



## Urology Services Inquiry

Urology Services Inquiry | 1 Bradford Court | Belfast BT8 6RB  
T: 02890 251005 | E: [info@usi.org.uk](mailto:info@usi.org.uk) | W: [www.urologyservicesinquiry.org.uk](http://www.urologyservicesinquiry.org.uk)

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Dr Seamus McAleer  
Belfast Health and Social Care Trust  
Headquarters  
51 Lisburn Road  
Belfast  
BT9 7AB

12 October 2023

Dear Sir,

**Re: The Statutory Independent Public Inquiry into Urology Services in the  
Southern Health and Social Care Trust  
Provision of a Section 21 Notice requiring the provision of evidence in the  
form of a written statement**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Yours faithfully

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 24 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 Seamus McAleer  
BHSC  
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 2<sup>nd</sup> 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 26<sup>th</sup> 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 12<sup>th</sup> day of October 2023

Signed:

Personal Information redacted by the USI

**Christine Smith QC**

Chair of Urology Services Inquiry

**SCHEDULE**  
**[No 24 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 (19<sup>th</sup> 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, or in your capacity as Clinical Director, 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 record of Dr Hughes' interview with Professor O'Sullivan on 4 January 2021 (at TRU-162262) states as follows:

*'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.'*

In his statement to the Inquiry, Dr Mitchell states: *I believe my first discussion with Dr McAleer occurred at the time of the informal discussions with Mr Haynes in 2019 outlined above. I advised Dr McAleer that I was contributing to a process of investigation of Mr O'Brien's practice and that I anticipated that as it evolved that it was likely I would have to provide evidence to any subsequent investigation within the southern trust. When I was invited to a*

*case review meeting with the southern trust on 1/10/2020 I also advised Dr McAleer of my role in this at that time. I have no documentation from these discussions. [WIT-96672]*

Please clarify:

- a. Whether Dr Mitchell raised concerns about Mr O'Brien's bicalutamide prescribing with you in 2011 or at any other time. To the extent that the answer is affirmative, please provide full details of all discussions, the content of those discussions, who was present for those discussions and any further action taken by you following same.
  - b. Whether anyone, at any stage, raised concerns about Mr O'Brien's bicalutamide prescribing with you in your capacity as Clinical Director. To the extent that the answer is affirmative, please provide full details of all discussions, the content of those discussions, who was present for those discussions and any further action taken by you following same.
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 from Craigavon Area Hospital 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

## UROLOGY SERVICES INQUIRY

**USI Ref:** Notice ...24... of 2023

**Date of Notice:** 12<sup>th</sup> October 2023

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**Witness Statement of: Dr Seamus McAleer**

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I, ...Seamus (James) McAleer..., will say as follows:-

1. PARAGRAPH 1

2. I am known as Seamus McAleer and am registered on the GMC register under James McAleer and my registration number is 2725136.

3. I trained in Medicine at Trinity College Dublin, qualifying in July 1981.

4. I worked as House Doctor and SHO at Altnagelvin Hospital, L'Derry for 3 years, followed by a year as Medical Registrar in the Royal Victoria Hospital Belfast.

5. I then entered Clinical Oncology as a Registrar in August 1985 at Belvoir Park Hospital, Belfast.

6. I spent 2 years doing research and a doctoral thesis on novel Oncology drugs in the Department of Haematology, Royal Victoria Hospital, Belfast.

7. I also did a 6-month clinical fellowship at Royal Marsden Hospital, Sutton, Surrey.

8. In September 1992 I started as a Joint Appointment Consultant Clinical Oncologist and Senior Lecturer between Belvoir Park Hospital (later moving the Cancer Centre at Belfast City Hospital, on 17 March 2006) and Queens University Belfast. I retired from this post on 1 October 2023, returning as a locum for 2 days per week.

9. Initially as a Consultant I managed cancer across all adult disease sites, I had a particular interest in breast and testicular cancers. I sub-specialised as the Consultant team expanded. I stopped managing prostate cancer around 2000 and I stopped managing testicular and kidney cancer around 2014.



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10. I was an examiner for post graduate examinations (FRCR) in Clinical Oncology at the Royal College of Radiologists (RCR) from 2003 to 2014. I also was Medical Director for Education and Training at the RCR from September 2014 to August 2017.
11. I was Clinical Director for Oncology and Haematology from 2008 until August 2014. I returned as acting Clinical Director for Oncology from June 2020 to July 2021
12. I became Clinical Lead for Service Development in Oncology from 2020 onwards
13. In my QUB role I was Academic Lead for Assessment from 2014 until 2022.

### 14. PARAGRAPH 2

#### 15. My involvement in matters within the scope of this enquiry.

16. As a Consultant I did not visit Craigavon, but a small number of patients with testicular or renal cancer were referred to me. I did not identify any issues with the care of these patients. However, their care pathway is much simpler than with prostate patients, as the urologist makes a diagnosis, operates and refers the patient.
17. I was Clinical Director for Oncology in the Cancer Centre from 2008 until August 2014. I returned to this position in an acting role from June 2020 until July 2021.
18. In this position I was clinical line manager for the Consultant Oncologists providing the Oncology service to Craigavon Area Hospital.
19. As Clinical Director, I worked with the service manager to provide a clinical service against a background of gaps in service for clinic cover and MDM attendance.
20. I believe that I was not involved in any email correspondence or meetings regarding any perceived shortcomings in the clinical care provided by Mr. O'Brien. I have searched my email to supplement my memory.
21. I am not a prostate cancer Oncologist and so was not included in their internal discussion on bicalutamide dose. I also did not participate in their Thursday morning pre-clinic discussions. I was not Clinical Director at the time of Dr Mitchell's 2014 email on this issue.
22. Dr Darren Mitchell did speak informally to me on two occasions in 2019 & 2020 about the investigation of urology when he had been asked to contribute to the Trust's look back exercise.



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To avoid duplication, this is detailed under the relevant specific questions asked of me in the schedule below.

### **23. PARAGRAPH 3.**

24. I have no documents to attach to date.

### **25. PARAGRAPH 4. Specific Questions**

### **26. PARAGRAPH 5 (i)**

27. (a) Please note that I am not “a member of the Oncology team treating prostate cancer”. I was not aware of the prescription of bicalutamide 50mg as monotherapy until mentioned to me by Dr Mitchell in 2019/2020 conversations.

28. (b) I am not aware of these patients.

29. (c) This is not known to me

30. (d) This is not known to me

31. (e) This is not known to me

32. (f) As above

33. (g) I am not expert on this, Dr Mitchell is the appropriate expert

34. (h) I was not aware.

35. (i) I was not aware.

36. (j) I am not expert on this, Dr Mitchell is the appropriate expert

37. 5(ii) I was not one of the Oncology team treating prostate cancer and cannot speak to their awareness of this issue.

38. 5(iii) I do not know whether Professor O’Sullivan’s assertion is true.

39. 5(iv) I became aware of this in my conversations with Dr Mitchell

40. 5(v) I have never attended the Thursday morning meeting

### **41. PARAGRAPH 6**

42. 6(a) I believe that Professor O’Sullivan corrected his evidence stating that the 2011 date was wrong and accepting that Dr Mitchell’s discussions with me were in 2019 and 2020. I can confirm that I have no recollection or record of a discussion with Dr Mitchell in 2011.

43. I do recall the two discussions with him in 2019 and 2020. In 2019 Dr Mitchell and I met to discuss a radiotherapy plan and in conversation he mentioned that he was



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contributing to a Southern Trust investigation into the practice of Mr. O'Brien. He mentioned the concern over bicalutamide dose and that there was some form of note review taking place. I encouraged him to participate and to chat again if there were any issues for him.

44. Since I was not Clinical Director, and this was an investigation already under way, I did not pursue it further.

45. In 2020, when I was Clinical Director, he updated me that he was being asked to participate in a case review in the Southern Trust. We had a brief discussion of the process and again we agreed that this would be a valuable role.

### 46. PARAGRAPH 7

47. The Oncology Service is chronically understaffed with gaps in consultant cover. This has been a problem since the Cancer Units opened in 1998 and this remains a challenge. The Craigavon Cancer Unit has three Consultants on Wednesday (Urology/Lung), two Consultants on each of Tuesday (breast Cancer), and Thursday (Gastro-Intestinal). There is also an Acute Oncology Service to the wards on Thursday morning. Some of the incumbents are locum cover and there is typically a Specialty registrar in attendance.

48. The Service has engaged in regular communication with the Commissioners over these and other shortages. The Commissioners have expanded staffing with the Consultant workforce has grown from 5 when I was appointed to over 55 at present.

49. However, the workload increases relentlessly leaving provision trailing demand.

50. When there is a single-handed or absent Consultant then it is very challenging to provide cross cover for gaps. In this setting the cover will be focused on patient-facing roles and gaps may persist in the MDM cover at the Cancer Unit. This is unsatisfactory but before 2020 there was little provision for virtual attendance and this issue was difficult to address.

### 51. PARAGRAPH 8

52. I have no specific knowledge of this.

### 53. PARAGRAPH 9





## Urology Services Inquiry

54. No additional Information.

### **Statement of Truth**

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

Personal Information redacted by the USI

Signed: \_\_\_\_\_

Date: \_\_\_\_\_ 20 November 2023 \_\_\_\_\_