The experience of men having androgen deprivation therapy for early stage prostate cancer in a regional setting

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Acknowledgements

Many thanks to Clinical Education and Training Institute (CETI) Rural Directorate for the funding support which enabled me to participate in the Rural Research Capacity Building Programme. To Dr Emma Webster and Dr David Lyle a big thanks for their patience, time, guidance and tolerance. A very special thanks to Tracie Reinten-Reynolds, trainee biostatistician from New South Wales Health Department for her grit, determination and tolerance in her dealings with a non-numerical person. I would also like to thank Chris Stanford my work colleague for the continual loan of her ears and her continued encouragement of this project and to Maureen McGovern, my manager, for her endless support. Last but not least, thanks to the men and their partners for providing me with such honest and heartfelt responses to the very personal questions.

Abbreviations

ADT	Androgen Deprivation Therapy
CIAP	Clinical Information Access Portal
CT	Computed Tomography
DRE	Digital Rectal Examination
FDA	Food and Drug Administration
HREC	Human Research Ethics Committee
LHRH	Luteinizing Hormone-Releasing agonists
ICD10 AM	International Classification of Diseases Australian Modification
MIMS	Monthly Index of Medical Specialties
MRI	Magnetic Resonance Imaging
NCAHS	North Coast Area Health Service
NEAF	National Ethics Application Form
NHMRC	National Health and Medical Research Council
PSA	Prostate Specific Antigen
TRUS	Trans Rectal Ultrasound

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Abstract

Aim: This study aims to understand the extent and impact of side effects experienced by men with non-metastatic prostate cancer who were treated with androgen deprivation therapy (ADT) in a regional cancer care centre. The study will examine if differences in side effects exist in men under or over 75 years and will also examine differences that may exist between age and prostate cancer risk categories. The role of the doctor in managing side effects will also be explored.

Study Design: A retrospective cross-sectional study. All eligible patients visiting a regional cancer care facility between 1 January 2007 and 31 December 2009 were invited to complete a questionnaire (n=451).

Method: Ethics approval was obtained from the North Coast Area Health Human Research Ethics Committee on 29th March 2010, with Site Specific Approval from the Coffs Harbour Health Campus on 20 May 2010 (NCAHS HREC No. 483N; NEAF – AU/1774/25292/1/499). Using the MOSAIQ electronic medical record participants names were generated in a report. The parameters used for selection of participants were ICD-10AM code C61 (prostate cancer) between 1st January 2007 and 31st December 2009 and were still alive.

Participants: Two hundred and seventy four men with early stage prostate cancer who were prescribed neo-adjuvant and/or adjuvant ADT with their radiotherapy.

Results: Ninety two percent of men in this study reported that they experienced at least one negative sexual, physical, emotional and cognitive side effect secondary to ADT.
The study revealed that n=129 men with intermediate and low risk prostate cancer were prescribed ADT regardless of a lack of evidence that it is beneficial in these risk groups.
N=116 men with two or more co-morbidities with n=51 of those being over the age of 75 were given ADT despite evidence that these comorbidities can be exacerbated by ADT. Men over 75 are less likely to discuss any negative effects with their doctors.

Conclusion and Implications for Practice: Cure is being considered at the expense of care when prescribing ADT for men with early stage prostate cancer. Treating clinicians need to be fully cognisant of the extent of ADT side effects and impact they are having on the lives of their patients. Treating specialists must discuss the likely side effects in a style and level that can be easily understood so that patients can make informed decisions. It is imperative a balanced opinion regarding the risks and benefits of treatment is given. Nurses need to advocate and empower the patients so they have all the information to make educated decisions about their treatment options and confidence to ask questions of the clinicians.

Key Words: androgen deprivation therapy, prostate cancer, non-metastatic, neo-adjuvant, adjuvant, cure, care, communication, side effects, rural

Background

Excluding non-melanoma cancers of the skin, prostate cancer was the most common cancer diagnosed in Australia followed by bowel and breast cancer according to the 2008 report released by the Australian Institute of Health and Welfare [1]**.** Prostate cancer is largely a disease of older men. Prostate cancer is the second leading cause of cancer deaths among men after lung cancer. Those men at higher risk include African-American men older than 60, farmers, and tyre plant workers. The lowest incidence occurs in Japanese men and vegetarians. Factors that increase the risk of prostate cancer include age, testosterone and a diet high in saturated fat.

The National Health and Medical Research Council (NHMRC) Clinical Practice Guidelines[3] for prostate cancer is categorised into low risk, intermediate risk and high risk based on information gathered from PSA blood test, digital rectal examination (DRE) and pathological specimens from Transrectal Ultrasound (TRUS)and prostate biopsy. The risk category determines not only the prognostic indication of the cancer but also the treatment options that are generally offered. For further assessment of clinical stage, usually in high risk patients, information can be ascertained from Computed Tomography (CT) scan, Magnetic Resonance Imaging (MRI) and radionuclide bone scans.

Rashid [27] (2011) describes localised disease as a PSA of less than 10, Gleason score of less than 8, moderate or minimal volume of prostate cancer, fit to have surgery and a life expectancy of ten years or more. Treatment options include active surveillance, radical prostatectomy with (or without) pelvic node dissection, external beam radiotherapy (with or without ADT) and brachytherapy (with or without ADT).

The setting for this study is Coffs Harbour, a regional cancer centre servicing a population of approximately 71,000 situated on the east coast of New South Wales. Prior to radiation therapy being provided locally, patients were required to travel to Sydney to access their radiation treatment. Men experienced a major upheaval in their life insofar as they were sent away from their family, friends, homes, and other support systems for a period of at least eight weeks for their radiotherapy treatment. Younger men who were in the workforce had to rely on empathetic bosses as treatment meant they were forced to arrange extended leave from their employment which proved difficult in a town with high unemployment and limited employment opportunities. Relinquishing regular income to go for treatment created enormous implications for families. Some farmers who worked their own properties refused treatment as they had nobody to take care of their farms if they went away. Single men who had pets were also known to refuse treatment as they had nobody to care for their animals and were unable to afford veterinary care for extended periods.

Radiation services commenced operation locally in June 2007, and with the opening of a new centre in the local area imminent, men with prostate cancer were refusing to travel to metropolitan cancer centres for eight to nine weeks of radiation treatment. Ongoing delays in the commencement of local radiation services meant that men were having a minimum of eight months neo-adjuvant ADT. ADT does not cure cancer. The men were advised that the ADT was to shrink the size of the prostate, prevent the spread of the cancer and increase their overall survival

benefit. Men with intermediate risk prostate cancer were advised there was little evidence to support this extended period of neo adjuvant ADT, and the men with low risk were advised that there was no evidence to support the use of ADT. The men were keen to continue with the ADT at the recommendation of their specialist. The local oncology staff were not really aware of the problems the men were experiencing with their ADT, because they were reporting their complaints to the staff at the metropolitan treatment centre not to the centre referring the patients.

It was during the time the men were staying locally for their treatment that staff became aware of the side effects men were experiencing. They were reporting to the nursing staff that the side effects of the ADT were having a negative impact on their sexual, physical, emotional and cognitive function. It was apparent that this group of patients had significant problems that needed to be investigated.

Literature Review

The 2010 Position Statement[5] on prostate cancer screening from Cancer Council Australia is as follows. “The benefits of population screening for prostate cancer are, at this time, unproven. The central concern is that many prostate cancers will not progress sufficiently to cause harm in the man’s lifetime, while others will progress and be lethal. No current test (including the PSA test) adequately differentiates between these types of cancer.” The position statement adds that many prostate cancers grow slowly without requiring treatment or intervention. This means that many men with prostate cancer can lead a normal life without being affected in any significant way by their cancer. Unfortunately, other men will experience life-threatening prostate cancer where the cancer grows and spreads rapidly.

Reviewing the literature relating to side effects of ADT, Medical Information Management Systems (MIMS) outlines the following side effects.

A Medline search through CIAP gave 566 references for combining “side effects” with “LHRH”. Kumar[4] (2005) et al. in their Cochrane review, concluded that hormone therapy is associated with common, and at times, significant, acute and long term complications such as vasomotor symptoms, impotence, impairment of cognitive function and increase in the risk of osteoporosis. They also found that more information was needed to further evaluate ADT side effects as this focus was missing in the majority of the twenty one studies presented in their review.

In May 2010 the United States Food and Drug Administration[8] (FDA) released a warning that patients receiving ADT were at an increased risk of diabetes, heart attack, stroke and sudden death. Supporting this claim were studies that found that men receiving LHRH hormone therapy are at a greater risk of developing metabolic syndrome, cardiovascular disease and diabetes[7]. For men with moderate or significant co-morbidities ADT was found to be harmful[9].

Evidence confirms that ADT, both neo-adjuvant and adjuvant in the high risk group is beneficial when considering survival benefit [10-14]. The New South Wales Cancer Institute’s standardised evidenced based, peer reviewed point of care cancer treatment protocols, known as eviQ, do not

recommend ADT in the low and intermediate risk group [15]. These guidelines suggest that for the intermediate risk group ADT be discussed with the patient but no evidence exists to support its use in this risk category.

Are men being given adequate information to make an informed decision about commencing ADT? Gray et.al.[16] (2005) in his qualitative study concluded that the impact of the side effects of ADT was often substantial and that men were not receiving sufficient information to prepare them to deal with side effects. These included dealing with changes in sexuality, navigating relationships and interpreting gender relevant changes. Ninety one percent of respondents were looking for more information regarding side effects of treatment particularly in the area of sexual dysfunction[17].

Focus groups report medical staff were generally not the most helpful when it came to dissemination of information, particularly about the most basic information such as what prostate cancer is, and its symptoms [18]. Knowledge deficiency of the patient after medical consultations led to poor decision making about treatment options [19].

Expectations of rural men, namely time to talk with the doctor, empathy and constructive communication is the key to the best dialogue between doctor and patient[20]. Exploring the information needs of men over the age of seventy five with a prostate cancer diagnosis found that as long as the doctor knew what they were doing, the men were satisfied. However, most men were unable to accurately articulate what the hormone therapy was for, despite all men receiving the same information about the therapy[21] .

Is consideration given to the current health status, life expectancy and ability to cope with the burden of side effects of ADT on quality of life, particularly in the older men?

ADT is more likely to cause clinically significant morbidity and mortality in those who are older and frail at the time of diagnosis[23]. There is a great deal of concern about the older men who are being treated with ADT for intermediate and low risk prostate cancer given that there is no evidence to support its use in this group of patients.

Like other cancers that are staged and graded, age should be staged and graded [24]. There are men aged in their sixties who function like a man in their eighties and the inverse is also true. There is recognition about the potential for serious medical problems associated with ADT and doctors should discuss the benefits and disadvantages of ADT with the patients. However, doctors should be more aware that patients no longer see themselves as passive recipients of care [25].

Modern medicine has exploited the hopes of all people for diminished mortality. There is no cure for old age, and death is inevitable[26].

Aim

This study aims to understand the extent and impact of side effects experienced by men with non-metastatic prostate cancer who were treated with ADT in a regional cancer care centre. The study will examine if differences in side effects exist in men under or over 75 years and will also examine differences that may exist between age and prostate cancer risk categories. The role of the doctor in managing side effects will also be explored.

Method

Ethics approval was obtained from the North Coast Area Health Human Research Ethics Committee on 29th March 2010, with Site Specific Approval from the Coffs Harbour Health Campus on 20 May 2010 (NCAHS HREC No. 483N; NEAF – AU/1774/25292/1/499).

Design

A retrospective cross sectional study design was applied to answer the study questions.

Sample

Using the MOSAIQ electronic medical record participants names were generated in a report. The parameters used for selection of participants were ICD-10AM code C61 (prostate cancer) between 1st January 2007 and 31st December 2009 and were still alive. This report generated 665 names. Each patient record was read and 214 men were excluded as they did not meet one or more of the inclusion criteria.

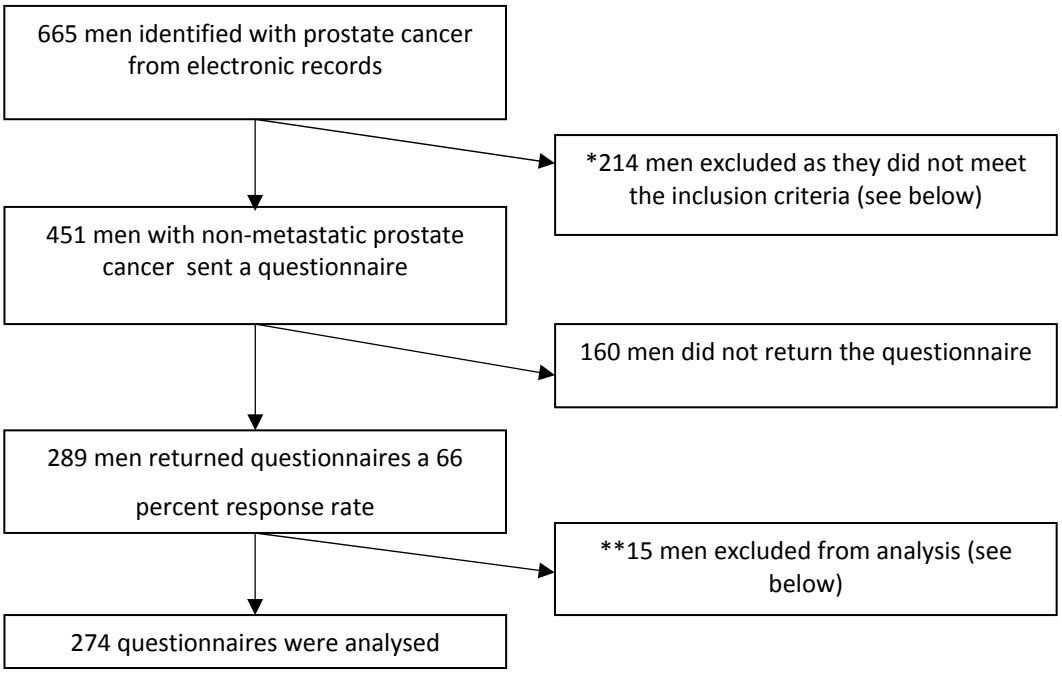
Inclusion Criteria

Men were included if they had a diagnosis of non-metastatic prostate cancer. They also must have had a consultation with the local Radiation Oncologist and consented to commence ADT as an adjunct to radiotherapy between 1 January 2007 and 31 December 2009.

Exclusion Criteria

Men diagnosed with prostate cancer that was proven to be metastatic either radiologically or pathologically were excluded from the study.

Figure 1: Demonstrates how the sample was determined and responses analysed



* The 214 men were excluded for one of the following:-

- Chose surgery as treatment option
- Chose active surveillance as treatment option
- Diagnosis was metastatic prostate cancer therefore treatment intent was palliative
- Low risk – no hormones

** The 15 men were excluded for the following:-

- 6 were excluded as envelopes returned unopened marked “address unknown”
- 2 men died in the period between accessing the information from the medical record and sending out the questionnaires.
- 7 were on long term non-adjuvant hormone

Survey Design and Piloting

A non-validated questionnaire was designed to capture all of the relevant information. Validated tools (FACT-P [21], UCLA-PI[22], EPIC[23]) were considered. The questionnaire was piloted with two men from a non English speaking background, two men with prostate cancer that were not eligible for the study, two researchers and various oncology clinicians. All feedback was taken into consideration and the final questionnaire prepared. No formal questionnaire validation study was undertaken due to time and resource constraints. The questionnaire included closed and open ended questions and can be found with the consent in the Appendix.

MOSAIQ electronic medical records were accessed to obtain name, address, age, cancer staging, PSA, Gleason score, prostate size, co-morbidities and baseline erectile function.

A calligraphic hand written purple envelope containing an eight page, seventeen question blue coloured questionnaire, yellow patient information sheet and a green stamped reply paid envelope was posted to each of the four hundred and fifty one study population with a twenty one day period to complete and return.
Consent to participate was the return of the completed questionnaire. Consent to participate in the focus group was by completing the name, address and contact details in the space provided at the end of the questionnaire. There were 134 men who agreed to be part of a focus group, but due to time constraints it was not possible to undertake this within this study. The consent form in the Appendix was to be completed at the time of focus group.

Data Collection and entry

All results were collected onto an excel spread sheet. Quantitative and qualitative information was collected on separate pages of the spread sheet and a coding book was also included within the spread sheet. All entries were checked for accuracy by a second person.

Data Analysis

All analyses were conducted using SAS version 9.2 software (SAS Institute Inc., 2004). Prevalence of side effects were calculated based on the number of men answering the questions, Chi-squared tests of significance were performed between men aged under 75 years and men aged over 75 years of age, for each side effect prevalence calculated. There were 489 free text comments written by the participants from the open ended questions and some of these are presented as quotes, where they give relevant description. They are identified only by participant number. No analysis of these descriptions has been undertaken.

Results

Table 1: Demographics of study participants, by age group, risk category, time on ADT, living arrangements and numbers of co-morbidities

		Under 75		75 and over		All		Difference (Chisq pvalue)
		%	n	%	n	%	n	
		58.0	*159*	*42.0*	*115*	-	*274*	
Age	under 55	0.6	1			0.4	1	
	55-64	21.4	34			12.4	34	
	65-74	78.0	124			45.3	124	
	75-84			97.4	112	40.9	112	
	85 plus			2.6	3	1.1	3	
Risk	High risk	46.5	74	61.7	71	52.9	145	0.028
	Intermediate risk	52.2	83	38.3	44	46.4	127	
	Low risk	1.3	2			0.7	2	
Amount of time on hormone therapy	less than 3 months	1.9	3	4.3	5	2.9	8	0.123
	3 to 6 months	20.8	33	14.8	17	18.2	50	
	6 to 12 months	36.5	58	28.7	33	33.2	91	
	> 12 months	40.9	65	52.2	60	45.6	125	
Gleason Score	6	7.5	12	13.0	15	9.9	27	0.010
	7	56.6	90	38.3	44	48.9	134	
	8-10	35.8	57	48.7	56	41.2	113	
PSA	≤ 4	3.8	6	1.7	2	2.9	8	0.523
	5-10	45.9	73	41.7	48	44.2	121	
	11-20	32.7	52	40.0	46	35.8	98	
	>20	17.6	28	16.5	19	17.2	47	
Number of comorbidities*	None	25.2	40	26.1	30	25.5	70	0.604
	1	34.0	54	29.6	34	32.1	88	
	2	24.5	39	30.4	35	27.0	74	
	3	11.9	19	12.2	14	12.0	33	
	4	4.4	7	1.7	2	3.3	9	
Living arrangements	living with spouse or partner	77.4	123	78.3	90	77.7	213	0.823
	in a significant relationship but not living together	5.0	8	3.5	4	4.4	12	
	not in a significant relationship	17.6	28	18.3	21	17.9	49	
Erectile Function pre-hormone treatment	yes	49.7	79	39.1	45	45.3	124	0.020
	no	28.9	46	40.0	46	33.6	92	
	partial	15.1	24	20.0	23	17.2	47	
	no secondary to RP before RP yes	6.3	10	0.9	1	4.0	11	

†Risk is determined using the Gleason score from the TRUS biopsy and PSA blood test .Other considerations may also be taken into account to determine risk. Some patients were numerically intermediate but treated by the doctor as high risk.
*Rao-Scott chi-square test for the difference between men aged under 75 and those aged 75 and over
**Co-morbidities include cardiovascular disease, diabetes, hypertension and hypercholesterolaemia

Loss of desire for sex

Table 2 shows that of the 215 men who experienced a loss of desire for sex (78.8,87.9 (95%CI) and P= 0.9096, age was not a factor, but men aged under 75 were twice as likely to have felt depressed about the loss of their desire to have sex compared to men aged over 75 (41% and 20%, respectively). Ten percent of the younger men (4.8,15.2 95%CI) reported to have had a change in their interactions with mates compared to two percent of the older group (0.0,5.4) P=0.0257.

Age was shown to be a factor when it came to discussing the loss of desire for sex with the doctor, where 35% of men under 75 years of age reported having this side effect to their doctor(27.6,44.2 95%CI) and only 25% of men over 75 years of age reporting (16.3,34.3 95%CI) P= 0.0945

Figure 2.

"Viagra was prescribed. I did not use it. I didn't JUST want an erection. I miss wanting sex with my partner."

(Participant number 65)

"At my age I suppose it doesn't matter but it is life and it's been taken away. The shrinking of the genitals is also a big worry."

(Participant number 330)

The loss of desire for sex made 40% of all men feel differently about themselves (34.4,47.5 95%CI) and P=0.1047 but only 12% said the loss of desire for sex made them feel differently about their partner (7.5,16.5 95%CI) P=0.1098.

The doctor was able to help almost 30% of the men with this side effect (20.3,35.6 95%CI).

Table 2: Number and proportion of men who indicated that they experienced a loss of desire for sex by age group

	Under 75		75 and over		All		Difference
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	(p value)*
Did you experience a loss of desire for sex?	128	83.1 (77.2,89.1)	87	83.7 (76.5,90.8)	215	83.3 (78.8,87.9)	0.9096
***Men were instructed to answer the following questions only if they answered 'YES' to the above question*							
Did it make you feel differently about your partner?	18	15.0 (8.6,21.4)	6	7.5 (1.7,13.3)	24	12.0 (7.5,16.5)	0.1098
Did it make you feel differently about yourself?	59	45.4 (36.8,54.0)	31	34.4 (24.6,44.3)	90	40.9 (34.4,47.5)	0.1047
Did it change your interactions with your mates?	13	10.0 (4.8,15.2)	2	2.2 (0.0,5.4)	15	6.8 (3.5,10.2)	0.0257
Did you feel depressed because of it?	54	41.2 (32.7,49.7)	18	20.0 (11.7,28.3)	72	32.6 (26.4,38.8)	0.0009
Did you discuss the side effect with your doctor?	47	35.9 (27.6,44.2)	23	25.3 (16.3,34.3)	70	31.5 (25.4,37.7)	0.0945
Was the doctor able to offer help to manage this side effect?	25	29.4 (19.6,39.2)	13	25.5 (13.4,37.6)	38	27.9 (20.3,35.6)	0.6217

*Rao-Scott chi-square test for the difference between men aged under 75 and those aged 75 and over

** Some men answered no to the first question but still responded to other questions

Loss of erections

Loss of erection was the highest reported side effect.

Table 3 shows that 92% of men (88.1,94.9 95%CI P=0.9805) surveyed were affected by the loss of erection.

The loss of erections made 30% of the men feel depressed (23.9,35.5 95%CI) P= 0.0655 and 31% felt "less of a man" (24.9,36.7 95%CI) P=0.2771.

The partners of 28 of the men under 75 were bothered by the mens loss of erection (16.0,31.5 95%CI) however, only 11 of the partners of the men over 75 were bothered (5.7,19.9) P=0.0498

Figure 3

"The loss of erections made for dysfunctional sex and Viagra wasn't very successful. at 76 felt because of my libido sex would still be very desirable and fulfilling for my partner."
(Participant number 198)

"Embarrassment is the main problem. At my age I would feel stupid asking for advice."
(Participant number 438)

Men under the age of 75 were much more likely to report their loss of erections to the doctor (30.7,47.0 95%CI) than the men over 75 years (15.4,32.7 95%CI) P=0.0180.

The doctor offered to manage the side effect for 34% (26.1,41.7) P=0.0561 of the men.

Table 3 : Number and proportion of men who experienced loss of erections by age group

	Under 75		75 and over		All		Difference
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	(p value)*
Did you experience the loss of erections?	140	91.5 (87.1,96.0)	98	91.6 (86.3,96.9)	238	91.5 (88.1,94.9)	0.9805
***Men were instructed to answer the following questions only if they answered 'YES' to the above question*							
Did the erections change your emotional relationship with your partner?	24	18.6 (11.8,25.4)	12	13.6 (6.4,20.9)	36	16.6 (11.6,21.6)	0.3340
Did the loss of erections make you feel "less of a man"?	47	33.6 (25.7,41.5)	27	27.0 (18.2,35.8)	74	30.8 (24.9,36.7)	0.2771
Did the loss of erections bother your partner?	28	23.7 (16.0,31.5)	11	12.8 (5.7,19.9)	39	19.1 (13.7,24.6)	0.0498
Did the loss of erections change the way you interacted with your mates?	13	9.4 (4.5,14.2)	2	2.0 (0.0,4.8)	15	6.3 (3.2,9.4)	0.0218
Did you feel depressed because of the loss of erections?	48	34.3 (26.4,42.2)	23	23.2 (14.9,31.6)	71	29.7 (23.9,35.5)	0.0655
Did you discuss this side effect with your doctor?	54	38.8 (30.7,47.0)	24	24.2 (15.7,32.7)	78	32.8 (26.8,38.8)	0.0180
Was the doctor able to offer anything to manage this side effect	37	39.8 (29.7,49.8)	14	24.6 (13.3,35.9)	51	34.0 (26.3,41.7)	0.0561

* Rao-Scott chi-square test for the difference between men aged under 75 and those aged 75 and over
** Some men answered no to the first question but still responded to other questions

Decreased length of penis

Table 4 shows that 115 of the men surveyed experienced a decrease in the length of their penis.

Of those men that experienced this side effect one in five (20.6%) of them needed to sit down to pass urine (15.0,26.1 95%CI).

Nearly a quarter of the men that experienced a decrease in the length their penis, felt depressed (17.7,29.4 95%CI) and "less of a man" (17.5,29.1 95%CI) because of it.

Only 34 of the 193 reported this side effect to their doctor, and the doctor offered to manage this side effect for 15% (9.1,22.3 95%CI) of those men.

Figure 4

"Makes urinating very difficult when the penis muscle shrinks but the foreskin does not."
(Participant number 308)

"I go swimming each morning and we have communal showers and I now feel uncomfortable around my mates."
(Participant number 35)

Table 4: Number and proportion of men who experienced a decrease in the length of their penis

	Under 75		75 and over		All		Difference
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	(p value)*
Did you experience a decrease in the length of your penis?	115	76.2 (69.3,83)	78	70.9 (62.4,79.5)	193	73.9 (68.6,79.3)	0.3400
***Men were instructed to answer the following questions only if they answered 'YES' to the above question*							
Did the decrease in the length of your penis require you to sit down to pass urine?	23	18.9 (11.9,25.9)	20	23.0 (14.1,31.9)	43	20.6 (15.0,26.1)	0.4659
Did the decrease in the length of your penis make you feel "less of a man"?	33	27.7 (19.6,35.8)	15	17.2 (9.2,25.2)	48	23.3 (17.5,29.1)	0.0786
Did the decrease in the length of your penis make you uncomfortable with your partner?	21	19.8 (12.2,27.5)	12	16.4 (7.9,25.0)	33	18.4 (12.7,24.2)	0.5674
Did the decrease in the length of your penis make you feel uncomfortable around your mates?	10	8.5 (3.4,13.7)	5	5.9 (0.8,10.9)	15	7.4 (3.8,11.1)	0.4758
Did you feel depressed about the decrease in the length of you penis?	32	27.1 (19.0,35.2)	16	18.6 (10.3,26.9)	48	23.5 (17.7,29.4)	0.1569
Did you discuss this side effect with your doctor?	23	19.5 (12.3,26.7)	11	12.8 (5.7,19.9)	34	16.7 (11.5,21.8)	0.2047
Was your doctor able to offer anything to manage this side effect?	14	19.2 (10.0,28.3)	5	10.4 (1.7,19.2)	19	15.7 (9.1,22.3)	0.1950

*Rao-Scott chi-square test for the difference between men aged under 75 and those aged 75 and over ($p < 0.05$)

** Some men answered no to the first question but still responded to other questions.

Loss of size of the testes

Table 5 shows that shrinkage of the testes was experienced by 59% of men surveyed.

There was a difference in the groups when reporting that they felt "less of a man" because of testicular shrinkage. The younger men reported this three times more (12.1,28.7 95%CI) than the men over 75 years of age 1.1,14.0 95%CI) P=0.0257.

Figure 5

"My testes did lose size and they also got very touchy and sore."
(Participant number 437)

"Yes it sucks!"
(Participant number 218)

The men under the age of 75 were also twice as depressed (12.0,28.4 95%CI) about the decrease in the size of their testes as the men aged over 75 (2.1,16.1) P=0.0565.

Table 5: Number and proportion of men who experienced a loss of size of their testes

	Under 75		75 and over		All		Difference
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	(p value)*
Did you experience the loss of size of your testes?	89	61.8 (53.8,69.8)	59	55.7 (46.1,65.2)	148	59.2 (53.1,65.3)	0.3286
***Men were instructed to answer the following questions only if they answered 'YES' to the above question*							
Did the decrease in the size of your testes make you feel "less of a man"?	19	20.4 (12.1,28.7)	5	7.6 (1.1,14.0)	24	15.1 (9.5,20.7)	0.0257
Did the decrease in the size of your testes make you feel uncomfortable with your partner?	14	16.5 (8.5,24.5)	7	13.2 (4.0,22.4)	21	15.2 (9.1,21.3)	0.6037
Did the decrease in the size of your testes make you feel uncomfortable with your mates?	8	8.5 (2.8,14.2)	5	7.8 (1.2,14.5)	13	8.2 (3.9,12.6)	0.8754
Did the decrease in the size of your testes stop you from going out socially?	4	4.2 (0.1,8.3)			4	2.5 (0.1,4.9)	na
Did you feel depressed about the decrease in the size of your testes?	19	20.2 (12.0,28.4)	6	9.1 (2.1,16.1)	25	15.6 (9.9,21.3)	0.0565
Did you speak with your doctor about this side effect?	19	20.4 (12.1,28.7)	9	13.8 (5.4,22.3)	28	17.7 (11.7,23.7)	0.2862
Was your doctor able to offer anything to manage this side effect	13	21.0 (10.7,31.3)	3	8.3 (0,17.5)	16	16.3 (8.9,23.8)	0.1028

*Rao-Scott chi-square test for the difference between men aged under 75 and those aged 75 and over ($p < 0.05$)

** Some men answered no to the first question but still responded to other questions.

Hot flushes

Hot flushes were the second highest of the reported side effects.

Table 6 shows that 88% of men surveyed experienced hot flushes. Hot flushes interfered with sleeping for 150 of the 234 men that were affected. More than one third of men under the age of 75 felt depressed by the hot flushes (35%).

There was a difference between the two age groups when discussing hot flushes with their doctor. 52% of men under 75 (43.7,60.7 95%CI) compared to 38% of the men over 75 (28.7,48.0 95%CI).

Figure 6

"I found hot flushes the most humiliating part."
(Participant number 279)

"Initially flushes were up to 30-40 per day. Still having flushes at night 2 years after the treatment."
(Participant number 123)

The doctor was able to manage this side effect for 37% of the men who reported it.

Table 6: Number and proportion of men who experienced hot flushes

	Under 75		75 and over		All		Difference
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	(p value)*
Did you experience hot flushes?	136	88.9 (83.9,93.9)	98	87.5 (81.3,93.7)	234	88.3 (84.4,92.2)	0.7282
***Men were instructed to answer the following questions only if they answered 'YES' to the above question*							
Did the hot flushes prevent you from doing everyday things?	24	17.6 (11.2,24.1)	14	13.9 (7.1,20.6)	38	16.0 (11.3,20.7)	0.4322
Did you find the hot flushes physically debilitating?	57	41.9 (33.6,50.3)	34	33.7 (24.4,42.9)	91	38.4 (32.2,44.6)	0.1967
Did the hot flushes interfere with your sleeping?	95	69.9 (62.1,77.6)	55	54.5 (44.7,64.2)	150	63.3 (57.1,69.5)	0.0150
Did you feel depressed about the hot flushes?	47	34.6 (26.5,42.6)	24	23.8 (15.4,32.1)	71	30.0 (24.1,35.8)	0.0728
Did you discuss this side effect with your doctor?	71	52.2 (43.7,60.7)	38	38.4 (28.7,48.0)	109	46.4 (40.0,52.8)	0.0359
Was the doctor able to offer anything to manage this side effect	39	38.2 (28.7,47.8)	24	35.3 (23.8,46.8)	63	37.1 (29.7,44.4)	0.6973

*Rao-Scott chi-square test for the difference between men aged under 75 and those aged 75 and over ($p < 0.05$)
** Some men answered no to the first question but still responded to other questions

Enlarged or tender breasts

Enlarged and tender breasts was the second lowest reported side effect.

Table 7 shows that more than half (53%) of the men experienced enlarged or tender breasts with age not being a factor.

One in 10 men "felt less of a man" because of their enlarged breasts but only 2% of men reported that the breast enlargement they experienced affected their relationship with their partner and 3% of men reported that the breast enlargement affected their social life. Twenty one men felt people noticed the change in their breasts and 12% of men changed the style of shirts they wore because of their enlarged breasts.

Figure 7

"It somewhat affected myself image."
(Participant number 318)

"Had very sensitive nipples - could not wear braces or anything tight over the nipples."
(Participant number 355)

Depression about breast enlargement was experienced by 12% men. Despite one hundred and thirty six men experiencing this side effect only twenty six men reported it to their doctor. The doctor was able to manage the side effect for half of those that reported.

Table 7: Number and proportion of men who experienced enlarged or tender breasts

	Under 75		75 and over		All		Difference
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	(p value)*
Did you experience enlarged or tender breasts?	83	55.7 (47.7,63.7)	53	48.2 (38.8,57.6)	136	52.5 (46.4,58.6)	0.2308
***Men were instructed to answer the following questions only if they answered 'YES' to the above question*							
Did the change in your breasts affect your relationship with your partner?	3	3.7 (0.0,7.9)			3	2.3 (0.0,4.8)	na
Did the change in your breasts impact on your social life?	3	3.4 (0.0,7.2)	2	3.4 (0.0,8.1)	5	3.4 (0.4,6.3)	0.9950
Did the change in your breasts make you feel "less of a man"?	9	10.1 (3.8,16.4)	6	10.2 (2.4,18.0)	15	10.1 (5.2,15.1)	0.9910
Did you feel like people noticed the change in your breasts?	13	14.6 (7.2,22.0)	8	13.6 (4.7,22.4)	21	14.2 (8.5,19.9)	0.8581
Did you have to change the style of shirts you wore because of the change in your breasts?	11	12.6 (5.6,19.7)	7	11.9 (3.5,20.2)	18	12.3 (6.9,17.7)	0.8882
Did you feel depressed about the change in your breasts?	12	13.6 (6.4,20.9)	5	8.5 (1.3,15.7)	17	11.6 (6.3,16.8)	0.3374
Did you discuss this side effect with your doctor?	17	19.8 (11.2,28.3)	9	15.5 (6.1,24.9)	26	18.1 (11.7,24.4)	0.5155
Was the doctor able to offer anything to manage this side effect	9	17.6 (7.0,28.3)	4	11.1 (0.6,21.6)	13	14.9 (7.3,22.6)	0.3997

*Rao-Scott chi-square test for the difference between men aged under 75 and those aged 75 and over ($p < 0.05$)
** Some men answered no to the first question but still responded to other questions

Weight gain

Weight gain was experienced by 154 men with age not being a factor. However, there was a difference between the men aged under 75 (52.5% (42.6,63.3 95%CI) and those aged over 75 (32.3%(20.8,43.8 95%CI) P=0.0141 when it came to worry about the physical impact of weight gain.

Twenty three percent of men under 75 were worried about what other people thought about their weight gain, with only 8% of the older group being worried about it.

Twice as many of the under 75 year old men (30.0% (20.9,39.1 95%CI) compared with the over 75 year age group (14.3% (5.6,23.0 95%CI) felt depressed about their weight gain. The doctor was able to help manage this side effect for 35.1% of those men that reported it.

Figure 8

Weight gain had a big affect on marriage. Got sick of being asked how my cancer is going, so stopped playing bowls and stopped going out."
(Participant number 416)

"I had to purchase new clothes!"
(Participant number 238)

Table 8: Number and proportion of men who experienced weight gain

	Under 75		75 and over		All		Difference
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	(p value)*
Did you experience any weight gain?	97	63.8 (56.1,71.5)	57	52.8 (43.3,62.3)	154	59.2 (53.2,65.2)	0.0743
***Men were instructed to answer the following questions only if they answered 'YES' to the above question*							
Did the weight gain stop you from going out socially?	4	3.9 (0.1,7.7)			4	2.4 (0.1,4.7)	na
Did you worry about the physical impact of the weight gain?	53	52.5 (42.6,62.3)	21	32.3 (20.8,43.8)	74	44.6 (36.9,52.2)	0.0107
Were you worried what other people thought about your weight gain?	23	22.8 (14.5,31)	5	7.9 (1.2,14.7)	28	17.1 (11.3,22.9)	0.0141
Did you feel depressed about your weight gain?	30	30.0 (20.9,39.1)	9	14.3 (5.6,23)	39	23.9 (17.3,30.5)	0.0220
Did you speak with your doctor about this side effect?	48	48.5 (38.5,58.4)	21	33.3 (21.6,45.1)	69	42.6 (34.9,50.3)	0.0573
Was the doctor able to offer anything to manage this side effect	30	40.5 (29.2,51.9)	10	25 (11.4,38.6)	40	35.1 (26.2,44.0)	0.0971

*Rao-Scott chi-square test for the difference between men aged under 75 and those aged 75 and over ($p < 0.05$)
** Some men answered no to the first question but still responded to other questions

Tiredness or fatigue

Table 9 shows that 1 in 8 men surveyed experienced tiredness or fatigue with age not being a factor. Age was also not a factor with reporting difficulty starting or finishing tasks with 60% in each group reporting.

Being too tired to attend social activities was experienced by 35% of men and 66% of men spent a lot of time sleeping or resting.

There were 38% of men who felt depressed by their fatigue.

Of the sixty four men that reported this side effect to the doctor, thirty four of them were offered something to help manage this side effect.

Figure 9

"Tiredness /fatigue was extreme at times which led to a huge loss of motivation."
(Participant number 270)

"I was just all over the place. I just didn't feel like doing things. I even sold all the cattle."
(Participant number 431)

Table 9: Number and proportion of men who experienced tiredness/fatigue

	Under 75		75 and over		All		Difference
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	(p value)*
Did you experience tiredness/fatigue?	124	81.0 (74.8,87.3)	81	77.1 (69.1,85.2)	205	79.5 (74.5,84.4)	0.4459
***Men were instructed to answer the following questions only if they answered 'YES' to the above question*							
Did the tiredness mean you had problems starting tasks?	75	61.0 (52.3,69.7)	51	60.7 (50.2,71.2)	126	60.9 (54.2,67.6)	0.9698
Did the tiredness mean you had problems finishing tasks?	73	59.8 (51.1,68.6)	50	60.2 (49.6,70.9)	123	60.0 (53.2,66.8)	0.9537
Were you too tired to attend social activities?	48	39.3 (30.6,48.1)	23	28.0 (18.2,37.9)	71	34.8 (28.2,41.4)	0.0968
Did you spend a lot of time sleeping or resting?	81	66.9 (58.5,75.4)	54	65.1 (54.7,75.4)	135	66.2 (59.6,72.7)	0.7802
Did you feel depressed about how tired you felt?	44	36.1 (27.5,44.7)	33	39.8 (29.1,50.4)	77	37.6 (30.9,44.2)	0.5919
Did you speak with your doctor about this side effect?	46	38.3 (29.6,47.1)	23	28.0 (18.2,37.9)	69	34.2 (27.6,40.8)	0.1301
Was your doctor able to offer anything to manage this side effect	24	29.3 (19.3,39.2)	10	20.0 (8.8,31.2)	34	25.8 (18.2,33.3)	0.2375

*Rao-Scott chi-square test for the difference between men aged under 75 and those aged 75 and over ($p < 0.05$)

** Some men answered no to the first question but still responded to other questions

Lack of concentration or difficulty thinking clearly

This was the least reported side effect, however provoked many emotional responses in the free text comments.

Table 10 shows that one hundred and sixteen men experienced lack of concentration and difficulty thinking with eighty six men having to write lists so they didn't forget things.

Fifty nine men had friends and family telling them they were being forgetful with forty eight men feeling depressed about is side effect.

Twenty two percent stopped doing the things that they enjoyed because of their inability to think clearly.

Twenty two percent of men were concerned about their safety.

Figure 10

"Lack of concentration/ difficulty thinking stopped me from doing things in life I enjoyed and made me feel depressed."
(Participant number 247)

"Driving my car safely was a concern as concentration lapsed from time to time."
(Participant number 412)

Table 10: Number and proportion of men who experienced lack of concentration or difficulty thinking clearly

	Under 75		75 and over		All		Difference
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	(p value)*
Did you experience a lack of concentration/difficulty thinking clearly?	71	47.3 (39.3,55.4)	45	43.7 (34.0,53.3)	116	45.8 (39.7,52.0)	0.5677
***Men were instructed to answer the following questions only if they answered 'YES' to the above question*							
Did you have to write yourself a list so that you didn't forget things?	54	71.1 (60.7,81.4)	32	59.3 (46.0,72.5)	86	66.2 (57.9,74.4)	0.1614
Did family and friends tell you that you were being forgetful?	38	50.7 (39.2,62.1)	21	38.9 (25.7,52.1)	59	45.7 (37.0,54.4)	0.1853
Did having difficulty thinking clearly stop you from doing the things in life you enjoyed?	20	27.0 (16.8,37.3)	8	15.1 (5.3,24.9)	28	22.0 (14.7,29.4)	0.1097
Did you feel concerned for your safety at any time?	17	22.7 (13.1,32.3)	12	22.2 (11.0,33.5)	29	22.5 (15.2,29.8)	0.9524
Did having difficulty thinking clearly make you feel depressed?	31	41.3 (30.0,52.6)	17	31.5 (18.9,44.0)	48	37.2 (28.8,45.7)	0.2534
Did you speak with your doctor about this side effect?	16	21.9 (12.3,31.5)	9	16.7 (6.6,26.7)	25	19.7 (12.7,26.7)	0.4619
Was your doctor able to offer anything to manager this side effect	8	18.6 (6.7,30.5)	5	15.2 (2.6,27.7)	13	17.1 (8.4,25.8)	0.6919

*Rao-Scott chi-square test for the difference between men aged under 75 and those aged 75 and over ($p < 0.05$)

** Some men answered no to the first question but still responded to other questions

Mood swings or depression

Table 11 shows that 59% of men surveyed experienced mood swings or depression secondary to their ADT.

Of the 150 men who reported mood swings or depression, 75% of them felt short tempered, cranky and irritable. About half of men reported they could cry easily.

Men under 75 were more likely to report this side effect (31.9% (22.4,41.4 95%CI) than the men over 75 (20.9% (11.1,30.7 95%CI) P=0.1220.

Of the 27% of all men that reported this side effect to the doctor, more younger men reported success in managing this side effect (32.1%(19.7,44.6 95%CI) than older men (14.0%(3.4,24.5 95%CI) P=0.0363

Figure 11

"Noticeably cranky, but was just a matter of self control. Certainly has improved since going off the hormones."
(Participant number 210)

"I have become uncharacteristically moody with depression and a sense of helplessness."
(Participant number 263)

Table 11: Number and proportion of men who experienced mood swings or depression

	Under 75		75 and over		All		Difference
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	(p value)*
Did you experience any mood swings or depression?	88	59.5 (51.5,67.4)	62	58.5 (49.0,67.9)	150	59.1 (53.0,65.1)	0.8769
***Men were instructed to answer the following questions only if they answered 'YES' to the above question*							
Did you feel short tempered, irritable, cranky?	72	76.6 (67.9,85.2)	49	72.1 (61.3,82.8)	121	74.7 (67.9,81.5)	0.5122
Did you feel you could cry easily?	52	54.7 (44.6,64.9)	36	52.2 (40.3,64.1)	88	53.7 (45.9,61.4)	0.7452
Did you feel depressed?	62	65.3 (55.6,74.9)	38	55.9 (44.0,67.8)	100	61.3 (53.8,68.9)	0.2252
Did you speak with your doctor about this side effect?	30	31.9 (22.4,41.4)	14	20.9 (11.1,30.7)	44	27.3 (20.4,34.3)	0.1220
Was your doctor able to offer you anything to manage this side effect	18	32.1 (19.7,44.6)	6	14.0 (3.4,24.5)	24	24.2 (15.7,32.8)	0.0363

*Rao-Scott chi-square test for the difference between men aged under 75 and those aged 75 and over ($p < 0.05$)

** Some men answered no to the first question but still responded to other questions

Summary of Key Results

Most common side effects for all men were:-

Loss of erection	(91.5%)
Hot Flushes	(88.3%)
Loss of desire for sex	(83.3%)

Least commons side effects were:-

Depression or mood swings	(59.1%)
Enlarged Breasts and tender nipples	(52.5%)
Loss of concentration or difficulty thinking	(45.8%)

Men under 75 experienced “feeling depressed” more often than the over 75 year old men on every side effect except tiredness and fatigue. Men under 75 also reported their side effects to the doctor, on every item more than the men over 75 years.

Men over 75 years only experienced two items more than the under 75 years men:-

Having to sit down to pass urine
Feeling depressed about how tired they felt

The doctor was best able to help with:-

Hot flushes	(37.1%
Weight Gain	(35.1%)
Loss of erections	(34%)

The doctor was least able to help with:-

Loss of size of testes	(16.3%)
Loss of length of penis	(15.7%)
Enlarged and tender breasts	(14.9%)

Free text comments for individual side effect

Loss of desire for sex -	28 comments
Loss of erections –	65 comments
Decreased length of penis-	36 comments
Loss of size of testes –	19 comments
Hot Flushes –	64 comments
Enlarged or tender breasts –	34 comments
Weight Gain -	32 comments
Tiredness or fatigue –	29 comments
Lack of concentration or difficulty thinking clearly–	22 comments
Mood swings or depression -	39 comments
Other comments	70 comments

Discussion

It is not difficult to learn about all of the side effects of ADT as this can be found by referring to MIMS. However, there is very little information written in the literature about the actual impact those side effects has on the lives of men and their families. Just as cancer has no barriers about whom it affects, likewise, there are no barriers as to who will suffer the consequences of the side effects of their cancer treatment.

The results of this study showed that neither age nor length of time on ADT made a difference to the impact of the side effects. Every man was equally susceptible. The most prevalent side effects were loss of erection (91.5%) and hot flushes (88.3%). These two side effects were able to be ameliorated by the doctor in a third of the men. Loss of concentration and difficulty thinking however, was the least prevalent side effect but it still impacted on nearly fifty percent of the men. Despite it being the least reported side effect, the impact was not inconsequential. This was expressed in the highly emotive descriptions in the free text comments which some describe as the side effect having the most negative impact on family and partners, particularly when it came to aspects of safety.

The free text comments also showed there is a disconnect between the doctor and patient in communication about side effects. Interpreting the free text comments, it appears that patients and doctors have a different perspective on ADT. Rightly, the medical staff has a focus on "cure" but generally the patients are considering their treatment from a "care" angle. There needs to be a concerted effort for both care and cure to be considered with equal importance. Patient advocacy by nurses is paramount in this context. The nurse must encourage and empower patients to ask questions of the medical staff. Details about risk benefit ratios, nomograms and other medical jargon that the lay person generally does not understand is not acceptable when patients are trying to make informed decisions about treatment options.

There are challenges in providing clinical decision making. Li (2009 demonstrated that for prescribed medication, information about possible side effects was regarded as the most important by the surveyed patients, but doctors rated it eleventh out of sixteen in importance.
Gray in his 2005 qualitative study about the experiences of men receiving ADT, found men's experiences with ADT was determined by the lack of preparation for what to expect either because they weren't told, or because the information given to them minimised the impact of the treatment. He found the gap between what was ideal and what was offered to the men is

particularly wide. He concluded that whilst men were grateful to receive potentially life–extending treatment, the challenge for the health care system was to provide men with the information and clinical support that will make their remaining years the best they can be. Fitzgerald (2004) points out, that care and cure are often used in adversarial terms. Cure (the usual aim of medical treatment) is usually so dominant, that care (the usual aim of nursing) can only be valued and flourish when pitted successfully against cure. Patients are best served by a balance of cure and care.

Pre-existing conditions appeared not to be a priority when men were prescribed ADT. This study identified that seventy five percent of men had more than one comorbidity prior to being exposed to ADT. Leahy (2008) in her study on the risk of cardiovascular disease and diabetes in ADT, describes the real potential for adverse effects of using ADT for localised prostate cancer. This too is where patient advocacy by the nursing staff is required to ensure all aspects of patient safety are considered.

The results from this study have three main implications.

Nurses are in a unique position to act as patient advocates because of the relationship they establish with a patient. The men and their partners in this study had at least one face to face interview prior to the commencement of their cancer treatment. This interview provided an opportunity to build a trusting nurse patient relationship. By creating a safe environment quickly the nurse was afforded the best opportunity to gather important personal information. Information from this study can support patients by empowering them to ask the doctors the right questions to get the answers to help them manage the side effects of their treatment for their cancer.

Doctors need to be asking the patients different questions and providing a level of information that the lay person can understand. The one size fits all consultation approach doesn't work for all patients given they have individualised requirements. Perhaps putting the onus on the patient's to set the agenda of the consultation might provide the patient with a more satisfactory outcome. Of course this approach may not work for the over 75's as they tend not to ask the doctor any questions. This could be a topic which requires further investigation.

Strengths

Strengths of the study include the saturation sample with a high response rate of 64%. There was genuine interest from the participants in being involved in the research by the amount of added information provided in the 489 free text comments. There were also more than 130 respondents that were interested in taking part in a focus group to discuss their concerns further.

Limitations

Limitations of the study were that a non-validated questionnaire was used which meant that comparison to other studies was not possible. Many of the patients in the study had a longer course of neo-adjuvant ADT than would be the norm, due to the delay of the opening of the new cancer centre.

Conclusion

This study gives a much sounder understanding of the negative impact of being on ADT and the effect on sexual, physical, emotional and cognitive function. Nurses should be advocating for their patients by ensuring the patients are having the opportunity to ask questions that are pertinent to their own situation and level of understanding. Ensuring patients are receiving appropriate and adequate information to make an informed decision about treatment options for their prostate cancer.

Implications for Practice

Some men are being prescribed ADT despite a lack of evidence to support its use. This has the potential to expose men to an exacerbation of pre-existing co-morbidities, as well as have a negative impact on their sexual, emotional and cognitive function. Prescribing ADT should be undertaken in conjunction with supporting research.

Medical staff are to be encouraged to consider cure and care with equal importance when considering treatment options. Honest, clear and accurate communication at a level that can be understood needs to be provided to the patient so that informed decisions are being made. It is imperative a balanced opinion regarding the risks and benefits of treatment is given.

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PARTICIPANT INFORMATION SHEET

Study Title:

"Androgen Deprivation Therapy for Prostate Cancer - The Lived Experience of patients and their partners."

Principal Investigator: Karen Gorzynska – North Coast Cancer Institute, Coffs Harbour.

You are being invited to participate in a research study.

This Participant Information Sheet contains detailed information about the research study. Its purpose is to explain to you as openly and clearly as possible what is involved in the study before you decide whether or not to take part in it.

Please read this Participant Information carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the study with a relative or friend or your local health worker. Feel free to do this.

By completing and returning the questionnaire you indicate that you understand the information and that you give your consent to participate in the research project.

You can retain this Participant Information Sheet to keep as a record.

This study is being undertaken by Karen Gorzynska, Clinical Nurse Consultant, Cancer Nurse Coordinator at the North Coast Cancer Institute, Coffs Harbour. The project is being funded in the form of a research scholarship by the New South Wales Institute of Rural Clinical Services and Teaching.

1. What is the purpose of the study?

This study is being done to find out how the side effects of the androgen deprivation therapy (hormone therapy) affected the quality of life for you and your partner.

2. Why have I been asked to participate in this study?

You have been selected to participate in this study because you have been prescribed hormone therapy as part of your treatment for your prostate cancer. Your opinion is important to us because of your personal experience with this treatment. Your answers will be very helpful for people facing the same situation in the future. About 450 people will participate in this study.

3. What if I don't want to take part in this study, or I want to withdraw later?

Participation in this study is voluntary. It is completely up to you whether or not you wish to participate. Your choice not to participate will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

Before you make your decision, the Investigator, Karen Gorzynska, will be available so you can ask any questions about the study. You can ask for any information you want. Complete the questionnaire only after you have had a chance to ask your questions and have received satisfactory answers.

If you wish to withdraw from the study you can do so at any time without having to give a reason.

4. What does this study involve?

If you agree to take part in this study, you will be asked to complete a questionnaire and return it to the investigator in the reply paid envelope. The questionnaire should take less than 30 minutes to complete.

Most of the questions are related to the hormone therapy you were prescribed as part of your treatment for your prostate cancer. There are also some questions about your age and your marital status.

When the results of the questionnaire have been collated, you/and your partner may be asked to participate in a small group discussion with other people who have taken part in the study. You/and your partner will be asked to sign a consent form prior to the small group discussion.

5. Are there any risks to me taking part in this study?

There are no physical risks involved in this study. Taking part in the study has no effect on your treatment or follow-up. Occasionally, some people may find the questions upsetting. Please let the Principal Investigator, Karen Gorzynska, know if the questions upset you so that we can arrange appropriate support.

Study information will be kept secure at all times and will be destroyed afterwards according to local hospital policy. Reports of the study will be published, but this will not include details that reveal the identities of patients who took part.

6. Will I benefit from the study?

The study aims to further knowledge and to help people faced with a similar situation in the future, however, it will not directly benefit you. Many people involved in similar studies appreciate the opportunity of expressing their views.

7. Will taking part in this study cost me anything?

There is no cost to you to be involved in this study .

8. How will my confidentiality be protected?

You will be allocated a code as your identifying information. Any identifiable information that is collected about you in connection with this study will remain confidential and will not be disclosed. All information regarding this study will be stored in a locked cabinet. Access to the cabinet will only be available to the Principal Investigator, Karen Gorzynska. As per the National Health and Medical Research Council National Statement all records will be retained for a minimum of 5 years after the completion of the study and then destroyed.

9. What happens with the results?

If you agree to participate in the study, results of this study may be presented at conferences or other professional forums, and published in peer-reviewed journals. In any publication, information will be provided in such a way that you cannot be identified. Results of the study can be provided to you, if you wish, by the Principal Investigator, Karen Gorzynska.

10. Further information or any problems?

If you require further information please contact the Principal Investigator

Name: Karen Gorzynska

Position: Cancer Nurse Coordinator

Telephone: 02 66 56 5737

The NCAHS Human Research Ethics Committee has approved this research project. Any complaints or concerns about this research project may be made to the NCAHS Human Research Ethics Committee through the Research Ethics Officer as follows:

Research Ethics Officer

NCAHS Human Research Ethics Committee

PO Box 126

Port Macquarie NSW 2444

Tel: (02) 6588 2941

Fax: (02) 6588 2942

Email: EthicsNCAHS@ncahs.health.nsw.gov.au

Thank you for taking the time to consider being part of this study. If you wish to take part please complete the questionnaire and return in the enclosed stamped envelope by 25th June 2010.

CONSENT FORM

SMALL DISCUSSION GROUP

"Androgen Deprivation Therapy for Prostate Cancer - The Lived Experience of patients and their partners."

I, ……(name)

Of ……..(address)

have read and understood the Information for Participants on the above named research study. I understand that I am agreeing to participate in a small discussion group which is part of the research study.

I understand that the research project will be carried out according to the principles in the National Health & Medical Research Council Statement on Ethical Conduct in Research Involving Humans.

I freely choose to participate in this study and understand I can withdraw at any time.

I also understand that the research is strictly confidential.

I hereby agree to participate in this study.

PARTICIPANT/PARTNER NAME: ……

PARTICIPANT/PARTNER SIGNATURE: ……

DATE: ……..

Research study funded by the NSW Institute of Rural Clinical Services and Teaching

Investigator: Karen Gorzynska……

Signature of Investigator:……

Date: ……..

"Androgen Deprivation Therapy for Prostate Cancer – the Lived Experience of patients and their partners"

Questionnaire

These questions relate to information discussed at your initial consultation regarding the side effects of hormone therapy.

Question 1 – Please indicate your age group with a tick.

Less than 50	☐
51-59	☐
60-69	☐
70-79	☐
80-89	☐

Question 2 - Please tick the statement that best describes your current relationship.

Living with spouse or partner	☐
In a significant relationship but not living together	☐
Not in a significant relationship	☐

Question 3 - Are you still on hormone therapy?

Yes ☐ No ☐

Question 4 - If you answered no to question 3, how long ago did you finish?

Weeks ☐
Months ☐
Years ☐

Question 5 - How long were you on hormone therapy? Please tick one box.

Less than 3 months ☐
3 to 6 months ☐
6 to 9 months ☐
3 Years ☐
Other ☐ How long?_____

Question 6 - For each side effect, please tick the box that best describes how you were affected.

Side Effect	No Impact	Minor Impact	Major Impact
Loss of desire to have sex			
Loss of erection			
Decrease in the size of the penis			
Decrease in the size of the testicles			
Hot flushes			
Enlarged breasts			
Tender breasts			
Weight gain			
Tiredness/lack of energy			
Lack of concentration/initiative			
Mood Swings			

Question 7

Did you experience any of the following symptoms?

	Yes	No	N/A
Loss of muscle strength			
Loss of chest and arm hair			
Aches and Pains			
Osteoporosis (thinning of bones)			
Anaemia (low blood count)			
Rise in cholesterol			
Worsening of diabetes			
Worsening of lung disease			
Other (please describe below)			

Question 8	Yes	No	N/A
Did you experience a loss of desire for sex? If 'Yes' please answer all questions on this page, if 'no' please go to question (9)			
• Did the loss of desire for sex make you feel differently about your partner?			
• Did the loss of desire for sex make you feel differently about yourself?			
• Did the loss of desire for sex change your interactions with your mates?			
• Did you feel depressed because of the loss of desire for sex?			
• Did you discuss this side effect with your doctor?			
• Was the doctor able to offer to help you manage this side effect eg. counselling, medication, referral to other health professional?			
• Do you have any other comments regarding your experience with the loss of desire for sex?			

Question 9	Yes	No	N/A
Did you experience the loss of erections? If 'Yes' please answer all questions on this page, if 'no' please go to question (10)			
• Did the loss of erections change your emotional relationship with your partner?			
• Did the loss of erections make you feel "less of a man?"			
• Did the loss of erections bother your partner?			
• Did the loss of erections change the way you interacted with your mates?			
• Did you feel depressed because of the loss of erections?			
• Did you discuss this side effect with your doctor?			
• Was the doctor able to offer you anything to help you manage this side effect eg. counselling, medication, referral to other health professional?			

- Do you have any other comments regarding your experience with the loss of erections?

Question 10	Yes	No	N/A
Did you experience a decrease in the length of your penis? If 'Yes' please answer all questions on this page, if 'no' please go to question (11)			
• Did the decrease in the length of your penis require you to sit down to pass urine?			
• Did the decrease in the length of your penis make you feel "less of a man"?			
• Did the decrease in the length of your penis make you uncomfortable with your partner?			
• Did the decrease in the length of your penis make you feel uncomfortable around your mates?			
• Did you feel depressed about the decrease in the length of your penis?			
• Did you discuss this side effect with your doctor?			
• Was the doctor able to offer you anything to help you manage this side effect eg. counselling, medication, referral to other health professional?			
• Do you have any other comments regarding your experience with the decrease in the length of your penis? _____ _____ _____ _____			

Question 11	Yes	No	N/A
Did you experience the loss of size of your testes? If 'Yes' please answer all questions on this page, if 'no' please go to question (12)			
• Did the decrease in the size of your testes make you feel "less of a man"			
• Did the decrease in the size of your testes make you feel uncomfortable with your partner?			
• Did the decrease in the size of your testes make you feel uncomfortable with your mates?			
• Did the decrease in the size of your testes stop you from going out socially?			
• Did you feel depressed about the decrease in the size of your testes?			
• Did you speak with your doctor about this side effect?			
• Was the doctor able to offer you anything to help you manage this side effect eg. counselling, medication, referral to other health professional?			
• Do you have any other comments regarding your experience with the loss of size of your testes? _____ _____ _____ _____ _____			

Question 12	Yes	No	N/A
Did you experience hot flushes? If 'Yes' please answer all questions on this page, if 'no' please go to question (13)			
• Did the hot flushes prevent you from doing everyday things?			
• Did you find the hot flushes physically debilitating?			
• Did the hot flushes interfere with your sleeping?			
• Did you feel depressed about the hot flushes?			
• Did you discuss this side effect with your doctor?			
• Was the doctor able to offer you anything to help you manage this side effect eg. counselling, medication, referral to other health professional?			

- Do you have any other comments regarding your experience with hot flushes?

Question 13	Yes	No	N/A
Did you experience enlarged or tender breasts? If 'Yes' please answer all questions on this page, if 'no' please go to question (14)			
• Did the change in your breasts affect your relationship with your partner?			
• Did the change in your breasts impact on your social life?			
• Did the change in your breasts make you feel "less of a man"?			
• Did you feel like people noticed the change in your breasts?			
• Did you have to change the style of shirts you wore because of the change in your breast?			
• Did you feel depressed about the change in your breasts?			
• Did you discuss this side effect with your doctor			
• Was the doctor able to offer you anything to help you manage this side effect eg. counselling, medication, referral to other health professional?			
• Do you have any other comments regarding your experience with enlarged or tender breasts?			

Question 14	Yes	No	N/A
Did you experience any weight gain? If 'Yes' please answer all questions on this page, if 'no' please go to question (15)			
• Did the weight gain stop you from going out socially?			
• Did you worry about the physical impact of the weight gain?			
• Were you worried about what other people thought about your weight gain?			
• Did you feel depressed about your weight gain?			
• Did you speak with your doctor about this side effect?			
• Was the doctor able to offer you anything to manage this side effect eg. counselling, medication, referral to other health professional?			

- Do you have any other comments regarding your experience with weight gain?

Question 15	Yes	No	N/A
Did you experience tiredness/fatigue? If 'Yes' please answer all questions on this page, if 'no' please go to question (16)			
• Did the tiredness mean you had problems starting tasks?			
• Did the tiredness mean you had problems finishing tasks?			
• Were you too tired to attend social activities?			
• Did you spend a lot of time sleeping or resting?			
• Did you feel depressed about how tired you felt?			
• Did you speak with your doctor about this side effect?			
• Was your doctor able to offer you anything to manage this side effect eg. counselling, medication, referral to other health professional?			

- Do you have any other comments regarding your experience with tiredness/fatigue?

Question 16	Yes	No	N/A
Did you experience a lack of concentration/ difficulty thinking clearly? If 'Yes' please answer all questions on this page, if 'no' please go to question (17)			
• Did having difficulty thinking clearly mean you had to write yourself a list so that you didn't forget things?			
• Did family and/or friends tell you that you were being forgetful?			
• Did having difficulty thinking clearly stop you from doing the things in life that you enjoyed?			
• Did having difficulty thinking clearly make you feel concerned for your safety at any time?			
• Did having difficulty thinking clearly make you feel depressed?			
• Did you speak with your doctor about this side effect?			
• Was your doctor able to offer you anything to manage this side effect eg.counselling, medication, referral to other health professional?			
• Do you have any other comments regarding your experience with lack of concentration / difficulty thinking clearly? _____ _____ _____ _____			

Question 17	Yes	No	N/A
Did you experience any mood swings or depression? If 'Yes' please answer all questions on this page if 'no' please go to next page			
• Did you feel short tempered, irritable, cranky etc.			
• Did you feel like you could cry easily?			
• Did you feel depressed?			
• Did you speak with your doctor about this side effect?			
• Was your doctor able to offer you anything to manage this side effect eg.counselling, medication, referral to other health professional?			
• Do you have any other comments regarding your experience with mood swings or depression?			

Any other comments about your experience with hormone therapy

Thank you very much for completing this survey.

If you / and your partner are interested in taking part in a small discussion group to explore and discuss some of the issues you have raised in this questionnaire please provide your name and contact details.

Name:_____

Phone Number(s): _____

_____

Best time for me to contact you: _____

Email address: _____