

APPENDIX K

TREATMENT AND MANAGEMENT QUESTIONNAIRE

PRIVATE AND CONFIDENTIAL – PATIENT RECORDS

Country

Centre

Patient Study

Date

The IMPACT Study

Identification of Men with a genetic predisposition to ProstAte Cancer: Targeted screening in *BRCA1/2* mutation carriers and controls.

Treatment Follow-up Questionnaire

We would be grateful if you could answer the following questions about the patient's treatment and his health. Please try to answer every question as completely as you can. The answers will be treated as strictly confidential and will only be used for medical research. If you have any queries please contact:

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Designed by Dr Reza Sharifi, Former Clinical Research Fellow, Royal Marsden Hospital. This questionnaire has been developed with the help of the EMBRACE, ProtecT and ERSPC studies.

Thank you for completing this questionnaire.

Thank you for collaborating in the IMPACT study. Your patient has been diagnosed with prostate cancer and this questionnaire asks about type of treatment, response, relapse and side-effects of treatment. We would be grateful if you would complete this questionnaire - most of the questions can be answered by ticking the box that corresponds to your answer. The information you provide will be used to study factors that may affect the specific treatment response and the survival rate in men with prostate cancer and a germline *BRCA1/2* mutation.

We will be asking for this information to be updated once a year and will send you this questionnaire on each occasion to be updated. All of this information is **strictly confidential** and will only be used for the IMPACT study.

Please answer the questions as accurately and thoroughly as you can. However, if you are unsure about your answer to any question or feel unable to answer for any reason, please indicate this on the questionnaire.

If you have any queries about this questionnaire or study, please contact the local co-ordinator or study centre in the UK:

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SECTION A: PATIENT'S DOCTOR & HOSPITAL INFORMATION

Please complete the following section to confirm the patient's treatment team and place.

A1. Today's date/...../..... (day/month/year)

A2. Name and designation of the person completing form:

Name:.....

Designation:.....

A3. Hospital name and Address:

Hospital/ Treatment Centre name:.....

Hospital Address:.....

.....

.....

Country:..... Post Code:.....

Telephone Number

Fax Number

A4. Doctors name and speciality (if *not the same as above*):

Please indicate the person who has direct responsibility of patient's treatment team.

Name:.....Speciality:.....

A5. Patient's GP or doctor who has day care responsibility of patient:

GP's Name:

GP's Address:

.....

.....Post Code

Telephone Number

SECTION B: PERSONAL INFORMATION

Please complete the following section to confirm and update the patient's details.

B1. Patient's Name:.....
First Name Other Name(s) Surname

B2. Patient's Address:
.....
.....

B3. Patient's date of birth:/...../..... (day/month/year)

B4. Patient's hospital number:

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B5. Is the patient:
Alive Dead

B6. If the patient is dead, please indicate the cause and date of death:

Cause:

Date:/...../..... (day/month/year)

B7. If the patient has declined for their treatment information to be used please state why.
.....
.....
.....
.....

SECTION C: MEDICAL HISTORY

C1. Has the patient had any operations, surgical procedures, serious medical problems, illnesses, accidents or injuries in the last 12 months?

Yes No If **no**, please go to C2

Please fill in the table below for each operation or illness. An example of a surgical procedure has been provided in the first row of the table.

Type of operation/ illness	Date of operation / illness	Reason for operation	Name of hospital
e.g. Vasectomy	1-10-04	Family planning	RMH Hospital, London

C2. Please ask the patient to score the following questions about sexual function:

1. How do you rate your <u>confidence</u> that you could get and keep an erection?		Very low 1	Low 2	Medium 3	High 4	Very high 5
2. When you had erections with sexual stimulation, <u>how often</u> were you erections hard enough for penetration (entering your partner)?	No sexual activity 0	Almost never or never 1	A few times (much less than half the time) 2	Sometimes (about half the time) 3	Most times (much more than half the time) 4	Almost always or always 5
3. During sexual intercourse, <u>how often</u> were you able to maintain your erection after you had penetrated (entered) your partner	No sexual activity 0	Almost never or never 1	A few times (much less than half the time) 2	Sometimes (about half the time) 3	Most times (much more than half the time) 4	Almost always or always 5
4. During sexual intercourse, <u>how difficult</u> was it to maintain your erection to completion of intercourse?	Did not attempt intercourse 0	Extrem ely difficult	Very difficult	Difficult	Slightly difficult	Not difficult
5. When you attempted sexual intercourse, <u>how often</u> was it satisfactory for you?	No sexual activity 0	Almost never or never 1	A few times (much less than half the time) 2	Sometimes (about half the time) 3	Most times (much more than half the time) 4	Almost always or always 5
SCORE						

Total Score _____

(If the score is 21 or less the patient may be showing signs of erectile dysfunction)

C3. Please ask the patient to score the following urinary symptoms:

Over the past month, how often have you...	Not at all	Less than 1 time in 5	Less than half the time	About half the time	More than half the time	Almost always	Score
1. ...had a sensation of your bladder completely after you finished urinating?	0	1	2	3	4	5	
2. ...had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5	
3. ...stopped and started again several times while urinated?	0	1	2	3	4	5	
4. ...found it difficult to postpone urination?	0	1	2	3	4	5	
5. ...had a weak urinary stream	0	1	2	3	4	5	
6. ...had to push or strain to begin urination	0	1	2	3	4	5	
	None	Once	Twice	3 times	4 times	5 times or more	
7. Over the last month how many times did you typically get up to urinate from the time you went to bed at night until you got up in the morning?	0	1	2	3	4	5	

Total Score _____

0 – no symptoms

1-7 indicate mild symptoms of an enlarged prostate

8-19 indicates moderate symptoms of an enlarged prostate

20-35 indicates severe symptoms

C4. Please indicate if the patient suffers from any of the following (*if yes please give details*):

A	Respiratory disease	Yes	No	Details:
B	Cardio-vascular disease	Yes	No	Details:
C	Renal problems	Yes	No	Details:
D	Neurological problems	Yes	No	Details:
E	Diabetes	Yes	No	Details:
F	Hypertension	Yes	No	Details:
G	Inflammatory bowel disease	Yes	No	Details:
H	Irritable bowel syndrome	Yes	No	Details:
I	Haemorrhoids	Yes	No	Details:
J	Other Cancer	Yes	No	Details:

SECTION D: PROSTATE CANCER DIAGNOSIS AND INVESTIGATIONS

D1. Date of Diagnosis:/...../..... (day/month/year)

D2. Hospital at which the diagnosis was made (*if different to section A*):

Name.....Address:.....

.....

.....

Country:.....Post Code.....

Tel:..... Fax:.....

D3. PSA value at diagnosis:

Total PSA (ng/ml):.....

Free/Total(%):.....

D4. Staging at diagnosis: (*The Prostate Staging, 1997TNM, has been accepted by IMPACT steering committee. A TNM staging sheet is attached.*)

T: T1 a b c
 T2 a b
 T3 a b
 T4

N: NX N0 N1

M: MX M0
 M1 M1a M1b M1c

D5. Histological Grade at diagnosis:
 (*Please attach a pathology report with this completed form*)

Date of Histology report :/...../..... (day/month/year)

Grading: G1 G2 G3 GX

Gleason Score at diagnosis:

Major Pattern: 1 2 3 4 5

Minor Pattern: 1 2 3 4 5

Total Score:.....

Pathologist's name:.....

Pathology centre:.....

Address:

.....

Country:.....Post Code:.....

Telephone NumberFax Number:.....

D6 Digital Rectal Exam result at diagnosis: Date:/...../.....(day/month/year)

Normal

Abnormal

D7. Imaging investigation at Diagnosis:

Type of Imaging		Date of report	Result (normal or abnormal – if abnormal please send copy of report)
CT Scan	1)		
	2)		
MRI	1)		
	2)		
Transrectal Ultrasound (TRUS)	1)		
	2)		
Bone Scan	1)		
	2)		
IVP (Intravenous Pyleogram)	1)		
	2)		
Other	1)		
	2)		

SECTION E: TREATMENT

E1. Please indicate what treatment is being undertaken by your patient following prostate cancer diagnosis:

- Watchful Waiting
- Active Surveillance
- Radical Prostatectomy only
- Radical Prostatectomy and adjuvant hormone therapy
- Radiotherapy alone
- Radiotherapy and adjuvant androgen ablation
- Cryoablation Therapy
- High-Intensity Focused Ultrasonography (HIFU)
- Immuno-vaccine therapy

E2. PSA value after treatment

- a) 1 month Date..... Total(ng/ml): Free:Total (%)
- b) 2 months Date..... Total(ng/ml): Free:Total (%)
- c) 3 months Date..... Total(ng/ml): Free:Total (%)
- d) 6 months Date..... Total(ng/ml): Free:Total (%)
- e) More than 6 months: Date..... Total(ng/ml): Free:Total(%).....

Details of treatment

Date...../...../.....

Hospital.....

Surgeon.....

E3.1 Radical Prostatectomy procedure:

- Radical perineal prostatectomy
- Radical retropubic prostatectomy
- Laparoscopic radical prostatectomy

E3.2: Was lymphadenectomy undertaken? Yes If yes please state:

- number of nodes resected
- number positive

No

E3.3: Additional treatment: Radiation Therapy

Adjuvant or Neo-adjuvant

Other: *please specify*:.....

- E.3.4: Complications: Myocardial infarction
 Deep venous thrombosis (DVT)
 Pulmonary embolism
 Blood transfusion
 Anastomotic stricture
 Inguinal hernia
 Incisional hernia
 Urinary incontinence
 Impotence
 Other: *please specify*.....

- E4. Radiotherapy External Beam Radiation (EBR)
 Brachytherapy
 Brachytherapy with combination of EBR
 EBR & Hormone Therapy

E4.1: Total Dose:

E4.2: Fractionation:.....

E4.3: Assessment for late side-effects after radiotherapy – please ask patient about the following symptoms. (Please Score symptoms over the last 4 weeks)

<p><u>Assessment for Late Side-Effects after Radiotherapy (Score symptoms over the last 4 weeks)</u> Please circle appropriate response</p>		
<p>URINARY SYMPTOMS (excluding urinary tract infections)</p>		
<p>Average daytime frequency</p> <ol style="list-style-type: none"> 1. >2 hourly 2. 2 hourly 3. 1-2 hourly (no treatment) 4. 1-2 hourly (simple out-patient management) 5. <1 hourly 9. Unknown 	<p>Nocturia</p> <ol style="list-style-type: none"> 1. 0-1 times 2. 2-3 times 3. 4-5 times 4. 6-8 times 5. >8 times 9. Unknown 	<p>Incontinence</p> <ol style="list-style-type: none"> 1. None 2. Occasional incontinence 3. Frequent incontinence requiring use of pads 9. Unknown
<p>BOWEL SYMPTOMS</p>		
<p>Frequency</p> <ol style="list-style-type: none"> 1. 1-2 times 2. 3-4 times (no medical treatment) 3. 3-4 times (simple out-patient management) 4. ≥ 5 times +/- treatment 9. Unknown 	<p>Rectal Bleeding</p> <ol style="list-style-type: none"> 1. None 2. Occasional (no treatment) 3. Moderate (simple outpatient management) 4. Severe (blood transfusion, surgery) 9. Unknown 	<p>Erectile Potency</p> <ol style="list-style-type: none"> 1. Normal Erection 2. Decreased 3. Absent 9. Unknown

<u>RTOG Gradings for late side effects after radiotherapy (Score symptoms over the last 4 weeks)</u>	
Please Grade 0-5	Grading System
Diarrhoea _____	Grade 0 – no symptoms
Proctitis _____	Grade 1 – minor symptoms requiring no treatment
Cystitis _____	Grade 2 – symptoms responding to simple outpatient management, lifestyle (performance status not affected)
Haematuria _____	Grade 3 – distressing symptoms altering patient’s lifestyle performance status). Hospitalisation for diagnosis or minor surgical intervention (such as urethral dilation) may be required
	Grade 4 – major surgical intervention (such as laparotomy, colostomy, cystectomy) or prolonged hospitalisation required
	Grade 5 – fatal complications
Diarrhoea is defined as a clinical syndrome characterised by frequent loose bowel movements <i>without</i> associated rectal irritation (tenesmus)	
Proctitis is defined as a clinical syndrome characterised by rectal irritation or urgency (tenesmus), presence of mucus or blood in the stool and, in some patients, with frequent, sometimes looses, bowel movements.	
Cystitis is defined as a syndrome characterised by irritative bladder symptoms such as frequency and dysuria.	
Haematuria may or may not be part of the clinical picture of cystitis.	

E4.4: Neo-Adjuvant Deprivation

3a.	Cyprocerone Acetate (CPA) (or equivalent)	Yes	No
b.	Date commenced CPA (or equivalent)		
c.	Date completed CPA (or equivalent)		
d.	Date commenced Lutinising Hormone Releasing Hormone (LHRH) (or equivalent)		
e.	Date completed LHRH (or equivalent)		
f.	Date of LHRH depot		
g.	Other (please specify)		

E4.5: Other type of treatment, please give details below:

.....

.....

.....

.....

SECTION F: FOLLOW UP

F1. PSA Values post-treatment:

Date	Treatment

F2. New treatment regime:

.....

.....

.....

.....

Please use the space below to inform us of anything that you feel would be relevant for our records.

.....

.....

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Please return (please tick) in the envelope provided:

1. The completed questionnaire

2. Histopathology reports

3. Imaging reports

Thank you very much for your help.