

Urology Services Inquiry | 1 Bradford Court | Belfast BT8 6RB T: 02890 251005 | E: info@usi.org.uk | W: www.urologyservicesinquiry.org.uk

Dr Lucy Jellett Belfast Health and Social Care Trust Headquarters 51 Lisburn Road Belfast BT9 7AB

13 December 2023

Dear Madam,

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

<u>Provision of a Section 21 Notice requiring the provision of evidence in the form of a written statement</u>

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.

WIT-106877

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

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

Yours faithfully



Anne DonnellySolicitor 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 30 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 Lucy Jellet

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 3**rd **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 27**th **December 2023**.

WIT-106880

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:

Christine Smith QC
Chair of Urology Services Inquiry

SCHEDULE

[No 30 of 2023]

- 1. Please summarise your qualifications and occupational history.
- 2. Having regard to the <u>Terms of Reference</u> 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, I would have been seeing a fairly small group of patients who fitted the correct criteria for brachytherapy, and there would have been a number of clinical oncologists who were job planned to provide cover for urology in

Craigavon, and they would have seen a greater number of cases. By proportion, I would have expected that they might have seen more cases of Bicalutamide 50." [TRA-07782]

- (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;
 - 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. On 20 November 2014, Dr Darren Mitchell forwarded you an email he had just sent to Mr O'Brien in which he challenged Mr O'Brien's prescription of Bicalutamide 50mg monotherapy [see WIT-96678 and AOB-71990]. Please detail:
 - (i) The background to the sending of this email, including all conversations you may have had with Dr Mitchell before it was sent, what those conversations were about, who was present during these conversations and how the decision

- was reached to send Mr O'Brien the email.
- (ii) What was the purported purpose of sending the email, as far as you were aware?
- (iii) Why was an email containing this information considered an appropriate manner in which to deal with concerns?
- (iv) Was any consideration given to other ways to address the concerns expressed in the email? If no, why not? If yes, were those ways also pursued and, if not, why not?
- (v) What do you understand the reason to have been for copying you into the email? Was it anticipated that you would do anything as a result?
- (vi) Do you know what was the response, if any, to the email? Did you do anything as a result of being copied into the email and/or as a result of your knowledge of the concerns raised in it?
- 7. 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?
- 8. 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.
- 9. 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 30 of 2023

Date of Notice: 13th December 2023

Witness Statement of: Dr Lucy Jellett

I, Lucy Jellett, will say as follows:-

- 1. I was awarded MB, BCh, BAO in Medicine from Queens University, Belfast in July 2000. I progressed to Membership of the Royal College of Physicians (UK) in 2005 and Membership of the Royal College of Radiologist (UK) in 2011. I completed my Certificate in Specialist Training in Clinical Oncology May 2013 and took up a post as Locum Oncology Consultant in Summer 2013.
- 2. (i) In late 2014 I covered the Uro-Oncology Clinic in Craigavon for a number of weeks as a locum consultant. My role was to provide Systemic Anti-Cancer Treatment and to see New Patients referred to the service. Those who were identified as requiring radiotherapy were then referred centrally (to Belfast Trust) for treatment.
- (ii) In November 2014 I met the patient outlined in Dr Mitchell's email at a New Patient clinic in Craigavon Area Hospital. He had originally been referred to the Urology service in 2012 with an elevated PSA. TRUS biopsy on 11/9/2012 had confirmed high grade prostate cancer. Staging investigations carried out in October 2012 confirmed organ confined disease. His case was discussed at the Urology MDM at time of biopsy and staging results, and the outcome was for referral to Oncology for radiotherapy. This referral was delayed by 2 years, during which time the patient had been taking BICALUTAMIDE 50mg as a monotherapy.

I referred this case to Dr Mitchell as chair of the regional MDM and senior consultant colleague. I raised concerns mainly relating to the delay in referral. At the



time I was concerned that the delay may have led to a negative outcome for the patient and also may have made him ineligible for clinical trials. I brought the case, in person, to Dr Mitchell in his office. He was extremely supportive and assured me that both the Belfast Trust and Southern Trust were aware of concerns regarding Mr O'Brien's clinical management and these were being addressed. I also spoke to Professor O'Sullivan at the time in his role of Clinical Director. I explained that as a very junior locum consultant I did not feel I had the experience required to address issues surrounding a very senior surgeon who was NICAN Chair at the time. Prof O'Sullivan was also very supportive and I was not required to continue covering Uro-Oncology clinic in Craigavon once alternative arrangements were made. This is the only relevant case I can recall and as stated above I only covered this service for a limited number of weeks in late 2014.

- 3. I have no relevant documentation
- 4. -
- 5. (i) a. The case outlined above is the only case I recall;
 - b. As above;
 - c. Late 2014;
 - d. Mr Aidan O'Brien;
 - e. Only one that I recall;
 - f. As outlined in previous answers;
 - g. I did not believe Bicalutamide 50mg was an appropriate treatment as a monotherapy as there was no clinical trial evidence that I was aware of to support its use;
 - h. I discussed this with senior colleagues as detailed above.
 - i. Not applicable;
 - j. I had raised my concerns with the Chair of the Regional MDM and the Clinical Director for Oncology in Belfast Trust. As a junior, locum consultant I believed that I had escalated my concerns appropriately.
 - k. Bicalutamide 50mg as a monotherapy is not supported by clinical trial evidence and therefore I generally would not consider it best practice and do not know of any circumstances where I would have prescribed it. I no longer treat prostate cancer and therefore no longer initiate Bicalutamide at any dose.



- (ii) I covered the Uro-oncology service in Craigavon in late 2014 by which time, I believe, these issues had already been raised with Mr O'Brien. Certainly in the case outlined above, the referral letter had stated the Bicalutamide had been increased to 150mg in May 2013 (though patient was still taking 50mg).
- (iii) I was aware of the issue but do not recall it being the main focus of my concerns. Delay in referral for radical treatment for potentially curative cancers was my concern generally and certainly in the case outlined in previous answers.
- (iv) Not applicable.
- (v) The Thursday morning pre-clinic team meeting was for the Central Uro-Oncology service and I was not involved with that meeting as a locum consultant.
- 6. (i) This email was sent in response to my discussion was Dr Mitchell regarding the above case. I cannot recall anyone else in the office at the time of our discussion.
 - (ii) I cannot comment on the purpose of another individual's email.
 - (iii) I cannot comment as I did not send the email.
 - (iv) I cannot comment as I did not send the email.
- (v) I understand the reason for me being copied into the email was to assure me that Dr Mitchell had listened to my concerns and was taking them forward in his role as Chair of the Regional MDM. It was not anticipated that I would do anything as a result.
 - (vi) I am not aware of a response and I did not action email further.
- 7.Regarding Oncology attendance at the MDM, I was only aware of shortages in general terms. Attendance at the MDM was not part of my job plan in the very short time that I was covering the clinic. I do not recall raising concerns as there was a general awareness of staff shortages.
- 8. I cannot comment on this issue



9.I have nothing further to add.

Statement of Truth

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

	Personal Information redacted by t USI	ne	
Signed:		<u> </u>	
Date:1	6/01/2024		_