem	Big problem
a. Dripping or leaking urine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Pain or burning on urination	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Bleeding with urination	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Weak urine stream or incomplete emptying	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Need to urinate frequently	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

5. Overall, how big a problem has your urinary function been for you DURING THE LAST 4 WEEKS? (Please select only one)

- No problem
- Very small problem
- Small problem
- Moderate problem
- Big problem

1	2	3	4	2014	1	1	1	1	1	1	1	1
5	6	7	8	2015	2	2	2	2	2	2	2	2
9	10	11	12	2016	4	4	4	4	4	4	4	4
					8	8	8	8	8	8	8	8
					P	P	P	P	P	P	P	P

PLEASE TURN PAGE OVER

6. How big a problem, if any, has each of the following been for you DURING THE LAST 4 WEEKS?

	No problem	Very small problem	Small problem	Moderate problem	Big problem
a. Urgency to have a bowel movement	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Increased frequency of bowel movements	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Losing control of your stools	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Bloody stools	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Abdominal/pelvic/rectal pain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

7. Overall, how big a problem have your bowel habits been for you DURING THE LAST 4 WEEKS? (Please select only one)

- No problem
- Very small problem
- Small problem
- Moderate problem
- Big problem

SEXUAL FUNCTION

This section is about your sexual function and satisfaction. Many of the questions are very personal, but they will help us understand the important issues that you face every day. Remember, your answers to this questionnaire will be kept confidential and will be used only for research purposes.

Please consider your function over THE LAST 4 WEEKS ONLY. Please answer even if you are using medications or devices, or are not currently sexually active.

8. How would you rate each of the following DURING THE LAST 4 WEEKS?

	Very good	Good	Fair	Poor	Very poor to none	Not applicable
a. Your ability to have an erection?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Your ability to reach orgasm (climax)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

9. How would you describe the usual QUALITY of your erections DURING THE LAST 4 WEEKS? (Please select only one)

- Firm enough for intercourse
- Firm enough for masturbation and foreplay only
- Not firm enough for any sexual activity
- None at all
- Not applicable

10. How would you describe the FREQUENCY of your erections DURING THE LAST 4 WEEKS? (Please select only one)

- I had an erection WHENEVER I wanted one
- I had an erection MORE THAN HALF the time I wanted one
- I had an erection ABOUT HALF the time I wanted one
- I had an erection LESS THAN HALF the time I wanted one
- I NEVER had an erection when I wanted one during the last 4 weeks
- Not applicable

11. Overall, how would you rate your ability to function sexually DURING THE LAST 4 WEEKS? (Please select only one)

- Very good
- Good
- Fair
- Poor
- Very poor
- Not applicable

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12. Overall, how big a problem has your sexual function or lack of sexual function been for you DURING THE LAST 4 WEEKS? (Please select only one)

- No problem
- Very small problem
- Small problem
- Moderate problem
- Big problem

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HORMONAL/VITALITY FUNCTION

This section is about your hormonal and vitality function. Please consider your function over THE LAST 4 WEEKS ONLY.

13. How big a problem, if any, has each of the following been for you DURING THE LAST 4 WEEKS?

13

	No problem	Very small problem	Small problem	Moderate problem	Big problem
a. Hot flashes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Breast tenderness/enlargement	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Feeling depressed	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Lack of energy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Change in body weight	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

a

b

c

d

e

14. The questions in this scale ask you about your feelings and thoughts during the last month. In each case, please indicate how often you felt or thought a certain way.

14

	Never	Almost never	Sometimes	Fairly often	Very often
a. In the last month, how often have you felt that you were unable to control the important things in your life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. In the last month, how often have you felt confident about your ability to handle your personal problems?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. In the last month, how often have you felt that things were going your way?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

a

b

c

d

1	1	1	1	1	1	1	1
2	2	2	2	2	2	2	2
4	4	4	4	4	4	4	4
8	8	8	8	8	8	8	8
P	P	P	P	P	P	P	P

3/8 PERF

15. Please read the *entire* list below of medications and treatments for prostate cancer and prostate cancer symptoms. Mark all of the treatments you have had SINCE JANUARY 2014 and provide the dates as best you can (if you cannot remember the month, include just the year).

Treatment/medication since January 2014 only	Start date or procedure date	End date or...	...Currently doing/taking?	FOR OFFICE USE ONLY
1. <input type="radio"/> No new treatment since January 2014	N/A	N/A	N/A	Treatment Code: 1 2 3 4 5 6 7 8
2. <input type="radio"/> No treatment ever / continued active surveillance	N/A	N/A	N/A	9 10 11 12 13 14 15 16
Procedures	month/year	month/year		17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32
3. <input type="radio"/> Radical prostatectomy		N/A		Start month/year: 1 2 3 4 Before 2014
➔ If radical prostatectomy, which type?	N/A	N/A		5 6 7 8 2014 2015
<input type="radio"/> laparoscopic	N/A	N/A		9 10 11 12 2016 2017
<input type="radio"/> robotic	N/A	N/A		End month/year: 1 2 3 4 2014 2015
<input type="radio"/> open / retropubic	N/A	N/A		5 6 7 8 2016 2017
<input type="radio"/> open / perineal	N/A	N/A		9 10 11 12
<input type="radio"/> don't know type	N/A	N/A		
4. <input type="radio"/> Radiation to the pelvis (external beam, proton beam, cyberknife, etc.)			<input type="radio"/>	
5. <input type="radio"/> Brachytherapy/seeds		N/A	<input type="radio"/>	Treatment Code: 1 2 3 4 5 6 7 8
6. <input type="radio"/> Orchiectomy		N/A	<input type="radio"/>	9 10 11 12 13 14 15 16
7. <input type="radio"/> Cryosurgery/cryoablation		N/A	<input type="radio"/>	17 18 19 20 21 22 23 24
8. <input type="radio"/> High intensity focused ultrasound		N/A	<input type="radio"/>	25 26 27 28 29 30 31 32
Oral medications	month/year	month/year		Start month/year: 1 2 3 4 Before 2014
9. <input type="radio"/> Casodex (bicalutamide)			<input type="radio"/>	5 6 7 8 2014 2015
10. <input type="radio"/> Eulexin (flutamide)			<input type="radio"/>	9 10 11 12 2016 2017
11. <input type="radio"/> Estrogens and DES			<input type="radio"/>	End month/year: 1 2 3 4 2014 2015
12. <input type="radio"/> Nilandron (nilutamide)			<input type="radio"/>	5 6 7 8 2016 2017
13. <input type="radio"/> Zytiga (abiraterone)			<input type="radio"/>	9 10 11 12
14. <input type="radio"/> Xtandi (enzalutamide)			<input type="radio"/>	
Injections/implants/infusions	month/year	month/year		Treatment Code: 1 2 3 4 5 6 7 8
15. <input type="radio"/> Lupron/Eligard/Viadur (leuprolide)			<input type="radio"/>	9 10 11 12 13 14 15 16
16. <input type="radio"/> Zoladex (goserelin)			<input type="radio"/>	17 18 19 20 21 22 23 24
17. <input type="radio"/> Trelstar (triptorelin)			<input type="radio"/>	25 26 27 28 29 30 31 32
18. <input type="radio"/> Abarelix (plenaxis)			<input type="radio"/>	Start month/year: 1 2 3 4 Before 2014
19. <input type="radio"/> Firmagon (degarelix)			<input type="radio"/>	5 6 7 8 2014 2015
20. <input type="radio"/> Vantas (histrelin)			<input type="radio"/>	9 10 11 12 2016 2017
21. <input type="radio"/> Zometa (zoledronic acid)			<input type="radio"/>	End month/year: 1 2 3 4 2014 2015
22. <input type="radio"/> Xgeva (denosumab)			<input type="radio"/>	5 6 7 8 2016 2017
23. <input type="radio"/> Jevtana (cabazitaxel)			<input type="radio"/>	9 10 11 12
24. <input type="radio"/> Taxotere (docetaxel)			<input type="radio"/>	
25. <input type="radio"/> Provenge (sipuleucel-T)			<input type="radio"/>	
26. <input type="radio"/> Xofigo (alpharadin)			<input type="radio"/>	
Other or prostate symptom controls	month/year	month/year		Treatment Code: 1 2 3 4 5 6 7 8
27. <input type="radio"/> Finasteride/Proscar			<input type="radio"/>	9 10 11 12 13 14 15 16
28. <input type="radio"/> Dutasteride/Avodart			<input type="radio"/>	17 18 19 20 21 22 23 24
29. <input type="radio"/> Flomax/Tamulosin/Alfuzosin			<input type="radio"/>	25 26 27 28 29 30 31 32
30. <input type="radio"/> Vaccine/clinical trial drug			<input type="radio"/>	Start month/year: 1 2 3 4 Before 2014
31. <input type="radio"/> OTHER, specify: <div style="border: 1px solid black; height: 40px; width: 100%; margin-top: 5px;"></div>			<input type="radio"/>	5 6 7 8 2014 2015
				9 10 11 12 2016 2017
32. <input type="radio"/> OTHER, specify: <div style="border: 1px solid black; height: 40px; width: 100%; margin-top: 5px;"></div>			<input type="radio"/>	End month/year: 1 2 3 4 2014 2015
				5 6 7 8 2016 2017
				9 10 11 12

15

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16. Which erectile dysfunction medications have you used since January 2014?

NAME OF MEDICATION/TREATMENT	STARTED COURSE BEFORE 2014	2014	2015	2016	2017	CURRENTLY TAKING						
<input type="radio"/> None												
<input type="radio"/> Viagra, Levitra, Cialis, other-related							<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/> Intraurethral/penile injectable medications							<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/> Vacuum devices							<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/> Penile prosthesis							<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/> Testosterone replacement therapy							<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/> Yohimbine							<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

17. Please list your PSA levels and dates of test (up to four) since January 2014 only:

I have not had a PSA test since January 2014

PSA level (ng/ml)	Test date	FOR OFFICE USE ONLY					
1.) _____	____/____ Month / Year	1	2	3	4	2014	2015
		5	6	7	8	2016	2017
		9	10	11	12		
2.) _____	____/____ Month / Year	1	2	3	4	2014	2015
		5	6	7	8	2016	2017
		9	10	11	12		
3.) _____	____/____ Month / Year	1	2	3	4	2014	2015
		5	6	7	8	2016	2017
		9	10	11	12		
4.) _____	____/____ Month / Year	1	2	3	4	2014	2015
		5	6	7	8	2016	2017
		9	10	11	12		

18. Have you ever had recurrence or progression of your prostate cancer, indicated by a rise in PSA?

- No – continue to question 19
- Yes – please complete the box below:

FOR OFFICE USE ONLY							
1	2	3	4	Before 2014			a
5	6	7	8	2014	2015		P
9	10	11	12	2016	2017		M
							Y
1	2	3	4	Before 2014			b
5	6	7	8	2014	2015		P
9	10	11	12	2016	2017		M
							Y

18a. When did your prostate cancer recur or progress, relative to your INITIAL DIAGNOSIS AND DISEASE MANAGEMENT? Please mark all that apply. If your prostate cancer has recurred more than once, please indicate the earliest recurrence.

After I received initial treatment, my prostate cancer recurred (came back)

If so, what was your lowest PSA level after your initial treatment?

_____ (ng/ml) ____/____ (test date)
 Month Year

- Before I received any treatment, my prostate cancer progressed (got worse)
- I have never received any treatment, and my prostate cancer progressed

18b. What was your first PSA level that indicated recurrence or progression?

_____ (ng/ml) ____/____ (test date)
 Month Year

3/8" PERF

19. Have you ever been diagnosed with metastases to lymph nodes, bone, or other organs?
 No – continue to question 20
 Yes – found *at* or *around* diagnosis (continue to question 20)
 Yes – found *after* diagnosis (please complete the box below):

FOR OFFICE USE ONLY

1	2	3	4	Before 2014	19	
5	6	7	8	2014	2015	M
9	10	11	12	2016	2017	Y

19a. Which site(s) were you diagnosed with metastases? Please mark all that apply.

Lymph nodes Date diagnosed: _____ / _____
 Month / Year

Bone Date diagnosed: _____ / _____
 Month / Year

Other organs, specify: _____ Date diagnosed: _____ / _____
 Month / Year

1	2	3	4	Before 2014	M	
5	6	7	8	2014	2015	Y
9	10	11	12	2016	2017	O

19b. What prompted a metastasis work-up? Please mark all that apply.

Pain
 PSA rise
 Other, specify: _____

1	2	3	4	Before 2014	M	
5	6	7	8	2014	2015	Y
9	10	11	12	2016	2017	O

19c. How were your metastases verified? Please mark all that apply.

Imaging (bone scan, CT, MRI)
 Metastatic biopsy
 Other, specify: _____

1	2	3	4	Before 2014	M	
5	6	7	8	2014	2015	Y
9	10	11	12	2016	2017	O

20. Have you ever had a broken bone or fracture?

No
 Yes – please complete the box below:

Site	Month	Year			
1	7	1	9	0	0
2	8	2	0	1	1
3	9	3	9	2	2
4	10	4	10	3	3
5	11	5	11	4	4
6	12	6	12	5	5

20a. If yes to broken bone or fracture, at which site(s)? And when did it occur?

20b. Did your doctor tell you that the fracture was related to your prostate cancer (i.e., the result of bone metastasis)?

Site	Month/Year	Related to prostate cancer?
1. <input type="radio"/> Ankle		<input type="radio"/> Yes <input type="radio"/> No
2. <input type="radio"/> Arm		<input type="radio"/> Yes <input type="radio"/> No
3. <input type="radio"/> Collarbone/clavicle		<input type="radio"/> Yes <input type="radio"/> No
4. <input type="radio"/> Foot		<input type="radio"/> Yes <input type="radio"/> No
5. <input type="radio"/> Hand		<input type="radio"/> Yes <input type="radio"/> No
6. <input type="radio"/> Hip		<input type="radio"/> Yes <input type="radio"/> No
7. <input type="radio"/> Leg		<input type="radio"/> Yes <input type="radio"/> No
8. <input type="radio"/> Pelvis		<input type="radio"/> Yes <input type="radio"/> No
9. <input type="radio"/> Rib		<input type="radio"/> Yes <input type="radio"/> No
10. <input type="radio"/> Wrist		<input type="radio"/> Yes <input type="radio"/> No
11. <input type="radio"/> Other:		<input type="radio"/> Yes <input type="radio"/> No
<div style="border: 1px solid black; height: 30px; width: 100%;"></div>		
12. <input type="radio"/> Other:		<input type="radio"/> Yes <input type="radio"/> No
<div style="border: 1px solid black; height: 30px; width: 100%;"></div>		

1	7	1	9	0	0	20
2	8	2	0	1	1	a
3	9	3	9	2	2	M
4	10	4	10	3	3	Y
5	11	5	11	4	4	O
6	12	6	12	5	5	a
				6	6	M
				7	7	Y
				8	8	O
				9	9	O

Site	Month	Year				
1	7	1	9	0	0	M
2	8	2	0	1	1	Y
3	9	3	9	2	2	O
4	10	4	10	3	3	
5	11	5	11	4	4	
6	12	6	12	5	5	
				6	6	
				7	7	
				8	8	
				9	9	

Site	Month	Year				
1	7	1	9	0	0	M
2	8	2	0	1	1	Y
3	9	3	9	2	2	O
4	10	4	10	3	3	
5	11	5	11	4	4	
6	12	6	12	5	5	
				6	6	
				7	7	
				8	8	
				9	9	

1	1	1	1	1	1	1	1
2	2	2	2	2	2	2	2
4	4	4	4	4	4	4	4
8	8	8	8	8	8	8	8
P	P	P	P	P	P	P	P

Thank you for your participation!

Please return to: Walter C. Willett, M.D. • 677 Huntington Ave. • Boston, MA 02115

3/8" PERF