



Urology Services Inquiry

Urology Services Inquiry | 1 Bradford Court | Belfast BT8 6RB
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Professor David Stewart
Belfast Health and Social Care Trust
Headquarters
51 Lisburn Road
Belfast
BT9 7AB

13 December 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.

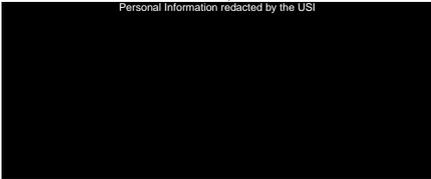
Given the tight time-frame within which the Inquiry must operate, the Chair of the Inquiry would be grateful if you would comply with the requirements of the Section 21 Notice as soon as possible and, in any event, by the date set out for compliance in the Notice itself.

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

Personal Information redacted by the USI


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 35 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: Professor David Stewart
BHSCT
Headquarters
51 Lisburn Road
Belfast
BT9 7AB

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 **3rd January 2024**.

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.

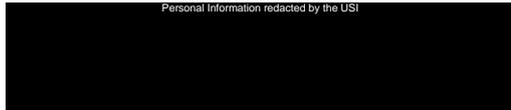
If you wish to make such a claim you should do so in writing to the Chair of the Inquiry at: **Urology Services Inquiry, 1 Bradford Court, Belfast, BT8 6RB** setting out in detail the basis of, and reasons for, your claim by noon on **27th December**

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 13th day of December 2023

Signed:

Personal Information redacted by the USI


Christine Smith QC
Chair of Urology Services Inquiry

SCHEDULE**[No 35 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, and why you consider they are better placed to respond

to this question.

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), 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. If patients referred to you from the Southern Trust were prescribed Bicalutamide 50 mg in circumstances where you considered that to be an inappropriate treatment regime for that patient, did you take, or did you consider taking, any steps to alert the Southern Trust? If yes, please explain. If not, why not?
- k. 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 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**

USI Ref: Notice 35 of 2023

Date of Notice: 13th December 2023

Witness Statement of: Prof David Stewart

I David Stewart, will say as follows:-

1. Qualifications BSc, MB, BCH, BAO, FRCR, MRCP, Consultant Clinical Oncologist from December 2001 until present day, employed at BHSCT until September 2015 and since September 2015 employed by WHSCT. Prior to my CCT in Clinical Oncology I trained initially in Belfast in General Medicine MRCP (1990-1993) followed by training in Clinical Oncology in London FRCR (1993-1998 at Charing Cross, Mount Vernon and Hammersmith hospitals). I passed Fellowship of Royal College of Radiologists in 1998 and completed specialist training in Northern Ireland in 2000 and did a one year fellowship at Peter MacCallum Cancer Centre, Melbourne 2001 in Lung, Head and Neck and Prostate Cancer. I was awarded the status and title of Visiting Professor Ulster University in January 2020.

2. (i) Between 2002 and 2009 I carried out an all day New and Review and Chemotherapy outpatient clinic at the Mandeville unit Southern Health and Social Care Trust for Urology and Lung Cancer patients. I was joined by Dr McAleese in 2006. (ii) I did not raise any issues or attend any meetings during this period or period after 2009 about concerns regarding urology services at Southern Trust.

3. No documents to declare. Dr McAleese has given me copy of his audit which he has already submitted to inquiry

5. (i)

(a) I would have been referred a number of patients by Mr O'Brien and Mr Young who were on Bicalutamide 50mg and who had not yet commenced LHRH agonist or had not



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yet increased dose to 150mg. Dr McAleese has audited patients over a 4 year period and there were 10 patients referred to me who had commenced Bicalutamide 50mg.

(b) See Dr McAleese audit, 10 patients referred to me who had started Bicalutamide 50mg and were subsequently commenced on LHRH agonist

(c) I am not sure of timeframe but referrals on Bicalutamide 50mg were likely also occurring in years prior to Dr McAleese commencing post in 2006

(d) Prescribing clinicians Mr O'Brien and Mr Young. The 31/62 day pathway started around the time period above so there would have been pressure on urologists to commence hormone treatment within 62 days to meet targets but ultimately they would have left the final choice particularly in relation to potentially curative treatment with radiotherapy to the oncologist to decide their preferred hormone treatment either LHRH agonist or Casodex 150mg

(e) See Dr McAleese audit 10 patients between August 2006 to October 2010 with details of duration

(f) See Dr McAleese audit

Median time on Bicalutamide 50mg for 10 patients referred was 1.0 mths,

Mean time 2.7 mths

Range 0.4 mths to 11.2 mths

Patient 1 with longest time on Bicalutamide 50mg 11.2 mths in this audit had been recommended to commence Bicalutamide 150mg by Mr O'Brien so uncertain as to why or if indeed he was on 50mg. Was treated with maximum androgen blockade (MAB) and subsequently radiotherapy. Patient passed away more than a decade later despite aggressive disease with no evidence of prostate cancer

Patient 2 was also on Bicalutamide 50mg for significant period of time 8.1mths but had poor tolerance of hormones during prior period of active monitoring of a Gleason 2+3 prostate cancer. He progressed on active monitoring to higher stage disease and was initially commenced on Bicalutamide 50mg. Mr O'Brien agreed with my decision for



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maximum androgen blockade. He had further difficulties tolerating hormones throughout his treatment period. Patient 2 passed away over a decade later no evidence of disease.

Patients 3-10 were only on Bicalutamide 50mg for short period of time (0.4-2.3mths) with the likely expectation that I would choose my preferred LHRH agonist Zoladex over Prostag which was preference of Mr O'Brien

(g) See above. Bicalutamide 50mg is usually prescribed to prevent flare when commencing LHRH for localized, locally advanced or metastatic disease. Bicalutamide 50mg is less effective than LHRH agonists in metastatic disease but has not been compared in localized or locally advanced disease. It only has a license for prevention of flare or when used in combination with LHRH agonist in advanced prostate cancer. Patient 1 possible drug error, Patient 2 it was not inappropriate to start at 50mg given previous side effects on hormone treatment. Patients 3-10 it was reasonable to commence Bicalutamide at 50mg with final choice of LHRH agonist to be made by oncologist.

Patients on Bicalutamide 50mg who were referred to me for radiotherapy or for the treatment of advanced disease were converted to Zoladex and Bicalutamide 50mg stopped after Zoladex administered. Zoladex was given for 6 mths or 2-3 years or lifelong depending on diagnosis. I rarely used Bicalutamide 150mg which at the higher dose required additional radiotherapy to both male breasts to prevent gynaecomastia. Bicalutamide at 150mg dose was only licensed for use in locally advanced disease but is widely used in other stages of disease by UK oncologists out with its license. There were also concerns during this time period re cardiovascular mortality of Bicalutamide 150mg in localized prostate cancer. In the EPC study Cardiovascular mortality was doubled in patients receiving Bicalutamide and this would have been a concern of Mr O'Brien and others including myself. Alert was issued by Dept of Health. Recently Tamoxifen the anti oestrogen used in breast cancer is now prescribed routinely for prevention of gynaecomastia rather than radiation but this is unlicensed use. Referring doctor Mr O'Brien or Mr Young and GP of patient both informed by letter of changes I made to hormone treatment. Patient informed that stronger anti hormone treatment was



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required before during and after radiotherapy or for continuous treatment of advanced disease. At no time did Mr O'Brien or Mr Young disagree with change to LHRH. My presumption was that patients following diagnosis while still undergoing diagnostic investigations and awaiting oncology new patient appointment were placed on low dose Bicalutamide to commence cancer treatment as soon as possible (31/62 day pathway) and to prevent progression and it was never intended to be a monotherapy or sole definitive treatment for localized or locally advanced disease and certainly never was for any patients I saw at Southern Trust

(h) See answer g above. I did not speak to anyone on this issue, I communicated with Mr O'Brien and Mr Young and GP by letter only in regard to final hormone decision. I did not discuss with any oncology colleagues

(i) I did not have concerns and did not escalate

(j) See previous answer

(k) I have not used Bicalutamide 50mg as a monotherapy. It was an option during COVID pandemic for patients with low/intermediate risk non metastatic prostate cancer who were unhappy with no treatment and likely would have reduced risk of progression. I don't believe there is any literature on dose reduction for patients who are having difficulty tolerating 150mg dose, patient would have to be informed of possible loss of efficacy, side effects of 50mg dose similar to 150mg but less severe. Most clinicians likely to recommend intermittent hormones instead of reducing dose for patients on long term Bicalutamide 150mg.

(ii) I was not aware of issue of Bicalutamide 50mg monotherapy issue until now. Review of patients audited by Dr McAleese over 4 year period shows that only 2 patients referred by Mr O'Brien to me were on Bicalutamide 50mg for extended period before commencing LHRH agonists. I left Southern Trust in 2009. I don't recall ever discussing Bicalutamide 50mg monotherapy with Dr McAleese with whom I did a joint oncology urology clinic at SHSCT when we worked together between 2006 and 2009. In the past I discussed difficult patients with Prof O'Sullivan for advice on an ad hoc one to one basis. I don't recall any patients I discussed with Prof O'Sullivan specifically around



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Bicalutamide 50mg monotherapy. I may have discussed Patient 2 who was on Bicalutamide 50mg for 8 months as I mention in notes that his case was discussed with others but discussion was mainly around potential benefit of pelvic radiotherapy in node positive disease.

(iii) I left Craigavon in 2009 so there may have been a greater awareness in subsequent years

(iv) I did receive 10 referrals see audit of Dr McAleese over 4 year period in most cases Bicalutamide was commenced at dose of 50mg prior to expected commencement of LHRH agonist (Zoladex)

(v) I did not attend the Thursday morning pre clinic team meeting which was an entirely separate clinic to my urology clinic

6. I was not aware of significant issues around quoracy of SHSCT urology MDMs until 2017. I am not sure when MDMs with oncology presence commenced at Craigavon but it was after my time as I left in 2009. I did help BHSCCT on a small number of occasions in 2017/2018 by providing cover as they were having difficulty providing oncology input to MDT and as some of the patients discussed were from Fermanagh and maybe referred to WHSCT Altnagelvin I offered to help out.

7. I have no knowledge of potential governance problems regarding the referral and screening of patients to Regional Urology, Belfast City Hospital

8. I would have been aware that two urologists at Craigavon with some support from Mr Brown in Daisyhill would not have been enough to provide optimum care for benign and malignant disease for the whole population of Southern Trust during my time. Despite this I was aware that during my time attending Craigavon it had lowest Prostate Cancer Mortality in Northern Ireland and Ireland. The Northern Ireland Cancer Registry has two publications (1) October 2007 [Microsoft Word - Survival of Cancer Patients in NI FINAL2.doc \(qub.ac.uk\)](#) from 1993-2004 and (2) All Ireland



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statistics published in 2009 [Microsoft Word - ALL IRELAND 1994-2004 v04.doc](#)
[\(qub.ac.uk\)](#)

Statement of Truth

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

Signed: Personal Information redacted by the USI
_____

Date: 23/1/24