



Urology Services Inquiry

Urology Services Inquiry | 1 Bradford Court | Belfast BT8 6RB
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Professor Joseph O'Sullivan
Consultant Clinical Oncologist
Belfast Health and Social Care Trust
Headquarters
51 Lisburn Road
Belfast
BT9 7AB

17 April 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 you may have knowledge relevant to the Inquiry's Terms of Reference. Inquiry understands that you will have access to all of the relevant

information required to provide the witness statement required 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. As you are aware the Trust has already responded to our earlier Section 21 Notice requesting documentation from the Trust as an organisation. However 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 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 5 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 Joseph O'Sullivan
Consultant Clinical Oncologist
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 **15th May 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 **8th May 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 17th April 2023

Signed:

Personal Information redacted by the USI

Christine Smith QC

Chair of Urology Services Inquiry

SCHEDULE
[No 5 of 2023]

The Inquiry asks that you address the following questions, providing all documentation relevant to your answers:

1. You were interviewed by Dr Dermot Hughes on 4 January 2021 in relation to the investigation of a number of SAls concerning former patients of Mr Aidan O'Brien. The record of that interview states as follows:

'JOS advised that when he came into post initially about 17 years ago, he had concerns in relation to the use of bicalutamide and that they had frequently challenged him about the treatment. He made recommendations in clinic letters questioning the use of bicalutamide 50mgs instead of the standard 150mgs or LHRH agonist therapy. In the cases he had seen, the dose of bicalutamide would not have resulted in a major detriment to the patient's therapy/outcome and therefore wasn't escalated further. JOS said he was aware that his colleague DM (as MDT Chair) had raised our concerns about AOB's bicalutamide prescribing with the then CD for oncology SMcA, probably in 2011.' [TRU-162262]

- (i) Confirm whether the above is an accurate record of the discussion during interview. To the extent that it is not, please identify any alleged inaccuracies and offer clarification of same.
- (ii) Please identify 'SMcA'.
- (iii) When did you first become concerned about the use of Bicalutamide?
- (iv) What was the cause of your initial concern?



- (v) Please indicate what, at that time, your specific concerns in relation to the use of Bicalutamide were.
- (vi) Please provide full details of the occasions on which you 'frequently challenged' Mr O'Brien about the treatment.
- (vii) Please provide further details in respect of the recommendations in clinic letters referred to above. Please provide the Inquiry with copies of any relevant clinic letters demonstrating the questioning of prescribing practices.
- (viii) Please provide any further comments you may have in respect of your indication that 'the dose of bicalutamide would not have resulted in a major detriment to the patient's therapy/outcome and therefore wasn't escalated further.'
- (ix) Please give details of any discussions you had with Dr Mitchell regarding shared concerns.
- (x) Were you aware of others who had knowledge of these issues or who may have shared similar concerns? Please provide details.
- (xi) Please identify every occasion on which you escalated concerns regarding Mr O'Brien's prescribing practices in respect of Bicalutamide and identify the individual(s) to whom your concerns were escalated. If it is the case that you did not escalate your concerns, please indicate why.

2. The Inquiry is aware of significant issues around the quoracy of SHSCT Urology MDMs, particularly in terms of Oncology attendance. On this issue, the record of the interview of 4 January 2021 (at TRU-162262) states:

'JOS said that the MDT improved with the attendance of two of the newer consultants about 7 years ago.'



Please explain this further and offer any further comments or observations which may assist the Inquiry in understanding this issue.

3. During the interview referred to above (at TRU-162262), in response to a comment by Dr Hughes to the effect that *'it would seem he [Mr O'Brien] worked in isolation despite being involved in a multi-disciplinary team'*, it is recorded: *'JOS said that was his impression of Mr AOB.'* What led you to have this impression of Mr O'Brien? Please provide full details.
4. In his Section 21 Statement to the Inquiry, at [WIT-84157] in reference to you and Dr Mitchell, Dr Hughes states:

'They had also written to him [Mr O'Brien] directly about his practice but did not escalate the issue to the SHSCT – this is something both individuals regretted and reflected upon.'

- (i) To the best of your recollection, please provide details of every occasion on which you wrote directly to Mr O'Brien about his practice and, where possible, provide copies of this correspondence together with any response received.
 - (ii) Please explain why the issue was never escalated to SHSCT, providing details of any real or perceived obstacles to such escalation.
 - (iii) Please provide any further comments/ reflections you may have on the failure to escalate, setting out what might perhaps have been done differently.
5. Please indicate whether, at any stage, you had concerns about or knowledge of issues around the use of Clinical Nurse Specialists. To the extent that your answer is affirmative, please provide further details.



6. Please provide any further details 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.



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UROLOGY SERVICES INQUIRY

USI Ref: Notice ...5... of 2023

Date of Notice: 17 April 2023

Witness Statement of: Professor Joe O'Sullivan

I, ...Prof Joseph O'Sullivan.....will say as follows:-

1. You were interviewed by Dr Dermot Hughes on 4 January 2021 in relation to the investigation of a number of SAls concerning former patients of Mr Aidan O'Brien. The record of that interview states as follows: 'JOS advised that when he came into post initially about 17 years ago, he had concerns in relation to the use of bicalutamide and that they had frequently challenged him about the treatment. He made recommendations in clinic letters questioning the use of bicalutamide 50mgs instead of the standard 150mgs or LHRH agonist therapy. In the cases he had seen, the dose of bicalutamide would not have resulted in a major detriment to the patient's therapy/outcome and therefore wasn't escalated further. JOS said he was aware that his colleague DM (as MDT Chair) had raised our concerns about AOB's bicalutamide prescribing with the then CD for oncology SMcA, probably in 2011.' [TRU-162262]
- (i) **Confirm whether the above is an accurate record of the discussion during interview. To the extent that it is not, please identify any alleged inaccuracies and offer clarification of same.**

The above statement is accurate except:

- a. I don't recall saying 'frequently challenged'. My intended phrase was 'challenged on a number of occasions'.
- b. I was incorrect about the date Dr. Mitchell discussed with Dr. McAleer – it was 2019 and not 2011. The discussion was about a proposed regional protocol concerning the use of hormone therapy in prostate cancer, rather than specifically about Mr. O'Brien's prescribing. I did have a discussion with Dr. Mitchell in 2014 regarding my recollection of a few cases (involving prescription of bicalutamide 50mg daily as monotherapy in prostate cancer) that I had encountered early in my consultant career.

- (ii) **Please identify 'SMcA'.**

Dr. Seamus McAleer, Clinical Director of Oncology, Belfast Trust at the time.



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(iii) When did you first become concerned about the use of Bicalutamide?

I can't recall the exact time I became aware of the issue, but it was during my initial few years as a consultant in Belfast (2004-2008). The vast majority of my referrals were from the Belfast City Hospital Urology team however I also received occasional referrals from Mr. O'Brien or other members of the Southern Trust urology team.

(iv) What was the cause of your initial concern?

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 a 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.

(v) Please indicate what, at that time, your specific concerns in relation to the use of Bicalutamide were.

My specific concern was that patients were receiving a non-evidence based hormone therapy dose which might be sub-optimal therapy for patients with prostate cancer.

(vi) Please provide full details of the occasions on which you 'frequently challenged' Mr O'Brien about the treatment.

As per point (i) above, I 'challenged on a number of occasions' in clinic letters. I don't have a record of these cases, but I estimate at least 3 patients were involved. I would have stated something along the lines of 'the patient was receiving a sub-optimal dose of bicalutamide and I have now changed to the evidence based dose of 150mg daily or to another form of hormone therapy e.g. a Lutenising Hormone releasing hormone agonist'

(vii) Please provide further details in respect of the recommendations in clinic letters referred to above. Please provide the Inquiry with copies of any relevant clinic letters demonstrating the questioning of prescribing practices.

I do not have any record of the patients involved. My recommendation would have been to commence evidence-based hormone therapy and radiotherapy if appropriate.

(viii) Please provide any further comments you may have in respect of your indication that 'the dose of bicalutamide would not have resulted in a major detriment to the patient's therapy/outcome and therefore wasn't escalated further.'

I believed that the harm to patients in the cases I had encountered was relatively low, and therefore did not feel the need to escalate. I was content that my clinic letters to Mr. O'Brien had adequately addressed the issue.



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- (ix) Please give details of any discussions you had with Dr Mitchell regarding shared concerns.

Dr. Mitchell, as chair of the Urology MDT raised concerns in 2014 to Mr. O'Brien in relation to a particular case which had been referred to the MDT and was receiving bicalutamide 50mg daily as monotherapy for prostate cancer. At that time, I mentioned to Dr. Mitchell about the historical cases I had remembered from my early years as a consultant in Belfast. This discussion would have taken place at one of our Thursday morning pre-clinic meetings at the Northern Ireland Cancer Centre.

- (x) Were you aware of others who had knowledge of these issues or who may have shared similar concerns? Please provide details.

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.

- (xi) Please identify every occasion on which you escalated concerns regarding Mr O'Brien's prescribing practices in respect of Bicalutamide and identify the individual(s) to whom your concerns were escalated. If it is the case that you did not escalate your concerns, please indicate why.

I did not escalate my concerns as I felt there was no substantial harm to patients from the bicalutamide prescribing I had encountered in my practice.

2. The Inquiry is aware of significant issues around the quoracy of SHSCT Urology MDMs, particularly in terms of Oncology attendance. On this issue, the record of the interview of 4 January 2021 (at TRU-162262) states: 'JOS said that the MDT improved with the attendance of two of the newer consultants about 7 years ago.' Please explain this further and offer any further comments or observations which may assist the Inquiry in understanding this issue.

I do not have a detailed knowledge of the oncology cover at the Southern Trust. This was a general comment in which I was referring to my personal understanding of the oncology presence at the Southern Trust Urology MDT. I understood that oncology cover had been absent or patchy for a period of time but that there had been new oncology consultants appointed who were job-planned to attend the MDT.

3. During the interview referred to above (at TRU-162262), in response to a comment by Dr Hughes to the effect that 'it would seem he [Mr O'Brien] worked in isolation despite being involved in a multi-disciplinary team', it is recorded: 'JOS said that was his impression of Mr AOB.' What led you to have this impression of Mr O'Brien? Please provide full details.

This impression was based on my experience with the cases that had been prescribed bicalutamide 50mg as monotherapy. My view was that an MDT would be unlikely to recommend this therapy and that it was probably the decision of Mr. O'Brien alone.

4. In his Section 21 Statement to the Inquiry, at [WIT-84157] in reference to you and Dr Mitchell, Dr Hughes states: 'They had also written to him [Mr O'Brien] directly about his



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practice but did not escalate the issue to the SHSCT – this is something both individuals regretted and reflected upon.'

- (i) **To the best of your recollection, please provide details of every occasion on which you wrote directly to Mr O'Brien about his practice and, where possible, provide copies of this correspondence together with any response received.**

As per answer 1(vi) above, I replied to referral letters outlining the need to change from the 50mg monotherapy dose to the standard dose. I did not write to Mr. O' Brien separately about the issue. I do not have recall of the patients involved.

- (ii) **Please explain why the issue was never escalated to SHSCT, providing details of any real or perceived obstacles to such escalation.**

I did not escalate the issue as I didn't feel it was serious enough.

- (iii) **Please provide any further comments/ reflections you may have on the failure to escalate, setting out what might perhaps have been done differently.**

On reflection, I should have challenged Mr. O'Brien more directly about his prescribing of bicalutamide 50mg monotherapy. There were no particular obstacles to escalating concerns apart from the fact that I was a relatively junior consultant at the time and likely felt reluctant to challenge an established senior colleague.

5. **Please indicate whether, at any stage, you had concerns about or knowledge of issues around the use of Clinical Nurse Specialists. To the extent that your answer is affirmative, please provide further details.**

I have no concern or knowledge of issues regarding the use of clinical nurse specialists.

6. **Please provide any further details which you consider may be relevant to the Inquiry Terms of Reference.**

I have nothing further to add.

Statement of Truth

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

Signature

Date:

17th May 2023