Urology Services Inquiry

Urology Services Inquiry | 1 Bradford Court | Belfast BT8 6RB
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Dr Johnathan McAleese
Belfast Health and Social Care Trust
Headquarters
51 Lisburn Road
Belfast
BT9 7AB

12 October 2023

Dear Sir,

Re: The Statutory Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust

Provision of a Section 21 Notice requiring the provision of evidence in the form of a written statement

I am writing to you in my capacity as Solicitor to the Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust (the Urology Services Inquiry) which has been set up under the Inquiries Act 2005 ('the Act').

I enclose a copy of the Urology Services Inquiry's Terms of Reference for your information.

You will be aware that the Inquiry has commenced its investigations into the matters set out in its Terms of Reference. The Inquiry is continuing with the process of gathering all of the relevant documentation from relevant departments, organisations and individuals. In addition, the Inquiry has also now begun the process of requiring individuals who have been, or may have been, involved in the range of matters which come within the Inquiry's Terms of Reference to provide written evidence to the Inquiry panel.

The Urology Services Inquiry is now issuing to you a Statutory Notice (known as a Section 21 Notice) pursuant to its powers to compel the provision of evidence in the form of a written statement in relation to the matters falling within its Terms of Reference.

This Notice is issued to you due to your held posts, within the Belfast Health and Social Care Trust, relevant to the Inquiry's Terms of Reference.

The Inquiry understands that you will have access to all of the relevant information required to provide the witness statement now or at any stage throughout the duration of this Inquiry. Should you consider that not to be the case, please advise us of that as soon as possible.

The Schedule to the enclosed Section 21 Notice provides full detail as to the matters which should be covered in the written evidence which is required from you. As the text of the Section 21 Notice explains, you are required by law to comply with it.

Please bear in mind the fact that the witness statement required by the enclosed Notice is likely (in common with many other statements we will request) to be published by the Inquiry in due course. It should therefore ideally be written in a manner which is as accessible as possible in terms of public understanding.

You will note that certain questions raise issues regarding documentation. If you in your personal capacity hold any additional documentation which you consider is of relevance to our work and is not within the custody or power of the Belfast Trust and has not been provided to us to date, then we would ask that this is also provided with this response.

If it would assist you, I am happy to meet with you and/or the Trust's legal representative(s) to discuss what documents you have and whether they are covered by the Section 21 Notice.

You will also find attached to the Section 21 Notice a Guidance Note explaining the nature of a Section 21 Notice and the procedures that the Inquiry has adopted in relation to such a notice. In particular, you are asked to provide your evidence in the form of the template witness statement which is also enclosed with this correspondence. In addition, as referred to above, you will also find enclosed a copy of the Inquiry's Terms of Reference to assist you in understanding the scope of the Inquiry's work and therefore the ambit of the Section 21 Notice.

Given the tight time-frame within which the Inquiry must operate, the Chair of the Inquiry would be grateful if you would comply with the requirements of the Section 21 Notice as soon as possible and, in any event, by the date set out for compliance in the Notice itself.

If there is any difficulty in complying with this time limit you must make application to the Chair for an extension of time before the expiry of the time limit, and that application must provide full reasons in explanation of any difficulty.

Finally, I would be grateful if you could acknowledge receipt of this correspondence and the enclosed Notice by email to Personal Information redacted by the USI.

Please do not hesitate to contact me to discuss any matter arising.

Yours faithfully

Anne Donnelly
Solicitor to the Urology Services Inquiry

Tel: Personal Information redacted by the USI
Mobile: Personal Information redacted by the USI

THE INDEPENDENT PUBLIC INQUIRY INTO
UROLOGY SERVICES IN THE
SOUTHERN HEALTH AND SOCIAL CARE TRUST

Chair's Notice

[No 23 of 2023]

pursuant to Section 21(2) of the Inquiries Act 2005

WARNING

If, without reasonable excuse, you fail to comply with the requirements of this Notice you will be committing an offence under section 35 of the Inquiries Act 2005 and may be liable on conviction to a term of imprisonment and/or a fine.

Further, if you fail to comply with the requirements of this Notice, the Chair may certify the matter to the High Court of Justice in Northern Ireland under section 36 of the Inquiries Act 2005, where you may be held in contempt of court and may be imprisoned, fined or have your assets seized.

TO: Dr Johnathan McAleese
BHSCT
Headquarters
51 Lisburn Road
Belfast
BT9 7AB

Issued by the Urology Services Inquiry on 12 October 2023. Annotated by the Urology Services Inquiry.

IMPORTANT INFORMATION FOR THE RECIPIENT

1. This Notice is issued by the Chair of the Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust on foot of the powers given to her by the Inquiries Act 2005.

2. The Notice requires you to do the acts set out in the body of the Notice.

3. You should read this Notice carefully and consult a solicitor as soon as possible about it.

4. You are entitled to ask the Chair to revoke or vary the Notice in accordance with the terms of section 21(4) of the Inquiries Act 2005.

5. If you disobey the requirements of the Notice it may have very serious consequences for you, including you being fined or imprisoned. For that reason you should treat this Notice with the utmost seriousness.

WITNESS STATEMENT TO BE PRODUCED

TAKE NOTICE that the Chair of the Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust requires you, pursuant to her powers under section 21(2)(a) of the Inquiries Act 2005 ('the Act'), to produce to the Inquiry a Witness Statement as set out in the Schedule to this Notice by noon **on 2nd November 2023.**

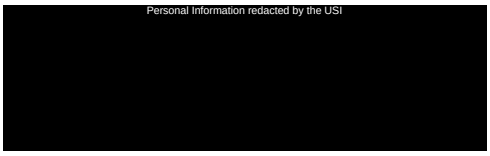
APPLICATION TO VARY OR REVOKE THE NOTICE

AND FURTHER TAKE NOTICE that you are entitled to make a claim to the Chair of the Inquiry, under section 21(4) of the Act, on the grounds that you are unable to comply with the Notice, or that it is not reasonable in all the circumstances to require you to comply with the Notice.

If you wish to make such a claim you should do so in writing to the Chair of the Inquiry at: **Urology Services Inquiry, 1 Bradford Court, Belfast, BT8 6RB** setting out in detail the basis of, and reasons for, your claim by noon **on 26th October 2023**.

Upon receipt of such a claim the Chair will then determine whether the Notice should be revoked or varied, including having regard to her obligations under section 21(5) of the Act, and you will be notified of her determination.

Dated this day 12th day of October 2023

Signed: 

Christine Smith QC

Chair of Urology Services Inquiry

SCHEDULE

[No 23 of 2023]

1. Please summarise your qualifications and occupational history.

2. Having regard to the Terms of Reference of the Inquiry, please provide a narrative account of your involvement in or knowledge of all matters falling within the scope of these Terms. This should include:

   (i) An explanation of your roles, responsibilities and duties within the Southern Health and Social Care Trust ("the Trust") and those roles within other organisations which engaged with the Trust or Urology on a regional basis in Northern Ireland, and

   (ii) A detailed description of any issues raised with or by you, meetings you attended, and actions or decisions taken by you or others to address or escalate any concerns regarding Urology services within the Trust.

   It would greatly assist the Inquiry if you would provide the above narrative in numbered paragraphs and in chronological order.

3. Please also provide any and all documents within your custody or under your control relating to the terms of reference of the Urology Services Inquiry ("USI"). Provide or refer to any documentation you consider relevant to any of your answers, whether in answer to Question 1 or to the questions set out below. Place any documents referred to in the body of your response as separate appendices set out in the order referred to in your answer. If you are in any doubt about document provision, please do not hesitate to contact either your own solicitor or the Inquiry Solicitor.

4. Please also address the following questions. If there are questions that you do not know the answer to, or if you believe that someone else is better placed to answer a question, please set this out in the statement and provide the name and role of that other person.

5. Professor Joseph O'Sullivan has provided a statement to the Inquiry, in which he states as follows:

> *'My concern was about the use of the oral anti-androgen, Bicalutamide 50mg as monotherapy for the treatment of localised prostate cancer. The correct monotherapy dose of bicalutamide is 150mg or alternatively LHRH agonist therapy. I noticed several cases where patients had been on bicalutamide 50mg as monotherapy, prescribed by Mr O'Brien. My concern was that bicalutamide 50mg was a sub-optimal dose of hormone therapy when used as a mono-therapy … I can't recall any specific discussion but I believe there was a general awareness of the issue amongst the oncology team treating prostate cancer.'* [WIT-96648]

Dr Darren Mitchell has also provided a statement to the Inquiry, in which he explains:

> *'I have been a Consultant Oncologist since June 2008 and believe there may have been a few cases referred to me who had also been on the Bicalutamide 50mg monotherapy regimen between 2008 and 2014.'* [WIT-96668]

> *'I believe the oncologists providing support as part of their job plan to the Craigavon urology service would have routinely been referred cases from Mr O'Brien and may have come across this off license prescribing. This would include Dr Johnathan McAleese, Professor David Stewart and Dr Fionnuala Houghton. I am not aware of any discussions they had if they had concerns.'* [WIT-96669]

In oral evidence to the Inquiry on Day 61 (19th September 2023), in reference to you, Professor Stewart and Dr Houghton, Dr Mitchell explained:

> *"So, these are the three consultants that I can remember who were job planned to provide an oncology service to the Southern Trust. And purely based on proportion, if I had seen a few cases of which a handful had prescribed*

Bicalutamide 50 monotherapy, if they had seen more cases there was a greater chance that they would have seen proportionally the same number of cases with the same prescription error. So, I was listing these as people who were job planned and may have seen more cases." [TRA-07851]

In oral evidence to the Inquiry on Day 62 (20th September 2023), Professor O'Sullivan stated as follows:

"So at that time when I started first, Dr David Stewart was the clinical oncologist who would visit from Belfast to Craigavon, do a weekly clinic, see patients on treatment, and also identify new patients for radiotherapy in Belfast, for example. So the vast majority of diagnosis from Southern Trust would come via the visiting oncologist." [TRA-07992]

"… I'd say most of Mr O'Brien's referrals would have gone, at that point, to Dr Stewart, who was the visiting oncologist from Belfast Trust … By far and away the most common was through Dr Stewart, who was attending the unit." [TRA-08031]

(i) Were you aware, at any time as a member of the oncology team treating prostate cancer, of the issues described by Professor O'Sullivan and Dr Mitchell, that is, the referral of patients who were being prescribed Bicalutamide 50mg as a monotherapy for the treatment of localised prostate cancer? If yes, please provide full details, including but not limited to:

a. The circumstances under which you became aware of the prescribing of Bicalutamide 50mg as a monotherapy in, for example, the treatment of localised prostate cancer;
b. Details of any patient referrals you recall which fell within this patient cohort;
c. The timeframe during or over which these referrals took place;
d. The name of the prescribing physician;
e. Patient numbers falling within this cohort;
f. All details of those patients that you recall;

g. Your view on the appropriateness of prescribing Bicalutamide 50mg to the patients you recall and whether you considered it an appropriate or inappropriate therapeutic regime for those patients and why;
h. If you considered Bicalutamide 50mg not to have been an appropriate treatment regime for the patients you recall, what, if anything, you did about it? Please provide details of all those with whom you spoke on this issue and what, if any, action was taken by you or others.
i. If you did have concerns and did not speak to anyone about them, please explain why;
j. Your view on the use of Bicalutamide 50mg as a monotherapy generally and, as appropriate, the circumstances in which you would use it as such.

(ii) Do you agree with Professor O'Sullivan's statement that there was "*a general awareness of the issue amongst the oncology team treating prostate cancer"* about the issue of Bicalutamide 50mg being prescribed as a monotherapy? If yes, please set out full details of your knowledge, including the prescribing physician, to include details of all conversations on this issue, who else was aware and what, if anything, was done in response.

(iii) If you do not agree with Professor O'Sullivan's statement, please explain your understanding as to why he and others in the oncology team, but not you, may have been aware of this issue?

(iv) If you did not receive any referrals as recalled by Dr Mitchell and Professor O'Sullivan, when did you first become aware of the issue of Bicalutamide 50mg being prescribed as a monotherapy (if at all), and under what circumstances?

(v) Do you recall any instances of discussion of the issue of Bicalutamide 50mg being prescribed as a monotherapy at the Thursday morning pre-clinic team meeting?

If yes, please set out full details of all conversations on this issue, including the identities of those involved in any such discussions and the identities of those present for same.

6. The Inquiry is aware of significant issues around the quoracy of SHSCT Urology MDMs, particularly in terms of Oncology attendance. Please indicate whether, at any stage, you had concerns about or knowledge of these difficulties and offer any further comments or observations which may assist the Inquiry in understanding this issue. If you had concerns, please set out in detail what they were, who, if anyone, you spoke to about those concerns, and what, if anything, was done?

7. To the extent that you have any knowledge of potential governance problems regarding the referral and screening of patients from Craigavon Area Hospital to Regional Urology, Belfast City Hospital, please provide details.

8. Please provide any further details, including details of any other observations or concerns, which you consider may be relevant to the Inquiry Terms of Reference.

NOTE:

By virtue of section 43(1) of the Inquiries Act 2005, "document" in this context has a very wide interpretation and includes information recorded in any form. This will include, for instance, correspondence, handwritten or typed notes, diary entries and minutes and memoranda. It will also include electronic documents such as emails, text communications and recordings. In turn, this will also include relevant email and text communications sent to or from personal email accounts or telephone numbers, as well as those sent from official or business accounts or numbers. By virtue of section 21(6) of the Inquiries Act 2005, a thing is under a person's control if it is in his possession or if he has a right to possession of it.

Urology Services Inquiry

UROLOGY SERVICES INQUIRY

USI Ref: Notice 23 of 2023

Date of Notice: 12th October 2023

Witness Statement of: Jonathan McAleese

I, …Jonathan McAleese…, will say as follows:-

Please be aware that my responses are as true an account as I can give, taking into account that the questions relate to a period of time over a decade ago

1. I qualified in the medical sciences from Cambridge University, then completed clinical training at the Edinburgh Medical school in 1996. I had various senior house officer jobs in hospitals in London. I undertook specialist training in clinical oncology at the Royal Marsden Hospital until 2002 and then at Belvoir Park hospital until 2006. I took up a consultancy post in clinical oncology in 2006, specializing in lung and genito-urinary malignancies.

2. (i) I was employed by the Belfast trust as a consultant clinical oncologist treating lung and urological patients. In 2006 I joined Dr Stewart's Southern Trust practice treating lung and Gu patients as a "visiting oncologist". Dr Stewart tended to take the lead on GU cancer patients, and attended the GU MDM. After 2010 my clinical duties switched to the care and treatment of lung and urological patients from the Northern Trust. I was clinical director for the Northern Ireland Cancer Centre between sept 2017 and early 2020.

(ii) I cannot recall any specific events or issues raised with me regarding Urology surgery services within the Southern Trust. I was aware of difficulties in the oncology cover of the Southern GU MDM, due to staff shortages and difficulties in recruiting in to the practice. In my role as clinical director (from late 2017) we struggled to recruit a

clinical oncologist to the lung Gu clinic in Southern Trust. I discussed recruitment difficulties with various stake-holders; with the Southern Trust cancer manager, with the Belfast Trust Divisional team , with the commissioning team and with the oncology consultants. We were able to recruit a locum medical oncologist to take on the systemic therapy work. The clinical oncology / radiotherapy assessments and treatments were managed with consultants volunteering for waiting list clinics. We offered to support consultants to attend the MDM as well, but these activities were more difficult for practitioners to cover, due to other commitments. In conjunction with the Southern Trust we developed a job plan for a substantive medical oncologist for lung GU which was recruited to. The clinical oncology role was eventually divided with one consultant taking on radiotherapy for lung cancer (Dr J O'Hare) and another appointed to take on radiotherapy for the urology role (Dr E Baird), which included cover of the urology MDM.

3. Report audit of Southern Trust referrals for Gu cancer 2006 to 2010

4. N/A

5. (i)

a) I became aware of casodex 50mg monotherapy when patients were referred to me from the Southern Trust urology team. The majority of these patients were referred with localized prostate cancer, although one was referred with malignant lymph nodes (node positive) (see report of southern trust audit)

b) 22 cases were deliberate casodex 50mg monotherapy (6% of all prostate cancer referrals). . 21 of these cases were referrals from Mr O'Brien and 1 from Mr Young. The number of deliberate casodex 50mg referrals seemed to decline over time (from 7% in 2006 to 2% in 2010). Most (95%) cases had the casodex 50mg prescription altered by either urology (45%) or oncology, with only 1 remaining on this therapy after a discussion with oncology about impotence. All cases had a letter sent to urology from oncology documenting changes in prescription. These patients were younger compared to those who were known not to be on casodex monotherapy (average age 64yr compared to 71yr (Ttest p 0= 0.015).

c) Between Aug 2006 and Oct 2010

d) 22 of these cases were referrals from Mr O'Brien's team and 1 from Mr Young's team. Of these cases Casodex 50mg monotherapy was initially prescribed by Mr O'Brien in 17 cases, Mr V Khoo (Urology registrar in 4) and Mr Glackin in 1. In

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addition the prescription was continued after a consultation with Mr Ho (Urology registrar) in 2 cases, Mr Krishna (urology registrar) in 2 cases, Mr Pahuja (Urology registrar) in 1 case and Mr McCleod (Urology registrar) in 1 case. In 1 case I (Dr McAleese) continued the prescription after a discussion with the patient.

e) 22 (overall 6% of referrals)

f) Details of patients referred on deliberate casodex 50mg monotherapy Table 1a Appendix Two of audit report – in appendix

Case N	Deliberate casodex	Initials	referrer	Year of referral	age	Stage	Oncology consultant	Time on casodex	Changed by	Final hormonal therapy	Notes
1	Bpr08/0827	[redacted]	o'brien	2008	[redacted]	cT2 mT3a Gl 5+ PSA 7	JMA	4	oncology	Casodex 150mg	Started casodex 5mg by AOB. Oncology noted concerns about impotence but increased to casodex 150mg PO
2	BPR07/4670		o'brien	2007		ctx mt3b Gl3+4 PSA 17.6	JMA	1.2	urology (STR)	Casodex 150mg	Started on casodex 50mg due to potency concerns then increased to casodex 150mg because ? not enough PSA fall
3	bpr09/0275		o'brien	2009		mT1c Gl3+4 PSA 11	JMA	5	urology (STR)	Nil	casodex 50mg started July 2008 but then increased to 150mg in Dec 2008 by STR (? reason) then wanted As and stopped casodex. Then relapsed and started LHRHa in 2011
4	BPR10/3749		o'brien	2010		ctx mt2 Gl4+4 PSA 10.7	JMA	13.9	oncology	Casodex 150mg	Gynecomastia prior to diagnosis so casodex 50mg given (As well as concerns of impotence)
5	BPR08/4963		o'brien	2008		ct2 mt2 Gl7 PSA 8.8	JMA	13	oncology	Casodex 150mg	" degree of androgen blockafe" " pleased to report that erectile function was normal"
6	BPR08/5013		o'brien	2008		ct2a mt3a Gl3+4 PSA8	JMA	4.3	urology (AOB)	Casodex 150mg	Started on casodex 50mg by AOB " degree of androgen blockade" ; monitored PSA and when it went up AOB increased casodex to 150mg in May 2008. This caused erectile dysfunction that responded to sildenafil, so felt patient was happy to continue.
7	bpr09/4645		o'brien	2009		ct2 mT2 Gl3+4 PSA 7	JMA	3.8	urology (STR)	Casodex 150mg	june 2009 casodex 50mg then increased to 150mg sept 2009 after seemingly patent initiated discussion about mdoe of action of anti-androgen
8	bpr07/2233		o'brien	2007		ct2 m?t3b Gl3+3 PSA17	JMA	6	Not changed	CASODEX 50mg continued	AOB staretd casodex 50mg " in order to prevent further disease progression, whilst hoping to maintain erectile function" . " patient anxious to maintain sexual function" . JMA – discussed role of radiotherapy or active surveillance .. given impotence rates keep him on casodex 50mg and try to start radiotherapy ASAP"
9	bpr07/1574		o'brien	2007		ctx mt3a Gl3+3 PSA17	JMA	3	oncology	LHRHA	AOB initiated a "degree of androgen bockade" . AOB also wrote apology to patient for not referring patient earlier
10	BPR09/0797		o'brien	2009		node positive	JMA	1	urology (AOB)	LHRHA	Started casodex 50mg then concerned that PSA had not fallen enough, so increased by AOB to 150mg
11	BPR08/4920		o'brien	2008		T3a Gl7 PSA5.7	dps	0.7	oncology	LHRHA	DPS "he has high risk prostate cancer and so it is inappoprpiate for him to be on casodex 50mg" changed to zoladex
12	BPR08/0257		o'brien	2008		ctx mt3a Gl4+4 PSA11	JMA	12.9	urology (A)	LHRHA	Staretd casodex 50mg AOB Dec 2006 " initiate some degree of androgen blockade in the interim" with a view to review in March 2007. Seen by Mr Akhtar Jan 2008 and started LHRHA
13	BPR07/5326		o'brien	2008		node positive	dps	11.2	urology (STR)	LHRHA	Started casodex 50mg by AOB Dec 2006 then on review with STR Nov 2007 " decided better to add on LHRHa and refer to oncology"
14	BPR08/1797		o'brien	2008		mt2 Gl3+4 PSA7.8	JMA	4	urology (X)	LHRHA	No ECR data. From COIS Hx ;started casodex 50mg in July 2007 the increased to 150mg in Nov 2007 by urology
15	BPR07/2903		o'brien	2007		ct3a mt3a Gl2+3 PSA5.9	dps	8.1	Oncology	LHRHA	June 2005 started LHRHA + casodex but then stopped due to toxicity (hot flushes) and put on casodex 50mg mono in Nov 2006, then switched to LHRH by oncology
16	bpr06/3851		Young	**2006**		mT2 Gl4+5 PSA10.7	JMA	2	N/a – stopped due to toxicity	LHRHA	Started casodex 50mg by STR MR Glackin and continued by STR Mr Pahuja. Had to stop casodex after 2 months due to rash- oncology started on ciprostat then LHRHA; 7 months of hormones stopped due to fatigue
17	bpr09/1270		o'brien	2009		ct2 mT3a Gl3+4 PSA 7	RSK	13	urology (AOB)	Casodex 150mg	AOB started casodex 50mg Dec2007 " initiated a degree of androgen blockade" and PSA responded but then increased 13/1/09 to 150mg and referred to oncology. Oncology noted delay in referral
18	BPR09/5272		o'brien	2009		mt2 Gl9 PSA 14.7	x	4	urology (AOB)	unknown - no RISOH	"I do appreciate that you may consider that the degree of androgen blockade to date has been sub optimal prior to radical radiotherapy. However, I would appreciate if you would consider proceeding to radical radiotherapy without the addition of an LH RH analog, in the hope that impotence can be avoided without compromising the
19	BPR09/3528		o'brien	2009		mT2 Gl3+4 PSA 40	JMA	28	oncology	unknown - no RISOH	Started casodex 50mg by AOB ; " initiated a degree of androgen blockade"
20	BPR08/187		o'brien	2008		ct3a mt3z Gl 7 PSA9	JMA	15	oncology	Casodex 150mg	" degree of androgen blockade"
21	BPR07/4956		o'brien	2007		ct1 mt3a Gl3+4 PSA7.7	DPS	0.7	oncology	LHRHA	" degree of androgen blockade"
22	bpr07/2401		o'brien	2007		ct2 mt3a gl4=3 PSA 7.2	JMA	2	oncology	LHRHA	

Personal Information redacted by the USI

from Audit report

g) Hormonal therapy was used in the palliative setting to control and delay disease (on average for 2 year – James et al NEJM 2017; 377 :338-51. The recognized

hormonal regimen was with an LHRHA. Hormonal therapy was also used to improve the rate of cure achieved with radical radiotherapy – “adjuvant setting”. The average improvement in cure was 7% (Horwitz et al Int Journal Radiation Oncology Biology Physics 2001 49(4) 947-56) but it was appreciated at the time that the benefit was more likely to be seen in patients with more locally advanced disease, compared to those with lower grade, early localized prostate cancer. The recognized hormonal regimens were LHRHA, or in some circumstances casodex 150mg. Casodex 50mg represents a dose reduction of a recognized drug, and carries a higher risk of the drug not meeting its therapeutic aim. Although, in my opinion, a short duration on the dose-reduced agent is unlikely to make a clinically significant difference. My view was that, in general the recognized hormonal regimens should be used. It cannot be excluded that a dose reduction may be necessary in some circumstances (eg to manage side effects). This would carry a higher risk of the therapy not working compared to the standard doses. With this in mind, my strategy for patients referred on casodex 50mg monotherapy was to switch them to the more conventional treatment. This was discussed with the patients. I was referred one patient on casodex 50mg who was concerned to preserve his sexual function and had been counselled that the lower dose may help this. He had localized prostate cancer and I felt was eligible for short course hormonal therapy (6 months) with curative intent radiotherapy. After discussion with him, including a discussion of more standard hormonal therapy I supported him in completing his hormonal course at the dose reduced level (casodex 50mg). I would expect that a dose reduction of casodex would have an impact on effectiveness but that this would be a minimal impact for patients with low risk disease.

h) I believe we discussed the hormonal prescription with all patients and discussed alternatives. The hormonal prescription was changed in all patients apart from 1. In those in whom the prescription was changed, the change was discussed with the patient and a letter was sent to the referring consultant and to the GP. I believe I would have discussed the practice with Dr Stewart, although I have no records of this discussion.

i) I was uneasy with the use of dose reduced casodex monotherapy, as I had not seen it prescribed in this fashion before. I did not raise this any further than a

letter with the referring consultant. It did not occur to me at the time to take the matter any further. I believe there were a number of reasons behind this. I was a junior consultant at the time, and was being referred patients from a senior urology consultant. A strategy of correcting the practice and documenting this in a letter back to the consultant seemed a reasonable approach at the time. The fact that the patients were infrequently referred and interspersed with other patients referred on more conventional hormonal therapy made it difficult to perceive the full pattern, and led to a conclusion that the practice may have been changing. I was not familiar with the other governance processes that I may have been able to access in the Southern Trust, which made it seem more difficult to do anything further. There were a number of other clinical concerns at the time, which it seemed more important to raise with my own clinical director. Chemotherapy and radiotherapy activity in the practice was increasing, and we were struggling to meet the demand. We had staff shortages, which necessitated hiring a locum consultant at one point. The practice was essentially concentrated into a single day at Craigavon hospital; a chemotherapy clinic, a lung cancer MDM and an outpatient clinic seeing new and review patients. This put a lot of pressure into that day. Similar oncology practices, for instance in Belfast, were spread out over multiple days with more time allocated to them. Other development needs also consumed my attention ; raising the profile of curative intent radiotherapy, facilitating the implementation of systemic cytotoxic chemotherapy for prostate cancer (docetaxel), and similar developmental needs regarding the lung practice.

j) I would not use casodex 50mg monotherapy. The recognized hormonal regimens were LHRHA, or in some circumstances casodex 150mg (for patients receiving radiotherapy). Casodex 50mg represents a dose reduction of a recognized drug, and carries a higher risk of the drug not meeting its therapeutic aim. Although, in my opinion, a short duration on the dose-reduced agent is unlikely to make a clinically significant difference. My view was that, in general, the recognized hormonal regimens should be used. It cannot be excluded that a dose reduction may be necessary in some circumstances (eg to manage side effects) but this would carry a higher risk of the therapy not working compared to the standard doses. Currently the thinking on hormonal therapy has evolved, and

because of concerns about its impact on bone health and cardiovascular health, hormone therapy is sometimes omitted in the treatment of low risk early stage patients treated with radiotherapy.

ii) Once the issue was flagged in the NICAN urology group there was a general awareness amongst the oncology team. I understood that the clinical management guidelines were being updated to recognize that the recommended hormonal therapies were LHRHA or casodex 150mg.

iii) See above

iv) I received referrals from the Southern Trust urology team of patients on casodex 50mg, whilst I was working in the uro-oncology practice there 2006-2010..

v) The Thursday morning pre-clinic team meeting is only for the Belfast team. I did not attend that meeting.

6. Quoracy of the SHSCT Urology MDM re Oncology. I was job planned to attend the Southern Trust MDM up until 2008. At this point my job plan was adjusted by the clinical director due to the need to undertake an additional lung clinic. It is my recollection that Dr Stewart was still in attendance at the Urology MDM. I left the Southern MDM practice in 2010 and Dr Houghton took up the role. I understand that when she left the practice the urology MDM was not covered.

In my role as clinical director (from late 2017) we struggled to recruit a clinical oncologist to the lung Gu clinic in Southern Trust. I discussed recruitment difficulties with various stake-holders; with the Southern Trust cancer manager, with the Belfast Trust Divisional team , with the commissioning team and with the oncology consultants. This was an ongoing issue (amongst many other service gaps) in my tenure as clinical director that we struggled to resolve. I enclose documents relating to this time (an early alert from Belfast Trust and a prioritization list for new jobs). We were able to recruit a locum medical oncologist to take on the systemic therapy work. The clinical oncology / radiotherapy assessments and treatments were managed with consultants volunteering for waiting list clinics. We offered to support consultants to cover the MDM as well, but these activities were more difficult for practitioners, as they had other work commitments at the time of the MDM. In conjunction with the Southern Trust we

developed a job plan for a substantive medical oncologist for lung GU which was recruited to. The clinical oncology role was eventually divided with one consultant taking on radiotherapy for lung cancer (Dr J O'Hare) and another appointed to take on radiotherapy for the urology role (Dr E Baird), which included cover of the urology MDM.

7. I am not aware of issues regarding the referral and screening of patients from Craigavon Area Hospital to Regional Urology.

8. With hindsight, the benefit of the audit that I have completed for this inquiry and maybe with the extra years of experience that I now have; there were a number of issues that when taken together could have raised alarm bells regarding Mr O'Brien's practice; He wrote much longer referral letters than his consultant urology colleagues. These tended to contain information on multiple clinical visits, all in a single letter. It seemed most likely, at the time that he was providing a summary of all the relevant clinical encounters, rather than a failure to document the prior encounters in a timely fashion. However this practice was very atypical compared to the other consultants. It seemed it had taken some time for him to refer some of the patients. He had a preference in some circumstances to prescribe dose reduced casodex as an alternative to conventional hormonal therapies. Re terminology of casodex 50mg monotherapy. There have been comments that casodex 50mg was an unlicensed drug. It is my understanding that the term "off-label" more accurately reflects the use of casodex 50mg monotherapy. This indicates that a license is not in place for the 50mg monotherapy indication , but that it is in place for another indication. There are many instances of oncology drugs that are off-label but in routine use because they have a recognized evidence base.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed: _____ [redacted]

Date: _____22/11/2023_____

Urology Services Inquiry

Appendix One

Report on audit of Southern Trust referrals to oncology for GU cancer 2006 to 2010 with reference to casodex 50mg monotherapy.

Dr J McAleese
19/11/2023

Summary

Aim ; To describe the practice of casdoex (bicalutamide) 50mg monotherapy in patients referred to the GU oncology service in the Southern Trust

Methods Records from Aug 2006 to Oct 2010 were searched on the electronic databases ECR and RISOH.

Results Out of 384 prostate cancer referrals , hormonal therapy could not be assessed in 3 (1%) cases due to insufficient information. 90% were not on casodex 50mg monotherapy and 36 (10%) were possible cases. In 3 cases there was insufficient information to determine the dose of casodex. There were 33 cases of confirmed casodex 50mg monotherapy; on further review it was felt that 11 of these were likely started with the intention of moving on to LHRHA, with the remaining 22 (6% of all prostate referrals) being deliberate casodex 50mg monotherapy. 21 of these cases were referrals from Mr O'Brien's team and 1 from Mr Young's team. The number of deliberate casodex 50mg referrals declined over time (from 7% in 2006 to 2% in 2010). Most (95%) cases had the casodex 50mg prescription altered by either urology (57%) or oncology, with only 1 remaining on this therapy after a discussion with oncology about impotence. All cases had a letter sent to urology from oncology documenting changes in prescription.

Conclusions

Deliberate casodex 50mg monotherapy was an unusual practice in S Trust urology (6%), with evidence of diminishing use over time. The practice was mainly from one consultant (AOB), but one case was from MY (albeit from his registrar). The practice of AOB seems to have been to consider casodex 50mg monotherapy because of toxicity concerns of other hormonal therapies(sexual dysfunction and cardiac disease), but then to monitor impact and adjust dependent on subsequent PSA readings. Most prescriptions were altered by either urology (45%) or oncology. There was evidence that AOB was aware that oncology did not support the use of casodex 50mg monotherapy based on its reduced efficacy compared to other hormonal therapies. There was some evidence of a decline in the practice over time. Only one patient was maintained on casodex 50mg monotherapy by oncology, after a discussion about very early sateg disease and impotence

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Table 3: Patients with limited data; uncertain if they were prescribed hormonal therapy by urology

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Appendix 4 ; development history of casodex monotherapy

Appendix Three

Background

In 2006 Dr McAleese (JMA) joined Dr Stewart (DPS) at the Southern Trust lung/ genito-urinary (GU) oncology clinic. As such we were employed by the Belfast Trust but undertook clinics on Southern trust premises and were characterised as "visiting consultants". Our own governance arrangements were understood to lie with the Belfast Trust. I cannot recall formal induction to the Southern trust governance or management systems or indeed any contact with Southern trust governance systems. We would contact the Southern Trust Oncology cancer unit manager regarding issues around the Lung / GU clinic – but these usually pertained to chemotherapy practises (eg capacity issues).

The Lung GU oncology southern trust clinic took referrals for lung cancer via the Southern Trust MDM which met on Wednesday lunchtimes, and from the Southern trust urologists (who met at the urology MDM on Thursday afternoon). The combined lung and Gu systemic therapy (chemotherapy) clinic ran on Wednesday morning , with an outpatient clinic for lung and Gu patients on Wednesday afternoon. This led to Wednesday feeling a pressurised day with the need to complete the chemotherapy clinic to get to the MDM and then get back for the out-patient clinic. Similar oncology practises (eg in Belfast) had more time for these activities and had spread them out over multiple sessions on multiple days. Radiotherapy treatments were planned by Dr Stewart and Dr McAleese at the NICC. On average approx. 100 new patient referrals for Gu cancer, and approx. 100 new patient referrals for lung cancer were received per year. This approximates to 4 new patients being seen per week – this is a relatively high workload.

This was a period of great change within the uro-oncology sphere. A decade or two previously most prostate cancer patients were treated mainly by urologists who managed early stage disease with curative prostatectomy and metastatic patients with hormonal therapy. Now a broad range of prostate cancer patients were expected to be referred to oncologists. At one end of the scale, patients with metastatic disease could gain a survival benefit from docetaxel chemotherapy (1,2). For patients with localised disease, radical radiotherapy with hormonal therapy was easier to tolerate than prostatectomy and offered promising (if not equivalent outcomes to surgery), but radiation could lead to long term bowel and urinary side effects. In addition it was becoming apparent that very early stage, low grade localised prostate cancer may not need any active therapy at all because patients

were more likely to die with the cancer than because of the cancer, and could therefore be simply monitored by active surveillance (3) . At the time the standard treatment for advanced prostate cancer was commencement of hormonal therapy and consideration of radiotherapy. The degree to which radical dose radiotherapy would benefit high grade locally advanced prostate cancer was still uncertain , with the PRO7 (4,5) study yet to report. Adjuvant hormonal therapy with LHRHA was known to improve overall survival in radical radiotherapy patients by 7% (6). The standard hormonal therapy was commencement of LHRHA under androgen antagonist cover (eg casodex 50mg). Hormonal treatment was know to cause fatigue and hot flushes and sexual dysfunction with an increasing awareness that it could lead to an increased risk of cardiovascular and osteoporotic events. Casodex 150mg (Appendix 4)was starting to be considered as an alternative to LHRHA therapy, with a suggestion that it carried less side effects (at least less risk of sexual dysfunction).

In Oct 2023 Dr McAleese was contacted by the Southern Trust urology inquiry. A number of questions were posed around the use of casodex 50mg monotherapy. Several of the questions asked about patient specific information.

References

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Aims. To determine the number of patients referred on casodex 50mg monotherapy and their subsequent hormonal therapy

Methods

Dr McAleese kept a prospective database of patient referrals running from Aug 2006 to Oct 2010, which captured referrals from the Southern Trust Urologists, their date of referral and date of appointment and basic clinical details. Additional information was added to the database using information from the electronic care record (ECR) and data that had transferred from the historical oncology notes system (COIS) to the current system (RISOH), with the aim of determining if the patients had been treated with casodex 50mg monotherapy.

Results

Urology Services Inquiry

Between 22/8/2006 and 8/10/2010 (4.1 years) 438 referrals were received by the oncology service from the Southern Trust urologists (average 106 per year). Over the period the majority of referrals were from 3 urology consultants ; Mr Akhtar (75, 20%), Mr O'Brien (AOB) (103, 27%) and Mr Young (MY) (166, 43%). There were 3 consultant oncologists over the period Dr McAleese (JMA), Dr Stewart (DPS) and Dr R Kaushal (RSK) who stood in as a locum during Dr Stewart's absence. JMA saw 60% of patients, DPS 29% and RSK 6%, with unknown oncologist in 5% (no COIS record).

384 cases (87%) were for prostate cancer (Fig 1 CONSORT diagram; appendix One). 3 cases (1%) had insufficient information to proceed further with analysis. 345 (90%) were not on casodex 50mg monotherapy. 33 were referred on casodex 50mg. 3 (1%) were on casodex but the dose was not specified in the notes. On review of the casodex 50mg monotherapy cases (appendix two) , 11 were likely to have been started on casodex 50mg with the intent that an LHRHA would be prescribed (as a "prelude to LHRHA"). 22 cases were categorised as deliberate monotherapy with casodex 50mg- this is 6% of all prostate cancer cases referred.

Note one (additional) patient on follow up after they were seen in 2007 for salvage radiotherapy after prosatetctomy was started on casodex 50mg by AOB in 2011. This case as not included in the analysis of monotherapy as casodex 50mg was not started before referred in 2006 to 2010.

Apparent Deliberate monotherapy cases (see Appendix two – table 1a and table 1b)

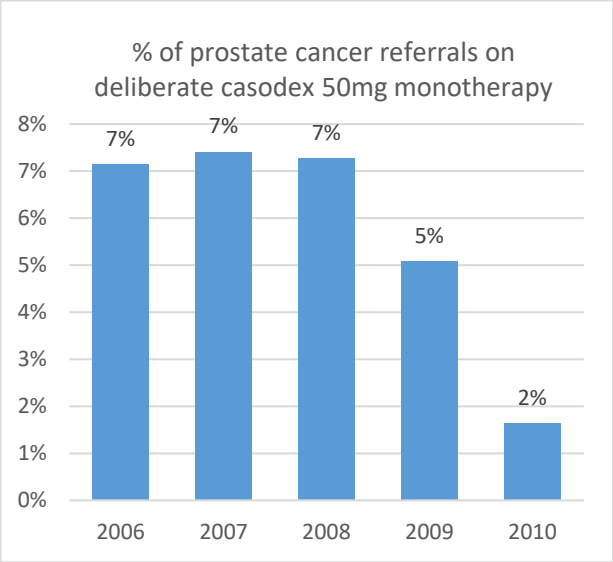
As described above there were 22 cases that seemed to be deliberate casodex 50mg monotherapy. 21 cases were referred from Mr O'Brien's team and 1 from Mr Young's team (albeit prescribed by a registrar) (see table 1b). These patients were younger compared to those who were known not to be on casodex monotherapy (average age 64yr compared to 71yr (Ttest p 0= 0.015). The number of patients referred on deliberate casodex monotherapy seemed to decline over time (from 7% in 2006 to 2% in 2010). The percentage of Mr O'Brien's patients who had been prescribed casodex 50mg monotherapy fell from 28% in 2008 to 11% in 2010 but this was not statistically a significant decline . The median duration of time on casodex 50mg was 5 months. Urology changed 45% of cases from casodex 50mg (to either LHRHA or casodex 150mg), with oncology changing 45%. One patient's treatment had to be stopped due to toxiocity. Only one patient (see case details appendix 3 – case 8 Personal Informati) remained on casodex 50mg monotherapy after they had been seen by oncology (by Dr McAleese). This was a case of early stage disease in which there was a discussion of active surveillance versus radical radiotherapy. The patient had been counselled about the impact of hormones on impotence and wished to have casodex 50mg. All cases had a letter from oncology documenting changes sent to urology

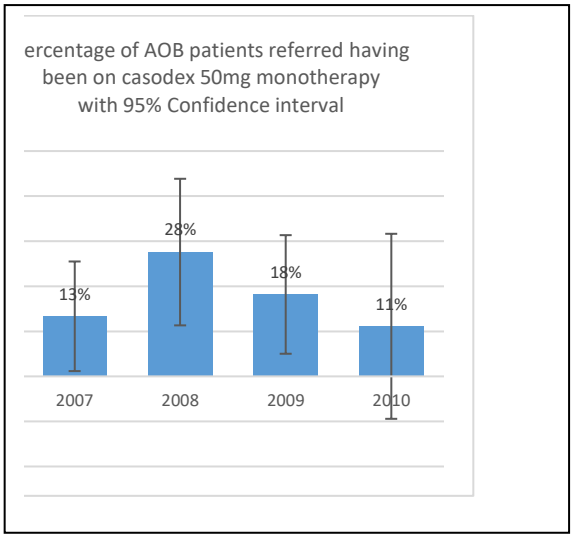
Thematic assessment

A thematic assessment identified that casodex 50mg monotherapy was associated with concerns about impotence, and possibly also about concerns of cardiac toxicuity (including one letter from a cardiologist, albeit for a patient felt have started on casodex 50mg as a prelude to LHRHA P7 table 2). The phrase " initiated a degree of androgen blockade" was used frequently. Patients were often monitored with sequential PSA readings and in many cases the casodex dose was increased based on follow-up PSA readings (failure to fall, or failure to fall enough). There was evidence that Mr O'Brien was aware that oncology did not agree with the practice – in case 19 (table 1- appendix2) ; " I do appreciate that you may consider that the

degree of androgen blockade to date has been sub optimal prior to radical radiotherapy. However, I would appreciate if you would consider proceeding to radical radiotherapy without the addition of an LH RH analog, in the hope that impotence can be avoided without compromising the prospect of cure".

Conclusions Deliberate casodex monotherapy seemed largely confined to one practice (AOB). This practice seemed to be based on the premise of reducing toxicity. Where monotherapy was initiated there was usually a plan to monitor effect with PSA readings and adjustment of the casodex prescription when it failed to achieve the desired effect. There was an awareness that this practice was not supported by oncology. The practice seemed to decline over time





Conclusions

Deliberate casodex 50mg monotherapy was an unusual practice in S Trust urology (6%), with evidence of diminishing use over time. The practice was mainly from one consultant (AOB), but one case was from MY (albeit from his registrar). The practice of AOB seems to have been to consider casodex 50mg monotherapy because of toxicity concerns of other hormonal therapies(sexual dysfunction and cardiac disease), but then to monitor impact and adjust dependent on subsequent PSA readings. Most prescriptions were altered by either urology (57%) or oncology. There was evidence that AOB was aware that oncology did nor support the use of casodex 50mg monotherapy based on its reduced efficacy compared to other hormonal therapies. There was some evidence of a decline in the practice over time. Only one patient was maintained on casodex 50mg monotherapy by oncology, after a discussion about very early stage disease and impotence.

Further Actions

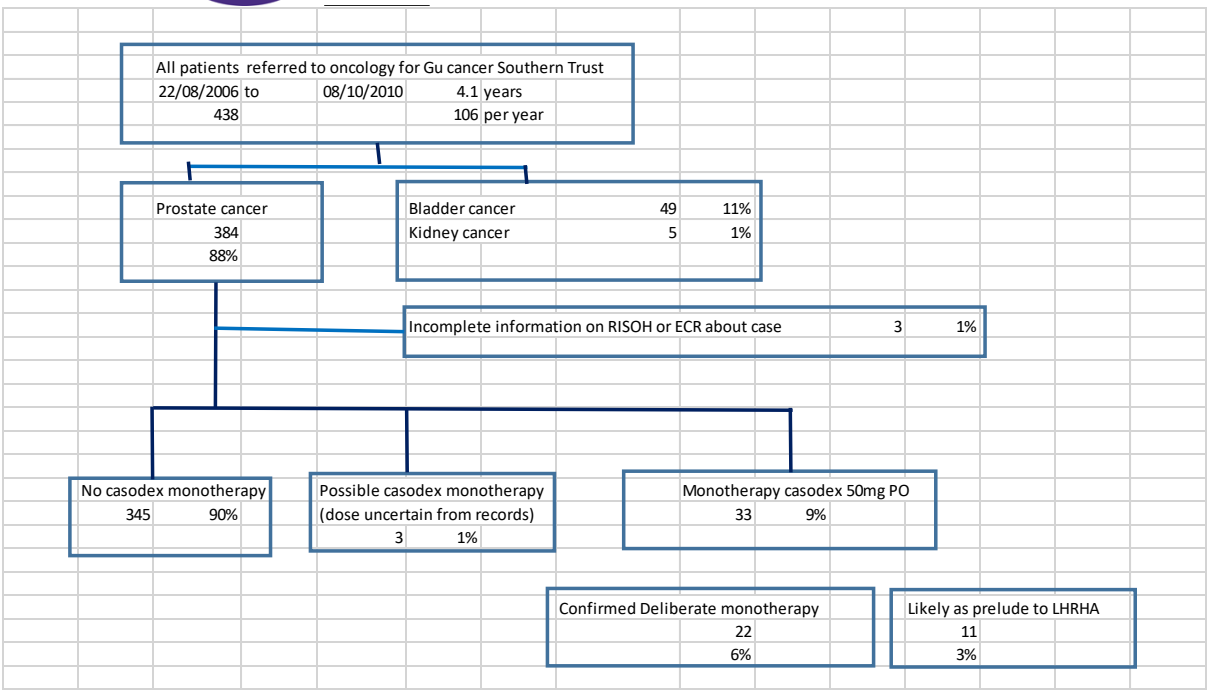
COIS notes requested on the following patients 7/11/2023 from Fiona Carville and Dianne Hanna.

Urology Services Inquiry

		Personal Information redacted by the USI	er	of referral	Personal Information redacted by the USI		ogy consultant	hormonal therapy		
	9/5752		n	009		4		wn - no RISOH		
	ppr07/4263		x	007		tatic	dps			
	ppr07/1176		x	007			dps			
	ppr07/1479		oung	007		ne refractory	JMA			
	BPR08/4156		oung	008		tatic	dps		arted on hormonal therapy by STR Mr Ho 11/8/2008 but uncertain which. Then saw oncology . In 2009 he was on LHRHA	
	ppr07/1747		oung	007		positive	dps			
	ppr06/4693		oung	006						

Appendix One : Figure 1 CONSORT Diagram

Urology Services Inquiry



Urology Services Inquiry

Appendix Two Tables

Table 1a; Casodex 50mg monotherapy ; deliberate casodex monotherapy patients

Urology Services Inquiry

Case N	Deliberate casodex	Initials	referrer	Year of referral	age	Stage	Oncology consultant	Time on casodex	Changed by	Final hormonal therapy	Notes
1	Bpr08/0827	Personal Information redacted by the USI	o'brien	2008	Personal Information redacted by the USI	cT2 mT3a Gl 5+ PSA 7	JMA	4	oncology	Casodex 150mg	Started casodex 5mg by AOB. Oncology noted concerns about impotence but increased to casodex 150mg PO
2	BPR07/4670		o'brien	2007		ctx mt3b Gl 3+4 PSA 17.6	JMA	1.2	urology (STR)	Casodex 150mg	Started on casodex 50mg due to potency concerns then increased to casodex 150mg because ? not enough PSA fall
3	bpr09/0275		o'brien	2009		mT1c Gl 3+4 PSA 11	JMA	5	urology (STR)	Nil	casodex 50mg started July 2008 but then increased to 150mg in Dec 2008 by STR (? reason) then wanted As and stopped casodex. Then relapsed and started LHRHa in 2011
4	BPR10/3749		o'brien	2010		ctx mt2 Gl 4+4 PSA 10.7	JMA	13.9	oncology	Casodex 150mg	Gynecomastia prior to diagnosis so casodex 50mg given (As well as concerns of impotence)
5	BPR08/4963		o'brien	2008		ct2 mt2 Gl 7 PSA 8.8	JMA	13	oncology	Casodex 150mg	"degree of androgen blockade" "pleased to report that erectile function was normal"
6	BPR08/5013		o'brien	2008		ct2a mt3a Gl 3+4 PSA8	JMA	4.3	urology (AOB)	Casodex 150mg	Started on casodex 50mg by AOB "degree of androgen blockade" ; monitored PSA and when it went up AOB increased casodex to 150mg in May 2008. This caused erectile dysfunction that responded to sildenafil, so felt patient was happy to continue.
7	bpr09/4645		o'brien	2009		ct2 mT2 Gl 3+4 PSA 7	JMA	3.8	urology (STR)	Casodex 150mg	june 2009 casodex 50mg then increased to 150mg sept 2009 after seemingly patent initiated discussion about mdoe of action of anti-androgen
8	bpr07/2233		o'brien	2007		ct2 m?t3b Gl 3+3 PSA17	JMA	6	Not changed	CASODEX 50mg continued	AOB staretd casodex 50mg " in order to prevent further disease progression, whilst hoping to maintain erectile function" . " patient anxious to maintain sexual function" . JMA – discussed role of radiotherapy or active surveillance .. given impotence rates keep him on casodex 50mg and try to start radiotherapy ASAP"
9	bpr07/1574		o'brien	2007		ctx mt3a Gl 3+3 PSA17	JMA	3	oncology	LHRHA	AOB initiated a "degree of androgen bockade" . AOB also wrote apology to patient for not referring patient earlier
10	BPR09/0797		o'brien	2009		node positive	JMA	1	urology (AOB)	LHRHA	Started casodex 50mg then concerned that PSA had not fallen enough, so increased by AOB to 150mg
11	BPR08/4920		o'brien	2008		T3a Gl 7 PSA5.7	dps	0.7	oncology	LHRHA	DPS "he has high risk prostate cancer and so it is inappropriate for him to be on casodex 50mg" changed to zoladex
12	BPR08/0257		o'brien	2008		ctx mt3a Gl 4+4 PSA11	JMA	12.9	urology (A)	LHRHA	Staretd casodex 50mg AOB Dec 2006 " initiate so me degree of androgen blockade in the interim" with a view to review in March 2007. Seen by Mr Akhtar Jan 2008 and started LHRHA
13	BPR07/5326		o'brien	2008		node positive	dps	11.2	urology (STR)	LHRHA	Started casodex 50mg by AOB Dec 2006 then on review with STR Nov 2007 " decided better to add on LHRHa and refer to oncology"
14	BPR08/1797		o'brien	2008		mt2 Gl 3+4 PSA7.8	JMA	4	urology (X)	LHRHA	No ECR data. From COIS Hx: started casodex 50mg in July 2007 the increased to 150mg in Nov 2007 by urology
15	BPR07/2903		o'brien	2007		ct3a mt3a Gl 2+3 PSA5.9	dps	8.1	Oncology	LHRHA	June 2005 started LHRHA + casodex but then stopped due to toxicity (hot flushes) and put on casodex 50mg mono in Nov 2006, then switched to LHRH by oncology
16	bpr06/3851		Young	**2006**		mT2 Gl 4+5 PSA10.7	JMA	2	N/a – stopped due to toxicity	LHRHA	Started casodex 50mg by STR M R Glackin and continued by STR M r Pahuja. Had to stop casodex after 2 months due to rash- oncology started on ciprostat then LHRHA; 7 months of hormones stopped due to fatigue
17	bpr09/1270		o'brien	2009		ct2 mT3a Gl 3+4 PSA 7	RSK	13	urology (AOB)	Casodex 150mg	AOB started casodex 50mg Dec 2007 " initiated a degree of androgen blockade" and PSA responded but then increased 13/1/09 to 150mg and referred to oncology. Oncology noted delay in referral
18	BPR09/5272		o'brien	2009		mt2 Gl 9 PSA 14.7	x	4	urology (AOB)	unknown - no RISOH	"I do appreciate that you may consider that the degree of androgen blockade to care has been sub optimal prior to radical radiotherapy. However, I would appreciate if you would consider proceeding to radical radiotherapy without the addition of an LH RH
19	BPR09/3528		o'brien	2009		mT2 Gl 3+4 PSA 40	JMA	28	oncology	unknown - no RISOH	Started casodex 50mg by AOB ; " initiated a degree of androgen blockade"
20	BPR08/187		o'brien	2008		ct3a mt3z Gl 7 PSA9	JMA	15	oncology	Casodex 150mg	" degree of androgen blockade"
21	BPR07/4956		o'brien	2007		ct1 mt3a Gl 3+4 PSA7.7	DPS	0.7	oncology	LHRHA	" degree of androgen blockade"
22	bpr07/2401		o'brien	2007		ct2 mt3a gl4=3 PSA 7.2	JMA	2	oncology	LHRHA	

Table 1b Details of prescribers of casodex 50mg monotherapy

Urology Services Inquiry

	ate casodex 50mg monotherapy	Initials	r	referral	ogy consultant	e on casodex 50mg	hanged by	ormonal therapy	x 50mg started by	x 50mg continued by	x 50mg stopped by
1	08/0827	Personal Information redacted by the USI	en	8	MA		cology	x 150mg			
2	07/4670		en	7	MA		gy (STR)	x 150mg			
3	0275			9	MA		gy (STR)				eod Urology STR
4	3749			0	MA	9	cology	x 150mg			
5	08/4963		en	8	MA		cology	x 150mg		Urology STR	
6	08/5013		en	8	MA		gy (AOB)	x 150mg			
7	4645			9	MA		gy (STR)	x 150mg			STR Urology
8	07/2233		en	7	MA		changed	DEX 50mg continued			
9	07/1574		en	7	MA		cology	HRHA			
10	0797			9	MA		gy (AOB)	HRHA			
11	08/4920		en	8	dps		cology	HRHA			
12	08/0257		en	8	MA	9	ogy (A)	HRHA			tar
13	07/5326		en	8	dps	2	gy (STR)	HRHA			hna Urology STR
14	08/1797		en	8	MA		ogy (X)	HRHA			
15	07/2903		en	7	dps		cology	HRHA	Urology STR	hna Urology STR	
16	06/3851		ng	6	MA		stopped due to toxicity	HRHA	kin Urology STR	a Urology STR	
17	1270			9	RSK		gy (AOB)	x 150mg		Urology STR	
18	5272			9	x		gy (AOB)	vn - no RISOH			
19	3528			9	MA		cology	vn - no RISOH		eod Uro STR	
20	1871			2008	MA		cology	x 150mg	Urology STR		
21	4956			7	DPS		cology		Urology STR		
22	2401			7	MA		cology		Urology STR	hna Urology STR	

Table 2 Casodex Monotherapy – felt on review to be likely as a prelude/ pre-treatment for LHRHA

Urology Services Inquiry

Case N	Monotherapy felt to be a prelude to LHRHA	Initials	referrer	Year of referral	age	Stage	Oncology consultant	Time on casodex 50mg (months)	Monotherapy altered by	Final hormonal therapy	Notes
P1	BPR07/2863	Personal Information redacted by the USI	young	2007	Personal Information redacted by the USI	CPG 5	dps	2.3m	urology	LHRHA	casodex 50mg in april by STR Dr Khoo then lhrah in juen 2007 by dr khoo
P2	BPR07/4740		young	2007		CPG 1	JMA	0.9 m	X (no COIS)	X (no COIS)	started casodex 50mg by mr Yoiung Oct 2007 and referred to oncology; nil on COIS so cannot see what ahppedne dnext
P3	BPR08/2168		young	2008		CPG 5	dps	0.4m	oncology	LHRHA	staretd casodex 50mg by mr young 21/5/2008 ? For oncology to do LHRHA ??
P4	bpr08/2684		young	2008		CPG 2	JMA	0.7m	oncology	LHRHa	"started on casodex 50mg until you see him" Seen by cardiology who noted " getting .. bicalutamide which can precipitate heart failure2"
P5	BPR08/4964		young	2008		node positive	dps	1.0m	X (no COIS)	X (no COIS)	No RISOH records
P6	bpr09/0310		young	2009		CPG 4	JMA	1.0m	oncology	LHRHA	" I have started him on some casodex awaiting your consult"
P7	bpr09/1057		young	2009		CPG 2	JMA	1.6m	Oncology	casodex 150mg	incarsed to 150mg by oncology
P8	BPR09/0466		young	2009		CPG 4	dps	0.5m	Oncology	LHRHA	
P9	BPR09/2959		young	2009		CPG 5	dps	1.0m	oncology	LHRHA	
P10	bpr09/3804		young	2009		CPG 2	JMA	1 m	Oncology	LHRHA	
P11	bpr09/5278		young	2010		CPG 4	dps	1.2m	Oncology	LHRHA	Not clear when he staretd casodex 50mg – not stated on urology letters

Table 3: Patients with limited data; uncertain if they were prescribed hormonal therapy by urology

N	tain (limited data)	s	er	of referral			ogy consultant	hormonal therapy			
	/3450	Personal Information redacted by the USI		006	Personal Information redacted by the USI		x		ar if nay hormonal therapy started at all		
	/5153			009		positive	JMA				
	or07/3617		oung	007		2	JMA		x		
	or07/4263		x	007		tatic	dps				
	R08/4156		oung	008		tatic	dps		arted on hormonal therapy by STR Mr Ho 11/8/2008 but uncertain which. Then saw oncology . In 2009 he was on LHRHA		
	or07/1747		oung	007		positive	dps				

Urology Services Inquiry

Appendix 3 ; Patient 8 Personal Information continued on casodex 50mg monotherapy

Template

		h	monal therapy	berate casodex 50mgmonotherapy
ent BPR	7/2233			
ent name				
state cancer	2	m Gl 3+3 (1 /20 cores) PSA 17		
ogy consultant	BRIEN	pril 2007	ed casodex 50mg April 2007	odex 50mg prescribed
ology consultant	CALEESE	2007	ed casodex 50mg April 2007 then seen 6/6/2007 - "to keep on casodex 50mg given impotence rates " for 6 months	odex 50mg continued

Personal Information old man with localised prostate cancer- low risk disease t2 Gl6 PSA 17.

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Urology Services Inquiry

Patient records

br07/2233	Pe rs	P er

2007 CLINICAL HISTORY **OPWL**
XRT
01/01/1900
DIAGNOSIS: Prostate carcinoma.
HISTORY: Personal Information old man, diagnosed with prostate carcinoma, Gleason 3+3, clinical T2, PSA 17. In September 2000 PSA 14, 2002 PSA 17. Jan 03 commenced on FINASTERIDE. TRUS biopsy Gleason 6 out of 1/20 cores. MRI 23/2/03 T1. March 06
PSA 14.9, August 06 PSA 13.7. 13/2/07 MRI query T3B.
January 07 Isotope bone scan - abnormality at right 7th rib, query metastases, query osteoarthritis. February 07 - Ultrasound of prostate 61 ccs. 20/3/07 PSA 13.7, 24/4/07 commenced on CASODEX 50 mg.
Feels well in himself. Lower urinary tract symptoms much better since commencing on CASODEX, nocturia once. Bowels working well, no PR bleeding. Energy levels good.
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DRUG HISTORY: CASODEX, XATROL, PROSCAR.
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Discussion about prostate cancer. Likely slow growing. I have given him the results of the isotope bone scan and MRIs. Discussed the role of radiotherapy or active surveillance. Keen to have radiotherapy.
Plan for PSA today. We need to get his MRI films from February 2003 and particularly December 2006 so that this can be reviewed at the Cancer Centre. I have completed a booking form for 74 Gy in 37 fractions.
Given impotence rates keep him on CASODEX 50 mg and try and commence radiotherapy ASAP once MRIs are through.
Letter to Mr O Brien cc GP. (7/6/07)
JMCAL

ECR records

The Urology Department Craigavon Area Hospital 16/05/07 Re: Patient Name: MR Personal Information redacted by the USI D.O.B.: CHI No: Personal Information redacted by the USi Date/Time of Clinic: 24/04/07

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17/05/07 Dr David Stewart Consultant in Clinical Oncology Northern Ireland Cancer Centre Lisburn Rd Belfast Dear David Re: Patient Name: MR Personal Informatio D.O.B.: Personal Information redacted by the USI CHI No: Personal Information redacted by the USI

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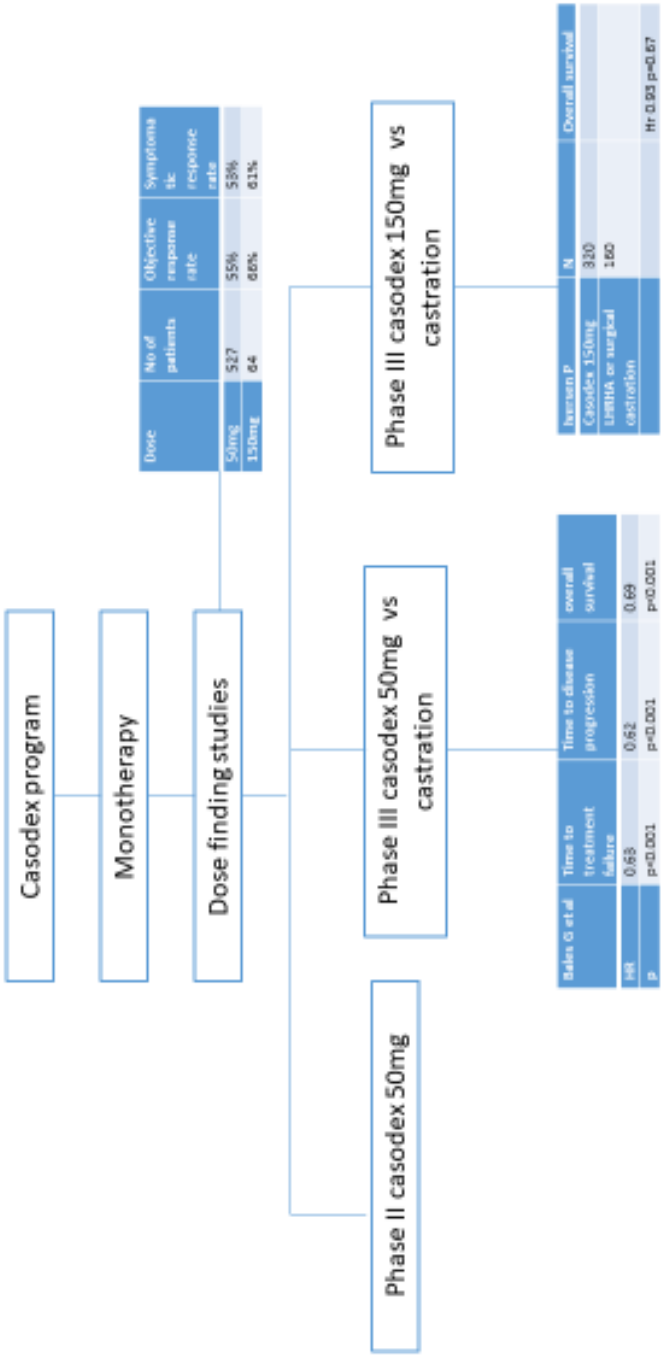
was initially referred to me in September 2000, with symptoms indicative of a degree of urinary outflow obstruction, and with a serum total PSA level of 14.1 ng/ml at that time. He was found on ultrasound scanning of his urinary tract to have a grossly enlarged prostate gland but to have satisfactory bladder voiding, he having a post micturitional residual urine volume of 60 mls then. Symptoms of urinary outflow obstruction were satisfactorily managed by alpha blockade. Over the subsequent 2 years, his serum total PSA level had increased to 17.1 ng/ml. Prostatic biopsies were performed in November 2002, when he was found to have a single focus of glandular atypia, with immuno-histochemical changes suspicious of, but not adequately diagnostic of carcinoma, in each of 2 of the 6 core biopsies performed. Finasteride was ordered to his alpha blockade in December 2002 when Perso had further prostatic biopsies performed in January 2003, he was found to have a single focus of prostatic adenocarcinoma of Gleason score 6, in one of the 10 core biopsies performed then. On MRI scanning performed in February 2003, there were no features of prostatic adenocarcinoma seen within his prostate, which did have all of the features of benign prostatic hypertrophy. When reviewed in April 2003, Personal Information's lower urinary tract symptoms had improved significantly since being prescribed Finasteride in addition to alphablockade 4 months previously. Regrettably, Personal was lost to follow up subsequently in March 2006, his serum total PSA level was found to be 14.9 ng/ml. Since then, his serum total PSA level has fallen to 13.7 ng/ml by August 2006, and has remained at that level most recently in March 2007, and without any change in his management. On further MRI scanning performed in December 2006, there is some suspicion that he may have bilateral involvement of his seminal vesicles. In view of low signal intensity in both T1 and T2 modalities, and in view of any other features of capsular infiltration, I am a little sceptical of the suspicion, though it remains entirely possible that he may have seminal vesicular infiltration. There is no evidence of any regional lymphadenopathy or of any distant metastatic disease. 2. You will note from the accompanying letter that Perso is a very youthful man who works in Personal Information redacted by the USI, is virtually devoid of any lower urinary tract symptoms and enjoys a normal libido and normal erectile function all of which he is anxious to maintain. He is entirely aware that he has, at worse, slowly progressive disease. I have initiated a degree of androgen blockade by prescribing Casodex 50 mgs daily, and I would be most appreciative if you would give consideration to proceeding with radical radiotherapy and to which he is entirely happy to have. I would be grateful if you would arrange an appointment for him and I look forward to your views in due course. Yours sincerely Dictated but not signed by Aidan O'Brien FRCS Consultant Urologist

17/05/07 CONFIDENTIAL MR Personal Informati Dear Perso I was pleased to have the opportunity of reviewing you on the 24th April 2007. I do hope that you have since begun taking Casodex 50 mgs daily, in addition to your other medication, and that you have had no problems with doing so. I write to advise you that I have written to Dr. David Stewart, Consultant in Clinical Oncology requested that he arrange an appointment for you to attend at Criagavon Area Hospital and with a view to giving consideration to you having radical radiotherapy to your prostate gland as discussed. You will receive a letter of appointment from him to attend him in due course. I look forward to meeting you again when you next attend for review. Yours sincerely Dictated but not signed by Aidan O'Brien FRCS Consultant Urologist

Urology Services Inquiry

Appendix Four; Development History of casodex 50mg monotherapy



Urology Services Inquiry

Appendix 3 ; Patient 8 Personal Informati continued on casodex 50mg monotherapy

Template

		seen	Hormonal therapy	Deliberate casodex 50mgmonotherapy
Patient BPR	bpr07/2233			
Patient name	Personal Information redacted			
Prostate cancer	CPG 2	Ct2 m Gl 3+3 (1 /20 cores) PSA 17		
Urology consultant	A O'BRIEN	24 April 2007	started casodex 50mg April 2007	CAsodex 50mg prescribed
Oncology consultant	J MCALEESE	6/6/2007	started casodex 50mg April 2007 then seen 6/6/2007 - "to keep on casodex 50mg given impotence rates " for 6 months	Casodex 50mg continued

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Urology Services Inquiry

Patient records

pr07/2233	Pers	Pe

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Report on audit of Southern Trust referrals to oncology for GU cancer 2006 to 2010 with reference to casodex 50mg monotherapy.

Dr J McAleese

15/11/2023

Summary

Aim ; To describe the practice of casdoex (bicalutamide) 50mg monotherapy in patients referred to the GU oncology service in the Southern Trust

Methods Records from Aug 2006 to Oct 2010 were searched on the electronic databases ECR and RISOH.

Results Out of 384 prostate cancer referrals , hormonal therapy could not be assessed in 6 (2%) cases due to insufficient information. 89% were not on casodex 50mg monotherapy and 36 (10%) were possible cases. In 3 cases there was insufficient information to determine the dose of casodex. There were 33 cases of confirmed casodex 50mg monotherapy; on further review it was felt that 11 of these were likely started with the intention of moving on to LHRHA, with the remaining 22 (6% of all prostate referrals) being deliberate casodex 50mg monotherapy. 21 of these cases were referrals from Mr O'Brien's team and 1 from Mr Young's team. The number of deliberate casodex 50mg referrals declined over time (from 7% in 2006 to 2% in 2010). Most (95%) cases had the casodex 50mg prescription altered by either urology (57%) or oncology, with only 1 remaining on this therapy after a discussion with oncology about impotence. All cases had a letter sent to urology from oncology documenting changes in prescription.

Conclusions

Deliberate casodex 50mg monotherapy was an unusual practice in S Trust urology (6%), with evidence of diminishing use over time. The practice was mainly from one consultant (AOB), but one case was from MY (albeit from his registrar). The practice of AOB seems to have been to consider casodex 50mg monotherapy because of toxicity concerns of other hormonal therapies(sexual dysfunction and cardiac disease), but then to monitor impact and adjust dependent on subsequent PSA readings. Most prescriptions were altered by either urology (45%) or oncology. There was evidence that AOB was aware that oncology did nor support the use of casodex 50mg monotherapy based on its reduced efficacy compared to other hormonal therapies. There was some evidence of a decline in the practice over time. Only one patient was maintained on casodex 50mg monotherapy by oncology, after a discussion about very early sateg disease and impotence

Contents

Appendix Three

Background

In 2006 Dr McAleese (JMA) joined Dr Stewart (DPS) at the Southern Trust lung/ genito-urinary (GU) oncology clinic. As such we were employed by the Belfast Trust but undertook clicnis on Soutehr trust premises and were characterised as "visiting consultants". Our own governance arrangements were understood to lie with the Belfast Trust. I cannot recall formal induction to the Southern trust governance or management systems or indeed any contact with Southern trust governance systems. We would contact the Southern Trust Oncology cancer unit manager regarding issues around the Lung / GU clinic – but these usually pertained to chemotherapy practises (eg capacity issues).

The Lung GU oncology southern trust clinic took referrals for lung cancer via the Southern Trust MDM which met on Wednesday lunchtimes, and from the Southern trust urologists (who met at the urology MDM on Thursday afternoon). The combined lung and Gu systemic therapy (chemotherapy) clinic ran on Wednesday morning , with an outpatient clinic for lung and Gu patients on Wednesday afternoon. This led to Wednesday feeling a pressurised day with the need to complete the chemotherapy clinic to get to the MDM and then get back for the out-patient clinic. Similar oncology practises (eg in Belfast) had more time for these activities and had spread them out over multiple sessions on multiple days. Radiotherapy treatments were planned by Dr Stewart and Dr McAleese at the NICC. On average approx. 100 new patient referrals for Gu cancer, and approx. 100 new patient referrals for lung cancer were received per year. This approximates to 4 new patients being seen per week – this is a relatively high workload.

This was a period of great change within the uro-oncology sphere. A decade or two previously most prostate cancer patients were treated mainly by urologists who managed early stage disease with curative prostatectomy and metastatic patients with hormonal therapy. Now a broad range of prostate cancer patients were expected to be referred to oncologists. At one end of the scale, patients with metastatic disease could gain a survival benefit from docetaxel chemotherapy (1,2). For patients with localised disease, radical radiotherapy with hormonal therapy was easier to tolerate than prostatectomy and offered promising (if not equivalent outcomes to surgery), but radiation could lead to long term bowel and urinary side effects. In addition it was becoming apparent that very early stage, low grade localised prostate cancer may not need any active therapy at all because patients were more likely to die with the cancer than because of the cancer, and could therefore be simply monitored by active surveillance (3) . At the time the standard treatment for advanced prostate cancer was commencement of hormonal therapy and consideration of radiotherapy. The degree to which radical dose radiotherapy would benefit high grade locally advanced prostate cancer was still uncertain , with the PRO7 (4,5) study yet to report. Adjuvant hormonal therapy with LHRHA was known to improve overall survival in radical radiotherapy patients by 7% (6). The standard hormonal therapy was commencement of LHRHA under androgen antagonist cover (eg casodex 50mg). Hormonal treatment was know to cause fatigue and hot flushes and sexual dysfnction with an increasing awareness that it could lead to an increased risk of cardiovascular and osteoporotic events. Casodex 150mg (Appendix 4)was starting to be considered as an alternative to LHRHA therapy, with a suggestion that it carried less side effects (at least less risk of sexual dysfunction).

In Oct 2023 Dr McAleese was contacted by the Southern Trust urology inquiry. A number of questions were posed around the use of casodex 50mg monotherapy. Several of the questions asked about patient specific information.

References

1. Tannock IF, de Wit R, Berry WR et al Docetaxel plus Prednisone or Mitoxantrone plus Prednisone for Advanced Prostate Cancer. New Eng J Med 2004; 351: 1502-1512
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3. Parker C Active surveillance: towards a new paradigm in the management of early prostate cancer Lancet oncol 2004 5(2) 101-6
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5. Brundage M et al Impact of Radiotherapy When Added to Androgen Deprivation Therapy for Locally Advanced Prostate Cancer: Long-Term Quality-of-Life Outcomes From the NCIC CTG PR3/MRC PR07 Randomized Trial JCO 2015 33919) 2151-2157
6. Bolla M et al Long-term results with immediate androgen suppression and external irradiation in patients with locally advanced prostate cancer (an EORTC study): a phase III randomised trial Lancet 2002 360 103-8

Aims. To determine the number of patients referred on casodex 50mg monotherapy and their subsequent hormonal therapy

Methods

Dr McAleese kept a prospective database of patient referrals running from Aug 2006 to Oct 2010, which captured referrals from the Southern Trust Urologists, their date of referral and date of appointment and basic clinical details. Additional information was added to the database using information from the electronic care record (ECR) and data that had transferred from the historical oncology notes system (COIS) to the current system (RISOH), with the aim of determining if the patients had been treated with casodex 50mg monotherapy.

Results

Between 22/8/2006 and 8/10/2010 (4.1 years) 438 referrals were received by the oncology service from the Southern Trust urologists (average 106 per year). Over the period the majority of referrals were from 3 urology consultants ; Mr Akhtar (75, 20%), Mr O'Brien (AOB) (103, 27%) and Mr Young (MY) (166, 43%). There were 3 consultant oncologists over the period Dr McAleese (JMA), Dr Stewart (DPS) and Dr R Kaushal (RSK) who stood in as a locum during Dr Stewart's absence. JMA saw 59% of patients, DPS 29% and RSK 6%, with unknown oncologist in 5% (no COIS record).

384 cases (87%) were for prostate cancer (Fig 1 CONSORT diagram; appendix One). 6 cases (2%) had insufficient information to proceed further with analysis. 342 (89%) were not on casodex 50mg monotherapy. 33 were referred on casodex 50mg. 3 (1%) were on casodex but the dose was not specified in the notes. On review of the casodex 50mg monotherapy cases (appendix two) , 11 were likely to have been started on casodex 50mg with the intent that an LHRHA would be prescribed (as a "prelude to LHRHA"). 22 cases were categorised as deliberate monotherapy with casodex 50mg- this is 6% of all prostate cancer cases referred.

Note one (additional) patient on follow up after they were seen in 2007 for salvage radiotherapy after prosatetctomy was staretd on casodex 50mg by AOB in 2011. This case as not included in the analysis of monotherapy as casodex 50mg was not started before referred in 2006 to 2010.

Apparent Deliberate monotherapy cases (see Appendix two – table 1a and table 1b)

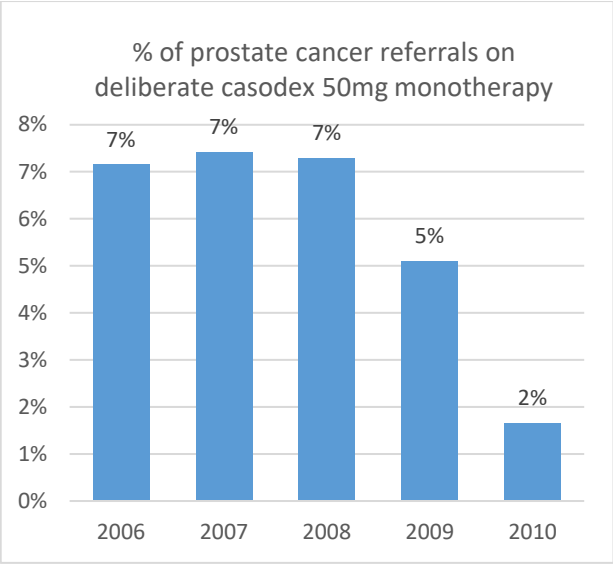
As described above there were 22 cases that seemed to be deliberate casodex 50mg monotherapy. 21 cases were referred from Mr O'Brien's team and 1 from Mr Young's team (albeit prescribed by a registrar) (see table 1b). These patienst were younger compared to those who were known not to be on casodex monotherapy (average age 64yr compared to 71yr (Ttest p 0= 0.015). The number of patients referred on deliberate casodex monotherapy seemed to decline over time (from 7% in 2006 to 2% in 2010). The percentage of Mr O'Brien's patients who had been prescribed casodex

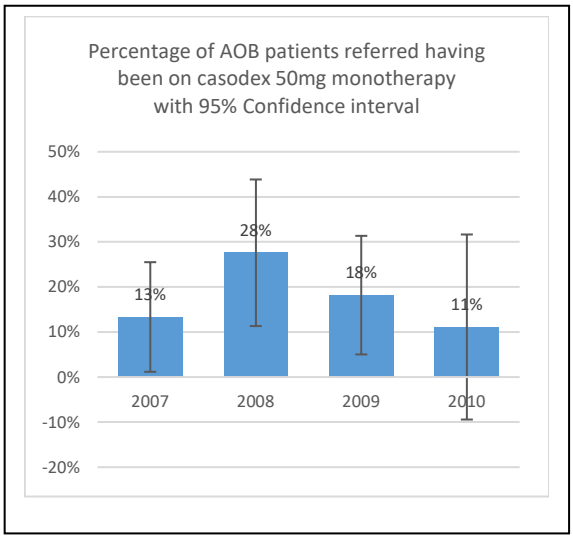
50mg monotherapy fell from 28% in 2008 to 11% in 2010 but this was not statistically signigicant decline . The median duration of time on casodex 50mg was 5 months. Urology changed 45% of cases from casodex 50mg (to either LHRHA or casodex 150mg), with oncology changing 45%. One patient's treatment had to be stopped due to toxiocity. Only one patient (see case details appendix 3 – case 8 [Personal Inform]) remained on casodex 50mg monotherapy after they had been seen by oncology (by Dr McAleese). This was a case of early stage disease in which there was a discussion of active surveillance versus radical radiotherapy. The patient had been counselled about the impact of hormones on impotence and wished to have casodex 50mg. All cases had a letter from oncology documenting changes sent to urology

Thematic assessment

A thematic assessment identified that casodex 50mg monotherapy was associated with concerns about impotence, and possibly also about concerns of cardiac toxicuity (including one letter from a cardiologist, albiet for a patient felt have started on casodex 50mg as a prelude to LHRHA P7 table 2). The phrase " initiated a adegree of androgen blockade" was used freqeunetly. Patients were often monitored with sequential PSA readings and in many cases the casodex dose was increased based on follow-ip PSA readings (failure to fall, or failure to fall enough). There was evidence that Mr O'Brien was aware that oncology did not agree with the practice – in case 19 (table 1- appendix2) ; " I do appreciate that you may consider that the degree of androgen blockade to date has been sub optimal prior to radical radiotherapy. However, I would appreciate if you would consider proceeding to radical radiotherapy without the addition of an LH RH analog, in the hope that impotence can be avoided without compromising the prospect of cure".

Conclusions Deliberate casodex moniotherapy seemed largely confined to one parcrtice (AOB). This partice seemed to be based on the premise of reducing toxicity. Where momnotherapy was initateied there was usually a plan to monitor effect with PSA readings and adjustment of the casodex prescription when it failed to achieve the desired effect. There was an awareness that this practice was not supported by oncology. The practice seemed to decline over time





Conclusions

Deliberate casodex 50mg monotherapy was an unusual practice in S Trust urology (6%), with evidence of diminishing use over time. The practice was mainly from one consultant (AOB), but one case was from MY (albeit from his registrar). The practice of AOB seems to have been to consider casodex 50mg monotherapy because of toxicity concerns of other hormonal therapies(sexual

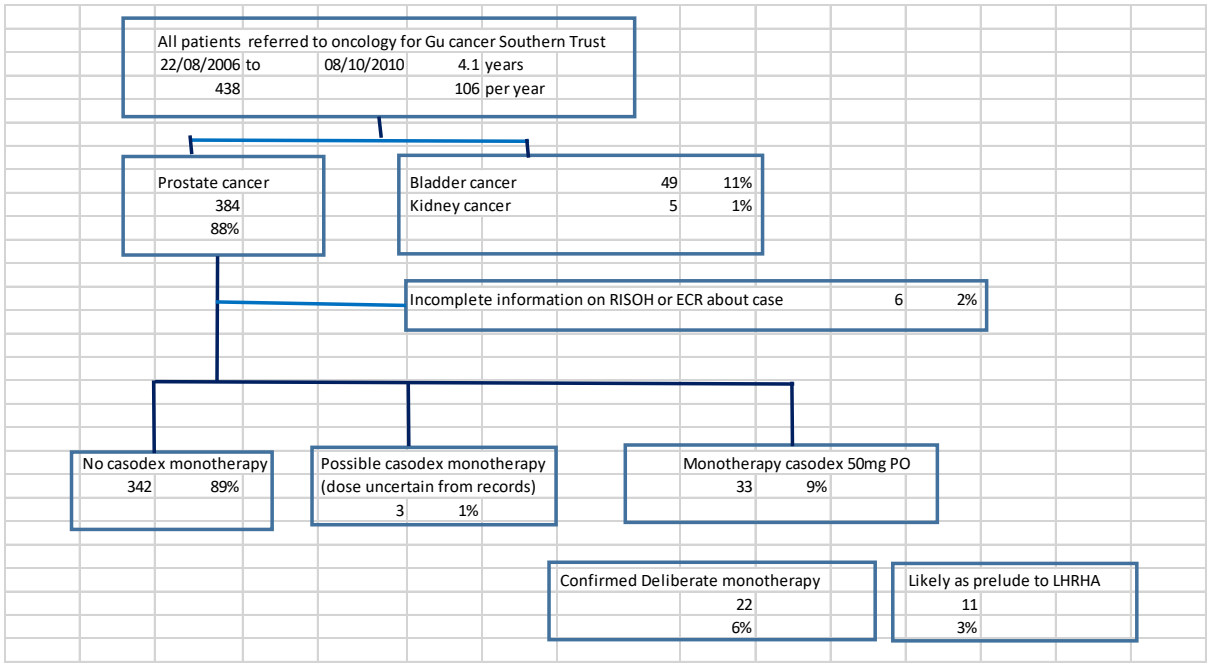
dysfunction and cardiac disease), but then to monitor impact and adjust dependent on subsequent PSA readings. Most prescriptions were altered by either urology (57%) or oncology. There was evidence that AOB was aware that oncology did nor support the use of casodex 50mg monotherapy based on its reduced efficacy compared to other hormonal therapies. There was some evidence of a decline in the practice over time. Only one patient was maintained on casodex 50mg monotherapy by oncology, after a discussion about very early sateg disease and impotence.

Further Actions

COIS notes requested on the following patients 7/11/2023 from Fiona Carville and Dianne Hanna.

N		Initials	referrer	Year of referral	age	Stage	Oncology consultant	Final hormonal therapy	Notes	
19	BPR09/5752	Personal Information redacted by the USI	o'brien	2009	Personal Information redacted by the USI	CPG 4	x	unknown - no RISOH		
U1	BPR08/1501		o'brien	2008		CPG 1	dps		steroids	
U2	BPR08/5153		akhtar	2009		node positive	JMA		x	
U3	bpr07/0897		batstone	2007		hormone refractory	JMA		x	
U4	BPR08/0256		young	2008		CPG 2	x		x	
U5	bpr07/3617		young	2007		CPG 2	JMA		x	
U6	BPR06/3450		young	2006		CPG 4	x		x	
U7	BPR08/1940		hagan	2008		CPG 4	JMA			
U8	BPR08/1779		x	2008		CPG 5	x			
U9	BPR08/2370		x	2008		metastatic	dps			
U10	bpr07/4263		x	2007		metastatic	dps			
U11	bpr07/1176		x	2007			dps			
U12	bpr07/1479		young	2007		hormone refractory	JMA			
U13	BPR08/4156		young	2008		metastatic	dps		started on hormonal therapy by STR Mr Ho 11/8/2008 but uncertain which. Then saw oncology . In 2009 he was on LHRHA	
U14	bpr07/1747		young	2007		node positive	dps			
U15	bpr06/4693		young	2006			x			

Appendix One : Figure 1 CONSORT Diagram



Appendix Two Tables

Table 1a; Casodex 50mg monotherapy ; deliberate casodex monotherapy patients

Case N	Deliberate casodex	Initials	referrer	Year of referral	age	Stage	Oncology consultant	Time on casodex	Changed by	Final hormonal therapy	Notes
1	Bpr08/0827	Personal Information redacted by the USI	o'brien	2008	Personal Information redacted by the USI	cT2 mT3a Gl 5+ PSA 7	JMA	4	oncology	Casodex 150mg	Started casodex 5mg by AOB. Oncology noted concerns about impotence but increased to casodex 150mg PO
2	BPR07/4670		o'brien	2007		ctx mt3b Gl3+4 PSA 17.6	JMA	1.2	urology (STR)	Casodex 150mg	Started on casodex 50mg due to potency concerns then increased to casodex 150mg because ? not enough PSA fall
3	bpr09/0275		o'brien	2009		mT1c Gl3+4 PSA 11	JMA	5	urology (STR)	Nil	casodex 50mg started July 2008 but then increased to 150mg in Dec 2008 by STR (? reason) then wanted As and stopped casodex. Then relapsed and started LHRHa in 2011
4	BPR10/3749		o'brien	2010		ctx mt2 Gl4+4 PSA 10.7	JMA	13.9	oncology	Casodex 150mg	Gynecomastia prior to diagnosis so casodex 50mg given (As well as concerns of impotence)
5	BPR08/4963		o'brien	2008		ct2 mt2 Gl7 PSA 8.8	JMA	13	oncology	Casodex 150mg	"degree of androgen blockafe" "pleased to report that erectile function was normal"
6	BPR08/5013		o'brien	2008		ct2a mt3a Gl3+4 PSA8	JMA	4.3	urology (AOB)	Casodex 150mg	Started on casodex 50mg by AOB "degree of androgen blockade" ; monitored PSA and when it went up AOB increased casodex to 150mg in May 2008. This caused erectile dysfunction that responded to sildenafil, so felt patient was happy to continue.
7	bpr09/4645		o'brien	2009		ct2 mT2 Gl3+4 PSA 7	JMA	3.8	urology (STR)	Casodex 150mg	june 2009 casodex 50mg then increased to 150mg sept 2009 after seemingly patent initiated discussion about mdoe of action of anti-androgen
8	bpr07/2233		o'brien	2007		ct2 m?t3b Gl3+3 PSA17	JMA	6	Not changed	CASODEX 50mg continued	AOB started casodex 50mg "in order to prevent further disease progression, whilst hoping to maintain erectile function" " patient anxious to maintain sexual function" . JMA – discussed role of radiotherapy or active surveillance . . given impotence rates keep him on casodex 50mg and try to start radiotherapy ASAP"
9	bpr07/1574		o'brien	2007		ctx mt3a Gl3+3 PSA17	JMA	3	oncology	LHRHA	AOB initiated a "degree of androgen bockade" . AOB also wrote apology to patient for not referring patient earlier
10	BPR09/0797		o'brien	2009		node positive	JMA	1	urology (AOB)	LHRHA	Started casodex 50mg then concerned that PSA had not fallen enough, so increased by AOB to 150mg
11	BPR08/4920		o'brien	2008		T3a Gl7 PSA5.7	dps	0.7	oncology	LHRHA	DPS "he has high risk prostate cancer and so it is inappopriate for him to be on casodex 50mg" changed to zoladex
12	BPR08/0257		o'brien	2008		ctx mt3a Gl4+4 PSA11	JMA	12.9	urology (A)	LHRHA	Stareld casodex 50mg AOB Dec 2006 "initiate some degree of androgen blockade in the interim" with a view to review in March 2007. Seen by Mr Akhtar Jan 2008 and started LHRHA
13	BPR07/5326		o'brien	2008		node positive	dps	11.2	urology (STR)	LHRHA	Started casodex 50mg by AOB Dec 2006 then on review with STR Nov 2007 " decided better to add on LHRHa and refer to oncology"
14	BPR08/1797		o'brien	2008		mt2 Gl3+4 PSA7.8	JMA	4	urology (X)	LHRHA	No ECR data. From COIS Hx :started casodex 50mg in July 2007 the increased to 150mg in Nov 2007 by urology
15	BPR07/2903		o'brien	2007		ct3a mt3a Gl2+3 PSA5.9	dps	8.1	Oncology	LHRHA	June 2005 started LHRHA + casodex but then stopped due to toxicity (hot flushes) and put on casodex 50mg mono in Nov 2006, then switched to LHRH by oncology
16	bpr06/3851		Young	**2006**		mT2 Gl4+5 PSA10.7	JMA	2	N/a – stopped due to toxicity	LHRHA	Started casodex 50mg by STR MR Glackin and continued by STR Mr Pahuja. Had to stop casodex after 2 months due to rash- oncology started on ciprostat then LHRHA: 7 months of hormones stopped due to fatigue
17	bpr09/1270		o'brien	2009		ct2 mT3a Gl3+4 PSA 7	RSK	13	urology (AOB)	Casodex 150mg	AOB started casodex 50mg Dec2007 "initiated a degree of androgen blockade" and PSA responded but then increased 13/1/09 to 150mg and referred to oncology. Oncology noted delay in referral
18	BPR09/5272		o'brien	2009		mt2 Gl9 PSA 14.7	x	4	urology (AOB)	unknown - no RISOH	I do appreciate that you may consider that the degree of androgen blockade to date has been sub optimal prior to radical radiotherapy. However, I would appreciate if you would consider proceeding to radical radiotherapy without the addition of an LH RH
19	BPR09/3528		o'brien	2009		mT2 Gl3+4 PSA 40	JMA	28	oncology	unknown - no RISOH	Started casodex 50mg by AOB ; "initiated a degree of androgen blockade"
20	BPR08/187		o'brien	2008		ct3a mt3z Gl 7 PSA9	JMA	15	oncology	Casodex 150mg	"degree of androgen blockade"
21	BPR07/4956		o'brien	2007		ct1 mt3a Gl3+4 PSA7.7	DPS	0.7	oncology	LHRHA	"degree of androgen blockade"
22	bpr07/2401		o'brien	2007		ct2 mt3a g\4=3 PSA 7.2	JMA	2	oncology	LHRHA	

Table 1b Details of prescribers of casodex 50mg monotherapy

Case N	Deliberate casodex 50mg monotherapy case	Initials	referrer	Year of referral	Oncology consultant	Time on casodex	Changed by	Final hormonal therapy	Casodex 50mg started by	Casodex 50mg continued by	Casodex 50mg stopped by
1	Bpr08/0827	Personal Information redacted by the USI	o'brien	2008	JMA	4	oncology	Casodex 150mg	AOB	nil	JMA
2	BPR07/4670		o'brien	2007	JMA	1.2	urology (STR)	Casodex 150mg	AOB	nil	JMA
3	bpr09/0275		o'brien	2009	JMA	5	urology (STR)	Nil	AOB	nil	A McCleod Urology STR
4	BPR10/3749		o'brien	2010	JMA	13.9	oncology	Casodex 150mg	AOB	AOB	JMA
5	BPR08/4963		o'brien	2008	JMA	13	oncology	Casodex 150mg	AOB	Mr Ho Urology STR	JMA
6	BPR08/5013		o'brien	2008	JMA	4.3	urology (AOB)	Casodex 150mg	AOB	nil	AOB
7	bpr09/4645		o'brien	2009	JMA	3.8	urology (STR)	Casodex 150mg	AOB	nil	M Elfar STR Urology
8	bpr07/2233		o'brien	2007	JMA	6	Not changed	CASODEX 50mg continued	aob	jma	jma
9	bpr07/1574		o'brien	2007	JMA	3	oncology	LHRHA	aob	nil	JMA
10	BPR09/0797		o'brien	2009	JMA	1	urology (AOB)	LHRHA	aob	nil	aob
11	BPR08/4920		o'brien	2008	dps	0.7	oncology	LHRHA	aob	nil	dps
12	BPR08/0257		o'brien	2008	JMA	12.9	urology (A)	LHRHA	AOB	nil	mr akhtar
13	BPR07/5326		o'brien	2008	dps	11.2	urology (STR)	LHRHA	aob	nil	Mr Krishna Urology STR
14	BPR08/1797		o'brien	2008	JMA	4	urology (X)	LHRHA	aob	x	aob
15	BPR07/2903		o'brien	2007	dps	8.1	Oncology	LHRHA	V Khoo Urology STR	Mr Krishna Urology STR	DPS
16	bpr06/3851		Young	**2006**	JMA	2	N/a – stopped due to toxicity	LHRHA	M Glackin Urology STR	A Pajuja Urology STR	x
17	bpr09/1270		o'brien	2009	RSK	13	urology (AOB)	Casodex 150mg	AOB	Mr Ho Urology STR	AOB
18	BPR09/5272		o'brien	2009	x	4	urology (AOB)	unknown - no RISOH	AOB	x	aob
19	BPR09/3528		o'brien	2009	JMA	28	oncology	unknown - no RISOH	AOB	A McCleod Uro STR	JMA
20	BPR08/1871		o'brien	2008	JMA	15	oncology	Casodex 150mg	V Khoo Urology STR	AOB	JMA
21	BPR07/4956		o'brien	2007	DPS	0.7	oncology	LHRHA	V Khoo Urology STR	x	DPS
22	bpr07/2401		o'brien	2007	JMA	2	oncology	LHRHA	V Khoo Urology STR	Mr Krishna Urology STR	JMa

Table 2 Casodex Monotherapy – felt on review to be likely as a prelude/ pretreatment for LHRHA

Case N	Monotherapy felt to be a prelude to LHRHA	Initials	referrer	Year of referral	age	Stage	Oncology consultant	Time on casodex 50mg (months)	Monotherapy altered by	Final hormonal therapy	Notes
P1	BPR07/2863	Personal Information redacted by the USI	young	2007	Personal Information redacted by the USI	CPG 5	dps	2.3m	urology	LHRHA	casodex 50mg in april by STR Dr Khoo then lhrah in juen 2007 by dr khoo
P2	BPR07/4740		young	2007		CPG 1	JMA	0.9 m	X (no COIS)	X (no COIS)	started casodex 50mg by mr Yoiung Oct 2007 and referred to oncology; nil on COIS so cannot see what ahppedne dnext
P3	BPR08/2168		young	2008		CPG 5	dps	0.4m	oncology	LHRHA	staretd casodex 50mg by mr young 21/5/2008 ? For oncology to do LHRHA ??
P4	bpr08/2684		young	2008		CPG 2	JMA	0.7m	oncology	LHRHa	"started on casodex 50mg until you see him" Seen by cardiology who noted " getting .. bicalutamide which can precipitate heart failure2"
P5	BPR08/4964		young	2008		node positive	dps	1.0m	X (no COIS)	X (no COIS)	No RISOH records
P6	bpr09/0310		young	2009		CPG 4	JMA	1.0m	oncology	LHRHA	" I have started him on some casodex awaiting your consult"
P7	bpr09/1057		young	2009		CPG 2	JMA	1.6m	Oncology	casodex 150mg	incarsed to 150mg by oncology
P8	BPR09/0466		young	2009		CPG 4	dps	0.5m	Oncology	LHRHA	
P9	BPR09/2959		young	2009		CPG 5	dps	1.0m	oncology	LHRHA	
P10	bpr09/3804		young	2009		CPG 2	JMA	1 m	Oncology	LHRHA	
P11	bpr09/5278		young	2010		CPG 4	dps	1.2m	Oncology	LHRHA	Not clear when he staretd casodex 50mg – not stated on urology letters

Table 3: Patients with limited data; uncertain if they were prescribed hormonal therapy by urology

Case N	Uncertain (limited data)	Initials	referrer	Year of referral	age	Stage	Oncology consultant	Final hormonal therapy	Notes		
U1	BPR06/3450	Personal Information redacted by the USI	young	2006	Personal Information redacted by the USI	CPG4	x	x	Unclear if nay hormonal therapy started at all		
U2	BPR08/5153		akhtar	2009		node positive	JMA		x		
U5	bpr07/3617		young	2007		CPG 2	JMA		x		
U10	bpr07/4263		x	2007		metastatic	dps				
U13	BPR08/4156		young	2008	Personal Information redacted by	metastatic	dps		started on hormonal therapy by STR Mr Ho 11/8/2008 but uncertain which. Then saw oncology . In 2009 he was on LHRHA		

U14	bpr07/1747	Personal Information redacted by the USI	young	2007	Personal Information	node positive	dps				

Appendix 3 ; Patient 8 [redacted] continued on casodex 50mg monotherapy

Template

		seen	Hormonal therapy	Deliberate casodex 50mgmonotherapy
Patient BPR	bpr07/2233			
Patient name	[redacted]			
Prostate cancer	CPG 2	Ct2 m Gl 3+3 (1 /20 cores) PSA 17		
Urology consultant	A O'BRIEN	24 April 2007	started casodex 50mg April 2007	CAsodex 50mg prescribed
Oncology consultant	J MCALEESE	6/6/2007	started casodex 50mg April 2007 then seen 6/6/2007 - "to keep on casodex 50mg given impotence rates " for 6 months	Casodex 50mg continued

[redacted] old man with localised prostate cancer- low risk disease t2 Gl6 PSA 17.

Patient had been started ion casodex 50mg due to wanting to maintain sexual function by AOB "and enjoys a normal libido and normal erectile function all of which he is anxious to maintain. He is entirely aware that he has, at worse, slowly progressive disease. I have initiated a degree of androgen blockade by prescribing Casodex 50 mgs daily,"

He was seen by Dr McAleese 6/6/2007 who noted that eh was on casodex 50mg and agreed to continue this dose level with curative dose radiotherapy, noting concerns regarding impotence and that this was relatively low risk disease

Patient records

bpr07/2233	[redacted]	[redacted]

2007 CLINICAL HISTORY **OPWL**
XRT
01/01/1900
DIAGNOSIS arcinoma.
HISTORY: Personal Information redacted by the USI old man, diagnosed with prostate carcinoma,
Gleason 3 T2, PSA 17. In September 2000 PSA 14, 2002 PSA

17. Jan 03 commenced on FINASTERIDE. TRUS biopsy Gleason 6 out of 1/20 cores. MRI 23/2/03 T1. March 06
PSA 14.9, August 06 PSA 13.7. 13/2/07 MRI query T3B.
January 07 Isotope bone scan - abnormality at right 7th rib, query metastases, query osteoarthritis. February 07 - Ultrasound of prostate 61 ccs. 20/3/07 PSA 13.7, 24/4/07 commenced on CASODEX 50 mg.
Feels well in himself. Lower urinary tract symptoms much better since commencing on CASODEX, nocturia once. Bowels working well, no PR bleeding. Energy level [redacted]

SOCIAL HISTORY: [redacted]

[redacted]state nodule left side, T2, no actual masses, no blood on glove.
Discussion about prostate cancer. Likely slow growing. I have given him the results of the isotope bone scan and MRIs. Discussed the role of radiotherapy or active surveillance. Keen to have radiotherapy.
Plan for PSA today. We need to get his MRI films from February 2003 and particularly December 2006 so that this can be reviewed at the Cancer Centre. I have completed a booking form for 74 Gy in 37 fractions.
Given impotence rates keep him on CASODEX 50 mg and try and commence radiotherapy ASAP once MRIs are through.
Letter to Mr O Brien cc GP. (7/6/07)
JMCAL

ECR records

The Urology Department Craigavon Area Hospital 16/05/07 Re: Patient Name: MR [redacted] D.O.B.: CHI No: [redacted] Date/Time of Clinic: 24/04/07

Further to my letter of the 16th October 2006 and to that of Mr. Krishna on the 25th October 2006 I write to advise you that [redacted] first had MRI scanning performed on the 13th December 2006, when his prostate gland was again found to be significantly enlarged, in keeping with benign prostatic hypertrophy, and in particular, was noted to have an enlarged medium lobe indenting the base of his bladder. The peripheral zone was compressed by the benign hypertrophy of the transitional zone and appeared to be of low signal intensity, consistent with the presence of adenocarcinoma. There was no capsular distortion seen. The recto prostatic angles were maintained. Even though capsular infiltration by carcinoma was not directly seen, both seminal vesicles were found to have low T2 signal intensity as well as having low T1 signal intensity. Therefore, there is a possibility of bilateral seminal vesicle infiltration. No lymphadenopathy was found. [redacted] had radio isotope bone scanning performed on the 10th January 2007 when he was found to have a focal area of moderately increased uptake of radio isotope seen at the costo vertical junction of the right seventh. He was also noted to have mild degenerative changes present in both hands and wrists. Even though [redacted] was able to relate that he had previously sustained rib injuries, chest radiography was performed on the 2nd April 2007, when no focal lesion of his right seventh rib was found. [redacted] had ultrasound scanning of his urinary tract performed on the 23rd February 2007, when his prostate gland was found again to be significantly enlarged, with a volume of 61 mls, and with satisfactory bladder voiding on micturition, he having a post micturitional, residual urine volume of 60 mls. When I reviewed [redacted] most recently on 24.4.07, I was pleased to find that his serum total PSA level had remained unchanged at 13.7 on the 20th March 2007. I advised him that I did not believe that there were any grounds to suspect that he had any skeletal metastatic disease. However, I did advise him that he may very well have had local progression of his disease since he previously had had MRI scan performed in February 2003. Whilst it is indeed entirely possible that [redacted] may have bilateral seminal vesicular infiltration by carcinoma, I am somewhat sceptical that he does have in view of low signal intensity in both T1 and T2 modalities. Conversely, whilst [redacted] may indeed have had some significant disease progression since he had been prescribed Finasteride in December 2002, at which time his peak total

PSA level had been 17.1 ng/ml, there has been no biochemical evidence of any ongoing disease progression during this past year. In fact, his serum total PSA level of 13.7 ng/ml in March 2007 is less than it had been in March 2006 when it was 14.9 ng/ml. Concurrent with that stability, [redacted] emphasised to me at recent review that he was keeping very well indeed. He is virtually devoid of any lower urinary tract symptoms. He has a normal libido and enjoys normal erectile function. He is particularly keen to maintain both. Even though [redacted] years old he works every day in [redacted] and is particularly keen that he continue to do so. He has also had the experience of having a brother in law who has had prostatic carcinoma in Belfast, and who has significantly from urinary incontinence. He is particularly keen to avoid any significant risk of becoming incontinent. For all of these reasons, in conjunction that the significant risk that [redacted] may no longer have organic confined disease, I believe that radical prostatectomy is contra indicated. However, I have to confess if I were he, I would give serious consideration to having radical radiotherapy. I advised him to remain on Xatral XL and Finasteride 5 mgs daily, and to both of which I have added Casodex 50 mgs daily, in order to prevent any further disease progression, whilst hoping to maintain erectile function. I have also taken the opportunity of referring [redacted] to Dr. David Stewart, Consultant in Clinical Oncology at the Northern Ireland Cancer Centre, requesting that he arrange an appointment for [redacted] to attend his clinic at Craigavon Area Hospital and with a view to consideration of radical radiotherapy. I have arranged to review [redacted] in 3 months. Yours sincerely Dictated but not signed by Aidan O'Brien FRCS Consultant Urologist

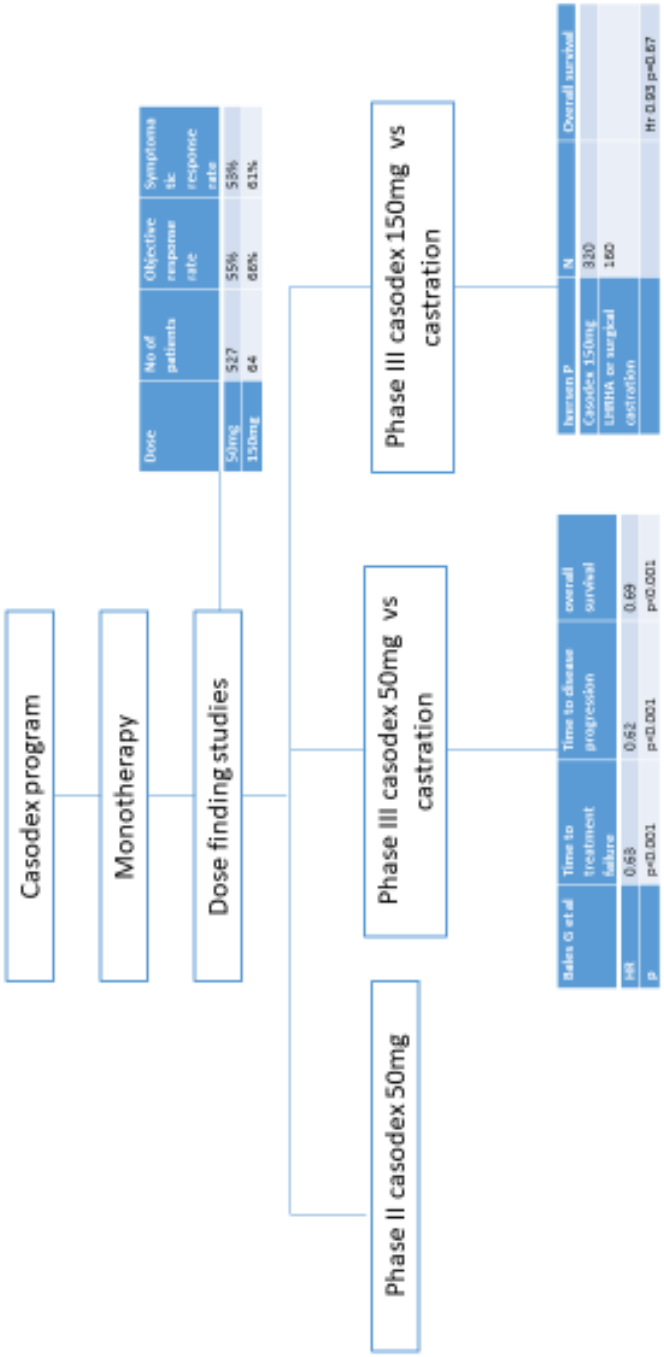
17/05/07 Dr David Stewart Consultant in Clinical Oncology Northern Ireland Cancer Centre Lisburn Rd Belfast Dear David Re: Patient Name: MR [redacted] D.O.B.: [redacted] CHI No: [redacted]

I enclose a copy of a recent letter pertaining to this [redacted] old gentleman for whom I would be grateful to arrange an appointment at Craigavon Area Hospital. [redacted] was initially referred to me in September 2000, with symptoms indicative of a degree of urinary outflow obstruction, and with a serum total PSA level of 14.1 ng/ml at that time. He was found on ultrasound scanning of his urinary tract to have a grossly enlarged prostate gland but to have satisfactory bladder voiding, he having a post micturitional residual urine volume of 60 mls then. Symptoms of urinary outflow obstruction were satisfactorily managed by alpha blockade. Over the subsequent 2 years, his serum total PSA level had increased to 17.1 ng/ml. Prostatic biopsies were performed in November 2002, when he was found to have a single focus of glandular atypia, with immuno-histochemical changes suspicious of, but not adequately diagnostic of carcinoma, in each of 2 of the 6 core biopsies performed. Finasteride was ordered to his alpha blockade in December 2002 when [redacted] had further prostatic biopsies performed in January 2003, he was found to have a single focus of prostatic adenocarcinoma of Gleason score 6, in one of the 10 core biopsies performed then. On MRI scanning performed in February 2003, there were no features of prostatic adenocarcinoma seen within his prostate, which did have all of the features of benign prostatic hypertrophy. When reviewed in April 2003, [redacted]'s lower urinary tract symptoms had improved significantly since being prescribed Finasteride in addition to alphablockade 4 months previously. Regrettably, [redacted] was lost to follow up subsequently in March 2006, his serum total PSA level was found to be 14.9 ng/ml. Since then, his serum total PSA level has fallen to 13.7 ng/ml by August 2006, and has remained at that level most recently in March 2007, and without any change in his management. On further MRI scanning performed in December 2006, there is some suspicion that he may have bilateral involvement of his seminal vesicles. In view of low signal intensity in both T1 and T2 modalities, and in view of any other features of capsular infiltration, I am a little sceptical of the suspicion, though it remains entirely possible that he may have seminal vesicular infiltration. There is no evidence of any regional

lymphadenopathy or of any distant metastatic disease. 2. You will note from the accompanying letter that Per is a very youthful man who works in [redacted], is virtually devoid of any lower urinary tract symptoms and enjoys a normal libido and normal erectile function all of which he is anxious to maintain. He is entirely aware that he has, at worse, slowly progressive disease. I have initiated a degree of androgen blockade by prescribing Casodex 50 mgs daily, and I would be most appreciative if you would give consideration to proceeding with radical radiotherapy and to which he is entirely happy to have. I would be grateful if you would arrange an appointment for him and I look forward to your views in due course. Yours sincerely Dictated but not signed by Aidan O'Brien FRCS Consultant Urologist

17/05/07 CONFIDENTIAL MR Personal Informa Dear Per I was pleased to have the opportunity of reviewing you on the 24th April 2007. I do hope that you have since begun taking Casodex 50 mgs daily, in addition to your other medication, and that you have had no problems with doing so. I write to advise you that I have written to Dr. David Stewart, Consultant in Clinical Oncology requested that he arrange an appointment for you to attend at Criagavon Area Hospital and with a view to giving consideration to you having radical radiotherapy to your prostate gland as discussed. You will receive a letter of appointment from him to attend him in due course. I look forward to meeting you again when you next attend for review. Yours sincerely Dictated but not signed by Aidan O'Brien FRCS Consultant Urologist

Appendix Four; Development History of casodex 50mg monotherapy



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NICC Oncology Pressures Paper, Updated September 2019

BHSCT hosts the Northern Ireland Cancer Centre and is also a local provider of oncology services to Belfast patients.
BHSCT Consultant Oncologists continue where possible to travel to the South Eastern, Northern and Southern HSC Trusts to provide a new, review and chemotherapy treatment service for lower GI, breast, lung and urology cancers (excluding renal and germ cell).

SHSCT CO Urology service – there is no substantive clinical oncology consultant covering this service. For the past three years this service has been covered by CO within NICC undertaking WLI clinics to see new patients at NICC, assess and plan for radiotherapy treatment and review post radiotherapy. Due to the impact of pension discussions the willingness and ability of CO Consultants to undertake WLI activity and decreased considerably from 8-12 NP appointments per week to 0-2 NP appointments. At present there is a NP and urgent review waiting list for patients to be appointed. There is no Consultant Oncologist input into the SHSCT Urology multidisciplinary team meeting.

SHSCT MO Lung/Urology SACT service – following numerous attempts by SHSCT to recruit to this substantive post it remains vacant. As discussed previously this service continues to be delivered by a MO locum Consultant who attends Craigavon once a week. There are serious governance issues regarding a single handed practice being delivered by a locum in a peripheral clinic out-with the oversight of a clinical team, with no clinical oversight leading to professional isolation and a lack of resilience. NICC have suggested the possibility of central assessment in NICC of these patients within the lung and GU teams. Patients would continue to have SACT delivered in Craigavon. A meeting with commissioners and SHSCT is scheduled for 02 October 19.

NICC have advertised a Medical Oncology Consultant post for the SHSCT Urology service. This is a funding pressure for NICC as it has decoupled the Lung and GU services delivered in the SHSCT. The expected dates of interview are December 2019. The successful recruitment will reduce the current governance concerns however the practice will remain single handed and vulnerable.
NICC are recruiting via agency a second locum Consultant to cover this practice from 04 November 2019.

NICC are submitting a paper to the HSCB on 02 October 2019 requesting additional 0.5 Consultant funding for the SHSCT Urology and Lung service to advertise a Consultant post for cross cover and would be confident of successful recruitment if funding was available.

Lung MO (New and Review)
All new and review lung appointments are now being delivered in NICC the Locum Consultant Medical Oncologist.
NICC are submitting a paper to the HSCB on 02 October 2019 requesting additional 0.5 Consultant funding for the SHSCT MO Lung service to advertise this post and would be confident of successful recruitment if funding was available.

Lung CO (New and Review)
All new and review lung radiotherapy appointments are now being delivered in the Northern Ireland Cancer Centre (previously delivered in Craigavon Hospital) by a substantive Consultant Clinical Oncologist.

NHSCT LGI service – following a recruitment exercise a substantive CO has been appointed to cover the NHSCT LGI service. All previous contingency plans have been stood down, all SACT assessments and new patients are seen and assessed in Antrim. This practice is currently delivered by a single handed practitioner and remains vulnerable. There is currently a waiting list for review patients to be seen, some patients may be offered appointments in NICC.
Further pressure is being caused as NWCC are unable to provide RT for patients residing in BT51-BT57 due to vacancies. These patients are being relocated to NICC.

NHSCT Breast service – this service is currently being covered by a substantive Consultant in the morning and the temporary relocation of a consultant from NICC leaving a significant gap within the central gynae team. This loss puts considerable strain on the service and the prescribers attending the clinic. There is no resilience and no Consultant presence in the afternoon during leave or other periods of absence. This leaves trainees attending a peripheral clinic with no Consultant presence.
NICC are submitting a paper to the HSCB on 02 October 2019 requesting additional 0.5 Consultant funding for the NHSCT Breast service to advertise this post and would be confident of successful recruitment if funding was available.

NHSCT Lung/GU service – this joint clinic is the only remaining joint Lung and GU clinic across the region. All other previously joined lung and GU clinics have been decoupled resulting in a funding pressure to NICC. This clinic remains single handed and is vulnerable.

BHSCT LGI service – this service was previously provided by 2 Clinical Academic Consultants. Following 1 resignation this service is currently being provided by one single handed Clinical academic on a temporary basis. BHSCT are in the process of recruiting a MO to cover the LGI service. This leaves the service single handed and vulnerable.
NICC are submitting a paper to the HSCB on 02 October 2019 requesting additional 0.5 Consultant funding for the BHSCT LGI service to advertise this post and would be confident of successful recruitment if funding was available.

BHSCT Thyroid service – this service is currently being delivered by a single handed CO and is vulnerable. This is epected to be raised as a serious concern when the service is peer reviewed in November 2019.
NICC are submitting a paper to the HSCB on 02 October 2019 requesting additional 0.5 Consultant funding for the BHSCT Thyroid service to advertise this post and would be confident of successful recruitment if funding was available.

Service pressures
The impact of new therapies, especially combination immunotherapy within renal will have a considerable impact on the service with additional medical and nursing time required to assess and prescribe the treatment and as this treatment is a replacement from an oral therapy to IV it will also have a considerable impact on chair capacity.

Impact of NWCC
As mentioned above vacancies within NWCC are causing a redirection of the following patients to NICC:

- LGI patients within BT51-BT57
- All patients requiring radiotherapy for skin cancer
- All patients with pacemakers requiring radiotherapy treatment

Early Phase Trials
This early phase trials service is currently single handed and covered by a clinical academic consultant. This issue has been flagged by the Scientific Advisory Board who assessed BHSCT ECMC status, QUB have also raised this as a concern to the Trust and asked for a plan to address the shortfall.
BHSCT are currently recruiting a MO, ECT is part of the job plan with an expected interview date of December 2019.

Immunotherapy
All patients requiring immunotherapy (with the exception of lung in SET) are being referred for treatment in NICC & NWCC. This is placing additional significant capacity within BWS.

Delivery of FEC-DTP from NHSCT
In May 2019 the Consultants delivering the breast service within Antrim highlighted that they were unable to prescribe FEC-DTP for patients as C4 requires 8 hours of chair time and Laurel House advised they were unable to support this. This regimen is prescribed and delivered in SET, SHSCT and NWCC day units as well as BWS. As an interim measure these patients are referred to NICC and are being admitted overnight to receive cycle 4 within ward 3A. The patients are then referred back to Laurel house to receive cycle 5 and cycle 6. This has been agreed on a short term basis only and BHSCT are waiting on an update for the service to revert back to Antrim.

Staffing deficits

As part of the oncology transformation project WOSCaN Nurse capacity tool identified Belfast had a SACT nursing deficit of 5.09 WTE required to deliver SACT activity based on November 2018 figures. There is currently no implementation team or plan to address this shortfall.

Other Concerns

1. The oncology service cannot currently implement RCP guidance for Senior review of all ISC/acutely unwell patients within 14 hours of admission. This has been raised at a number of forums and is being added to the BHSCT Risk register. In order to implement this standard 30 PAs of consultant and SpR time is required.
2. Radiotherapy peer review – colleague peer review of radiotherapy volumes and plans is recommended by the RCR and is not fully implemented within NICC. The estimated additional PAs to deliver peer review across all sites is 12.625 PAs for NICC / SET/ Antrim/ Southern practices.
3. MDM cross cover for radiation oncology is an agreed peer review standard. During times of leave, planned or unplanned there is a gap in radiation oncology input at MDMs. This has also been flagged via the transformation project.
4. AOS – following peer review there are recognised and known gaps within the BHSCT AOS service. These include a lack of AOS service to all hospital sites with an emergency department, expansion of the nursing resource within the RVH and development of Advanced Nurse practitioner roles to support the assessment and management of acutely unwell patients attending the Acute Oncology unit in the cancer centre. BHSCT has recently had the opportunity to complete an AOS expansion paper.
5. Bank Holidays – BHSCT are currently completing an options paper including staff and patient questionnaires in relation to delivering a full SACt service on bank holidays. Initial feedback from patients and staff would support this view. There has been recent media interest regarding the impact of bank holidays on treatment schedules for patients.
6. Development of a regional CUP service is a priority across Northern Ireland – individual numbers of inpatients suitable for intervention are relatively low within each Trust – it is inevitable that a CUP service will attract referrals from primary care / other secondary care professionals for fitter outpatients who may require further diagnostics and work-up. HOWEVER, this cannot and should not be an oncology stand-alone service – adequate rapid access to diagnostics, CUP MDM etc must be adequately resourced and commissioned with clear referral guidelines.

These service gaps across 3 Trusts, and their likely duration, represent significant risks to patient care, timeliness of care and continuity of care if arrangements cannot be identified to maintain these two services. These risks are described below:

- Waiting times for new patients likely to grow with impact on outcomes, eg. for patients referred with advanced disease, there is often an urgent need for assessment with the potential to miss the window of opportunity for treatment.
- Inequitable waiting times and treatment times for patients across NI, with worsening of oncology review backlog in these two Trusts, and impact on other services where Consultants are doing additional work to support NHSCT and SHSCT.
- Poor patient experience due to extended waiting times and increased travel time.
- Inability to provide oncology input to all MDTs with concern that oncology options may not be comprehensively considered.
- Increased pressure on Cancer Centre Consultant staff, nursing and admin staff at a time when services are already struggling due to reduction in STRs and support being given to WHSCT during their transition phase.
- Potential risk that chemotherapy service cannot be covered due to significant gaps within the Consultant workforce leading to the creation of waiting lists for new patients to start chemotherapy and deferrals for existing patients already on chemotherapy treatment

Options to Address (26/09/19)

Request for funding from HSCB to proceed with recruitment of 3 Consultant posts from February 2020. The 3 posts will cover the following services:

1. **SHSCT Lung and BHSCT LGI (medical Oncology)**
2. **NHSCT Breast and BHSCT Thyroid (clinical oncology)**
3. **BHSCT Urology and SHSCT Lung and GU cross cover (medical oncology)**

NICC are confident of successfully filling these 3 posts if funding was available.

Oncology Trainee Planned Completion Dates

There a number of trainees completing core training within Oncology in the next 12-18 months. The confirmed number depends on varying actors including out of programme research opportunities. Currently there are 11 trainees hoping to complete.

Table 1: Trainees by speciality with expected date of completion of CCT

Speciality	Expected Completion date
MO	Oct 19
CO	Feb 20
MO	April 20
CO	Aug 20
CO	Aug 20
CO	Aug 20
MO	Aug 20
CO	Nov 20
MO	Sept 20
CO	Dec 20
CO	Feb 21

There are a known number of current Oncology service gaps. This have been raised on a variety of forums. The BHSCT has issued an early alert to the DoH regarding significant gaps in the ability to deliver a full Oncology service. Table 2 (below) lists out these gaps.

Table 2: Current Oncology Service Gaps

Location	**Site**	**Speciality**	**Comments**
BHSCT	Renal	MO	
	Breast	MO	
	Urology	MO	Post 3 above
	Skin	MO	
	LGI	MO	Interview date September 19
	ECT	MO	Interview date September 19
	ECT	MO	
	LGI	MO	Post 1 above
	Thyroid	CO	Post 2 above
	Lung	CO	
Antrim	Breast	MO	

	Breast	CO	Post 2 above
	Lung	MO	
	GU	MO	
	LGI	MO	
CAH	Lung	MO	Post 1 above
	GU	MO	Interview date September 19
	Lung/GU crosscover	MO	Post 3 above
	LGI	MO	
SET	Lung	MO	

Funding for Consultant workforce to deliver the Regional model (BHSCT, NHSCT, SHSCT and SEHSCT) sits within BHSCT. Due to a multitude of factors including an increasing incidence of cancer, increasing lines of treatments, patients living with and beyond their cancer diagnosis and implementing royal college guidance in terms of peer review within radiotherapy, the oncology service has expanded significantly over the last 20 years since the last service review. Subsequently the service does not have sufficient funding to cover all the Oncology service gaps. Funding is sought for the funding shortfall of 6 WTE Consultants.

Current FSL/ASL within Medical Consultants

FSL 35.29

ASL 33.95

Variance 1.34 (1.0 WTE for MO post being interviewed in December 2019).