



Urology Services Inquiry

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

12 October 2023

Dear Madam,

**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 trust and any knowledge you may have, that may be 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. If you in your personal capacity hold any 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 21 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 Fionnuala Houghton
Consultant Oncologist
BH SCT
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 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 25th 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 October 2023

Signed:

Personal information redacted by the USI

Christine Smith QC

Chair of Urology Services Inquiry

SCHEDULE
[No 21 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, Dr McAleese and Professor Stewart, 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]

- (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.



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UROLOGY SERVICES INQUIRY

USI Ref: Notice 21 of 2023

Date of Notice:

Witness Statement of: Dr Fionnuala Houghton

I, Dr Fionnuala Houghton, will say as follows:-

1. I qualified in medicine in 1999 from Queens University Belfast with the degrees Bachelor of Medicine, Bachelor of Surgery and Bachelor of Obstetrics (MB BCh BAO). I undertook general medical training in Northern Ireland, gaining Membership of the Royal College of Physicians 2003, and then worked for one year as a registrar in radiation oncology in St Lukes Hospital, Dublin. Subsequently, I commenced registrar training in clinical oncology in Northern Ireland for a period of five years completing in 2009. This was followed by a fellowship in Princess Margaret Hospital, Toronto specialising in the treatment of head and neck cancer for 18 months followed by a consultant post in the Belfast Health and Social Care Trust in 2011.

My consultant post is in the treatment of head and neck cancer, providing radiotherapy and chemotherapy in this disease site centrally in Belfast. I was also initially involved in the provision of the treatment of lung cancer and urological cancer, both chemotherapy and radiotherapy to the Southern Health and Social Care Trust. My job plan changed after my second maternity leave, meaning I no longer covered the Southern Trust from February 2015. I currently treat head and neck cancer only.



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2. (i) My role was to provide oncology services, to patients in the Southern Trust area who had lung or urological cancers. For urology this was to provide chemotherapy services and radiotherapy services. From memory there were three consultant urologists referring patients to me as well as the population treated by the previous oncologists, Dr McAleese and Professor Stewart.

I attended Craigavon Hospital's Mandeville Unit one day a week which was on a Wednesday. For the morning session I reviewed patients for chemotherapy, both lung and urology. There was a lung cancer Multi-Disciplinary Meeting at the lunch time on site, and I then consulted with new and review patients in the afternoon, again both urology and lung cancer. I would have had the assistance of a clinical oncology registrar at this clinic. Patients requiring radiotherapy for prostate cancer were seen at this clinic, and then again in Belfast by myself for consent and radiotherapy planning. Whilst chemotherapy services are delivered locally at the Mandeville unit all patients receiving radiotherapy do so in Belfast.

(ii) I do not recall any issues being raised by me or others escalating concerns regarding urology services within the Southern Trust.

3. I have no documents within my custody or under my control.



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4. (a) I became aware of the prescribing of Bicalutamide 50mg as a mono therapy during my time training as a registrar. During my five years of training I had several rotations to the oncology clinic in Craigavon. When patients were referred to oncology after discussion with the supervising consultant, they were changed to what was recognised to be the correct treatment and also taken forward for radiotherapy.
- (b) I have no specific details of these patients.
- (c) As a consultant, from January 2011- February 2015, I would have seen 3-4 of these new patients a year, on the background of seeing approximately 300 new patients a year, and over 1000 review patients.
- (d) From memory these were patients with low risk disease under the care of Mr O'Brien, who also referred patients on the correct hormone treatment.
- (e) Approximately 10-12 patients.
- (f) I cannot recall any of these patients details.
- (g) I do not consider bicalutamide 50mg mono therapy an appropriate treatment in prostate cancer, and on consultation with each patient I would explain we are changing this to LHRH (luteinizing hormone-releasing hormone agonist) injections and they would proceed with radiotherapy. This consultation would probably mainly have focused on the side effects of radiotherapy and the practicalities involved. I would then have written to Mr O'Brien, copying in the GP, explaining patient was changing dose of hormones, which was not challenged by Mr O'Brien.



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(h) For any patient I saw I ensured they were on the correct treatment going forward and wrote to Mr O'Brien regarding the change of treatment.

(i) I would not have raised this further as this is something I observed as a registrar, and as a new consultant coming into practice I assumed others had discussed this before with Mr O'Brien. I felt there was no patient harm from the Casodex 50mg, rather suboptimal dosing, and it allowed me to change to my preferred hormone treatment, LHRH injection, without any delay. I believed Mr O'Brien was using a lower dose as he was concerned about the side effects, especially potency. I would also add I have only spoken with Dr O'Brien on a handful of occasions, I did not know him, and would not have considered him a peer, as he is a surgeon, not an oncologist.

(j) I would not use Bicalutamide 50mg mono therapy in any situation treating prostate cancer, as it is unlicensed.



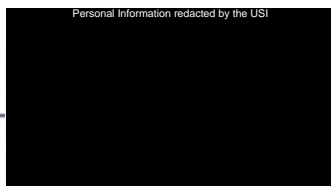
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5.
 - (ii) I agree with Professor O'Sullivan's statement that there was a general awareness, as I came across it first as a trainee and then as a consultant. I cannot recall specific conversations around it.
 - (iii) Again I agree with Professor O'Sullivan's statement.
 - (iv) I did receive referrals.
 - (v) As regards the Thursday morning pre clinic team meeting, this is specific to those oncologists practicing in Belfast (urology) and is not something I attended.
6. I believe from memory the urology MDM commenced after I had taken up post, perhaps in 2011, and I was tasked to provide clinical oncology cover for this during my time there. I did raise concerns that due to my workload I would be not be able to cover this commitment adequately. I also raised concerns over the single handed nature of this. I raised those concerns with my Clinical Director Dr McAleer. Several efforts were made to task senior registrars to support me with the workload. Over time the Southern Trust appointed an oncologist themselves, Dr Carser, which would help ease this pressure.
7. I have no knowledge of any potential governance problems referring patients to Regional Urology.

Statement of Truth

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

Signed:



Date: 22nd November, 2023