

Appendices

Appendix figure 1: Questionnaire given to patients in the standard group

PRIMETIME Information Giving Study Questionnaire A

For centre staff to complete

Centre / Hospital _____ Screening ID **S**

Patient's initials _____ Date of birth _____

Date of issue _____

Day Month Year Day Month Year

Questions below to be completed by the patient

Please only complete this form if you are happy for this information to be sent to the Clinical Trials and Statistics Unit at the Institute of Cancer Research, who are coordinating this study.

Date of completion _____

Day Month Year

Did you read the PRIMETIME main study patient information sheet? Yes No

Did you look at the PRIMETIME diagrams? Yes No

Which type of information did you find most useful?
Please tick one of the following:

PRIMETIME Information Sheet 1 2 3 4 5

PRIMETIME Diagrams 1 2 3 4 5

Please rank 1 -5
(1 = least useful and 5 = most useful)

Which treatment option do you prefer? Please tick one:

Participating in the PRIMETIME main study Standard treatment not part of the PRIMETIME main study

Considering the option you prefer, please answer the following questions:

	Strongly Agree	Agree	Neither Agree Or Disagree	Disagree	Strongly Disagree
1. I know which options are available to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I know the benefits of each option.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I know the risks and side effects of each option.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am clear about which benefits matter most to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I am clear about which risks and side effects matter most.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I am clear about which is more important to me (the benefits or the risks and side effects).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I have enough support from others to make a choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I am choosing without pressure from others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I have enough advice to make a choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I am clear about the best choice for me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I feel sure about what to choose.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. This decision is easy for me to make.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I feel I have made an informed choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. My decision shows what is important to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. I expect to stick with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I am satisfied with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Decisional Conflict Scale © AM O'Connor, 1993, revised 2005

Please tick your highest educational level

School certificate, O-level/ GCSE/ NVQ (or equivalent) Post graduate degree/ degree/ professional qualification

A-level/HND None of the listed

Appendix figure 2: Questionnaire given to patients in the enhanced group



Information Giving Study Questionnaire B

For centre staff to complete

Centre / Hospital Screening ID **S**

Patient's initials Date of birth

Date of issue

Day Month Year Day Month Year

Questions below to be completed by the patient

Please only complete this form if you are happy for this information to be sent to the Clinical Trials and Statistics Unit at the Institute of Cancer Research, who are coordinating this study.

Date of completion

Day Month Year

Did you read the PRIMETIME main study patient information sheet? Yes No

Did you look at the PRIMETIME diagrams?

Did you watch the PRIMETIME video?

Which type of information did you find most useful? Please tick one of the following: Please rank 1 -5
(1 = least useful and 5 = most useful)

PRIMETIME Information Sheet	(1) (2) (3) (4) (5)
PRIMETIME Diagrams	(1) (2) (3) (4) (5)
PRIMETIME Video	(1) (2) (3) (4) (5)

Which treatment option do you prefer? Please tick one:

Participating in the PRIMETIME main study Standard treatment not part of the PRIMETIME main study

Considering the option you prefer, please answer the following questions:

	Strongly Agree	Agree	Neither Agree Or Disagree	Disagree	Strongly Disagree
1. I know which options are available to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I know the benefits of each option.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I know the risks and side effects of each option.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am clear about which benefits matter most to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I am clear about which risks and side effects matter most.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I am clear about which is more important to me (the benefits or the risks and side effects).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I have enough support from others to make a choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I am choosing without pressure from others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I have enough advice to make a choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I am clear about the best choice for me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I feel sure about what to choose.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. This decision is easy for me to make.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I feel I have made an informed choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. My decision shows what is important to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. I expect to stick with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I am satisfied with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

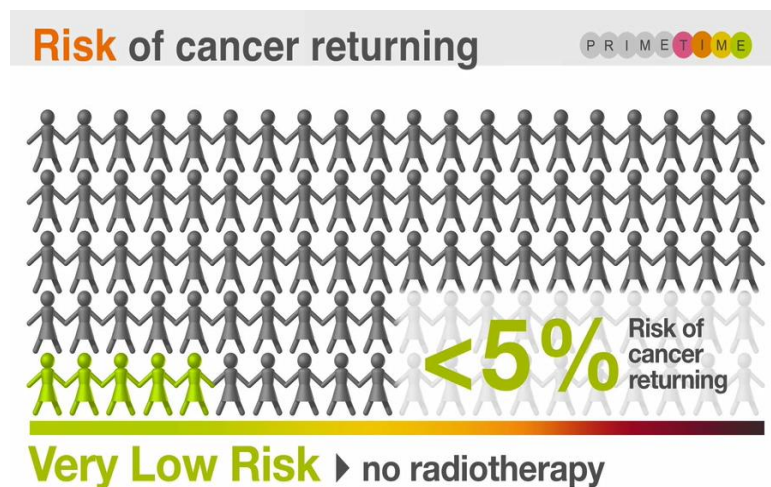
Decisional Conflict Scale © AM O'Connor, 1993, revised 2005

Please tick your highest educational level

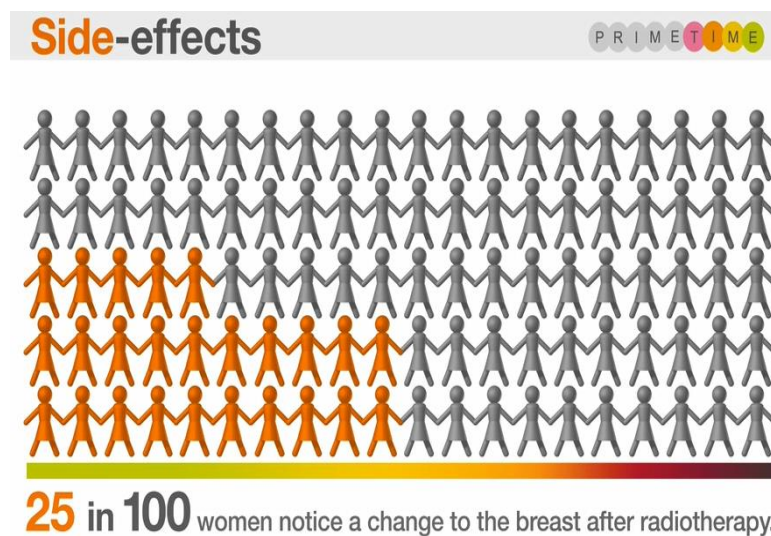
School certificate, O-level/ GCSE/ NVQ (or equivalent) Post graduate degree/ degree/ professional qualification

A-level/HND None of the listed

Appendix figure 3: Summary of the risk of recurrence in very low risk patients



Appendix figure 4: Summary of change in breast appearance in women treated with radiotherapy



Appendix table 1: Summary of script structure

Script Structure: 1) Why are we running the PRIMETIME study? 2) What do we need to know to work out your risk? 3) What are the benefits of radiotherapy? 4) What are the side-effects of radiotherapy? 5) How do we weigh up the risks and benefits of radiotherapy? 6) Why do we think that patients who are at 'very-low' risk don't need radiotherapy? 7) What happens if I have radiotherapy and what happens if I don't?
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Appendix table 2: Summary of association of age and education level with decisional conflict

Baseline characteristics (n= patients with available data)	Mean decisional conflict (SD)	Median decisional conflict (IQR)	*Coefficient value (95% confidence interval), p value
Age (years)			
60-64 (n=64)	9.58 (14.28)	1.56 (0-17.19)	-
65-69 (n=100)	9.22 (10.91)	1.56 (0-20.31)	0.12 (-2.49-2.74), p=0.93
70-74 (n=101)	8.69 (10.53)	3.13 (0-17.19)	-0.69 (-3.65-2.28), p=0.65
≥75 (n=53)	12.59 (11.99)	10.94 (0-25)	3.67 (-0.47-7.82), p=0.08
Age tested as a continuous variable	-	-	0.12 (-0.08-0.31), p=0.25
Education Level			
PG degree/degree (n=75)	7.87 (12.80)	1.56 (0-12.5)	-
A-level/HND (n=49)	9.71 (10.69)	4.69 (0-17.19)	1.79 (-2.51-6.10), p=0.41
School cert/O-level (n=103)	9.31 (11.21)	3.13 (0-20.00)	1.57 (-1.84-4.97), p=0.37
Not listed (n=75)	11.08 (12.31)	4.69 (0-25)	2.89 (-0.63-6.41), p=0.11
Education tested as a continuous variable			0.86 (-0.27-1.99), p=0.22

*Coefficient value represents the difference between the means of the decisional conflict scales in the standard and enhanced groups

Appendix table 3: Summary of decisional conflict subscales results

Decisional Conflict Subscales	Mean score in Standard Group (standard deviation) N=184	Mean score in Enhanced Group (standard deviation) N=337	*Coefficient value (95% confidence interval)	P value
Uncertainty	13.45 (15.82)	11.98 (15.30)	-1.03 (-3.84-1.78)	0.47
Informed	9.84 (11.78)	7.90 (11.91)	-2.04 (-4.17-0.09)	0.06
Values Clarity	11.93 (14.36)	9.25 (13.35)	-2.46 (-4.85-0.06)	0.05
Support	8.82 (11.78)	7.12 (11.37)	-1.65 (-3.73-0.43)	0.12
Effective	10.47 (12.96)	8.78 (12.82)	-1.74 (-3.91-0.42)	0.11

*Coefficient value represents the difference between the means of the decisional conflict scales in the standard and enhanced groups